US006561190B1

(12) **United States Patent**
Kwok

(10) **Patent No.: US 6,561,190 B1**
(45) **Date of Patent: *May 13, 2003**

(54) **MASK AND A VENT ASSEMBLY THEREFOR**

(75) Inventor: **Philip R. Kwok**, West Pymble (AU)

(73) Assignee: **ResMed Limited**, North Ryde (AU)

(*) 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.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **09/021,541**

(22) Filed: **Feb. 10, 1998**

(30) **Foreign Application Priority Data**

Feb. 10, 1997 (AU) PO5045

(51) **Int. Cl.**[7] **A62B 18/10**

(52) **U.S. Cl.** **128/207.12**; 128/207.16; 128/205.24; 128/204.18; 128/206.12; 128/206.21

(58) **Field of Search** 128/207.12, 207.13, 128/207.14, 201.25, 206.12, 205.25, 205.27, 205.28, 206.15, 206.21, 206.22, 863, 204.18, 204.23, 205.24, 200.28, 200.29, 205.13–205.17, 204.22, 206.18

(56) **References Cited**

U.S. PATENT DOCUMENTS

781,516	A	1/1905	Guthrie
812,706	A	2/1906	Warbasse
1,081,745	A	12/1913	Johnston et al.
1,192,186	A	7/1916	Greene
1,653,572	A	12/1927	Jackson

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

AU	77110/91	* 11/1991
AU	91/77110 B	11/1991
AU	94/64816 B	12/1994
AU	95/16178 B	7/1995
AU	A 32914/95	2/1996

(List continued on next page.)

OTHER PUBLICATIONS

Mask 1 Photographs, Respironics Inc., Reusable Full Mask (small) Part # 452033 Lot #951108.

Mask 2 Photographs, Puritan—Bennett, Adam Curcuit, Shell Part # 231700, Swivel Part # 616329–00, Pillows (medium) Part #616324.

Mask 3, Photographs, DeVilbiss Healthcare Inc., DeVilbiss Seal–Ring and CPAP Mask Kit (medium), Part 73510–669.

Mask 4 Photographs, Respironics Inc., Monarch Mini Mask with Pressure Port. Part # 572004, Monarch Headgear, Part # 572011.

Mask 5 Photographs, Healthdyne Technologies, Nasal CPAP Mask (medium narrow), Part # 702510.

Mask 6 Photographs, Healthdyne Technologies, Soft Series Nasal CPAP Mask, Part # 702020.

Mask 7 Photographs, DeVilbiss Healthcare Inc., Small Mask and Seal Rings, Part # 73510–668.

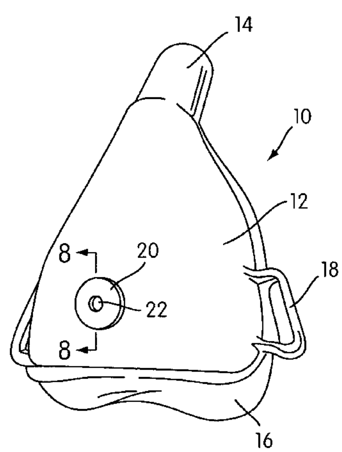
(List continued on next page.)

Primary Examiner—Aaron J. Lewis
Assistant Examiner—Teena Mitchell
(74) *Attorney, Agent, or Firm*—Pillsbury Winthrop LLP

(57) **ABSTRACT**

A mask (**10**) for use with a system for supplying breathable gas pressurised above atmospheric pressure to a human or animal's airways. The mask (**10**) includes a mask shell (**12**) which is, in use, in fluid communication with a gas supply conduit (**30**), and a gas washout vent assembly (**20**). At least the region of the mask shell (**12**) or conduit (**30**) surrounding or adjacent the vent assembly is formed from a relatively flexible elastomeric material.

