(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
18 March 2004 (18.03.2004)

PCT

(10) International Publication Number
WO 2004/022147 A1

(51) International Patent Classification[7]: A61M 16/08, A62B 9/00

(21) International Application Number: PCT/AU2003/001162

(22) International Filing Date: 5 September 2003 (05.09.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

10/235,846	6 September 2002 (06.09.2002)	US
60/424,695	8 November 2002 (08.11.2002)	US
60/474,928	3 June 2003 (03.06.2003)	US

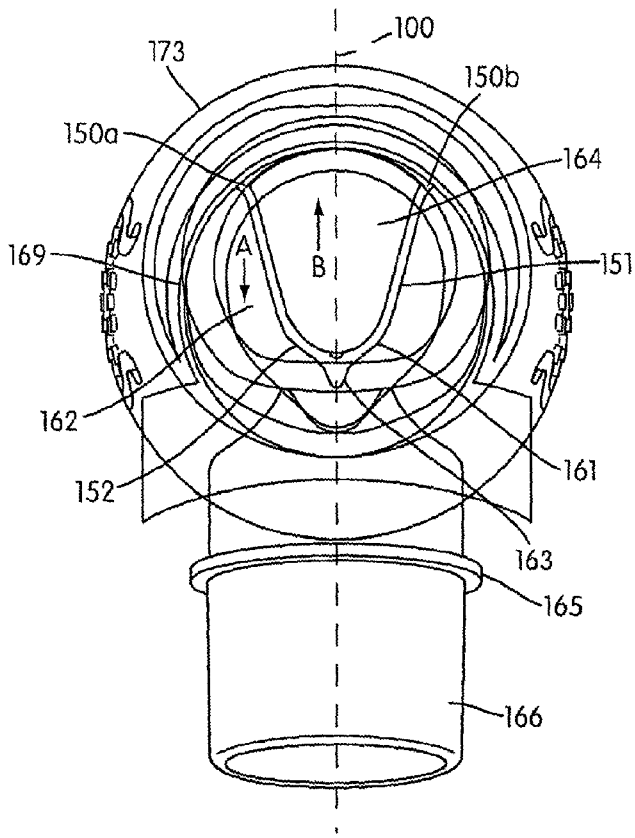
(71) Applicants (*for all designated States except US*): **RESMED LIMITED** [AU/AU]; 97 Waterloo Road, North Ryde, New South Wales 2113 (AU). **LJUBOJEVIC, Borivoje** [AU/AU]; Unit 6/711 Victoria Road, Ryde, New South Wales 2112 (AU).

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **DREW, Joanne, Elizabeth** [GB/AU]; 82 Curban Street, Balgowlah Heights, New South Wales 2093 (AU). **GUNEY, Memduh** [AU/AU]; 52 Eastgate Avenue, Killara, New South Wales 2071 (AU). **AMARASINGHE, Amal, Shirley** [AU/AU]; 29 Grace Avenue, Beecroft, New South Wales 2119 (AU). **LITHGOW, Perry, David** [AU/AU]; 9 Staff Avenue, Glenwood, New South Wales 2768 (AU). **GING, Anthony, Michael** [AU/AU]; Unit 5/15 Dover Street, Summer Hill, New South Wales 2130 (AU). **DARKIN, Donald** [GB/AU]; 2 Athella Place, Dural, New South Wales 2158 (AU). **ASTON, Grahame, Bruce** [AU/AU]; 21 Rangers Road, Yagoona, New South Wales 2199 (AU).

[Continued on next page]

(54) Title: ELBOW FOR MASK ASSEMBLY



(57) Abstract: An elbow assembly for use in a respiratory mask, which includes an elbow, (160), an inlet port (162), an exhaust port (164) and a baffle (161) separating the inlet port from the exhaust port. A mask assembly includes a cushion (30) comprising at least one gusset and an aperture (42) for connection to the elbow assembly (20).

WO 2004/022147 A1

(74) Agents: DAVIDSON, Geoffrey, Robert et al.; Halford & Co., Level 7, 1 Market Street, SYDNEY, New South Wales 2000 (AU).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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.

ELBOW FOR MASK ASSEMBLY

CROSS-REFERENCE TO PRIORITY APPLICATIONS

The present application claims priority to U.S. Provisional Application Serial No. 60/424,695 filed November 8, 2002, U.S. Provisional Application Serial No. 60/474,928 filed June 3, 2003, and U.S. Non-Provisional Application Serial No. 10/235,846 filed September 6, 2002, which in turn claims priority to U.S. Provisional Application No. 60/317,486 filed September 7, 2001 and U.S. Provisional Application Serial No. 60/342,854 filed December 28, 2001. Each of the above identified applications is incorporated herein by reference in its entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to a mask frame and elbow for use with a mask system for Non-invasive Positive Pressure Ventilation (NPPV) and for continuous positive airway pressure (CPAP) therapy of sleep disordered breathing (SDB) conditions such as obstructive sleep apnea (OSA).

