**Title:** OXYGEN THERAPY METHOD AND APPARATUS

**Abstract**

A rebreathing apparatus is designed to minimize the amount of oxygen required in oxygen therapy to maintain a given or desired oxygen level in the blood and includes a changeable volume chamber (15, 25, 35, 45, 55) having a maximum volume less than the maximum volume of the respiratory tract of a user and to which a continuous source of oxygen is supplied so that the initial gas exhaled on exhalation is directed into the changeable volume chamber and so that the remainder of the exhaled gas is vented to the ambient. Oxygen is supplied to the apparatus via inlets (13, 23, 33, 43, 56) to increase the oxygen content of the retained gas as some of it is displaced from the apparatus so as to create a bolus of oxygen enriched gas. On inhalation this quantity is initially taken into the respiratory tract and the latter is then filled concurrently with ambient air and gas from the apparatus. This sequence is followed as long as the therapy is administered.
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TITLE: OXYGEN THERAPY METHOD AND APPARATUS

BACKGROUND OF THE INVENTION

The invention described in this specification pertains to a new and improved method and apparatus which are primarily intended to be utilized in oxygen therapy but which are also capable of being used in administering other gases.

One of the oldest methods of delivering oxygen to a patient in order to maintain a given or desired oxygen level in the blood of the patient involves locating an appropriate delivery structure such as a set of nasal cannula immediately adjacent to the nose of the patient and then constantly supplying a metered or controlled supply of oxygen to the delivery structure as the patient inhales and exhales. This method of supplying oxygen is unquestionably highly utilitarian. It is also comparatively undesirable because of the amount or quantity of oxygen which has to be utilized in order to achieve the desired oxygen level of the blood. This is because with this type of procedure significant amounts of oxygen normally escape to the ambient air and are not effectively utilized by the patient.

There are, of course, many variants on the type of procedure indicated in the preceding discussion. Thus, for example, it is well known to substitute for a set of cannula a so-called "tent" which is used to maintain an oxygen enriched atmosphere completely surrounding the head of a patient. It is also known to utilize various mechanical or fluidic switching type mechanisms or structures which are intended only to supply oxygen to a patient during inhalation. Many of such prior structures are constructed so that the patient will re-breathe some or a part of the gas exhaled.
Fortunately an understanding of the present invention does not require a detailed discussion of all of the various different devices of the latter categories. Frequently such devices have been undesirably bulky in character; often they have been of a comparatively complex nature. A result of such complexity, frequently they have been undesirably expensive to manufacture. Often they have been somewhat difficult to use and at other times they have been somewhat unreliable. It is not considered that any of these devices having mechanical or fluidic parts for controlling the delivery of oxygen to a patient have been constructed so as to effectively minimize the amount of oxygen required to maintain a given oxygen level in the blood to a desired extent.

As a result of these considerations it is believed that there is a need for improvement in connection with the administration of oxygen. More specifically it is considered that there is a need for both a new method and a new apparatus for delivering oxygen which minimizes the amount of oxygen required in order to maintain a given or desired oxygen level in the blood. It is also considered that there is a need for a method and an apparatus which are both simple in character as to be relatively inexpensive to manufacture and to be relatively free from any sort of "mechanical" type problems tending to preclude their utilization.

BRIEF SUMMARY OF THE INVENTION

A broad objective of the present invention is to fulfill the needs briefly discussed in the preceding. Thus, the invention is intended to provide both a new method and a new apparatus for delivering oxygen to a patient while minimizing the amount of oxygen required
in order to maintain a desired oxygen level in the blood of the patient. It should be noted that this invention can be utilized to deliver other gases or gas mixtures other than oxygen or oxygen mixtures to a patient although it is not intended for such utilizations.

The invention is also intended to provide devices or apparatuses which are primarily intended for use in delivering oxygen, which are relatively simple, which are normally relatively small and of a shape adapted to a patient's needs, which may be easily and conveniently manufactured at a comparatively nominal cost, and which are advantageous in that they can be utilized by a patient without the patient manipulating any sort of a movable mechanical structure. The invention is especially intended to provide apparatuses as indicated in the preceding discussion which can be utilized over a prolonged period with no maintenance.