76 Claims, 6 Drawing Sheets



Fisher & Paykel Ex. 1445
IPR Petition - USP 9,119,931

U.S. PATENT DOCUMENTS

1,926,027	A		9/1933	Biggs	
2,123,353	A		7/1938	Catt	
2,248,477	A		7/1941	Lombard	
2,254,854	A		9/1941	O'Connell	
2,317,608	A		9/1943	Heidbrink	
2,371,965	A		3/1945	Lehmberg	
2,376,871	A		5/1945	Fink	
2,415,846	A		2/1947	Randall	
2,438,058	A		3/1948	Kincheloe	
2,578,621	A		12/1951	Yant	
2,931,356	A		4/1960	Schwarz	
D188,084	S		5/1960	Garelick	
2,939,458	A		6/1960	Lundquist	
3,013,556	A		12/1961	Galleher	
3,182,659	A	*	5/1965	Blount	128/207.12
3,189,027	A		6/1965	Bartlett	
3,193,624	A	*	7/1965	Webb et al.	128/207.12
3,238,943	A		3/1966	Holley	
3,315,674	A		4/1967	Bloom et al.	
3,330,273	A		7/1967	Bennett	
3,362,420	A		1/1968	Blackburn et al.	
3,363,833	A		1/1968	Laerdal	
3,556,122	A		1/1971	Laerdal	
3,580,051	A		5/1971	Blevins	
3,680,556	A	*	8/1972	Morgan	128/201.15
3,700,000	A		10/1972	Hesse et al.	
3,720,235	A		3/1973	Schrock	
3,796,216	A		3/1974	Schwarz	
3,799,164	A		3/1974	Rollins	
D231,803	S		6/1974	Huddy	
3,877,425	A	*	4/1975	O'Neill	128/202.19
3,958,275	A	*	5/1976	Morgan et al.	128/201.27
4,077,404	A		3/1978	Elam	
D250,131	S		10/1978	Lewis et al.	
4,167,185	A		9/1979	Lewis	
4,219,020	A	*	8/1980	Czajka	128/207.13
4,226,234	A		10/1980	Gunderson	
4,245,632	A		1/1981	Houston	
4,274,406	A	*	6/1981	Bartholomew	128/204.25
D262,322	S		12/1981	Mizerak	
4,304,229	A		12/1981	Curtin	
4,328,797	A		5/1982	Rollins, III et al.	
4,347,205	A		8/1982	Stewart	
4,354,488	A		10/1982	Bartos	
4,402,316	A		9/1983	Gadberry	
4,412,537	A		11/1983	Tiger	
4,454,881	A	*	6/1984	Huber et al.	128/206.15
4,467,799	A		8/1984	Steinberg	
4,522,639	A		6/1985	Ansite et al.	
4,558,710	A		12/1985	Eichler	
4,616,647	A		10/1986	McCreadie	
4,622,964	A		11/1986	Flynn	
4,655,213	A		4/1987	Rapoport et al.	
4,665,570	A		5/1987	Davis	
4,671,271	A		6/1987	Bishop et al.	
4,677,975	A		7/1987	Edgar et al.	
4,677,977	A		7/1987	Wilcox	
D293,613	S		1/1988	Wingler	
4,739,755	A	*	4/1988	White et al.	128/206.12
4,770,169	A		9/1988	Schmoegner et al.	
4,774,941	A		10/1988	Cook	
4,782,832	A		11/1988	Trimble et al.	
4,799,477	A	*	1/1989	Lewis	128/206.24
4,809,692	A		3/1989	Nowacki et al.	
4,819,629	A		4/1989	Jonson	
4,821,713	A		4/1989	Bauman	
4,841,953	A		6/1989	Dodrill	
4,848,334	A		7/1989	Bellm	
4,848,366	A		7/1989	Aita et al.	
4,907,584	A		3/1990	McGinnis	
4,910,806	A		3/1990	Baker et al.	
4,919,128	A		4/1990	Kopala et al.	
4,938,210	A		7/1990	Shene	
4,938,212	A		7/1990	Gnook et al.	
4,944,310	A		7/1990	Sullivan	
D310,431	S		9/1990	Bellm	
4,971,051	A		11/1990	Toffolon	
4,974,586	A	*	12/1990	Wandel et al.	128/206.28
4,986,269	A		1/1991	Hakkinen	
4,989,596	A	*	2/1991	Moreis et al.	128/207.12
4,989,599	A		2/1991	Carter	
5,005,568	A		4/1991	Loescher et al.	
5,005,571	A		4/1991	Dietz	
5,018,519	A	*	5/1991	Brown	128/203.29
5,038,776	A		8/1991	Harrison et al.	
5,042,473	A		8/1991	Lewis	
5,042,478	A		8/1991	Kopala et al.	
5,046,200	A		9/1991	Feder	
5,063,922	A		11/1991	Hakkinen	
5,065,756	A	*	11/1991	Rapoport	128/204.18
5,069,205	A		12/1991	Urso	
5,080,094	A	*	1/1992	Tayebi	128/205.29
D323,908	S		2/1992	Hollister et al.	
5,109,839	A	*	5/1992	Blasdell et al.	128/203.12
5,109,840	A		5/1992	Daleiden	
5,121,745	A		6/1992	Israel	
5,133,347	A		7/1992	Huennebeck	
5,140,980	A	*	8/1992	Haughey et al.	128/201.25
5,140,982	A		8/1992	Bauman	
5,159,938	A		11/1992	Laughlin	
5,178,138	A		1/1993	Walstrom et al.	
D334,633	S		4/1993	Rudolph	
5,231,983	A		8/1993	Matson et al.	
5,233,978	A		8/1993	Callaway	
5,243,971	A	*	9/1993	Sullivan et al.	128/204.18
5,265,595	A		11/1993	Rudolph	
5,279,289	A		1/1994	Kirk	
5,280,784	A		1/1994	Kohler	
5,297,544	A	*	3/1994	May et al.	128/202.22
5,311,862	A		5/1994	Blasdell et al.	
5,322,057	A		6/1994	Raabe et al.	
5,343,878	A		9/1994	Scarberry et al.	
5,357,951	A		10/1994	Ratner	
5,368,020	A	*	11/1994	Beux	128/204.22
5,372,130	A		12/1994	Stern et al.	
5,388,571	A		2/1995	Roberts et al.	
5,404,871	A		4/1995	Goodman et al.	
5,419,318	A		5/1995	Tayebi	
5,429,126	A		7/1995	Bracken	
5,429,683	A		7/1995	Le Mitouard	
5,431,158	A		7/1995	Tirotta	
5,438,981	A		8/1995	Starr et al.	
5,441,046	A		8/1995	Starr et al.	
D362,061	S		9/1995	McGinnis et al.	
5,477,852	A	*	12/1995	Landis et al.	128/207.18
5,479,920	A		1/1996	Piper et al.	
5,488,948	A		2/1996	Dubruille et al.	
5,492,116	A		2/1996	Scarberry et al.	
5,501,214	A		3/1996	Sabo	
5,509,404	A		4/1996	Lloyd et al.	
5,517,986	A		5/1996	Starr et al.	
5,538,000	A		7/1996	Rudolph	
5,540,223	A		7/1996	Starr et al.	
5,542,128	A		8/1996	Lomas	
5,546,936	A	*	8/1996	Visag et al.	128/207.14
RE35,339	E	*	10/1996	Rapoport	128/204.18
5,560,354	A		10/1996	Berthon-Jones et al.	
5,570,682	A		11/1996	Johnson	
5,570,689	A		11/1996	Starr et al.	
D377,089	S		12/1996	Starr et al.	
5,592,938	A		1/1997	Scarberry et al.	

