Jan. 20, 1970 S. L. GREENFIELD 3,490,452

THERAPEUTIC FACE MASK

Filed June 20, 1967 4 Sheets-Sheet 1

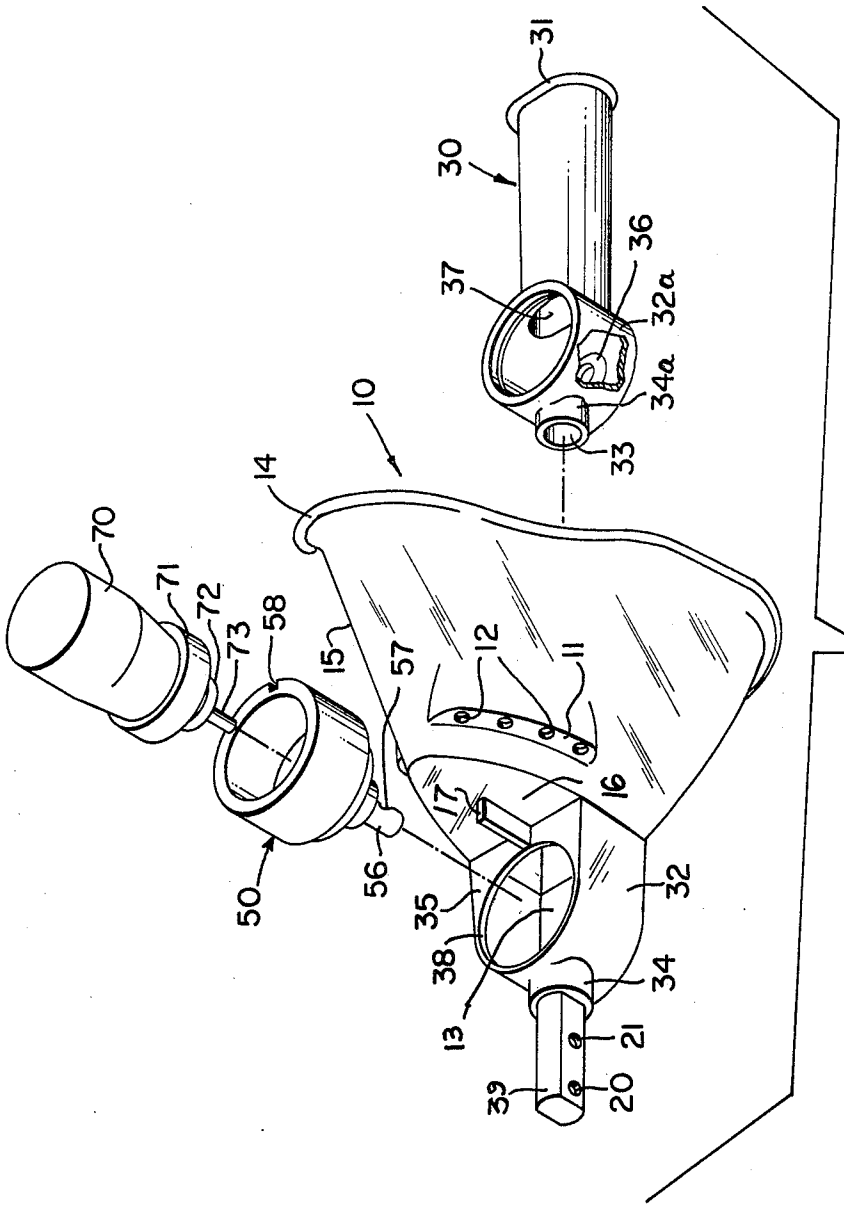

FIG. 1

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THERAPEUTIC FACE MASK

Filed June 20, 1967 4 Sheets-Sheet 2