The invention is also intended to provide a new and improved method as indicated which is of a comparatively simple character. As a result of the simplicity of this invention, this process is carried out automatically during breathing once the apparatus used has been located in a desired, operative location relative to the nose of a patient. As a consequence, the ease of practicing or carrying out the process of this method is especially desirable for use in those circumstances where it is not desirable to restrict the mobility of a patient or in those circumstances when the breathing of the patient will not be monitored as, for example, during sleep.

Those aspects of the present invention pertaining to a process are achieved by providing a process of oxygen therapy in which a structure receives oxygen from an oxygen source and supplies oxygen to the nos-
trials of a person receiving the therapy the improvement which comprises: said structure having an internal volume, at least a portion of said internal volume being capable of being changed in response to a force developed from the movement of gas by said person breathing normally, said changeable portion having a lesser volume than the volume of the respiratory tract of said person, continuously supplying oxygen to the interior of said structure, the volume of oxygen supplied being less than the volume of gas inhaled by said person, locating said structure relative to said person's nose so that during breathing cycles exhaled gas will be preferentially breathed into said structure in preference to being breathed to the ambient and so that during inhalation gas from within said structure will be preferentially inhaled in preference to being inhaled from the ambient, carrying out said process during each inhalation-exhalation breathing cycle of said person in accordance with the following steps, at the start of inhalation cycle inhaling a volume of oxygen enriched gas from within the interior of said structure in preference to the inhalation of ambient air while concurrently reducing the internal volume of said structure to an amount corresponding to the amount of gas inhaled, finishing the inhalation by concurrently inhaling ambient air and gas from within the interior of said structure at the start of exhalation using the force developed from the gas exhaled to increase the internal volume of said changeable portion in an amount corresponding to the volume of oxygen enriched gas previously inhaled during the breathing cycle, admixing the gas exhaled into said structure with the oxygen introduced into said structure during the entire exhalation cycle so as to form a volume of oxygen enriched gas within said structure for use at the start of inhalation, and finishing the exhalation cycle by venting to the ambient any exhaled gas not entering said structure and any gas emitted from
said structure as a result of the introduction of oxygen into said structure during this part of the exhalation cycle.

Those aspects of the present invention which pertains to an apparatus are achieved by providing an apparatus which is primarily intended for use in oxygen therapy, said apparatus including means for conveying oxygen to the nose of a user of said apparatus and means for supplying oxygen to said means for conveying oxygen, the improvement which comprises: said apparatus including a structure having an internal volume, at least a portion of which is capable of being changed so as to be increased or decreased in response to a force developed from the movement of gas as a user of said apparatus breathes, said changeable portion having a lesser volume than the respiratory tract of said person, said means for conveying being shaped so as to be capable of being located relative to said user's nose so that during breathing cycles exhaled gas will be breathed into said structure in preference to being breathed to the ambient and so that during inhalation gas from within said structure will be inhaled in preference to being inhaled from the ambient, said means for supplying being connected to convey oxygen into the interior of said structure in a location in which it will be mixed with gas exhaled into the interior of said structure during exhalation as a result of contact with such gas.

BRIEF DESCRIPTION OF THE DRAWING

Because of the generic nature of this invention it is best more fully described with reference to the accompanying drawing in which:

Fig. 1 is a diagrammatic view of one form of an apparatus in accordance with this invention;
Fig. 2 is a diagrammatic view of a modified form of an apparatus in accordance with this invention;

Fig. 3 is a diagrammatic view of a further modified form of an apparatus in accordance with this invention;

Fig. 4 is a diagrammatic view of an additional further modified form an apparatus in accordance with this invention; and

Fig. 5 is still another diagrammatic view of another modified apparatus in accordance with this invention.

The various figures shown in the drawing are intended to show the principles or concepts of various different structures or apparatuses for carrying out the invention. Each of the various items shown is considered to have one or more advantages over each of the other items shown. These advantages frequently -- but not always -- relate to convenience of use of a specific structure in accordance with a specific person's needs or desires. Because of this it would be inaccurate to refer to any specific one of the apparatuses shown as being always preferable to the others.

The accompanying drawing is not intended to illustrate all of the detailed aspects and features of any specific apparatus in this invention. As will be apparent from the consideration of the appended claims forming a part of this specification this invention pertains to certain generic concepts which may be incorporated within or used within a wide variant of different appearing, differently constructed items of equipment through the use or exercise of routine engineering skill. Different of such apparatuses have different advantages. As a result some of them more suitable for some applications than others.
DETAILED DESCRIPTION

In Fig. 1 of the drawing there is shown an apparatus 10 in accordance with this invention which includes a set or pair of conventional nasal cannula 11 both of which are connected to an elongated conduit 12. This conduit 12 is provided with an inlet or inlet line 13 which is adapted to be utilized in continuously supplying oxygen to the apparatus 10 at a constant rate. Normally this line 13 will be connected to a tank of compressed oxygen (not shown) or other oxygen source through a usual flow control valve (not shown) and pressure regulator (not shown).