5,608,647	A		3/1997	Rubsamen et al.	
5,642,730	A		7/1997	Baran	
5,645,049	A	*	7/1997	Foley et al.	128/203.29
5,647,355	A		7/1997	Starr et al.	
5,647,357	A		7/1997	Barnett et al.	
5,649,532	A		7/1997	Oren	
5,649,533	A		7/1997	Griffiths	
5,655,520	A		8/1997	Howe et al.	
5,655,527	A		8/1997	Scarberry et al.	
5,657,493	A		8/1997	Ferrero et al.	
5,657,752	A	*	8/1997	Landis et al.	128/207.13
5,662,101	A		9/1997	Ogden et al.	
5,666,946	A		9/1997	Langenback	
5,685,296	A		11/1997	Zdrojkowski et al.	
5,687,715	A		11/1997	Landis et al.	
5,715,814	A		2/1998	Ebers	
5,732,695	A	*	3/1998	Metzger	128/206.12
5,746,201	A		5/1998	Kidd	
5,813,423	A		9/1998	Kirchgeorg	
5,832,918	A		11/1998	Pantino	
6,006,748	A	*	12/1999	Hollis	128/205.24
6,019,101	A	*	1/2000	Cotner et al.	128/207.13
6,135,109	A	*	10/2000	Blasdell et al.	128/206.28

FOREIGN PATENT DOCUMENTS

AU	9459430			2/1996
AU	A 41018/97			4/1998
AU	A 89312/98			1/1999
CA	1039144			9/1978
DE	459104			4/1928
DE	701 690			1/1941
DE	159396			6/1981
DE	3015279	A1		10/1981
DE	3345067	A1		6/1984
DE	3537507	A1		4/1987
DE	3539073	A1		5/1987
DE	4004157	C1		4/1991
DE	WO 94/01290		*	2/1994
DE	4343205	A1		6/1995
DE	197 35 359			1/1998
DE	297 23 101			7/1998
DE	298 10846	U1		8/1998
EP	0 054 154			10/1981
EP	0 252 052	A1		1/1988
EP	0 264 772	A1		4/1988
EP	0 386 605	A1		2/1990
EP	0427474	A2		5/1991
EP	0 462 701	A1		12/1991
EP	0 602 424			11/1993
EP	0 608 684	A1		8/1994
EP	0697 225	A2		7/1995
EP	0 697 225			7/1995
EP	178 925	A2		4/1996
EP	0 747 078	A2		12/1996
EP	0 821 978			2/1998
FR	2 574 657	A1		6/1986
FR	2 658 725	A1		8/1991
FR	2 749 176			12/1997
GB	1395391			5/1975
GB	1 467 828			3/1977
GB	2145335	A		3/1985
GB	2147506	A		5/1985
GB	2 164 569	A		3/1986
GB	2 267 648	A		12/1993
JP	09/216240	A		8/1997
WO	WO 80/01044			5/1980
WO	WO 82/03548			10/1982
WO	WO 86/06969			12/1986
WO	WO 87/01950			4/1987
WO	WO 91/03277			3/1991
WO	WO 92/15353			9/1992
WO	WO 92/20395			11/1992
WO	WO 93/01854			2/1993
WO	WO 94/02190			2/1994
WO	WO 94/16759			8/1994
WO	WO 94/20051			9/1994
WO	WO 95/02428			1/1995
WO	WO 96/17643			6/1996
WO	WO 96/25983			8/1996
WO	WO 96/39206			12/1996
WO	WO 97/07847			3/1997
WO	WO 97/41911			11/1997
WO	WO 98/04310			2/1998
WO	WO 98/11930			3/1998
WO	WO 98/18514			5/1998
WO	WO 98/24499			6/1998
WO	WO 98/26829			6/1998
WO	WO 98/26830			6/1998
WO	WO 98/48878			11/1998

OTHER PUBLICATIONS

Mask 8 Photographs, Respironics Inc., Reusable Contour Mask (medium), Part # 302180.

Mask 9 Photographs, Healthdyne Technologies, Healthdyne Large Headgear.

Mask 10 Photographs, Respironics Inc., Soft Cap (medium), Part # 302142.

Mask 11 Photographs, Weinmann: Hamburg, Nasalmaskensystem mit Schalldämpfer (medium), Part # WN 23105.

Mask 12 Photographs, Life Care.

Mask 13 Photographs, Healthdyne Technologies.

Mask 14 Photograph, King System.

Mask 15 Photographs, Respironics Inc., Paediatric Mask.

Mask 16 Photographs, Hans Rudolph Inc., Hans Rudolph Silicone Rubber Face Mask/8900.