2. Background of the Invention

The use of NPPV for treatment of SDB, such as OSA was pioneered by Sullivan (see, for example, U.S. Pat. No. 4,944,310, the contents of which are hereby incorporated in their entirety by reference). Apparatus for this treatment involves a blower which delivers a supply of air at positive pressure to a patient interface via an air delivery conduit. The patient interface may take several forms such as nasal masks and nose and mouth masks. Patients must wear a mask all night while sleeping to receive the therapy.

Masks typically comprise a rigid shell or frame and a soft face-contacting cushion that spaces the frame away from the face and forms a seal with the patient's face. The frame and cushion define a cavity which receives the nose, or nose and mouth. The mask is held in position by headgear, which usually comprises an arrangement of straps that passes along the side of the face to the back or crown of the head.

Kwok *et al.* (U.S. Pat. No. 6,112,746), the contents of which are hereby incorporated in their entirety by reference, describe a nasal mask and mask cushion. The mask cushion is a substantially triangularly shaped frame from which extends a membrane. The mask frame has a scalloped edge by which the mask cushion is affixed to a mask frame. The membrane has an aperture into which the user's nose is received. The membrane is spaced away from the rim of the frame, and its outer surface has substantially the same shape as the rim.

Frater *et al.* (PCT Patent Application AU01/00746, published as WO 01/97893), the contents of which are hereby incorporated in their entirety by reference, describes a mask system for delivering air to a user includes a suspension mechanism to allow relative movement between a face-contacting cushion and a mask frame. The suspension mechanism also provides a predetermined force to the cushion that is a function of mask pressure, displacement of the cushion, or both.

During the course of the respiratory cycle patients inhale air, largely comprising a mixture of nitrogen and oxygen, and exhale a mixture of gases including a relatively higher fraction of CO_2. In a nasal mask system where the patient breathes through the nose, there can be a build-up of CO_2 in the mask cavity which can lead to undesirable CO_2 re-breathing. Hence a variety of vents have been developed for use with masks. The amount of CO_2 in the mask cavity is a function of vent geometry, mask geometry, flow patterns within the mask and the amount of dead-space within the mask cavity.

The mask is typically joined to the air delivery conduit using a friction fit. Since the blower is typically placed beside a patient's bed, it is typical that the air delivery conduit be at least 1 meter long. Occasionally, movement of the air delivery conduit can disrupt the seal. Furthermore, some patients prefer to have the conduit in one position (for example passing over their heads), whereas other patients prefer to have it in another position (for example to the left or right side). Hence swivel elbows were developed for some masks.

Swivel elbows typically include: (i) a cylindrical first portion, having an axis aligned in a first direction and being adapted for connection to an air delivery conduit; and (ii) a cylindrical second portion, having an axis aligned in a second direction and being adapted for connection to a frame of a mask.

The first and second directions typically are at right angles to one another. The first portion has an outer diameter slightly smaller than the inner diameter of typical air delivery conduit tubing, so that the tubing can overfit the first portion and be held in position by friction. A free end of the second portion is adapted to pass through an orifice in the mask frame. Such known swivel elbows typically include a vent. While some vents are simply holes, such as those in the Puritan-Bennett SOFTFIT mask (Figure 10a), others are more sophisticated, such as those used with the ResMed ULTRA MIRAGE® mask.

A problem with the prior art swivel elbows incorporating a simple vent, such as the Puritan-Bennett SOFTFIT (Figure 10a), the Respironics CONTOUR-DELUXE (Figure 10c) and the related art Tiara ADVANTAGE elbows (Figure 10b), is that air from the blower can simply short-circuit the mask and pass straight out of the vent. This is a particular problem when a patient is being given supplemental oxygen, which is expensive. A significant portion of the oxygen being fed to the elbow simply passes out the vent without entering the mask.

Figures 8a, 8b, 9a, and 9b show prior art elbows manufactured by ResMed Limited for the STANDARD and MODULAR masks respectively. Figures 8c, 8d, 9c, and 9d show related art elbows manufactured by ResMed Limited for the ULTRA MIRAGE® and MIRAGE® VISTA masks respectively. Figures 11a to 11f show prior art elbows in the WHISPER swivel I and swivel II masks manufactured by Respironics. Figures 12 and 13 show a prior art mask SERENITY mask manufactured by DeVilbiss in which the interior of the nasal cavity includes a baffle B for redirecting incoming gas.

A mask that includes a cushion with a gusset will have a larger cavity, and hence more dead-space than a mask without a gusset, everything else being equal. Hence in a mask assembly with a gusset, particular attention needs to be paid to venting the mask to ensure that sufficient CO_2 is washed out by a continuous influx of fresh air.

Since the mask is to be used by sleeping users, it is also desirable to reduce or eliminate noise from all sources, including those caused by the venting of gases from the mask.

Kwok (PCT/AU98/00067, published as WO 98/34665), the contents of which are hereby incorporated in their entirety by reference, describes a mask and a vent. In one form the vent comprises a soft flexible insert piece with a series of orifices.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.

WHAT WILL YOU BUILD? | **sales@docketalarm.com** | **1-866-77-FASTCASE**

fastcase® Smarter legal research.