The extremity 14 of the conduit 12 remote from the cannula 11 is connected to a very loose, floppy type, exceedingly light weight impervious diaphragm 15 which may, as in the apparatus 10, take the shape of a floppy bag. This diaphragm preferably is formed of a thin, impervious, light weight material or synthetic rubber. It may or may not be slightly elastic in character. This bag is normally protected by a perforate housing 16 serving to prevent it from being damaged.

The nature of this diaphragm 15 is quite important with the present invention. It can be compared to a theoretical frictionless, weightless piston in a cylinder because of its function in the apparatus 10. It must be capable of being expanded and contracted so as to change in volume by the forces developed from the movement of gas caused by a user of the apparatus 10 breathing. The force involved in such movement is normally less than that developed or manifested at the nostrils of the user (not shown) by an amount corresponding to the loss of any energy by the movement of gas through and/or within the apparatus 10. It is
considered that this is best explained by discussing the "use" of the apparatus 10.

As this apparatus 10 is used the cannula 11 are inserted within the nostrils of the user (not shown) so as to be in a position such that exhaled gas will flow into the cannula 11 and so that during inhalation gas will be inhaled from the apparatus 10 through these cannula 11. The cannula 11 must not completely block or close the nostrils of the user. Instead they must be spaced relative to the nostrils of the user so as to permit flow around them or between them and the interiors of the nostrils of a user (not shown) as the apparatus 10 is used. Normally the achievement of such flow presents no problem when the usual round cannula are used because of the fact that the nostrils of the person are of a non-round configuration.

The manner in which the cannula 11 fit is quite important in achieving what is referred to herein as preferential flow. When the apparatus 10 is initially to be used, not only are the cannula 11 positioned as indicated, but in addition oxygen at a very low flow rate as subsequently discussed will be supplied through the line 13. This will tend to fill the apparatus 10 and to expand the diaphragm 15 so as to increase the internal volume within the apparatus 10. As the person using the apparatus 10 initially inhales at this point the person will inhale a quantity of gas which approximately corresponds to the volume to which the diaphragm 15 has been expanded. Of course, this volume will also correspond to the volume to which the diaphragm can be collapsed.

Because of the position of the cannula 11 at the start of inhalation the person will inhale this volume of gas from within the apparatus 10 preferentially to
inhaling any ambient air from around the cannula 11. It is important that this diaphragm 15 move or collapse quite easily so as to permit what may be regarded as a bolus of oxygen enriched gas to be the first gas inhaled by the user at the start of inhalation. This initially inhaled gas will tend to be that gas which reaches the lowermost part of the respiratory track in the lungs where oxygen is transferred to the blood.

When this initial bolus or quantity of gas from within the apparatus 10 is within the respiratory track the only additional gas which can be drawn into the respiratory track from the apparatus 10 by the breath during the remainder of the inhalation part of the breathing cycle will correspond to the volume of oxygen delivered to the apparatus through the line 13. As this limited or restricted amount of gas is drawn into the body through the cannula 11 the additional and principal gas necessary to fill the respiratory track will be drawn in from around the cannula 11 until such time as the breathing cycle changes to exhalation. The flow of oxygen must not be at a pressure or at a volume which would be capable of causing inflation of the diaphragm 15 during this last part of the inhalation cycle.

On exhalation the initial gas exhaled will be that generally within the upper portion of the upper respiratory track which has not reached the lungs. It will contain substantially the oxygen content of the gas inhaled during the last part of inhalation. This oxygen content will, of course, be that of the ambient air as enriched by gas displaced from the conduit 12 by the oxygen traveling into the apparatus 10 through the line 13 during the last part of inhalation. This initial quantity or bolus of exhaled gas will, of course, be captured within the apparatus 10 as the diaphragm 15 expands.
It is noted that the gas which accumulates within the diaphragm 15 during this initial part of exhalation will normally include and indeed may consist entirely of gas which remained within the apparatus 10 at the close of the inhalation cycle. The fact that this gas within the diaphragm 15 may not be that captured on exhalation is immaterial so long as the apparatus 10 is constructed so that those internal portions of it (not separately numbered) closest adjacent to the cannula 11 contain largely air from the ambient which has not reached the lungs enriched slightly with oxygen.