* cited by examiner

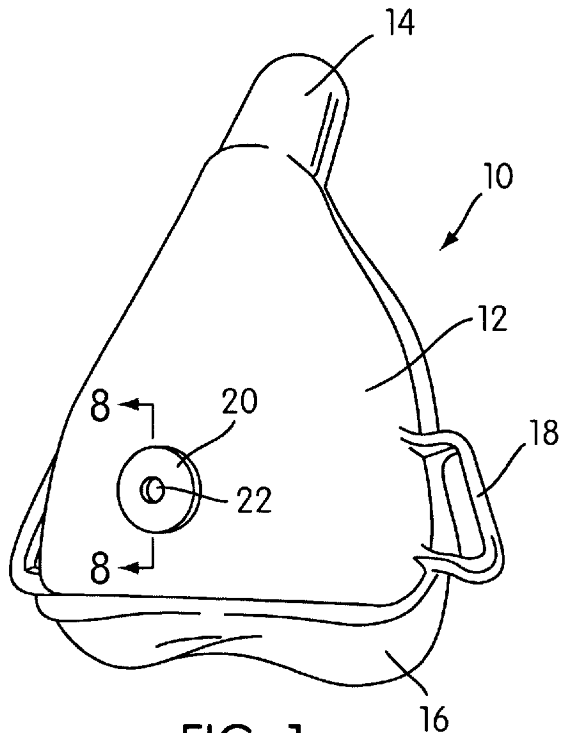


FIG. 1

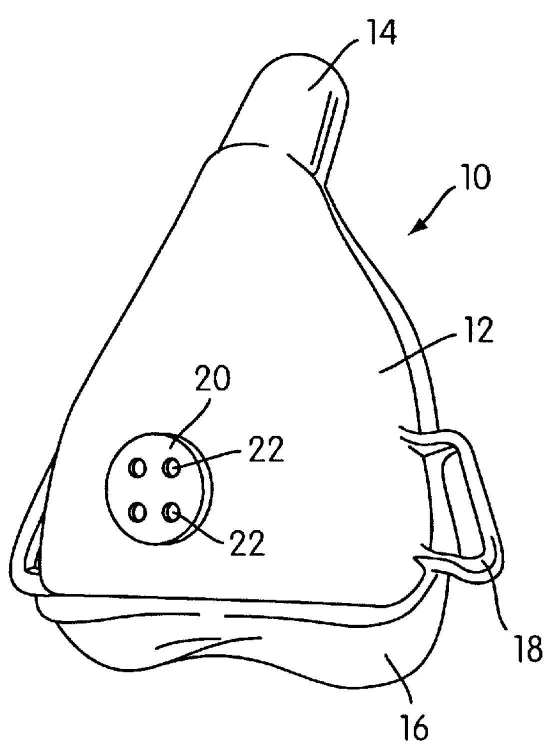


FIG. 2

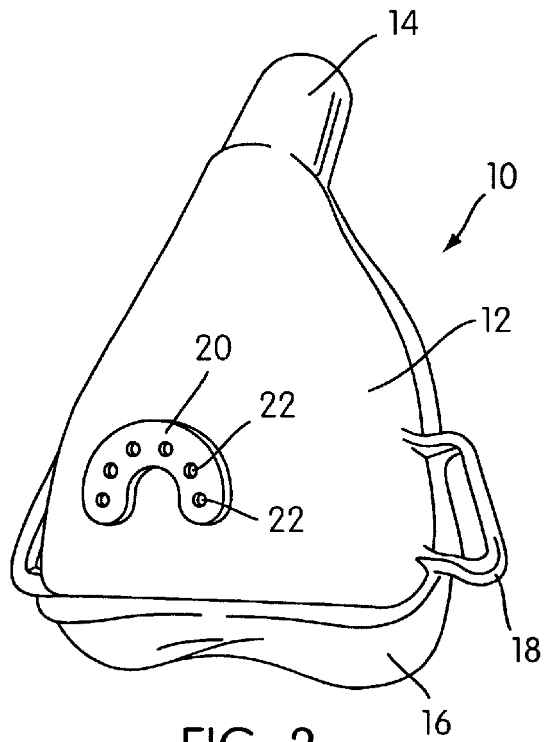


FIG. 3

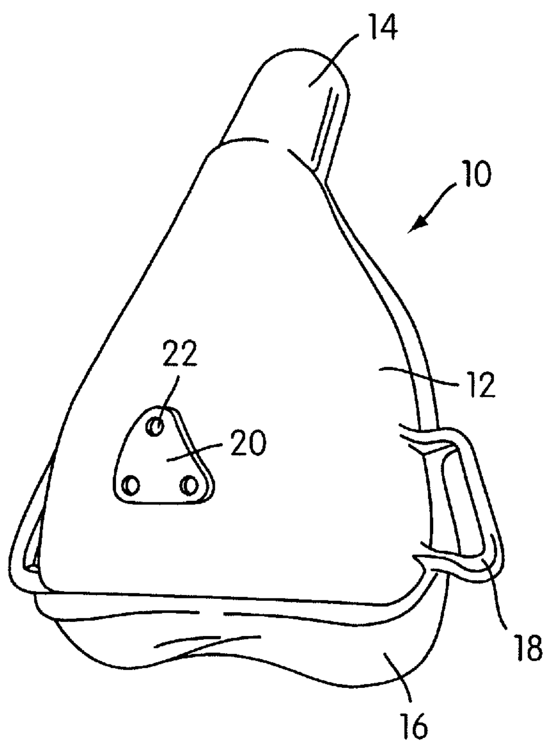


FIG. 4

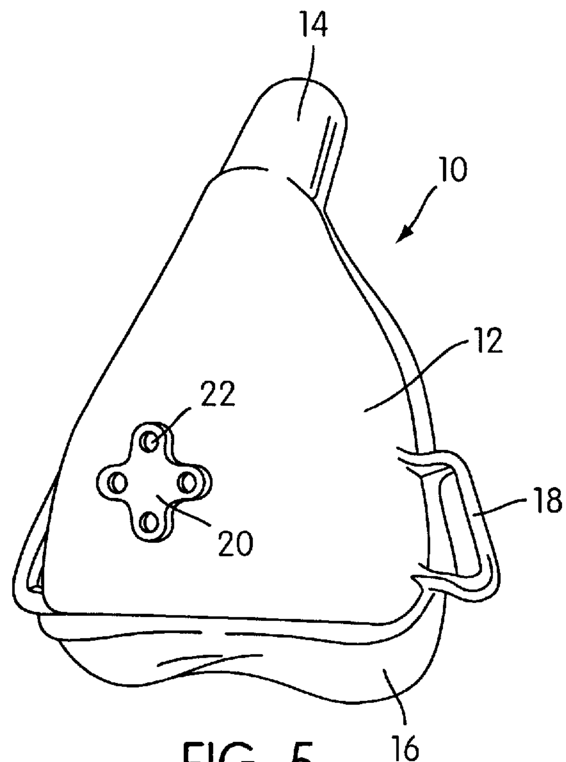


FIG. 5

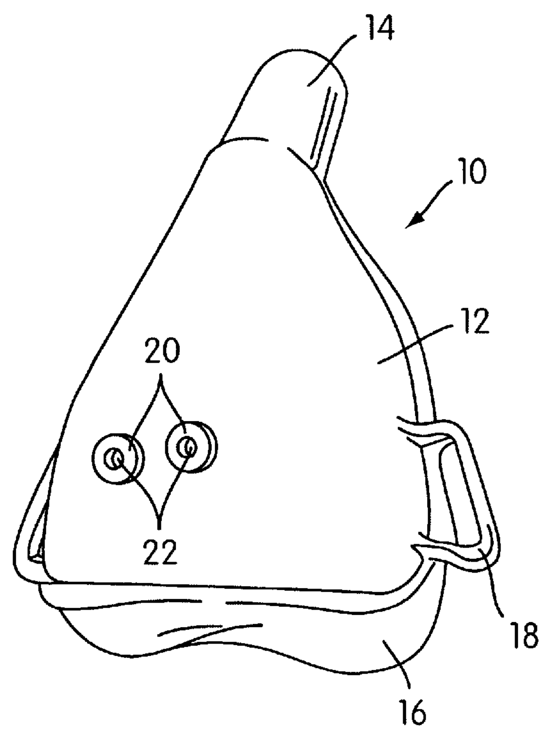


FIG. 6

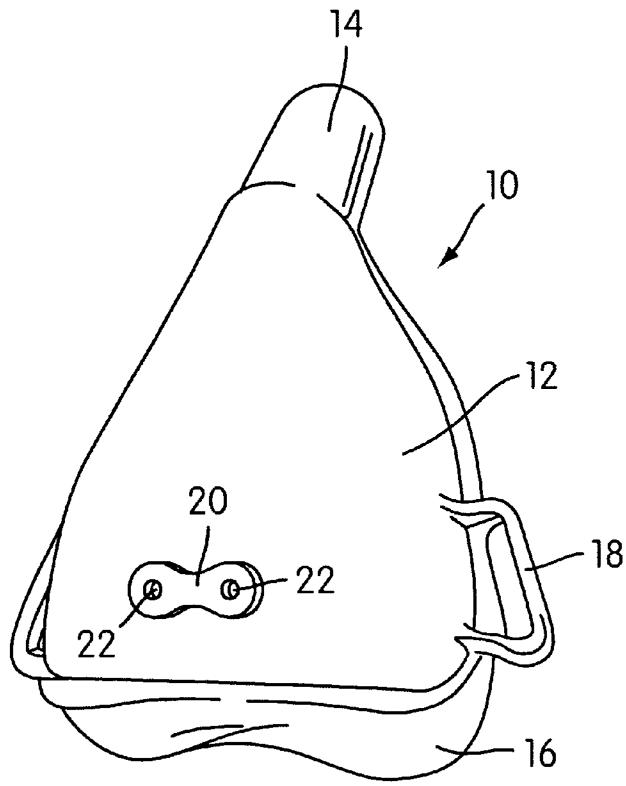


FIG. 7

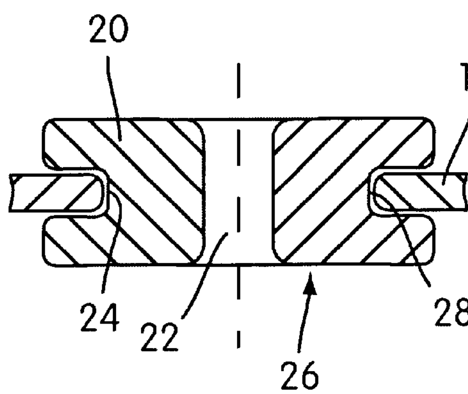


FIG. 8

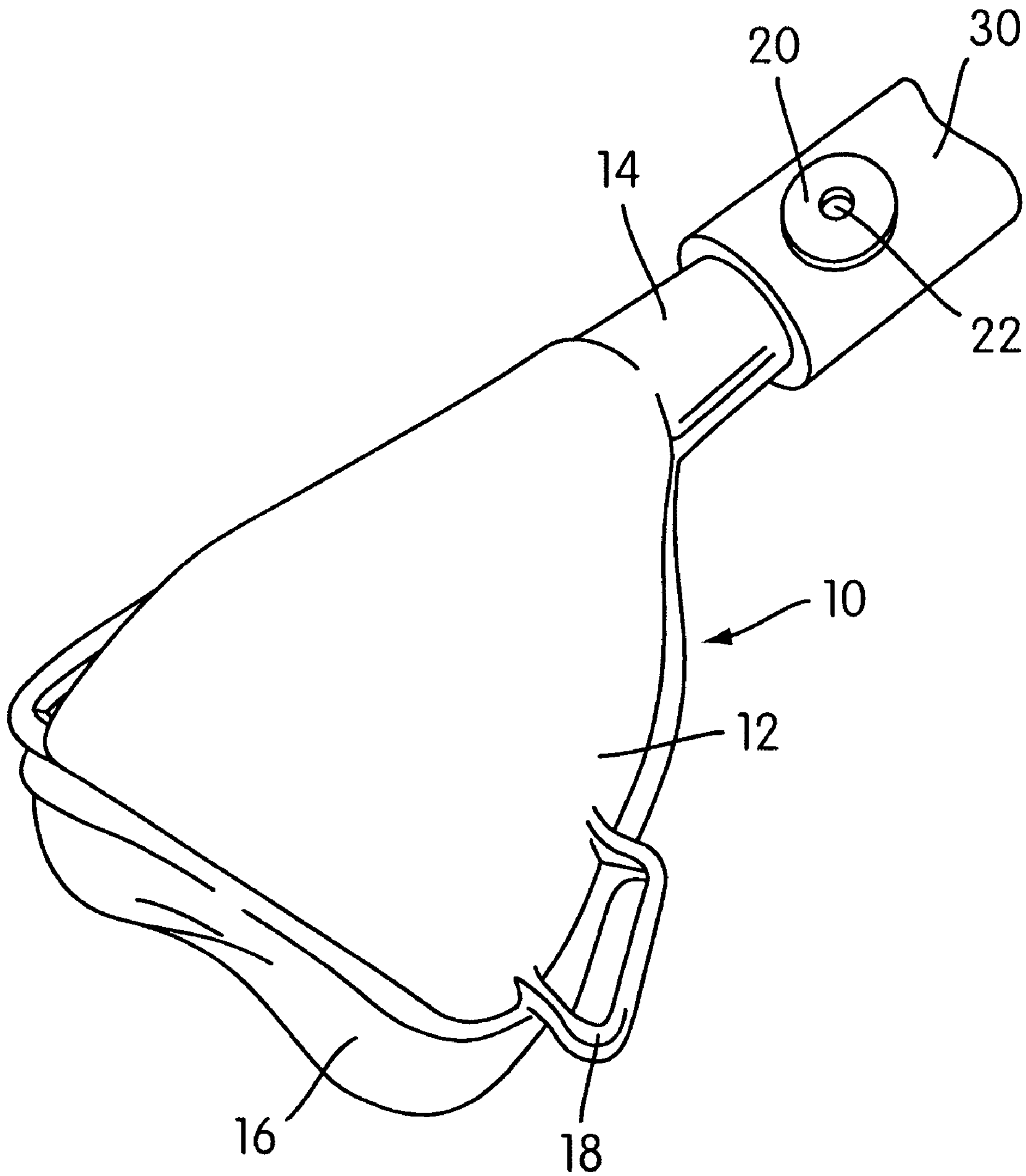


FIG. 9

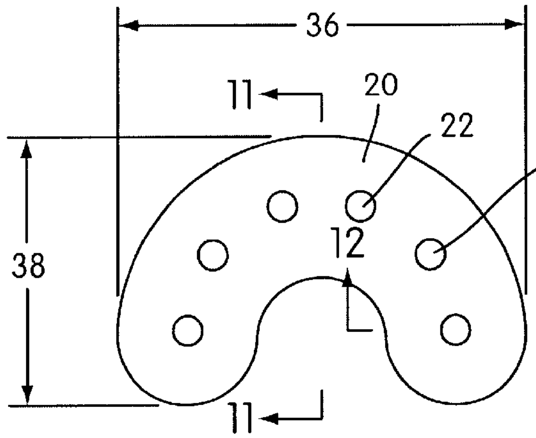


FIG. 10

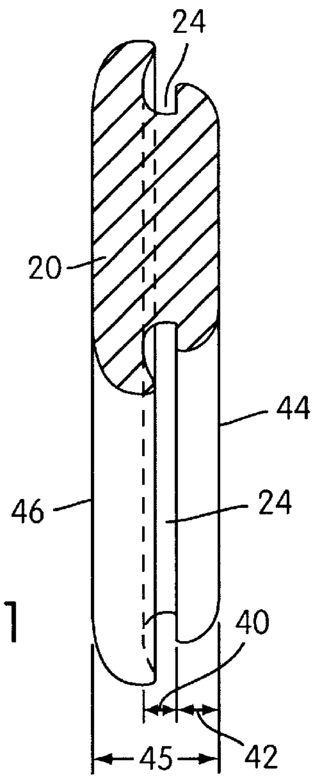


FIG. 11

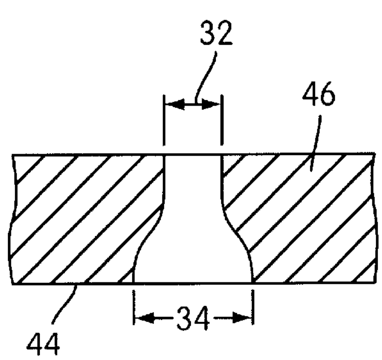


FIG. 12

1

MASK AND A VENT ASSEMBLY THEREFOR

FIELD OF THE INVENTION

The present invention relates to a mask and a vent assembly therefor.

The mask and vent assembly according to the invention have been developed primarily for the venting of washout gas in the application of continuous positive airway pressure (CPAP) treatment in conjunction with a system for supplying breathable gas pressurised above atmospheric pressure to a human or animal. Such a system is used, for example, in the treatment of obstructive sleep apnea (OSA) and similar sleep disordered breathing conditions. However, the invention is also suitable for other purposes including, for example, the application of assisted ventilation or respiration.

The term "mask" is herein intended to include face masks, nose masks, mouth masks, nasal pillows, appendages in the vicinity of any of these devices and the like.

BACKGROUND OF THE INVENTION

Treatment of OSA by CPAP flow generator systems involves the continuous delivery of air (or other breathable gas) pressurised above atmospheric pressure to a patient's airways via a conduit and a mask.