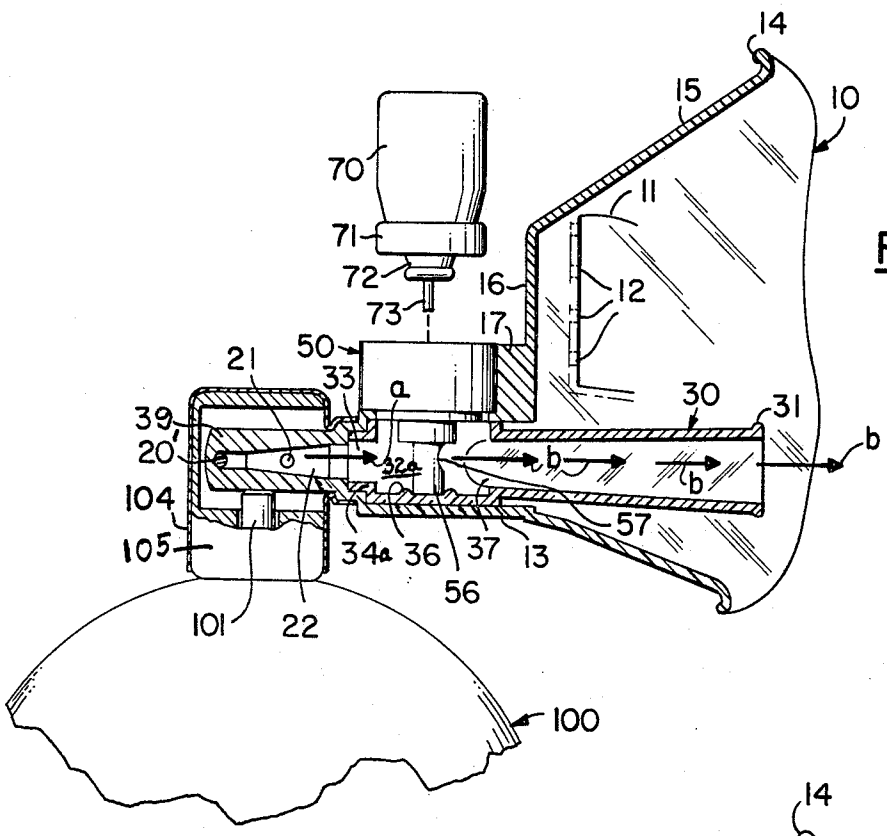

FIG. 2

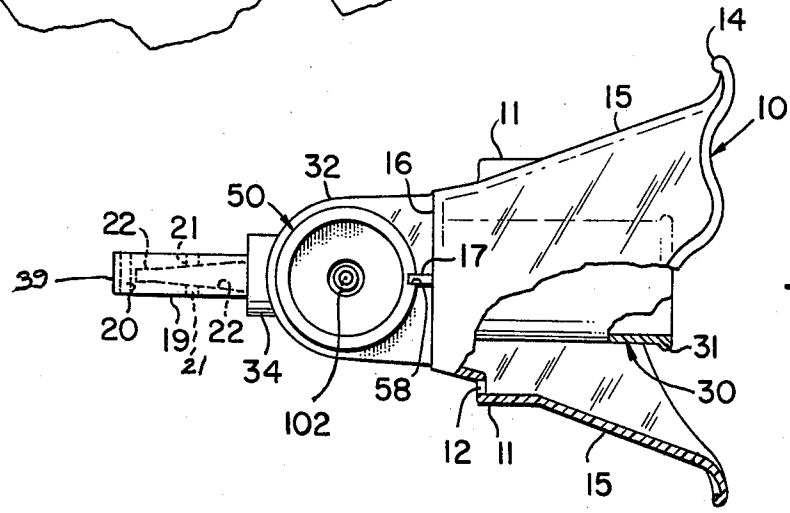

FIG. 3

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THERAPEUTIC FACE MASK

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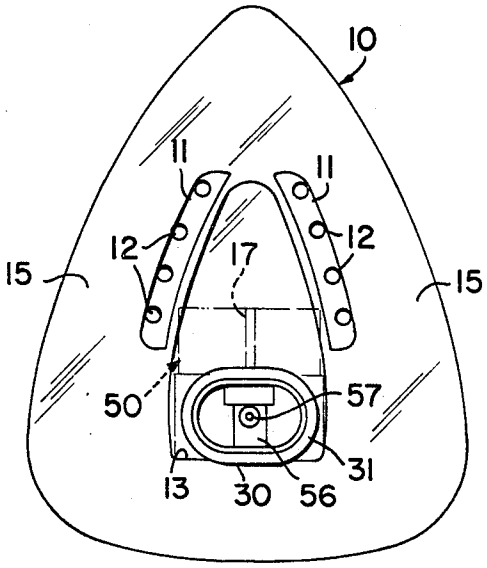