During exhalation as the apparatus 10 is being filled as noted with exhaled air oxygen will, of course, be flowing into this apparatus 10. In order to achieve such flow it is necessary that the oxygen being moved into the apparatus 10 be at a pressure greater than the pressure of the exhaled gas during normal breathing. The oxygen that flows into this apparatus 10 during this initial part of the exhalation cycle will tend to mix with the gas already within the apparatus 10 and that exhaled into it. This mixing will, of course, be accompanied by a gradual oxygen enrichment of the gas within the apparatus 10 during the initial part of the exhalation cycle.

After the apparatus 10 tends to become full and after the diaphragm 15 has expanded during exhalation, additional flow into the apparatus 10 from the respiratory tract of the user is prevented and as a result the additional exhaled gas will be vented to the ambient around the cannula 11. It is noted that this last gas exhaled to the ambient will tend to be diluted somewhat by a gas mixture from within the conduit 12 as a result of displacement caused by the continuous flow of oxygen through the line 13. Further this last gas exhaled will
contain the principal byproduct gas of the breathing cycle --carbon dioxide. As a consequence of this these gasses will not remain in the "system" consisting of the apparatus 10 and the respiratory track of the user of this apparatus 10.

At this point the user of the apparatus 10 will normally commence the next respiratory cycle by inhalation. This will result in the user inhaling an oxygen enriched bolus or quantity of exhaled gas from within the conduit 12 adjacent to the cannula 11 until such time as the diaphragm 15 has been collapsed. At this point the cycle of operations indicated in the preceding will continue indefinitely as long as the apparatus 10 is used.

In order for an apparatus 10 to function in the manner indicated in the preceding discussion it is necessary for the volume change caused by the movement of the diaphragm 15 to be less than the volume of gas which is normally moved into or out of the respiratory tract of a user of this apparatus. It is considered that it would be inefficient to use a volume of this latter size and that it is preferable to use an apparatus 10 constructed so that this volume is no greater than about the volume required in the respiratory tract to cover the alveolar membranes during inhalation. This will, of course, vary from patient to patient. The objective of the use of such a volume is to make reasonably certain that an effective amount of oxygen for oxygen therapy reaches only those parts of the lungs where oxygen transference takes place. This is difficult to achieve because of the fact that some gas will remain in the respiratory tract after expiration.

Of course the higher the oxygen content of the bolus of gas taken into the respiratory tract at the
start of inhalation and the larger the size of this bolus the greater the amount of oxygen which can be expected to reach those portions of the lungs where the alveolar membranes are located. The volume of gas which is supplied to a user at the start of inhalation with the apparatus 10 should be limited in order to insure preferential movement of gas from within the apparatus at the start of inhalation. If this volume is greater than about 60 ml. normally the inertia of the gas and the diaphragm 15 will be so great that the entire content of this volume will not be "snapped" into the respiratory tract on the start of inhalation, but instead will be sufficiently large to delay flow from the apparatus 10 to a user such an extent that bolus of oxygen enriched gas will be significantly diluted by ambient air flowing around the exteriors of this cannula 11.

When this occurs the initially inhaled gas tending to reach the alveolar membranes will not have as high an oxygen content as reasonably possible. On the other hand if the volume capable of being taken up by or delivered by the apparatus 10 is so small it is considered that it will contain an amount of oxygen which is too small to be effective in oxygen therapy -- regardless of the oxygen content of this volume. As a consequence of this it is considered that the apparatus 10 should be constructed so as to be capable of delivering at least 8 ml. of any oxygen enriched gas mixture. It is presently considered that preferred results are achieved when this value of oxygen enriched gas is within the range from about 10 to about 20 ml. since such a quantity of gas can be easily and rapidly moved through the use of the apparatus 10 without being accompanied by a significant movement of collateral ambient air.
For such a volume to be effective in oxygen therapy it is necessary that its oxygen content be as high as can be reasonably achieved in the apparatus 10. The total oxygen content of the volume within the apparatus 10 will, of course, vary in accordance with this volume and the rate at which oxygen is introduced into it as well as in accordance with the manner in which the exhaled gas captured in the apparatus 10 is mixed with and displaced from the apparatus as the oxygen flows into the apparatus 10. To obtain a bolus of oxygen enriched gas in the apparatus 10 without any noticeable waste of the oxygen it is believed necessary for the internal volume within the apparatus between the oxygen inlet and the ends (not numbered) of the cannula 11 to be at least as great as the volume to be delivered to a user on inhalation. This will normally correspond to the volume change within the apparatus caused by either the expansion or the contraction of the diaphragm 15.

