United States Patent [19]

LeMon

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[54] **RADIOACTIVE GAS INHALATOR**

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[52] **U.S. Cl.** ..... **128/2 A;** 128/2.08; 250/303

[51] **Int. Cl.** **A61b 5/08**

[58] **Field of Search** ..... 128/2.08, 2.07, 2 R, 2 A, 128/145.8, 188; 250/106 T, 71.5 S, 43.5 R, 303

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[57] **ABSTRACT**

The present invention relates to an "inhalator"; and more particularly relates to apparatus for permitting a patient to inhale a radioactive gas, in order to provide a diagnostic test of the patient's lung area. The disclosed apparatus provides a simple, trouble-free mechanism for achieving this result; and, furthermore, provides an improved testing method. Moreover, the disclosed apparatus has the capability of gradually introducing the test condition in a manner that makes it easy for the patient to become acclimated to it.

4 Claims, 7 Drawing Figures

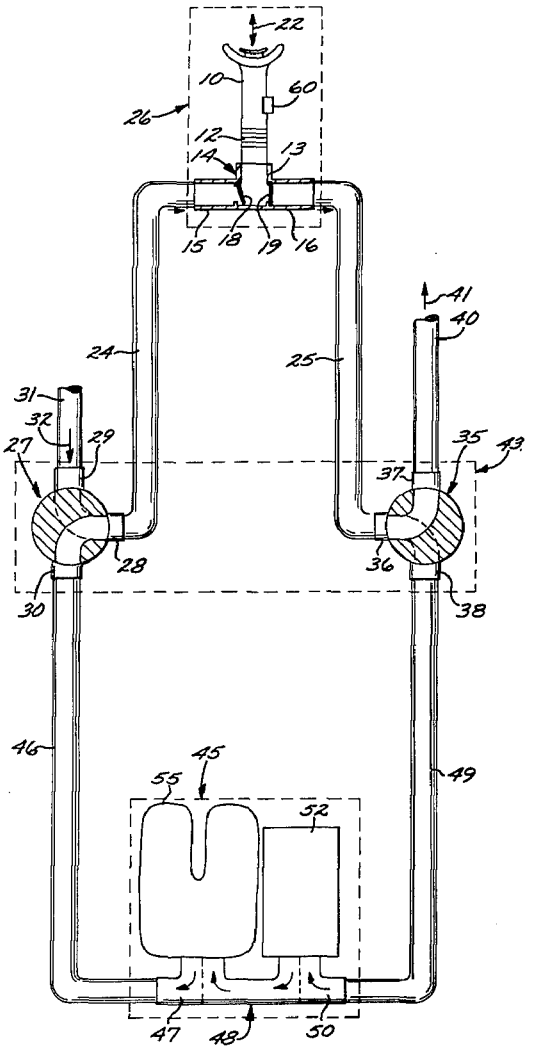


FIG. 1

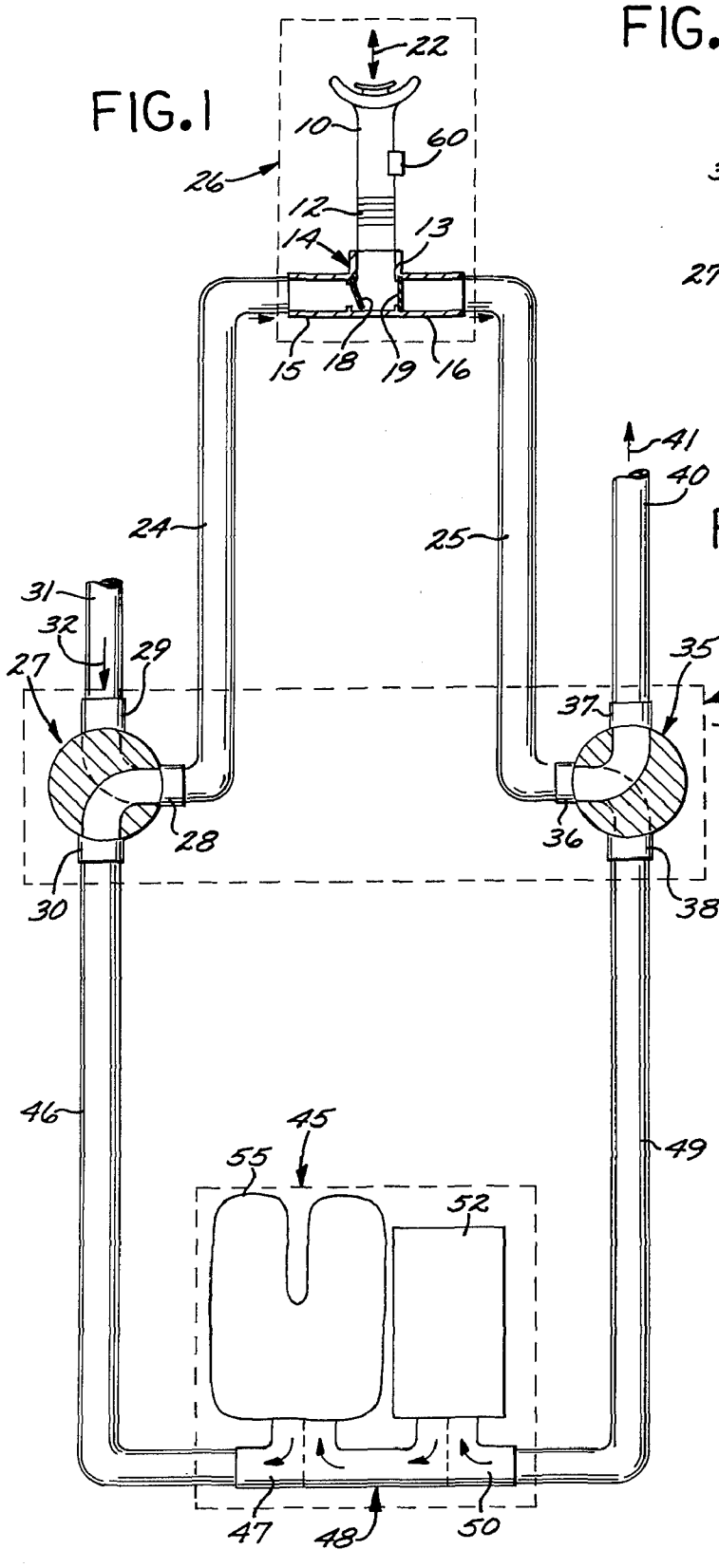


FIG. 2

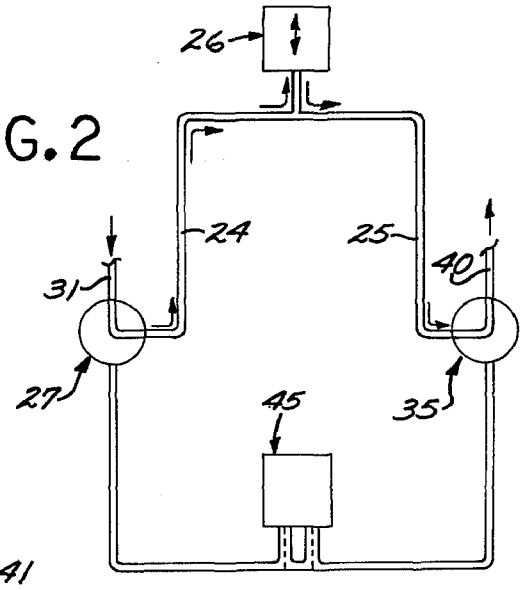


FIG. 3

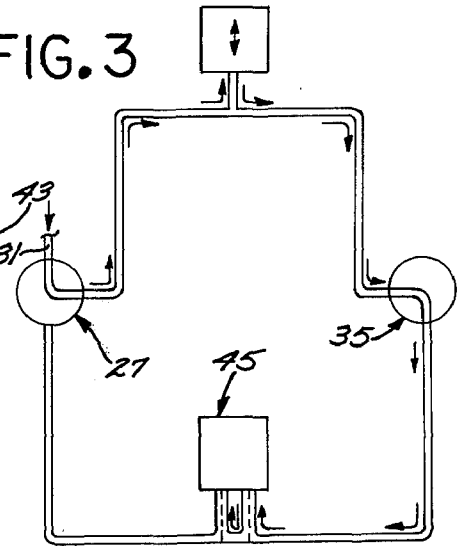
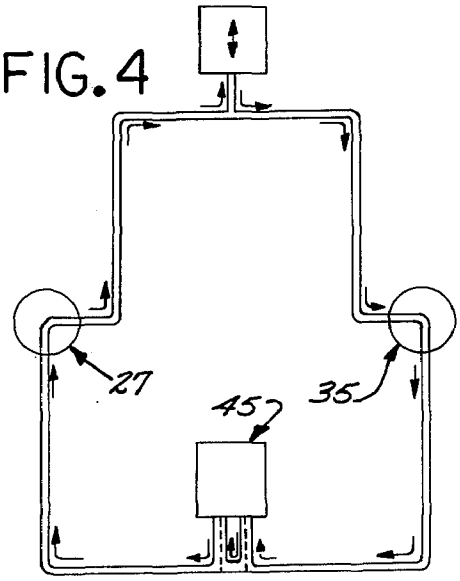