FIG. 4

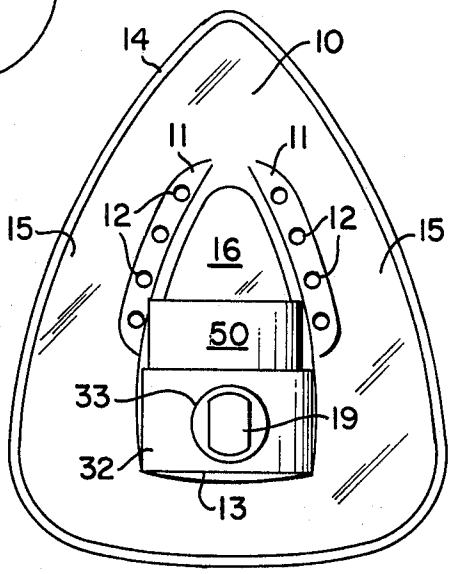
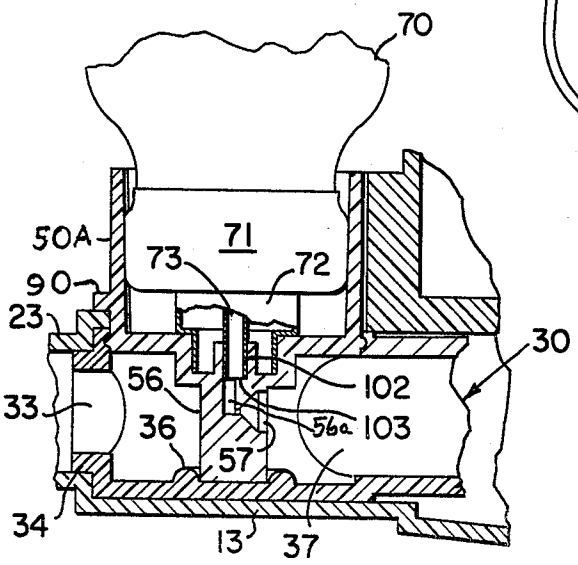


FIG. 5

FIG. 6



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Filed June 20, 1967 4 Sheets-Sheet 4