In general it is considered that most effective utilization of oxygen occurs when the oxygen flow rate is such that during the latter part of the exhalation cycle that the quantity of gas to be delivered on inhalation located adjacent to and within the cannula will be enriched with oxygen so as to have an oxygen content of at least 50% but less than 100% by weight. If the latter degree of enrichment is sought there is danger of oxygen being unnecessarily lost to the ambient air. It is presently considered that preferred results are achieved when the oxygen content of the bolus of gas to be delivered at the start of inhalation is from about 80 to about 98% by weight.

In Fig. 2 of the drawing there is shown a modified apparatus 20 of the present invention in which a diaphragm 25 corresponding to the diaphragm 15 in the form of a sleeve is located generally between on oxygen
inlet 23 and a conduit 22 carrying cannula 21. In this apparatus 20 a perforated canister-like housing 26 serves to protect the diaphragm 25 and may also serve to prevent it expanding to an undesired extent.

In Fig. 3 of the drawing there is shown a further modified apparatus 30 of the present invention which includes an elongated cup-like housing 36 having a perforate wall 37. A diaphragm 35 corresponding to the diaphragm 15 is secured in this housing 36 so as to enclose that portion of the housing (not separately numbered) of an imperforate character. An inlet line 33 leads into the housing 36 and an outlet 38 is provided so as to lead from it to cannula 31. If desired these cannula 31 may be located so as to extend directly from the housing 36. This apparatus 30 is of such a nature that in use the diaphragm 35 will, at the end of exhalation, close off, or substantially close off the outlet 38 from the inlet 33 until it is moved by incoming oxygen. With this structure 30 the expansion of the diaphragm 35 can be controlled by either its construction or by the geometry of the housing 36.

All of these apparatuses 10, 20 and 30 operate or are operated in substantially the same manner. As a consequence of this it is not considered necessary to discuss their operation in detail. These apparatuses 10, 20 and 30 differ from two other apparatuses 40 and 50 shown in the drawing in that these other two apparatuses do not use nasal cannula, but utilize perforate, more or less, cup-like enclosures or masks 41 and 51 which are adapted to be located on the face of a patient so as to generally cover and enclose at least the nose and frequently the nose and the mouth of the patient. These masks 41 and 51 are thus used in locations when a patient has to exhale into them and inhale from them. In order to promote patient comfort these nose masks 41
and 51 should preferably be formed of a soft, self-supporting, deformable rubber.

In the apparatus 40 the mask 41 is connected through a conduit 42 to a diaphragm 45 which is held within a perforate housing 46. An inlet oxygen line 43 leads into the conduit 42 in substantially the same manner in which the apparatus 10 was constructed. The apparatus 50 is somewhat different in that the mask 51 has a perforate bottom 52 leading into an imperforate cylindrical housing wall 53 which in turn is enclosed by a perforate wall 54. A diaphragm 55 is mounted within the wall 53 so as to be capable of being moved so as to expand and contract the volume within the wall 53 adjacent to the wall 52. An oxygen line 56 is provided for constantly conveying oxygen on the side (not numbered) of the diaphragm 55 adjacent to the wall 52.

The action achieved during the use of these two apparatuses 40 and 50 is quite similar to the action achieved in connection with the apparatus 10 previously described. The principal important difference relates to the fact that these apparatuses 40 and 50 do not use the nasal cannula and hence avoid the problems and complications which are encountered in the use of such cannula. This type of advantage is achieved at a cost -- the cost related to the effectiveness and operation of the devices 40 and 50.

Because of their construction and the manner in which they are used these devices 40 and 50 will tend to trap due to preferential flow the initially exhaled quantity or bolus of gas on exhalation and to vent the remainder of exhaled gas to the ambient through openings 47 and 57 located generally at the sides (not separately numbered) of the masks 41 and 51. With these apparatuses 40 and 50 at the start of inhalation there will be
a tendency for the initial bolus or quantity of gas to be inhaled to come directly from within them and then to be followed by the introduction of gas from the ambient through the holes 47 and 57. In all other ways these apparatus 40 and 50 operate or are operated in the same manner as the apparatus 10.