FIG. 4



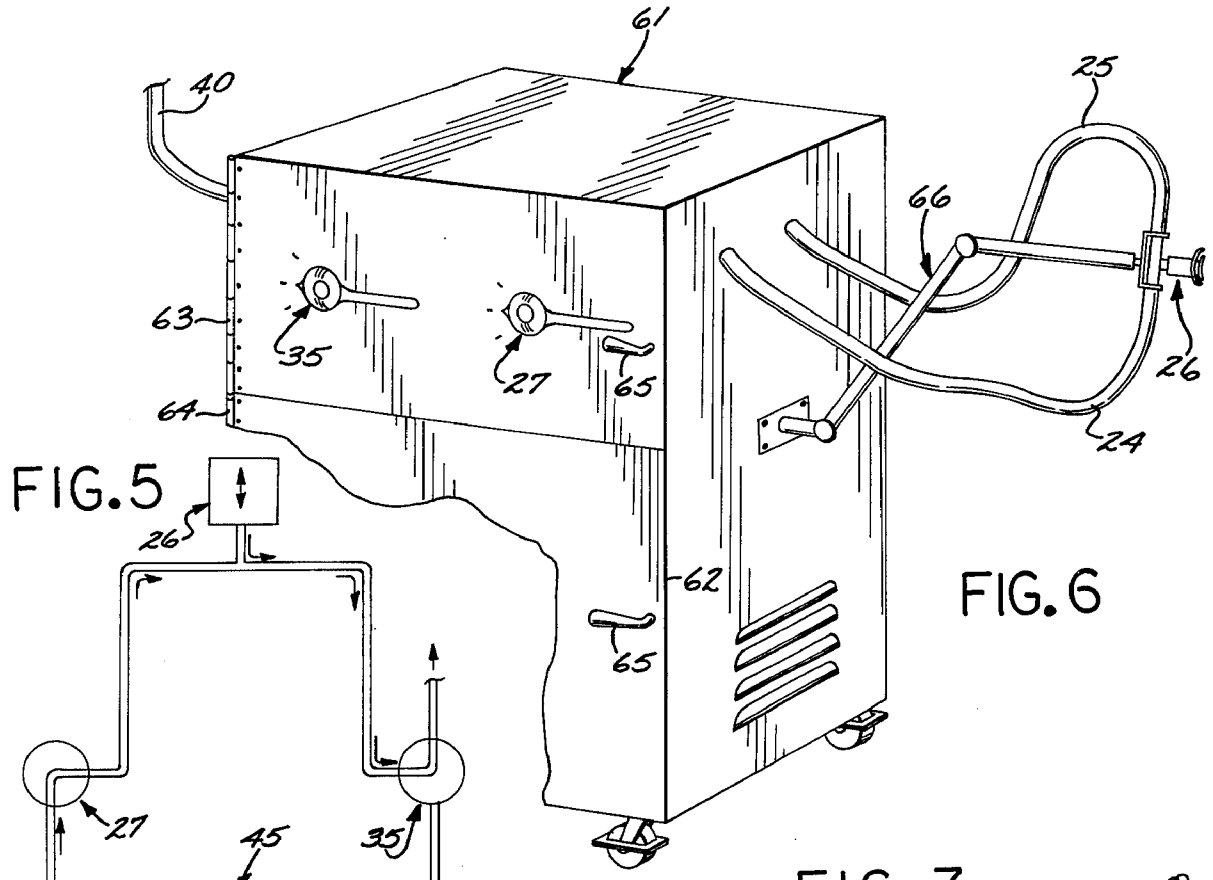
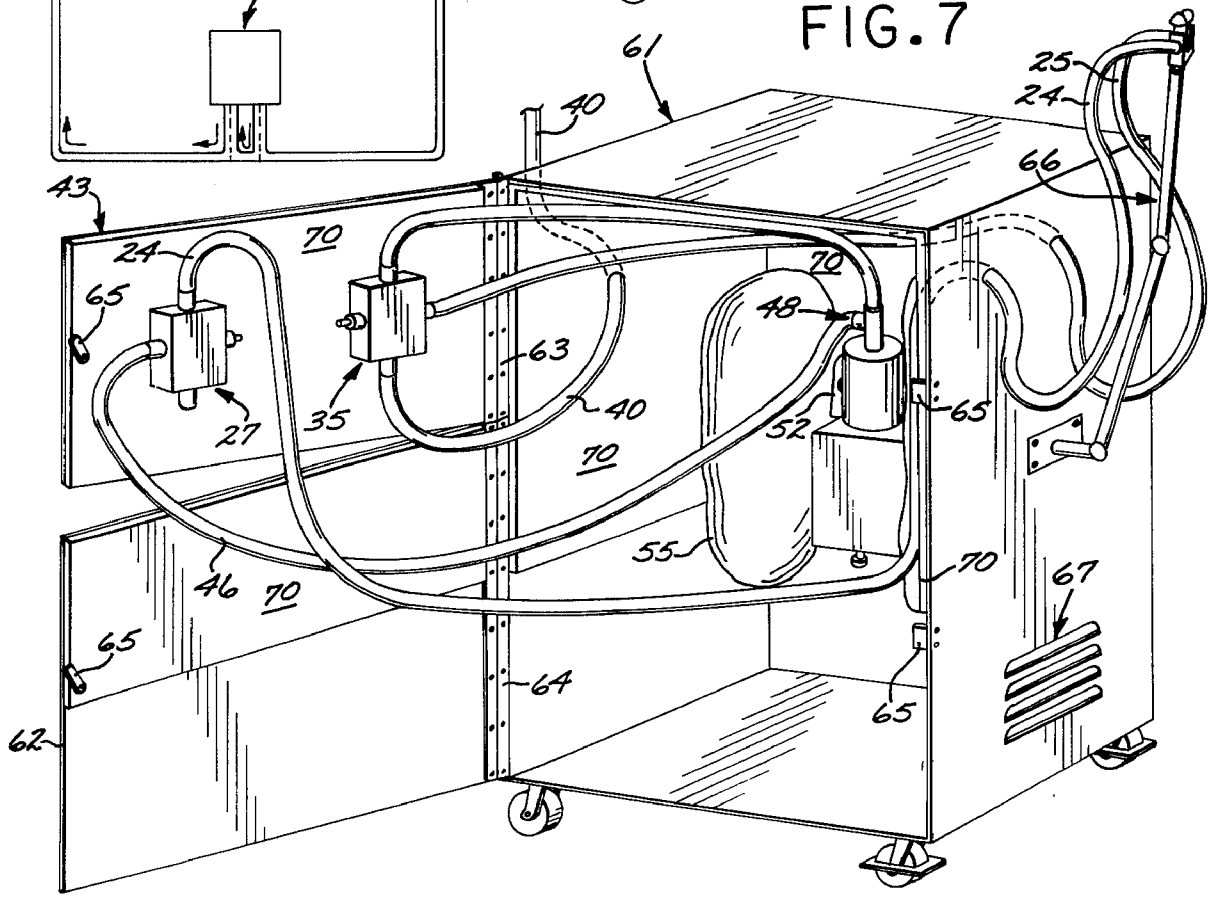