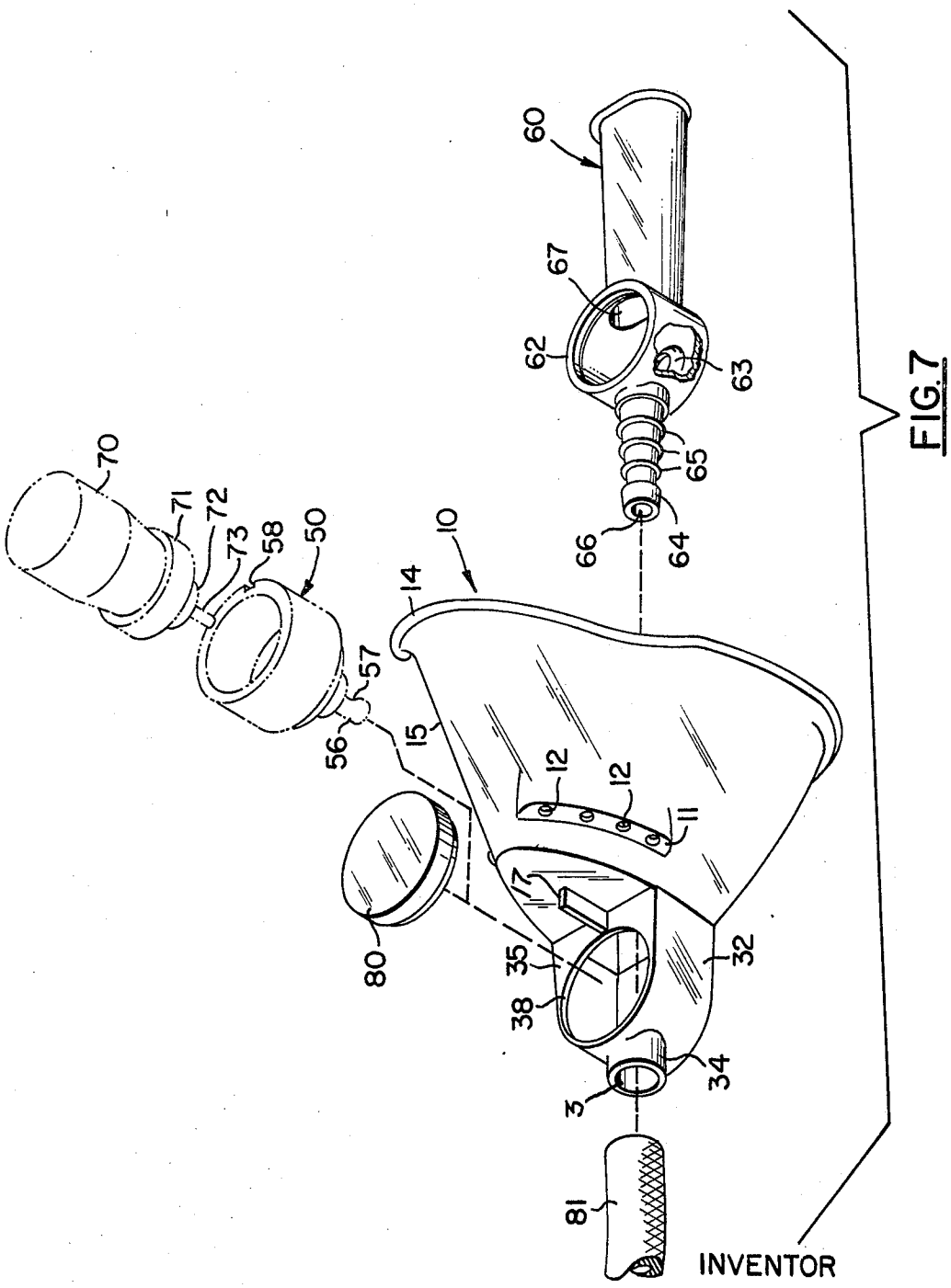

FIG. 7

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United States Patent Office 3,490,452
Patented Jan. 20, 1970

3,490,452

THERAPEUTIC FACE MASK

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Filed June 20, 1967, Ser. No. 647,496
Int. Cl. A61j 7/00; A61m 15/00, 16/00
U.S. Cl. 128—196 5 Claims

ABSTRACT OF THE DISCLOSURE

The therapeutic face mask is formed from two separable parts. One part consists of a face mask portion which is provided at its forward end with an integral receiving chamber having an open top and also with a side inlet port adapted to be connected to a suitable oxygen supply source. The second part of the face mask consists of an elongated mouth tube which is positioned within the face mask and extends horizontally therein. One end of the mouth tube terminates in a cylindrical nebulizer chamber which is received and retained in the receiving chamber in nested relation. The nebulizer chamber is provided with an inlet port which is adapted to communicate with an oxygen supply source. A removable adapter head is provided which can be positioned in the nebulizer chamber. A conventional aerosol cartridge containing therapeutic agents is adapted to be received in the adapter head for supplying a controlled stream of nebulized therapeutic agents to the nebulizer chamber. The oxygen stream and nebulized stream supplied by the cartridge are commingled in the nebulizer chamber and are then fed into the mouth tube and directly into the patient's mouth.

BACKGROUND OF THE INVENTION

Field of the invention

Nebulization therapy is concerned with delivering a dose of medication in the treatment of patients suffering from chronic bronchitis, emphysema, asthma and other diseases. In such cases the pulmonary airways are constricted, congested, or edematous, and obstructed with thick secretions. It is therefore necessary to achieve effective bronchodilation and mucosol decongestion and in some cases to administer antibiotics, steroids, liquefying agents, etc. Deposition of the necessary agents is accomplished by delivery of medication by nebulization; that is, by administering the medication in droplets suspended in air or other gases which are deposited in the respiratory tract upon inhalation of the nebulized medication.

Description of prior art

It has been found that the droplets in nebulized streams tend to coalesce when the stream changes direction of flow or encounters a baffling action; coalescence of droplets also occurs when turbulence is increased in the nebulized stream. In recent years cartridge-type bronchodilator aerosol generators have become available. A self-contained propellant (Freon, etc.) delivers a metered stream of bronchodilator particles when a plunger is depressed. These metered dose cartridges are very convenient for administering bronchodilator or bronchodilator-decongestant drugs, especially in ambulatory patients. Their main disadvantage is that production of mist occurs over too short a time to allow full utilization of slow, deep inhalation. Furthermore, losses of the nebulized drugs occur when such cartridge generators are used on account of "rain-out" or coalescence of the particles.

SUMMARY OF THE INVENTION

The present invention provides a face mask which is constructed to retain a cartridge-type aersol generator containing the prescribed medicinal agents so that the medication can be self-administered by the patient by manually depressing the plunger provided in such cartridges. The nebulized stream of medication is administered directly into the mouth and is inhaled by the patient orally so that treatment of the entire respiratory tract and depths of the lungs is accomplished. The present face mask also provides means for supplying a stream of oxygen or other gas to the face mask and simultaneously supplying a nebulized stream of medication which are commingled and inhaled by the patient to ensure that the entire respiratory tract and lungs are treated with the medication and to maintain the medication droplets in the optimum droplet size for deposition in the respiratory tract. The present invention also ensures that any "rain-out" of the medication is reduced to a minimum and if any coalescence of the drops occurs, the secondary stream of oxygen or other gas fed to the mask will nebulize the coalesced drops.

