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(54) **NASAL MASK**

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(*) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(52) **U.S. Cl.** **128/207.13; 128/207.18;**
128/206.24; 128/207.17; 128/205.25

(58) **Field of Search** **128/207.13, 204.18,**
128/206.24, 206.25, 206.18, 204.12, 207.17,
206.27

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Primary Examiner—John G. Weiss

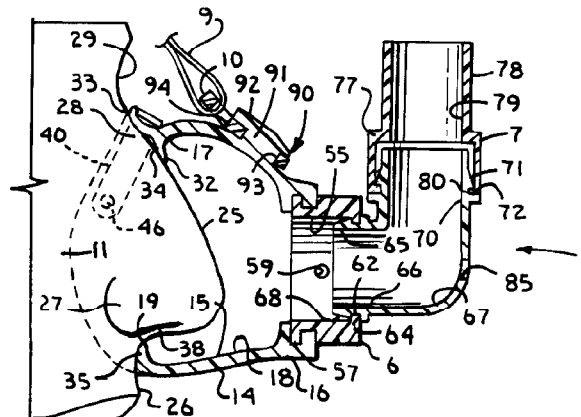
Assistant Examiner—V. Srivastava

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(57) **ABSTRACT**

A nasal mask configured to be as unobtrusive as possible while providing an air-tight seal around the nose of a wearer comprises a flexible nasal cup having a nasal opening formed by an inner circumferential edge or rim thereof and opening into a nasal chamber. The cup also includes inner and outer sealing flanges extending around the rim for forming an air-tight seal during use. The nasal cup is sized such that, when the nasal cup is positioned over a wearer's nose, the rim generally extends across the wearer's upper lip, around the alae of the nose, and across the dorsum of the nose. Opposite ends of a malleable strip are secured to the outer sealing flange and the strip extends across the portion of the outer sealing flange adapted to be positioned over the nasal dorsum. The strip is manually adjustable so that a user may selectively adjust the shape of the mask about the nose to improve the seal across the nose. An airflow passageway extends through the mask at an outer end thereof and is in flow communication with the nasal chamber for delivering air to and removing exhaled air from the nasal chamber. The nasal mask is specifically shaped to provide adequate airflow to the wearer's nose.

1 Claim, 2 Drawing Sheets



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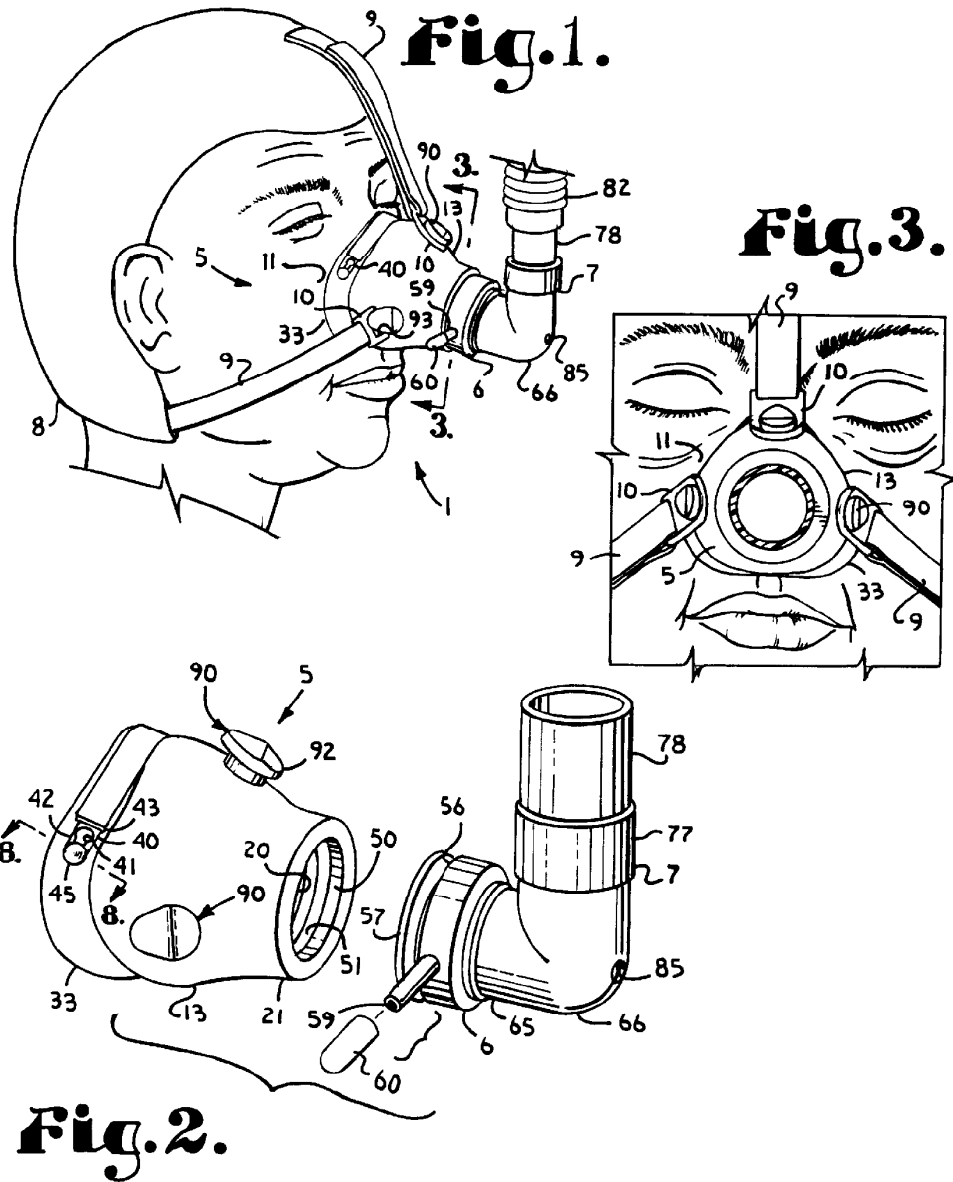
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Photographs of a nasal mask produced by Hans Rudolph, Inc., units of which were sold more than one year prior to the filing date of the above-captioned application.