FIG. 6

FIG. 5

FIG. 7



RADIOACTIVE GAS INHALATOR

BACKGROUND

Unfortunately, in the art of medical diagnosis, many individual tests do not — of themselves — distinguish between a given illness and other illnesses that have similar symptoms. Therefore, it is becoming increasingly important to perform a plurality of tests that provide results that permit the diagnostician to make such a differentiation. Such situations arise with ever increasing frequency in the field of "pulmonary" studies; i.e, studies of the heart/lung interrelationship.

In this field, the most common testing technique is that of radiology; the resultant X-ray radiograph indicating differences in the tissue density; and this density graduation becomes quite meaningful to the radiologist. Unfortunately, these radiographs tend to be rather vague in many instances; since a number of different medical problems will produce substantially identical radiographs.

OBJECTIVES AND DRAWINGS

It is therefore the principal objective of the present invention to provide an improved medical testing apparatus.

It is another object of the present invention to provide an improved testing apparatus for pulmonary studies.

It is still another objective of the present invention to provide an improved medical testing apparatus using radioactive materials.

It is a further objective of the present invention to provide an improved medical testing apparatus using a radioactive material and electronic detection apparatus.

It is a still further objective of the present invention to provide apparatus for performing the improved medical radioactive testing.

The attainment of the above objectives and others will be realized from a study of the following specification, taken in conjunction with the drawings of which:

FIG. 1 shows a schematic representation of the disclosed apparatus;

FIG. 2 - 5 show various air flow configurations;

FIG. 6 shows an external view of a cabinet that houses the disclosed apparatus; and

FIG. 7 shows a typical internal view of a cabinet that houses the disclosed apparatus.

SYNOPSIS

The present invention discloses a radioactive gas inhalator apparatus that provides a closed loop breathing configuration into which may be introduced the desired radioactive gas for circulation into and out of the patient's lungs. Suitable air-conditioning apparatus dehydrates the patient's exhalations, and removes the carbon dioxide 13 so that re-circulation of the radioactive gas may be continued as long as necessary for the testing procedure. Suitable detection equipment provides visual monitoring, as well as pictures or taped results for subsequent studies.

The "washout" portion of the test, during which the radioactive gas is removed from the patient's lungs, provides additional data for further diagnostic interpretation.