The mask is designed to serve a dual purpose—for acute emergency situations and for daily or as needed therapy.

The essential features of its construction permit a controlled flow of oxygen into the mask and the use of nebulizer mouthpiece built into the mask as one unit. The nebulizer is designed for the use of cartridge-type aerosol generators containing the appropriate medication and prescribed by the patient's physician. This is inhaled into the lungs through a mouthpiece.

While primarily designed to be adapted to a small portable source of medicinal oxygen, it can be connected to any other oxygen intake including "piped in" oxygen in hospital rooms.

The oxygen when released flows directly through the nebulizer mouthpiece portion and can be used independently or simultaneously with the flow of nebulized medication. Likewise, the aerosol medication can be used independently.

Thus the oxygen can be used separately for emergency purposes or when combined with the medicinal mist cause it to break down into finer particles resulting in deeper penetration into the air sacs (alveoli) of the lungs with greater therapeutic effect. The patient can obtain the initial beneficial effects of his medication and then immediately follow with some inhalations of oxygen for additional comfort.

While most of the aerosol cartridge-type medical inhalants to be used in this adapter will be of the decongestant, bronchodilating type, to correct the interference with the normal movement of air in and out of the lungs, such as in asthma, emphysema, "chronic bronchitis," other types of aerosol medication have been or will be developed which can be used in this unit—for instance one recently released for treatment of migraine headaches.

According to the present invention the face mask is constructed to enclose the mouth and nose portions of the face of a patient for medical treatment of his respiratory system or other system for which aerosol medication by inhalation is available. The mask is preferably formed of two separable parts. These parts can be assembled and easily disassembled for cleaning or sterilizing the parts after use. One part consists of a face receiving chamber which is open at the top. The other part consists of a removable mouth tube which is open at its front end to be receivable within the mouth of a patient and the other end terminates in a cylindrically shaped nebulizer chamber. The mouth tube is adapted to be positioned within the face mask portion so as to extend lengthwise therein with the nebulizer chamber being positioned within the receiving chamber of the face mask portion in nested relation. These two chambers are generally complemental in shape. The mouth tube and face mask portion if desired can be formed in an integral unit without being separable.

The nebulizing chamber has an open top for receiving a removable adapter which receives and retains an aerosol cartridge filled with a suitable aerosol therapeutic drug composition which is ejected under pressure by actuating a valve provided in the aerosol cartridge. The nebulizer chamber is also provided with an inlet port through which a stream of oxygen or other gas under suitable pressure is supplied. The stream of oxygen or other gas and aerosol drug composition are mixed in the nebulizer chamber and flow through the mouth tube extending forwardly within the face mask. The open end of the mouth tube is adapted to be received in the mouth of the patient and to be sealed by his lips. The stream of nebulized therapeutic composition is thus fed directly into the mouth of the patient in completely nebulized condition for inhalation by the patient. The present mask construction facilitates the administration of combined medicinal oxygen and selected drugs such as bronchodilating, vasoconstricting, mucolytic and other drugs for treating the respiratory system by inhalation, or other systems when such medication is available.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a perspective view of the disassembled face mask showing the separate components thereof,

FIGURE 2 is a vertical sectional view of the assembled components of the face mask shown in FIGURE 1 and connected to a source of oxygen,

FIGURE 3 is a plan view of the assembled face mask partially broken away,

FIGURE 4 is an elevational front view of the assembled face mask,

FIGURE 5 is an elevational rear view of the assembled face mask,

FIGURE 6 is an enlarged vertical sectional view showing a modified construction of the cartridge adapter head, and