Because of the geometry of any mask used it is considered that the type of construction illustrated in Figs. 4 or 5 cannot achieve the efficiency of operation through the direct administration of a reasonably distinct bolus or quantity of oxygen enriched gas that is substantially free from exhalation byproducts obtainable from the apparatuses 10, 20 and 30. However, there may very well be circumstances where apparatuses corresponding to the apparatuses 40 and 50 are much more desirable than the apparatuses 10, 20 and 30 due to patient discomfort and other considerations.

It is possible to modify the operation of the apparatus 10 or any of the other different apparatuses discussed to a slight or limited extent by being sure that the diaphragm 15 or the corresponding diaphragm used in any of these other apparatuses is slightly elastic and is capable of stretching slightly in response to the exhaled breath of a user. With this type of construction the rapid change in pressure within the apparatus 10 or any of the other apparatuses described on inhalation will enable any such diaphragm to return to its initial configuration as a result of the energy stored within it. This is considered to be slightly beneficial as facilitating inhalation.
WE CLAIM:

1. In a process of oxygen therapy in which a structure receives oxygen from an oxygen source and supplies oxygen to the nostrils of a person receiving the therapy the improvement which comprises:

   said structure having an internal volume, at least a portion of said internal volume being capable of being changed in response to a force developed from the movement of gas by said person breathing normally, said changeable portion having a lesser volume than the volume of the respiratory tract of said person,

   continuously supplying oxygen to the interior of said structure, the volume of oxygen supplied being less than the volume of gas inhaled by said person,

   locating said structure relative to said person's nose so that during breathing cycles exhaled gas will be preferentially breathed into said structure in preference to being breathed to the ambient and so that during inhalation gas from within said structure will be preferentially inhaled in preference to being inhaled from the ambient,

   carrying out said process during each inhalation-exhalation breathing cycle of said person in accordance with the following steps,

   at the start of inhalation cycle inhaling a volume of oxygen enriched gas from within the interior of said structure in preference to the inhalation of ambient air while concurrently reducing the internal volume of said structure to an amount corresponding to the amount of gas inhaled,

   finishing the inhalation by concurrently inhaling ambient air and gas from within the interior of said structure,

   at the start of exhalation using the force developed from the gas exhaled to increase the internal volume of said changeable portion in an amount corre-
sponding to the volume of oxygen enriched gas previously inhaled during the breathing cycle,

admixing the gas exhaled into said structure with the oxygen introduced into said structure during the entire exhalation cycle so as to form a volume of oxygen enriched gas within said structure for use at the start of inhalation, and

finishing the exhalation cycle by venting to the ambient any exhaled gas not entering said structure and any gas emitted from said structure as a result of the introduction of oxygen into said structure during this part of the exhalation cycle.

2. A process as claimed in claim 1 wherein:
said structure includes nasal cannula which are fitted within said person's nostrils without completely filling or completely blocking flow between said cannula and said nostrils when said structure is located relative to said person's nose.

3. A process as claimed in claim 2 wherein:
the volume of said volume of oxygen enriched gas is from about 8 to about 60 ml. and
the oxygen content of said volume of oxygen enriched gas is from about 50 to about 100% by weight.

4. A process as claimed in claim 2 wherein:
the volume of said volume of oxygen enriched gas is from about 10 to about 20 ml. and
the oxygen content of said volume of oxygen enriched gas is from about 80 to about 98%.

5. A process as claimed in claim 1 wherein:
said structure includes a mask which covers at least said person's nose.
6. A process as claimed in claim 5 wherein:
said mask covers both said person's nose and
mouth.

7. A process as claimed in claim 5 wherein:
the volume of said volume of oxygen enriched gas
is from about 8 to about 60 ml. and
the oxygen content of said volume of oxygen
enriched gas is from about 50 to about 100% by weight.

8. A process as claimed in claim 5 wherein:
the volume of said volume of oxygen enriched gas
is from about 10 to about 20 ml. and
the oxygen content of said volume of oxygen
enriched gas is from about 80 to about 98%.

