

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
17 January 2008 (17.01.2008)

PCT

(10) International Publication Number
WO 2008/007985 A1

(51) International Patent Classification:
A61M 16/06 (2006.01)

(21) International Application Number:
PCT/NZ2007/000185

(22) International Filing Date: 13 July 2007 (13.07.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
548575 14 July 2006 (14.07.2006) NZ
551103 6 November 2006 (06.11.2006) NZ

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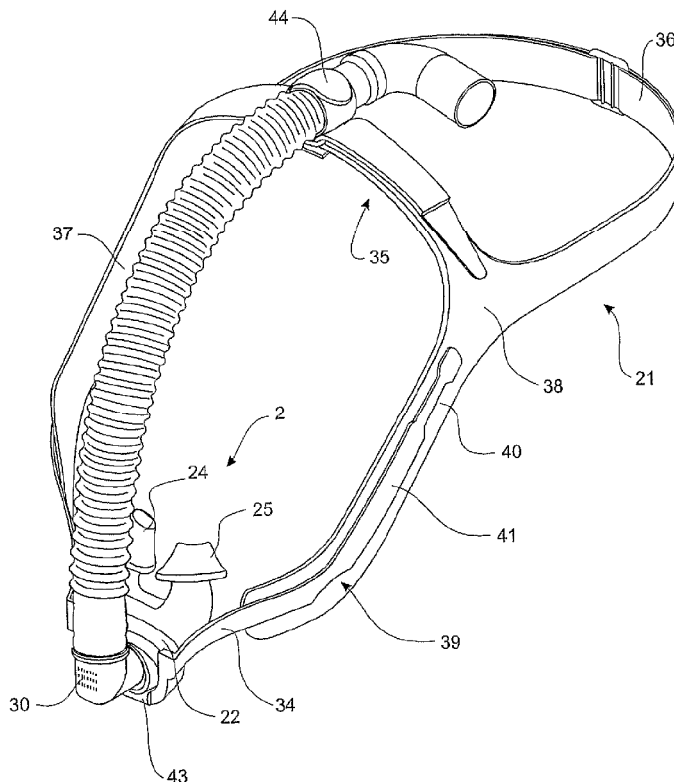
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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL,

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(54) Title: BREATHING ASSISTANCE APPARATUS



(57) Abstract: Headgear for use with a respiratory mask is described. The headgear comprises a continuous and substantially curved elongate member extending in use below a user's nose and at least two headgear straps capable of attachment to the ends of the elongate member. A mask attachment on the elongate member is disposed to sit below or on one of said user's nose, mouth, upper lip and an inlet to the mask. The attachment is capable of receiving the mask.

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PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY,
TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA,
ZM, ZW.

PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM,
GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL,

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

BREATHING ASSISTANCE APPARATUS

BACKGROUND OF THE INVENTION

Technical Field

5 The present invention relates to apparatus for treating sleep apnoea. More specifically, the present invention provides a nasal interface for the supply of respiratory gases, but most particularly positive pressure gases.

Summary of the Prior Art

10 In the art of respiration devices, a variety of respiratory masks which cover the nose and/or mouth of a human user in order to provide a continuous seal around the nasal and/or oral areas of the face are well known. Masks that provide gas at positive pressure within the mask for consumption by the user are also well known. The uses for such masks range from high altitude breathing (i.e., aviation applications) to mining and fire fighting applications, to various medical diagnostic and therapeutic applications.

15 Obstructive Sleep Apnoea (OSA) is a sleep disorder that affects up to at least 5% of the population in which muscles that normally hold the airway open relax and ultimately collapse, sealing the airway. The sleep pattern of an OSA sufferer is characterised by repeated sequences of snoring, breathing difficulty, lack of breathing, waking with a start and then returning to sleep. Often the sufferer is unaware of this pattern occurring. Sufferers of OSA
20 usually experience daytime drowsiness and irritability due to a lack of good continuous sleep.

 In an effort to treat OSA sufferers, a technique known as Continuous Positive Airway Pressure (CPAP) was devised. A CPAP device consists of a gases supply (or blower) with a conduit connected to supply pressurised gases to a patient, usually through a nasal mask. The pressurised air supplied to the patient effectively assists the muscles to keep the patient's
25 airway open, eliminating the typical OSA sleep pattern.