FIGURE 7 is a perspective view of a modified construction of a disassembled face mask showing the separate components thereof.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to the drawings, FIGURE 1 shows an illustrative embodiment of my invention. The face mask is preferably formed from a normally rigid plastic material, such as acrylic resin, polypropylene and the like. The face portion is designated generally by numeral **10**. The mouth tube is designated generally by numeral **30**. The cartridge adapter is designated generally by numeral **50**. The aerosol cartridge is designated generally by numeral **70**. These parts are suitably dimensioned so that they can be readily assembled into an operable unit, as shown in FIGURE 2, and connected to a suitable source of oxygen, designated in general by numeral **100**. These parts are preferably individually separable and can be readily assembled manually for use. The parts are suitably proportioned so that they interfit closely to avoid gas leakage and the respective passageways and parts provided therein are precisely aligned. The separate parts are assembled by first inserting mouth tube **30** within the face mask portion **10** so that it extends lengthwise therein with the aerosol chamber **32***a* being positioned within the receiving chamber **32** in nested relation as shown in FIGURES 2 and 3. The cartridge adapter **50** is then positioned within the open top of the aerosol chamber **32***a* in the position shown in FIGURE 2. The aerosol cartridge **70** is shown in FIGURE 2 in elevated position prior to its insertion in the adapter **50** for the sake of clarity. The cartridge **70** contains a selected pressurized inhalation aerosol therapeutic composition suitable for treatment of a specific pulmonary condition or other disease of a patient. The cartridge **70** is preferably provided with a valve housing **71** terminating in a neck portion **72** and hollow plunger **73**. The specific valve construction is disclosed in Patent 2,721,010, Oct. 18, 1955, which dispenses measured

amounts of the aerosol composition stored in the cartridge. A suitable desired therapeutic inhalation composition is stored in the cartridge **70** which is suitably pressurized with non-toxic volatile lower alkane conventional propellants, such as dichloro difluoromethane, 1,2-dichloro-1,2,2-tetrafluoroethane, their mixtures, and the like. When the assembled mask is connected to the oxygen cylinder **100**, as shown in FIGURE 2, and the cartridge **70** is positioned in the cartridge adapter, upon manually tilting the front end of the mask downwardly from its horizontal position as shown in FIGURE 2, plunger pin **101** of the oxygen cylinder **100** will be depressed and pressurized oxygen will flow through inlet port **21** and port **22** in the stem **39** of the mouth tube **30**, into the aerosol chamber **32***a* as indicated by arrow *a* where the oxygen stream will commingle with the aerosol therapeutic stream ejected, through port **57** of the cartridge adapter when cartridge **70** is manually depressed so as to actuate plunger **73**. The combined nebulized stream then flows through the mouth tube as indicated by the arrows *b* into the mouth of the patient.

The face mask portion **10** is suitably dimensioned and contoured to receive the nose and mouth portions of the patient. The face mask is generally conical in shape and may be provided in different sizes for use by adults, children or infants. The open end of the face mask is provided with an outwardly beaded or rolled rim **14** to facilitate snug sealing contact with the face portions of the patient. The side wall portions **15** of the face mask are formed with integral elevated portions **11** which are provided with a plurality of spaced openings **12** to permit escape of excess gas pressure or air expelled by the patient when in position on the patient's face.

The face mask portion is provided at its upper front portion with a flat vertical wall **16** having integral therewith a projecting key portion **17**. The lower portion of face mask is connected to a receiving chamber **32** and communicates therewith (see FIGURE 1). The chamber **32** is open at the top **38** and closed at the bottom **13**. The opposed side walls and bottom wall **13** of the receiving chamber are connected to the sides and bottom wall of the mask portion and form continuous extensions thereof. The side walls **13** of the receiving chamber merge in a forward rounded end wall which is provided with a sleeve portion **34** having a passageway **33** for receiving stem **39** of the mouth tube **30** (see FIGURE 2).

The stem **39** is provided with an internal channel or port **22** which extends longitudinally thereof, as shown in FIGURES 2 and 3. The channel **22** communicates with opposed inlet ports **21** provided in stem **39** and which extend at right angles thereto, as shown in FIGURE 3. Channel **22** communicates with chamber **32***a*, as shown in FIGURE 2. The outer end of stem **39** is provided with a hole **20** adapted to receive a pivot pin **20'**, as shown in FIGURE 2, and which is carried by the head portion **105** of oxygen cylinder **100**. Valve pin **101** in the head portion **105** controls the flow of oxygen stored under pressure in cylinder **100**. The details of this valve construction are disclosed in Patent 3,186,407, June 1, 1965. When the entire face mask assembly is manually tilted downwardly on the pivot pin **20'** from its horizontal position shown in FIGURE 2, valve pin **101** will be depressed by virtue of the leverage applied by stem **39** against it. The head portion **105** is enclosed by a flexible rubber cover **104** which also embraces and seals sleeve **34** and thus prevents escape of oxygen.