Copy of packaging of All-Seasons Dust Mask of Ace Hardware Corporation, sold more than one year prior to the filing date of the above-captioned application.

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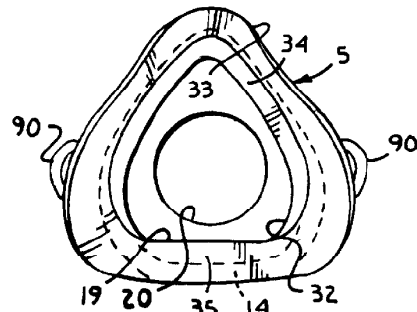


Fig. 4.

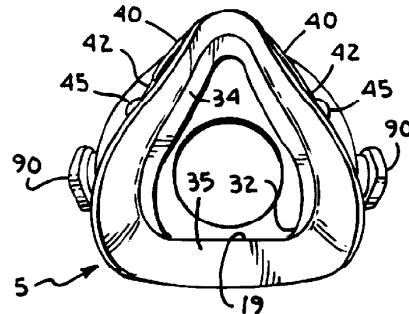


Fig. 5.

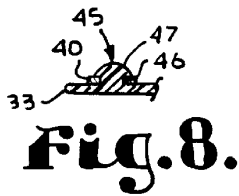


Fig. 8.

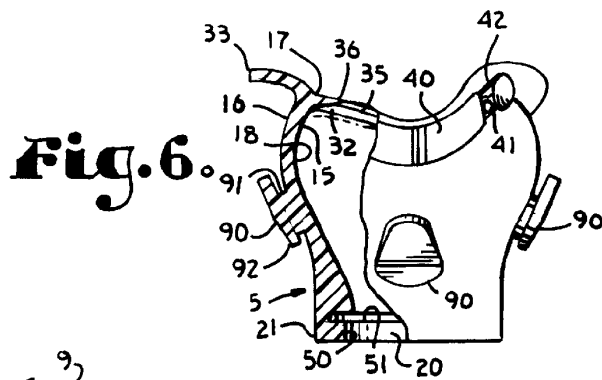


Fig. 6.

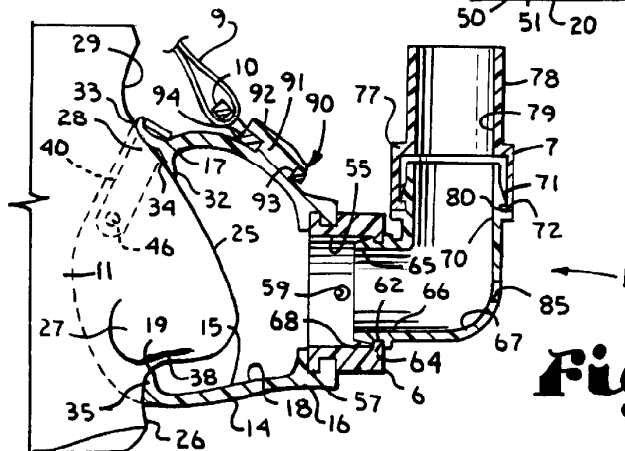


Fig. 7.

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NASAL MASK

BACKGROUND OF THE INVENTION

The present invention relates to an improved nasal mask for delivering positive air pressure to the nasal passages to facilitate treatment of breathing disorders such as sleep apnea, ventilation difficulties or anesthetic gas administration.

Obstructive sleep apnea is caused by obstruction of the upper airway during sleep which results in the absence of airflow through the nose or mouth for at least 10 seconds. Obstructive sleep apnea episodes are usually most severe during periods of REM (Rapid Eye Movement) sleep, when muscle tone is inhibited. The upper airway then narrows as a result of the relaxation of a number of muscles. The suction pressure of inspiration then causes further narrowing or collapse of the airway. The lack of airflow causes the oxygen level in the blood to drop causing arousal which then restores upper airway muscle tone allowing normal breathing.