For either the treatment of OSA or the application of assisted ventilation, the pressure of the gas delivered to a patient can be at a constant level, bi-level (ie. in synchronism with patient inspiration and expiration) or autosetting in level to match therapeutic need. Throughout this specification the reference to CPAP is intended to incorporate a reference to any one of, or combinations of, these forms of pressure delivery.

The masks used in CPAP treatment generally include a vent for washout of the gas to atmosphere. The vent is normally located in the mask or in the gas delivery conduit adjacent the mask. The washout of gas through the vent is essential for removal of exhaled gases from the breathing circuit to prevent carbon dioxide "re-breathing" or build-up, both of which represent a health risk to the mask wearer. Adequate gas washout is achieved by selecting a vent size and configuration that will allow a minimum safe gas flow at the lowest operating CPAP pressure, which, typically can be as low as around 4 cm H_2O for adults and 2 cm H_2O in paediatric applications.

Prior art masks are generally comprised of a rigid plastic shell which covers the wearer's nose and/or mouth. A flexible or resilient rim (or cushion) is attached to the periphery of the shell which abuts and seals against the wearer's face to provide a gas-tight seal around the nose and/or mouth.

A prior art washout vent utilized one or more holes or slits in the rigid shell or in a rigid portion of the delivery conduit to allow the washout gas to vent to atmosphere. In some masks, the holes or slits were formed during the moulding process. In others, they were drilled or cut as a separate step after the shell or conduit had been moulded.

The flow of gas out the holes or slits in the shell or conduit to atmosphere creates noise and turbulence at the hole or slit outlet as the delivered gas, and upon expiration, the patient-expired gas (including CO_2) exits. Bi-level and autosetting gas delivery regimes tend to generate more noise than a constant level gas delivery regime. This is thought to be due to the extra turbulence created by the gas accelerating and

2

decelerating as it cycles between relatively low and relatively high pressures. The noise adversely affects patient and bed-partner comfort.

Another prior art vent included hollow rivets or plugs manufactured from stainless steel or other rigid materials attached to openings in the rigid shell. The outer edges of the rivets were rounded to help reduce noise. However, this approach was expensive, required an extra production step and did not prove effective in reducing noise.

Another approach to reduce noise involved the use of sintered filters at the gas outlet of the mask shell. However, the filters were prone to blocking, especially in the presence of moisture. Accordingly, sintered filters were impractical for use in CPAP treatment as they were easily blocked by the moisture from the patient's respiratory system or humidifiers or during the necessary regular cleaning of the mask and associated componentry.

Foam filters wrapped around the air outlets in the shell were also attempted. However, they also suffered from the disadvantages of being prone to blocking, difficult to clean and requiring constant replacement.

Remote outlet tubes have been used to distance the noise source from the patient. However, these tubes are difficult to clean, are prone to entanglement by the patient and/or their bed partner and suffer the further disadvantage that a volume of exhausted gas is retained in the tube adjacent the mask.

It is an object of the present invention to substantially overcome or at least ameliorate the prior art disadvantages and, in particular, to reduce the noise generated by gas washout through a mask.