The cylindrical cartridge adaptor **50** is preferably made of a suitable plastic material and is provided with an external longitudinal groove **58**, as shown in FIGURES 1 and 3, for receiving the key portion **17**. A slightly modified construction of the adapter is shown in FIGURE 6. In both constructions the adapter is provided with an internal longitudinal bore **56***a* which communicates with outlet port **57** positioned at right angles thereto. This construction is shown in FIGURE 6.

Mouth tube **30** is provided with a beaded edge **31** at its outer open end which is adapted to be contacted and sealed by the lip portions of the patient when in use. The other end **37** of the mouth tube terminates and communicates with a cylindrical nebulizer chamber **32***a* which is provided with an inlet port **33** in sleeve **34**. The nebulizer chamber **32***a* is proportioned and shaped so as to be receivable and nestable within the chamber **32** as shown in FIGURE 2 when the mouth tube **30** is positioned longitudinally within the mask. The lower wall portion of the nebulizer chamber **32***a* is provided with circular area defined by a circular protrusion or ridge **36** integral with the lower wall of the chamber, as shown in FIGURES 1 and 2. This circular ridge serves to locate and position the stem **56** of adapter **50**, as shown in FIGURE 2, when the adapter is positioned within the nebulizer chamber **32***a*. The vertically extending groove **58** in adapter **50** is positioned in the side wall of the adapter so that the exit port **57** is aligned with the inlet port **33** of the mouth tube.

The adapter **50** is suitably dimensioned to receive the cylindrical valve housing **71** of cartridge **70**. The collar portion terminates in neckportion **72** which retains the hollow valve-actuating plunger **73**. When the cartridge **70** is positioned in adapter **50** the hollow plunger **73** will extend into the longitudinal port **102** provided in adapter **50** (see FIGURE 6). When the cartridge **70** is manually depressed the plunger **73** will move inwardly of the valve housing provided in the cartridge **70** and actuate the valve to permit a measure amount of aerosol material to be ejected through the bore **103** of the plunger **73**. The aerosol stream will then flow downwardly through the bore **103** in adapter **50** and then laterally through orifice **57** into the aerosol chamber **32***a* provided at the inner end of the mouth tube **30** as previously described. The aerosol stream supplied from cartridge **70** will commingle with a stream of oxygen which is supplied to the aerosol chamber through inlet port **33** as previously described. The commingled oxygen and aerosol stream will flow in a straight unimpeded path directly into the inlet port **37** of the mouth tube **30** in a straight unimpeded path as shown by arrows *b* in FIGURE 2 and then directly into the mouth of the patient.

It is to be understood that the invention is not restricted to the specific embodiment previously described and that changes and modifications may be made which embody the essential features of the invention. The adapter for receiving the aerosol cartridge may obviously be replaced by other modified constructions for receiving other types of aerosol cartridges. For example, FIGURE 6 illustrates a modified construction of the cartridge adapter which is designated by numeral **50A**. It is similar to the adapter **50** shown in FIGURE 1 except that it is provided with a flange **90** adapted to seat on the shoulder **23** of the inner end of the mouth tube **30**. The foot portion **56** of the adapter seats in the area defined by circular ridge **36** as in the construction shown in FIGURE 2. The aerosol stream flows through the bore **103** of hollow plunger **73** of the aerosol cartridge **70** into the vertical passageway **56***a* in the adapter and then laterally through exit port **57** which in turn communicates with the inlet **37** of the mouth tube **30**.

FIGURE 7 illustrates a modified face mask construction. The face mask **10** has the same general construction as the mask shown in FIGURE 1 except that sleeve **34** is not provided with a stem **39** as in FIGURE 1. Mouth tube **60** is similar to the mouth tube in FIGURE 1 except that the sleeve **34** is provided with a connector stem **64** having a bore **66** extending therethrough and communicating with nebulizing chamber **62**. Chamber **62** has a port **67** which communicates with mouth tube **60**. The mouth tube **60** is adapted to be inserted within the face mask portion **10** so that nebulizing chamber **62** is positioned and nested within receptacle portion **32**. Connector stem **64** will then extend externally through the opening **3** of sleeve **34** in the same relation as stem **39** extends from chamber **32** as shown in FIGURE 1. Stem **64** is provided with a grooved surface **65** for frictionally retaining the end of hose **81** which is connected to a suitable source of oxygen, such as a conventional oxygen cylinder or to a "piped-in" oxygen system used in hospitals. In event a cartridge **70** is not required for supplying medication to mask **10** and only oxygen or other gas is to be supplied from cylinder **100**, the open end **38** of receiving chamber **32** can be closed by a closure or cover **80**. In the event it is desired to administer oxygen and an aerosol inhalant composition, the closure **80** is remved and the cartridge adapter **50** is inserted in the receptacle **32**. An aerosol cartridge is then positioned in the adapter to supply an aerosol stream of inhalant composition as desired.