 The procedure for administering CPAP treatment has been well documented in both the technical and patent literature. Briefly stated, CPAP treatment acts as a pneumatic splint of the airway by the provision of a positive pressure, usually in the range 4 to 20 cm H₂O. The air is supplied to the airway by a motor driven blower whose outlet passes via an air delivery
30 hose to a nose, full face, nose and mouth, or oral mask that is sealingly engaged to a patient's face, preferably by means of a harness or other headgear. An exhaust port is usually also provided in the delivery tube proximate to the mask or on the mask itself. More sophisticated

forms of positive airway pressure devices, such as bi-level devices and auto-titrating devices, are described in US Patent No. 5,148,802 of Respironics, Inc. and US Patent No. 5,245,995 of Rescare Limited, respectively.

5 One requisite of respiratory masks has been that they provide an effective seal against the user's face to prevent leakage of the gas being supplied. Commonly, in prior mask configurations, a good mask-to-face seal has been attained in many instances only with considerable discomfort for the user. A common complaint of a user of CPAP therapy is pressure sores caused by the mask about the nose and face and in particular in the nasal bridge region of the user. This problem is most crucial in those applications, especially medical
10 applications, which require the user to wear such a mask continuously for hours or perhaps even days. In such situations, the user will not tolerate the mask for long durations and optimum therapeutic or diagnostic objectives thus will not be achieved, or will be achieved with great difficulty and considerable user discomfort.

US Patent No. 5,477,852 of Airways Ltd, Inc. discloses a nasal positive airway
15 pressure device that has a pair of nasal members each having a cannula tip to be inserted into the nares of the patient. Each cannula is tapered from a substantially circular cross section outside the patient's nostril to a substantially oval cross section at the tip inserted into the nostril. An inflatable cuff surrounds each cannula with the interior space of the cuff communicating with the lumen of the cannula through at least one aperture in the sidewall of
20 the cannula. The nasal members are connected to one or more flexible hoses that, in turn, are connected to a source of positive air pressure. In use, positive air pressure is supplied to each cannula tip through the air hoses and nasal members. The positive air pressure inflates the cuffs to hold the nasal members in place and to effect treatment. The nasal device of US Patent No. 5,477,852 is attached to headgear that is located about a patient's head. This
25 headgear could be considered by many patients as cumbersome and uncomfortable.

Conventional nasal masks used for administering CPAP treatment are also considered uncomfortable and cumbersome, and prior art nasal masks can be noisy due to air leaks. These disadvantages in many cases are a formidable obstacle to patient acceptance of such treatment. Therefore, a substantial number of patients either cannot tolerate treatment or choose to forego
30 treatment. It is believed a number of such patients might benefit from a nasal positive airway pressure apparatus that is more convenient to use and comfortable to wear, thereby resulting in increased treatment compliance.

Innomed Technologies, Inc. manufactures a nasal cannula device called the NASALAIRE™. In this device air or oxygen travels down a wide bore conduit to nasal cannula. The NASALAIRE™ creates a physical seal between the nares and itself, and relies on the absence of leaks around the cannula and the nares to deliver pressure supplied by a continuous positive airway pressure (CPAP) blower to the airway of the wearer.

US6,119,694 of Respiroics Georgia, Inc discloses a nasal mask having a nare seal and lateral support members to support the mask.

WO2004/073778 of ResMed Limited discloses a nasal mask including a frame where headgear is provided with rigid sections that extend to the nasal mask.

WO04/041341 of ResMed Limited discloses headgear for a patient mask that includes a sewn on rigid section to the back area of headgear straps to provide rigidity to the straps.

US6,907,882 of ResMed Limited discloses a nasal mask and headgear that is attachable to the frame of the nasal mask. The headgear straps have rigid sections integral with the releasable connectors that attach the headgear to the mask.

DISCLOSURE OF THE INVENTION

It is an object of the present invention to attempt to provide a patient interface that goes some way to overcoming the abovementioned disadvantages in the prior art or which will at least provide the industry with a useful choice.

In a first aspect the present invention consists in headgear for use with a respiratory mask comprising:

a continuous and substantially curved elongate member extending in use below a patient's nose,

at least two headgear straps capable of attachment to the ends of said elongate member, and

a mask attachment on said elongate member disposed to sit below or on one of said user's nose, mouth, upper lip and an inlet to the mask, said attachment capable of receiving said mask.

In a second aspect the present invention consists in a breathing assistance apparatus for use with delivery of respiratory gases to a user comprising:

a mask having a base and body, said body having two flexible nasal pillows that in use rest in a substantially sealed manner against said user's nares,

a continuous and substantially curved elongate member extending in use below a

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