Heavy snoring and daytime sleepiness are the most common symptoms associated with obstructive sleep apnea syndrome. Other complaints include night-time thrashing, sleep walking, enuresis, disorientation, personality changes, intellectual deterioration, sexual dysfunction, hypnagogic hallucinations, automatic behavior and morning headaches. The prevalence of episodes of obstructive apnea and the frequency of occurrence increase with age. Men are much more commonly affected than women and nearly 50% of elderly men have 20 or more apneic episodes each night. Other known risk factors include obesity, chronic alcoholism, chronic obstructive pulmonary disease and postmenopausal state. Altogether more than 30,000 patients are treated each year for obstructive sleep apnea.

The most effective and frequent therapy for obstructive sleep apnea is application of continuous positive airway pressure (CPAP). For such therapy, a patient is fitted with a tight fitting nasal mask connected through an airway to a blower which supplies air at a slight positive pressure to the nasal passages. The application of the slight positive pressure is immediately effective in reversing airway obstruction in most patients with obstructive sleep apnea. Although the therapeutic results of nasal CPAP are often dramatic and immediate, it is only effective when used properly and on a regular basis. Failure to apply nasal CPAP for even a single night results in recurrence of hypersomnolence the next day.

Problems associated with wearing existing masks or positive airway pressure delivery systems during periods of attempted sleep are sufficient to deter many patients from continuing CPAP therapy. Some problems include excessive noise and irritation resulting from leaks around improperly fitting masks or general discomfort caused by the design of the mask or the CPAP delivery system. Leakage of air between the mask and the face often allows air to blow on the eyes which wakes the patient and/or substantially irritates the eyes.

SUMMARY OF THE INVENTION

The present invention comprises a nasal mask configured to be as unobtrusive as possible while providing an air-tight seal around the nose of a wearer. The mask comprises a flexible nasal cup having a nasal opening extending across an inner circumferential edge thereof and having a nasal chamber formed therein. The nasal cup is sized for insertion over a portion of the wearer's nose (preferably almost the entire nose), such that the inner circumferential edge of the

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cup generally extends across the upper lip, around the alae of the nose, and across the dorsum of the nose.

The nasal mask includes an inner and an outer sealing flange extend inward and outward respectively from the inner circumferential edge of the nasal cup. The sealing flanges cooperate to provide an improved seal. An airflow passageway extends through the mask at an outer end thereof and in communication with the nasal chamber for delivering air to and removing exhaled air from the nasal chamber. The nasal mask is specifically shaped to provide adequate air-flow to the wearer's nose.

The nasal mask includes a malleable pliable strip secured to the outer sealing flange so as to extend up and over the portion of the mask extending over the rear of the wearer's nose. The pliable strip may be bent or shaped to modify the shape of the mask to adjust the fit of the mask and improve the seal of the mask across the nose.

OBJECTS AND ADVANTAGES OF THE INVENTION

The objects of the present invention include providing a nasal mask which is as unobtrusive as possible while providing an air-tight seal; to provide such a mask which provides adequate air-flow around the wearer's nose; to provide such a mask which may be firmly secured to a wearer's face; to provide such a mask having means for adjusting the fit of the mask across the nose of a wearer's face; to provide such a mask comprising a nasal cup into which the nose of a wearer may be inserted such that an inner circumferential edge of the nasal cup extends across the upper lip below the wearer's nose, around the alae of the nose and across the dorsum of the nose; to provide such a mask having inner and outer sealing flanges extending inward and outward from the inner circumferential edge of the nasal cup respectively for providing a seal; to provide such a mask in which the outer sealing flange does not extend across portions of the eye sockets; to provide such a mask in which an upper edge of the mask engages the nose below the root of the nose; to provide such a mask in which the nasal cup is formed from flexible material; to provide such a mask in which the nasal cup is adapted to be secured to tubing for supplying gas under pressure to the interior of the mask; to provide such a mask in which the tubing is swivelably connected to the nasal cup; to provide such a mask which is relatively easy to assemble; to provide such a mask which is relatively easy to put on by a wearer; to provide such a mask which is relatively inexpensive to manufacture and which is particularly well adapted for its intended purpose.

Other objects and advantages of this invention will become apparent from the following description taken in conjunction with the accompanying drawings wherein are set forth, by way of illustration and example, certain embodiments of this invention.

The drawings constitute a part of this specification and include exemplary embodiments of the present invention and illustrate various objects and features thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the nasal mask assembly, including a nasal mask, in accordance with the present invention secured to a wearer over the wearer's nose.

FIG. 2 is an enlarged and exploded perspective view of the nasal mask and associated airflow tubing assembly.

FIG. 3 is a fragmentary front elevational view of the mask secured to the face of a wearer, as shown in FIG. 1, with portions of the airflow tubing assembly broken away to show detail.

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