SUMMARY OF THE INVENTION

Accordingly, the invention, in a first aspect, discloses a mask for use with a system for supplying breathable gas pressurised above atmospheric pressure to a human or animal's airways, the mask includes a mask shell which is, in use, in fluid communication with a gas supply conduit, a gas washout vent assembly, wherein at least the region of the mask shell or conduit surrounding or adjacent the vent assembly is formed from a relatively flexible elastomeric material.

In an embodiment, the entire mask is formed from the elastomeric material.

In another embodiment, the mask shell and/or conduit is formed from a relatively rigid material and the region surrounding or adjacent the vent assembly is formed from the relatively flexible elastomeric material.

In a second aspect, the invention discloses a vent assembly for the washout of gas from a mask or conduit used with a system for supplying breathable gas pressurized above atmospheric pressure to a human or animal, wherein the vent assembly is formed from the relatively flexible elastomeric material.

In a preferred embodiment, the vent assembly is an insert of relatively flexible elastomeric material, wherein the insert is attachable to the mask shell or conduit. The insert preferably has at least one orifice therethrough.

In a preferred form, the rigid plastics mask shell is formed from polycarbonate and the insert is formed from Silastic™ or Santoprene™.

Desirably, the insert is substantially crescent-shaped and includes a plurality of orifices therethrough.

The insert preferably includes a groove around its periphery, the groove adapted to locate the insert against a correspondingly sized rim of an opening formed in the mask shell or conduit.

In other embodiments, the insert is substantially circular, triangular, cross or peanut shaped.

The mask shell and/or the conduit can desirably also include one or more inserts.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention will now be described, by way of examples only, with reference to the accompanying drawings in which:

FIG. **1** is a perspective view of a first embodiment;

FIG. **2** is a perspective view of a second embodiment;

FIG. **3** is a perspective view of a third embodiment;

FIG. **4** is a perspective view of a fourth embodiment;

FIG. **5** is a perspective view of a fifth embodiment;

FIG. **6** is a perspective view of a sixth embodiment;

FIG. **7** is a perspective view of a seventh embodiment;

FIG. **8** is a partial cross-sectional view of the first embodiment along the line **8**—**8** of FIG. **1**;

FIG. **9** is a perspective view of an eighth embodiment;

FIG. **10** is a plan view of the insert of the third embodiment;

FIG. **11** is a cross-sectional view of the third embodiment insert along the line **11**—**11** of FIG. **10**; and

FIG. **12** is a partial cross-sectional view of the third embodiment insert along the line **12**—**12** of FIG. **10**.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring firstly to FIG. **1**, there is shown a mask **10** for use with a system (not shown) for supplying breathable gas pressurised above atmospheric pressure to a human or animal's airways. The mask includes a rigid plastics shell **12** having an inlet tube **14** for connection to a supply conduit to communicate breathable gas from a flow generator (not shown) to the nasal passages of the mask wearer. The mask shell **12** also includes a flexible sealing membrane **16** which is used to provide a gas tight seal between the face of the wearer and the interior of the shell **12**. The shell **12** also includes lugs **18** for connecting the mask **10** to a head strap (not shown) to retain the mask in place.

The mask includes a Silastic™ insert **20** through which is provided an orifice **22** for gas washout. As best shown in FIG. **8**, the insert **20** has a recess or groove **24** around its periphery. A correspondingly sized opening **26** bounded by a rim **28** is provided in the shell **12** to enable the insert **20** to be retained in place in the fashion of a grommet. The opening **26** can be moulded in the shell **12** or drilled or punched as a post-moulding step. The flexibility of the Silastic™ allows the insert **20** to be initially squeezed through the opening **26** before resiliently expanding to the configuration shown in FIG. **8** and engaging the rim **28**.

FIGS. **2** to **7** show further embodiments in which corresponding reference numerals are used to indicate like features. In all these embodiments the insert **20** has an external groove or recess **24** which engages the rim **28** of a corresponding shaped opening **26** in the mask shell **12** to retain the insert **20** in place.

In the embodiment shown in FIGS. **2** to **5** and **7** the insert **20** includes more than one orifice **22**. In the embodiment shown in FIG. **6**, two inserts **20** are provided in the shell **12**.

In the embodiment shown in FIG. **9**, the insert **20** is provided in a gas supply conduit **30**.

FIGS. **10** to **12** show the insert **20** of the third embodiment of FIG. **3**. The dimensions **32**, **34**, **36**, **38**, **40**, **42** and **45** are approximately diameter 1.73 mm, diameter 3.30 mm, 28.80 mm, 19.00 mm, 1.20 mm, 1.20 mm and 3.60 mm respectively.

The side **44** of the insert **20** faces the patient's face in use and the side **46** faces atmosphere.

The mask shell **12** is manufactured from polycarbonate. Other rigid plastics materials can equally be used. The insert **20** can be manufactured from an elastomer sold as Silastic™ (produced by the Dow Corning Corporation) or a thermoplastic elastomer sold as Santoprene™ (produced by Monsanto). Other flexible elastomeric materials can be used also.

The mask **10** produces less noise than an identical mask having a similar sized and shaped orifice(s) formed directly in the mask shell **12** instead of formed in the flexible insert **20**. It is thought that the noise reduction occurs due to the flexible insert **20** damping vibrations caused by air passage through the orifice(s) **22** which produce vibrations or similar in the mask shell **12**.

A prototype of the embodiment of the invention shown in FIG. **3** has been tested over a range of constant and bi-level CPAP treatment pressures. For comparison purposes, an identical mask to that shown in FIG. **3** but formed entirely from polycarbonate and having six identical arcuately spaced boles **22** drilled directly through the mask shell was also tested. In both masks the six holes had a diameter of 1.7 mm. The results of the test are summarised in the Tables below:

TABLE 1

Constant level gas delivery		
Pressure	Noise levels 1 m from mask (dBA)	
(cm H_2O)	With flexible insert	Without flexible insert
4	26.8	35.2
10	33.4	43.1
18	39.3	49.2

TABLE 2

Bi-level gas delivery		
Pressure	Noise levels 1 m from mask (dBA)	
(cm H_2O)	With flexible insert	Without flexible insert
5–10	30.8–38.5	37.2–43.0
10–15	38.6–43.7	42.9–47.9

As the results show, the mask shown in FIG. **3** produced less radiated noise than a similar mask not including the flexible elastomeric insert **20** representing a significant advantage in terms of the comfort of the mask wearer and their bed partner.