The present invention provides convenient means for administering oxygen alone or admixed with nebulized drugs for inhalation therapy. Mist is always changed as it passes through conventional equipment; large droplets are selectively removed by any bend or change in direction in flow. At the same time, turbulence increases the coalescence of smaller droplets. In the present mask construction the aerosol stream generated from the cartridge which issues from the 90-degree bend through orifice **57** is promptly diluted and evaporated to smaller droplet size as the stream enters the nebulizer chamber **32***a* and commingles with the oxygen stream entering the nebulizer chamber **32***a* through inlet **33**. Any "rain-out" of the aerosol stream will be promptly evaporated to smaller droplets in the nebulizer chamber as well as in the month tube. The interior side wall of the nebulizer chamber **32***a* is preferably cylindrical in shape and it has a smooth and continuous surface which facilitates complete mixing of the oxygen stream and aerosol stream of medicament agents fed into the nebulizer chamber without turbulence. Such construction ensures minimum "rainout" of the aerosol stream and facilitates the evaporation of the droplets so as to produce the smallest possible droplet size of the therapeutic agents for inhalation by the patient. Penetration of the medication into the bronchi of the patient is thus achieved by making delivery of a very fine aerosol and deposit of the medication agent throughout the depths of the lung. The present construction assures more penetration of the medication through the mouth into the alveoli by achieving complete evaporation and reduction of particle size of the droplets before they are inhaled.

It is to be understood that modifications and changes may be made in the specific details of the embodiments of the invention previously described and that such modifications embodying the essential features of this invention are intended to be included within the scope of the appended claims.

I claim:

1. A face mask for administering therapeutic agents to a patient for inhalation in nebulized condition which comprises a mask portion having an open end, side walls, a bottom wall, and a vertically extending forward end wall, terminating short of the bottom wall, the open end of the mask portion being dimensioned and contoured to receive the nose and mouth portions of the patient and contact the adjacent face portions in sealing relation, a receiving chamber extending forwardly of the lower portion of the said forward vertical end wall of the mask portion, said receiving chamber consisting of opposed side walls, a bottom wall and top wall, the said opposed side walls of the receiving chamber being aligned with the adjacent side walls of the mask portion and the said bottom wall of the receiving chamber being aligned with the adjacent bottom wall of the mask portion to provide an unobstructed passageway from the receiving chamber into the mask portion, the said top wall of the receiving chamber being provided with an opening retaining nebu-

lizer means to supply a stream of nebulized therapeutic agents, a mouth tube positioned and extending horizontally within the said mask portion, the open end of said mouth tube being dimensioned to be receivable within the mouth of the patient and embracingly sealed by the lips of the patient, the forward end of the mouth tube being integrally connected to a nebulizer chamber, said nebulizer chamber having an open top receiving therethrough said means to supply a stream of nebulized therapeutic agents, said nebulizer chamber being generally complemental in shape with the receiving chamber and positioned in nested relation within said receiving chamber, and said nebulizer means being adapted to feed into said nebulizer chamber a controlled stream of nebulized therapeutic agents, said stream of nebulized therapeutic agents being adapted to flow through said nebulizer chamber and mouth tube into the mouth of the patient for inhalation by the patient.

2. A face mask as defined in claim 1 wherein the nebulizer chamber is provided with a generally cylindrical smooth interior side wall.

3. A face mask as defined in claim 1 wherein the nebulizer chamber is provided with a side inlet port for supplying therein a stream of gas under pressure.

4. A face mask as defined in claim 1 wherein the nebulizer chamber is open at the top for receiving an adapter head for retaining an aerosol cartridge containing therapeutic agents, said cartridge having valve means for controlling the emission of a stream of nebulized therapeutic agents therefrom, and means in said adapter head for actuating said valve means.

5. A face mask as defined in claim 1 wherein the nebulizer chamber is provided with an inlet port for supplying therein a stream of gas under pressure and said nebulizer chamber is open at the top and receives an adapter head, said adapter head being provided with a cylindrical bore and receiving an aerosol cartridge comprising and nebulizer means containing therapeutic agents and said cartridge having valve means for controlling the emission of a stream of nebulized therapeutic agents therefrom, and means in said adapter head for actuating said valve means.

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U.S. Cl. X.R.

128—173, 173.1