INTRODUCTION

As indicated above, it is frequently difficult — using present testing techniques — to distinguish between various pulmonary illnesses; partly becuase most of the readily available tests depend upon X-ray radiology, which indicates a tissue density difference. One of the recent innovations has been a technique using a radioactive material. In principle, this radioactive material method requires that a radioactive material be introduced into the lining of the lungs; and that, while the radioactive material is in this location, an "image" of its radioactive radiations is obtained.

One prior art radioactive method used a radioactive material such as Iodine-131 hydroxide particles that were "attached" to albumin particles of a carefully controlled size; so that the albumin particles acted as "tagged" carriers. The thus-tagged albumin particles were injected into the patient's bloodstream; this injection method being known as "profusion." The tagged albumin particles eventually became trapped at the lung lining; and, while in this trapped location, the various radioactive particles emitted a plurality of radiations (beta particles, gamma rays, X-rays, etc). A suitable radiation detector (such as a well-known scintillation detector) detects the instantaneous area concentration of the trapped radioactive materials; and the detector was moved across these areas to produce an "image" that could be recorded — i.e., photographed, viewed, taped, etc.

A later detection technique used a plurality of fixedly positioned scintillation detectors; and electronically correlated the output of each individual detector with a given area, so that an overall image was quickly produced. This procedure is known as "scanning"; and the resultant image is known as a "scan."

The above radioactive material method had a number of shortcomings. Among these were the following inherent problems. As the tagged albumin particles traveled through the bloodstream, they should, theorotically, become trapped at the blood-vessel/lung lining interface when they tried to traverse the walls of the bloodvessels into the lungs.

In a healthy patient, the lung surface (or "alveoli") is a highly convoluted surface; so that many tagged particles were trapped in a fairly random manner — the resultant scan showing an even density of spots that clearly depicted the lungs.

However, in a patient with relatively poor blood circulation — as may be caused by a clot, by scar tissue, or the like — the radioactive tagged particles never even reach the alveoli; so that the scan shows one or more dark areas. Therefore, such a scan was indicative of an unhealthy patient; but it did not point out whether the difficult was in the lung's blood supply or a defect at the alveolar stage. Therefore, more tests were necessary.

In other cases, such as emphysema, the alveoli is not convoluted; and there is minimal trapping of the tagged particles. Thus, this condition also produces dark areas in the scan. Here too, the dark areas must be explained by other tests.

Another disadvantage is that the tagged albumin particles must be of such a size as to be readily trapped by the lungs; and the body requires several days to "untrap" them. During this untrapping interval, the radioactive materials continue to emit their radiations; and

while these radiations are relatively weak, they tend to prevent repetition of the tagged-albumin test.

Thus, while the profusion type of radioactive material method was helpful, it was an additional testing technique that too often was not very indicative by itself. An improved method was therefore much to be desired.

In the present radioactive material type of test, a radioactive gas is introduced directly into the lungs of the patient; and is removed as part of the test.

The Mouthpiece Arrangement

The basic inventive concept will be understood from FIG. 1; this indicating the apparatus in a somewhat schematic manner. In FIG. 1 the patient (not shown) breathes through a mouthpiece **10** that may, if desired, use a length of mouthpiece tubing **12** that connects the mouthpiece **10** to the mouthpiece port **13** of an inhalator valve **14** that also has an air inlet port **15** and air outlet port **16.** Inhalator valve **14** — which may be Model 1400 made by Hans Rudolph, Inc. at Kansas City Mo. — is indicated to have one or more flow direction control flaps **18** and **19** therein; although, depending upon its design, the flow direction control flaps may be replaced by various types of check valves, diaphragms, or the like.

The operation of the apparatus thus far described is as follows. When the patient inhales — as indicated by the outpointing end of the double ended arrow **22** — the intake flap **18** of the inhalator valve **14** opens to admit air from an air inlet tubing **24**; the outlet flow direction control flap **19** remaining closed. When the patient exhales — as indicated by the inpointing end of the double-ended arrow **22** — the second flap **19** of the inhalator valve **14** opens to exhaust air to an air outlet tube **25**; the intake flow direction control flap **18** remaining closed.

For convenience, the mouthpiece arrangement will be identified by the reference character **26.**

The Air Inlet Valve

As indicated in FIG. **1,** the air inlet tube **24** is connected to a suitable air inlet valve **27**; the air inlet valve **27** having at least three active ports — and "inner" port **28,** and "upper" port **29** and "lower" port **30** — the fourth port (not shown) of the valve **27** being plugged.