9. In an apparatus which is primarily intended
for use in oxygen therapy, said apparatus including
means for conveying oxygen to the nose of a user of said
apparatus and means for supplying oxygen to said means
for conveying oxygen, the improvement which comprises:

said apparatus including a structure having an
internal volume, at least a portion of which is capable
of being changed so as to be increased or decreased in
response to a force developed from the movement of gas
as a user of said apparatus breathes, said changeable
portion having a lesser volume than the respiratory
tract of said person,

said means for conveying being shaped so as to
be capable of being located relative to said user's nose
so that during breathing cycles exhaled gas will be
breathed into said structure in preference to being
breathed to the ambient and so that during inhalation
gas from within said structure will be inhaled in prefer-
ence to being inhaled from the ambient,

said means for supplying being connected to
convey oxygen into the interior of said structure in a
location in which it will be mixed with gas exhaled into
the interior of said structure during exhalation as a
result of contact with such gas.

10. An apparatus as claimed in claim 9 wherein:
said means for conveying comprise nasal cannula.

11. An apparatus as claimed in claim 10
wherein:
said changeable portion of said volume can be
changed in amounts of from about 8 to about 60 ml. and
the internal volume between said means for
supplying and said means for conveying is from about 8
to about 60 ml.

12. An apparatus as claimed in claim 10
wherein:
said changeable portion of said volume can be
changed in an amount of from about 10 to about 20 ml.
and
the internal volume between said means for
supplying and said means for conveying is from about 8
to about 60 ml.

13. An apparatus as claimed in claim 9 wherein:
said means for conveying comprises a mask
capable of conveying at least the nose of a user.

14. An apparatus as claimed in claim 13
wherein:
said mask is sized so as to be capable of
conveying to the nose and the mouth of a user.

15. An apparatus as claimed in claim 13
wherein:
said changeable portion of said volume can be
changed in amounts of from about 8 to about 60 ml. and
the internal volume between said means for supplying and said means for conveying is from about 8 to about 60 ml.

16. An apparatus as claimed in claim 13 wherein:
    said changeable portion of said volume can be changed in an amount of from about 10 to about 20 ml. and
    the internal volume between said means for supplying and said means for conveying is from about 8 to about 60 ml.
**INTERNATIONAL SEARCH REPORT**

**I. CLASSIFICATION OF SUBJECT MATTER** (If several classification symbols apply, indicate all)

- IPC: A61M 16/00
- U.S. Cl.: 128/207.18

**II. FIELDS SEARCHED**

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<td>128/207.18, 207.16, 205.13, 205.14, 203.22, 204.24, 204.26, 205.17, 205.15, 205.16, 205.25, 205.12</td>
</tr>
</tbody>
</table>

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched.

**III. DOCUMENTS CONSIDERED TO BE RELEVANT**

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of Document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to Claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>U.S., A, 4,054,133 13 October 1977 MYERS</td>
<td>1-4, 7, 8, 9-12, 15, 16</td>
</tr>
<tr>
<td>X</td>
<td>U.S., A, 4,120,300 17 October 1978 TIEP</td>
<td>1-4, 7, 8, 9-12, 15, 16</td>
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<td>X</td>
<td>U.S., A, 3,973,564 10 August 1976 CARDEN</td>
<td>1-4, 7, 8, 9-12, 15, 16</td>
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<td>Y</td>
<td>U.S., A, 3,045,671 24 July 1962 UPDEGRAFF</td>
<td>5, 6, 13, 14</td>
</tr>
<tr>
<td>A</td>
<td>U.S., A, 2,208,633 23 July 1940 HEIDBRINK</td>
<td></td>
</tr>
</tbody>
</table>

* Special categories of cited documents:
  - "A" document defining the general state of the art which is not considered to be of particular relevance
  - "E" earlier document but published on or after the international filing date
  - "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
  - "O" document referring to an oral disclosure, use, exhibition or other means
  - "P" document published prior to the international filing date but later than the priority date claimed
  - "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
  - "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step
  - "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
  - "A" document member of the same patent family

**IV. CERTIFICATION**

- Date of the Actual Completion of the International Search: 15 December 1983
- Date of Mailing of this International Search Report: 04 JAN 1984
- Signature of Authorized Officer: [Signature]

Form PCT/ISA/210 (second sheet) (October 1981)
V. OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHEABLE

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers __________, because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claim numbers __________, because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

VI. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This International Searching Authority found multiple inventions in this international application as follows:

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest
☒ The additional search fees were accompanied by applicant’s protest.
☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (supplemental sheet (2)) (October 1981)