Air inlet valve **27** is shown to have its inner port **28** connected to the air inlet tube **24**; whereas its upper port **29** is connected to an atmosphere tube **31** that is open to the atmosphere, as indicated by the inpointing arrow **32.**

The Air Outlet Valve

FIG. 1 shows the air outlet tube **25** to be connected in a similar manner to a suitable air outlet valve **35**; the air outlet valve **35** having at least three active ports — an "inner" port **36,** an "upper" port **37,** and a "lower" port **38.** Air outlet valve **35** is shown to have its inner port **36** connected to the air outlet tube **25** from the inhalation valve **14**; whereas its upper port **37** is shown to be connected to an exhaust tube **40** — the air flow through the exhaust tube **40** being in the direction indicated by the outpointing arrow **41.** For reasons that will become clear from a later discussion, the exhaust tube **40** terminates via a suitable exhaust port (not shown) at the roof of the building, or the like.

For convenience, the air inlet valve **27** and the air outlet valve **35** — along with suitable strapping for the various tubes — may be mounted on a suitable control panel **43.**

The Air-conditioner

For reasons that will become apparent later, an "air-conditioner" **45** (not of the usual cooling type) has to be used; and a secondary air inlet tube **46** is connected between the lower port **30** of the air inlet valve **27** and the outlet port **47** of an air-conditioner valve **48.**

In a similar manner, a secondary air outlet tube **49** is connected between the lower port **38** of the air outlet valve **35** and the inlet port **50** of the air-conditioner valve **48.**

The air-conditioner **45** has a dual function, as follows. First of all, it has to "condition" the air that is exhaled by the patient; and to do this, the air-conditioner **45** has a replaceable dehydration cannister **52** that contains a dehydrating material such as a compound of sodium (Na). The sodium compound combines with the moisture in the patient's exhalations, and thus performs a dehydration function; the dehydrant also combines with the carbon dioxide in the patient's exhalations, and thus purifies the air for recirculation. It should be noted, in passing, that the chemical reactions that take place in the cannister develop an appreciable amount of heat; so that the heat tends to sterilize the air passing through the air-conditioner. Such dehydration cannisters are widely used; and are available under part number 45,151 from the Mine Safety Appliance Company of Pittsburgh, Pa. These cannisters generally have an attachable/detachable arrangement that permits a new cannister to be installed in such a manner that when its seals are pierced, the interior of the cannister is simultaneously and automatically connected into the system.

The air-conditioner **45** also contains a sac **55** or "breathing bag" that may take the form of a set of Navy rebreathing lungs. For reasons to be discussed later, sac **55** preferably is flexible; and, when activated, has a volume that is approximately equal to the volume of the patient's lungs.

It will be noted that the cannister **52** and the sac **55** are connected in such a way, as indicated by the dotted lines and arrows of valve **48,** that there is a serial air flow through them.

OPERATION

The Test Procedure

One operational technique is as follows, although it should be realized that the disclosed technique may be modified in a number of respects. Since the patient finds it easier to breathe while he is sitting or standing, it has been found advisable to have the patient sit in a chair in a "western" style; i.e., resting his arms on the top of the chair back, as this arm-position enables the patient to minimize his movements to prevent motion on the film. The patient inserts the mouthpiece into his mouth; and starts to breathe through it.

At this time, the settings of the air inlet valve **27** and the air outlet valve **35** will be best understood from FIG. **2;** which is a simplified version of the apparatus illustrated in FIG. **1.**

FIG. **2** shows that the air inlet valve **27** has been set to connect the primary air inlet tube **24** to the atmosphere tube **31**; and further shows that the air outlet valve **35** has been set to connect the primary air outlet tube **25** to the exhaust tube **40.**

In this breathing configuration, each time the patient inhales, he receives air from the atmosphere; and each time that the patient exhales, the exhalations are ex-

hausted to the reservoir or the atmosphere — as indicated by the flow arrows of FIG. 2.

The patient is encouraged to take a number of breaths with the breathing configuration of FIG. 2; and he thus becomes acclimated to the slightly increased breathing difficulty.

When the patient seems to be fairly relaxed, the valves of the control panel are set to the breathing configuration shown in FIG. 3. In this case, the air inlet valve 27 is as shown above and air outlet valve 35 has been reset so that the patient now inhales room air, and fills the air-conditioner 45; as indicated by the flow arrows. This requires several breaths.

As soon as the patient is again relaxed, the breathing configuration shown in FIG. 4 is established; and it will be noted that a closed loop breathing configuration has been established, as indicated by the flow arrows. In this closed loop breathing configuration, the breathing is re-inforced by the oxygen or air from the charged air-conditioner 45. As a result, the patient inhales dehydrated air from the air-conditioner; and exhales moist air to the cannister where it is dried.

The patient experiences no lack of air or oxygen during the entire breathing procedure. During the breathing configuration of FIG. 2 the patient breathes room air. During the breathing configuration of FIG. 3 the patient also breathes room air. During the breathing configuration of FIG. 4, the patient breathes air from the air-conditioner.

When the patient is fairly well relaxed with the closed loop breathing configuration, he is asked to take about three breaths; and to maintain the exhaled condition. At this time a controlled volume of radioactive gas, such as Xenon-133 (Xe133), — is introduced into the closed loop breathing configuration; and it has been found that the most convenient way to accomplish this gas introduction is by means of a "gun" comprising syringe like arrangement that uses a hollow needle to pierce a piercable diaphragm such as 60 that is conveniently incorporated into the mouthpiece structure 10 of the FIG. 1, the diaphragm 60 sealing itself as soon as the needle is withdrawn. Such a "gun" is provided, free of charge, when the radioactive gas is obtained from New England Nuclear — Radiopharmaceutical Division — of North Billerica, Mass.

Alternatively, since various radiopharmaceutical suppliers use various sized containers, a graduated glass syringe and hollow needle can also be used to withdraw the desired concentration of radioactive material. The inhalator system presented here incorporates a needle permeable membrane, whereby the Xe-133 introduction can be accomplished with any hollow needle apparatus.

As soon as the radioactive gas has been introduced into the closed loop breathing configuration of FIG. 4, the patient is asked to take a deep breath; and to hold it — this being known as a "holding breath" technique, which insures full inspiration of the radioactive gas; and with his first inhalation, most of the radioactive gas passes directly into the patient's lungs. The Xe-133 radioactive gas attaches itself to carbon dioxide molecules, which are thus "tagged" by the radioactive material; and the tagged carbon dioxide molecules tend to traverse from the alveoli into the blood vessels — and their tagged condition produces an immediate radioactive image, or scan. About eight pictures are usually taken, at about 30 second intervals; one of these pictures being, if desired, a holding breath accumulation scan.

This initial scan may not be the most desirable radiograph, so an equilibrium is achieved by having the patient breathe normally for a few breaths. It will be recalled that the sac 55 of the air-conditioner preferably has a volume that is substantially equal to the volume of the patient's lungs. Therefore, after a few normal breaths, the radioactive gas is equally distributed throughout the closed loop breathing configuration; thus, establishing an air/radioactive gas equilibrium.

It should be noted that each time that the patient exhales, this action tends to clear the lungs of excess untrapped undiffused radioactive gas particles; and that each inhalation therefore tends to produce identical scans that may be recorded on film, on computer tape, or in any other desirable manner.

In the present case, the radioactive particles are introduced directly into the patient's lungs — leading to the designation "ventilated" so that, to a great extent, the problem of poor blood circulation is bypassed.

After a few breaths, the scan tends to repeat itself; so that ordinarily after seven or eight scans and visual monitoring of the scans on a cathode ray tube, the test is practically completed.

The Wash Out Procedure

To terminate the test, the breathing configuration of FIG. 5 is established; but this so-called "wash out" may be used as a part of the test. As explained above, the patient now gradually empties his lungs and the air-conditioner of radioactive particles; about eight pictures being taken at about 10-second intervals.

Scans are taken of this wash out interval, as they may reveal something of importance. For example, if there is any alveolar defect, it will show up by an increase or a decrease of the radioactive concentration during the wash out scan; and these wash out scans thus provide additional information to the diagnostician.

Gas Disposal

It should be noted that the amount and strength of the radioactive gas used is minimal; the dosage being typically a vial of about 6 milli-liters (mL) volume and a strength of about 10 milli-curies (mCi). When this amount of Xe-133 is used for the test; it is diluted by twice the volume of the patient's lungs (because of sac 55); and therefore, it may be ordinarily exhausted into the atmosphere — where it is diluted even further.

Moreover, since Xe-133 has a "half-life" of about 5 days, its strength decreases very rapidly. In general, there is no prohibition against exhausting the Xe-133 residue into the atmosphere. However, where required, residue from the test may be stored in a reservoir, along with the radioactive wastes from other processes; and then discarded in accordance with specified procedures.

External View of Cabinet

FIG. 6 illustrates an external view of a typical cabinet 61 for containing the previously described apparatus. The typical cabinet may be about 5 feet tall, about 3 feed wide, and about 1½ feet deep; and may have a control panel 43 that may be about 2 feet high. Preferably, the control panel 43 and the cabinet front 62 are suitably hinged to the cabinet body; as for example, by piano hinges 63 and 64 or the like — and suitable door latches 65 may be used. Thus, there is easy access to the interior of the cabinet.

FIG. 6 shows an exhaust tube **40** extending from cabinet **61**; and further shows an air inlet tube **24** and an air outlet tube **25** that are connected to a mouthpiece assembly **26.** An adjustable position tube holder **66** supports the air inlet tube **24** and the air outlet tube **25**; the tube holder **66** preferably being multi-articulated, and adapted to have its joints tightened at the most convenient position. Preferably, the mouthpiece assembly **26** is angularly pivotable relative to the tube holder **66**; as this pivotal adjustment permits the patient to assume any desired posture, and — in extreme cases — even permits the patient to lie down during the test.

It has been found desirable to have the cabinet **61** equipped with wheels or casters that are individually pivotable; as this facilitates placing the cabinet and its contained apparatus as close to the patient as desired — rather than having to move the patient to the cabinet. It has also been found desirable to equip the cabinet **61** with locking casters, especially on the wheels adjacent to the patient — in order to assure that the cabinet and its apparatus does not move away from the patient during the test.

Internal View of Cabinet

FIG. 7 shows a view of the interior of the cabinet **61**; the control panel **43** and the cabinet front **62** having been swung open to reveal the interior of the cabinet. In general, the flexible hoses may be resiliently supported (not shown) within the cabinet; suitable means being provided for their movement when the control panel is to be opened. Ordinarily, the only servicing required is the replacement of the cannister **52**; and this may be replaced by opening only the cabinet front **62,** so that the tubes are not disturbed. Alternatively, a service door (not shown) may be provided at some other convenient location of the cabinet.

It will be recalled that one port of the inlet valve **27** is open to the atmosphere, so that air may enter this open port when the test procedure requires this. In the present case, it has been found desirable to include one or more louvers **67**; the louvers being backed up by a suitable air filter (not shown) — although generally, since the disclosed apparatus is used in clean rooms, no problem arises in this respect.

The disclosed size of the cabinet permits the air inlet and air outlet tubes **24** and **25** to be at a convenient height for use by the patient. This structure leads to a cabinet that has an appreciable amount of room in the lower portion thereof; and this room may be used for storage of ancillary apparatus, or — if desired — for the inclusion of some of the electronic detection apparatus.

It will be noted that a closed loop breathing configuration is desirable for certain portions of the test; and it should also be noted that this closed loop arrangement has another advantage. This advantage is that the radioactive material is always contained within the closed loop breathing system; even at the time it is being exhausted. This advantage has a concurrent advantage that there is no leakage of the radioactive material to produce spurious signals or a fogging of the scan. *It may be desirable to line the upper portions of* the cabinet with lead sheeting **70** to minimize radiations that might affect the detection apparatus.

SUMMARY

The disclosed apparatus has many advantages over the prior art systems. First of all, it is simple and trouble-free. Second, it is extremely convenient for both the patient and the operator. Third, the testing may be continued as long as desired. Fourth, the dosage is so small as to be practically harmless, and is — in general — permissibly exhaustable into the atmosphere. Fifth, the radioactive material used has an extremely short half-life; and therefore tests may be repeated after a very short interval. Sixth, there is no danger to either the patient or to the operator. Seventh, the testing can be performed by a single operator. Eighth, the apparatus is readily mobile; and may be rolled to the location that is most convenient for the patient. Ninth, the apparatus — while mobile — may be locked in a desired location for the duration of the tests. Tenth, the apparatus tends to be self-sterilizing, and, finally, the apparatus is easy to maintain in instantly operable condition.

I claim:

1. A radioactive gas inhalator apparatus comprising:
an inhalator valve having an air inlet port, an air outlet port and a mouthpiece port;
an inhalator mouthpiece connected to said mouthpiece port;
means for producing a closed breathing loop between said air inlet port and said air outlet port;
a source of radioactive material;
means for introducing a single injection of radioactive material into said closed breathing loop for causing said radioactive material to be introduced into the lungs of a patient with every breath;
said means for introducing said radioactive material comprising a self-sealing needle-pierceable diaphragm.

2. The apparatus of claim **1** wherein said pierceable diaphragm is included in said inhalator mouthpiece.

3. A radioactive gas inhalator apparatus comprising:
an inhalator valve having an air inlet port, an air outlet port and a mouthpiece port;
an inhalator mouthpiece connected to said mouthpiece port;
means for closing the breathing loop between said air inlet port and said air outlet port;
said loop closing means comprising an air-conditioner having a sac and a dehydrant cannister;
air-conditioner valve means for causing air to flow serially through said sac and said cannister;
said loop closing means comprising air inlet valve means for permitting the entry of atmospheric air into said air inlet port, or for permitting the entry of air from said air-conditioner into said air inlet port;
said loop closing means comprising air outlet valve means for permitting the exhausting of the exhaled air from said air outlet port, or for permitting the flow of the exhaled air from said air outlet port into said air-conditioner;
means for introducing a single injection of a radioactive gas into said closed breathing loop;
said introducing means comprising a self-sealing needle-pierceable diaphragm.

4. The apparatus of claim **3** wherein said pierceable diaphragm is positioned in said inhalator mouthpiece.

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