In addition to the noise reduction discussed above, the masks **10** possesses other advantages over those of the prior art. Firstly, the insert **20** is very easy to install into the mask shell **12** during either assembly of the mask which, is often supplied in kit form, or before and after cleaning which is regularly required and often carried out in the home environment. Secondly, the mask shell **12** may be produced with a single size of opening **26** and provided with a range of different inserts **20** which allows the outlet size to be "tuned" to give an optimum gas washout rate for a particular patient's treatment pressure level.

Although the invention has been described with reference to specific examples, it will be appreciated by those skilled in the art, that the invention may be embodied in many other forms.

I claim:

1. A mask assembly for use with a system for supplying breathable gas pressurized above atmospheric pressure to a human or animal patient's airways, the mask assembly comprising:

(a) a mask which is adapted for fluid connection with a gas supply conduit,

(b) a region of the mask defining a first venting orifice adapted for gas washout, and

(c) an insert formed of an elastomeric material positioned within said first venting orifice, said insert having at least one orifice therethrough for gas washout, said at least one orifice having a cross-sectional contour from a side of the orifice on the patient's side of the mask to an atmosphere side of the orifice, the cross-sectional contour remaining substantially constant in size as gas is passed therethrough.

2. A mask assembly as in claim **1**, wherein the mask is formed from an elastomeric material.

3. A mask assembly as in claim **1**, wherein the mask is formed from a material that is relatively rigid compared to the elastomeric material of the insert.

4. A mask assembly as in claim **3** wherein the relatively rigid material is polycarbonate and the elastomeric material is selected from the group consisting of Silastic™ and Santoprene™.

5. A mask assembly as in claim **1**, wherein the insert is substantially crescent-shaped and includes a plurality of orifices therethrough.

6. A mask assembly as in claim **1**, wherein the insert comprises a groove around a periphery of the insert, the groove being adapted to locate the insert against a correspondingly sized rim of the first venting orifice.

7. A mask assembly as in claim **1**, wherein the insert is selected from a shape consisting of substantially circular, triangular, cross or peanut shaped.

8. A mask assembly as in claim **1**, wherein the mask includes a plurality of said inserts.

9. A mask assembly in claim **1**, wherein a portion of the cross-sectional contour of the orifice near the atmosphere side of the orifice is smaller than a portion of the cross-sectional contour of the orifice near the side of the orifice on the patient's side of the mask.

10. A mask assembly as in claim **1**, wherein a central portion of the cross-sectional contour of the orifice has a constant diameter.

11. A mask assembly as in claim **1**, wherein the cross-sectional contour of the orifice is symmetrical between the side of the orifice on the patient's side and the atmosphere side of the orifice.

12. A mask assembly as in claim **1**, wherein the cross-sectional contour of the orifice is asymmetrical between the side of the orifice on the patient's side of the mask and the atmosphere side of the orifice.

13. A vent assembly for washout of gas from a mask having a vent opening used with a system for supplying breathable gas pressurized above atmospheric pressure to a human or animal patient, comprising:

an insert formed from an elastomeric material, said insert having at least one orifice therethrough for gas washout, said at least one orifice having a cross-sectional contour from a side of the orifice on the patient's side of the mask to an atmosphere side of the orifice, the cross-sectional contour remaining substantially constant in size as gas is passed therethrough.

14. A vent assembly as in claim **13**, wherein the insert is formed from a material selected from the group consisting of Silastic™ and Santoprene™.

15. A vent assembly as in claim **13**, wherein the insert is substantially crescent-shaped and includes a plurality of orifices therethrough.

16. A vent assembly as in claim **13**, wherein the insert includes a groove around a periphery of the insert, the groove being adapted to locate the insert against a correspondingly sized rim of the mask vent opening.

17. A vent assembly as in claim **13**, wherein the insert is selected from a shape consisting of substantially circular, triangular, cross or peanut shaped.

18. A vent assembly as in claim **13**, wherein a portion of the cross-sectional contour of the orifice near the atmosphere side of the orifice is smaller than a portion of the cross-sectional contour of the orifice near the side of the orifice on the patient's side of the mask.

19. A vent assembly as in claim **13**, wherein a central portion of the cross-sectional contour of the orifice has a constant diameter.

20. A vent assembly as in claim **13**, wherein the cross-sectional contour of the orifice is symmetrical between the side of the orifice on the patient's side of the mask and the atmosphere side of the orifice.

21. A vent assembly as in claim **13**, wherein the cross-sectional contour of the orifice is asymmetrical between the side of the orifice on the patient's side of the mask and the atmosphere side of the orifice.

22. A mask assembly for use with a system for supplying breathable gas pressurized above atmospheric pressure to a human patient=**3** s airways, the mask assembly including:

a) a mask which is adapted for fluid communication with a gas supply conduit, said mask including an opening therein and having a first thickness in a direction substantially normal to a planar surface of said mask adjacent said opening; and

b) an insert of a substantially constant second thickness in said direction formed of an elastomeric material and at least partially positioned within said opening, said insert having at least one orifice therethrough for gas washout,

wherein said second thickness is greater than said first thickness.

23. A mask assembly as in claim **22**, wherein the mask is formed from an elastomeric material.

24. A mask assembly as in claim **22**, wherein the mask is formed from a material that is relatively rigid compared to the elastomeric material of the insert.

25. A mask assembly as in claim **24**, wherein the relatively rigid material is polycarbonate and the insert is formed from a material selected from the group consisting of Silastic™ and Santoprene™.

26. A mask as in claim **22**, wherein the insert is attachable to the mask.

27. A mask assembly as in claim **26**, wherein the mask includes a plurality of said inserts.

28. A mask assembly as in claim **22**, wherein the insert is substantially crescent-shaped and includes a plurality of orifices therethrough.

29. A mask assembly as in claim **22**, wherein the insert comprises a groove around a periphery of the insert, the groove being adapted to locate the insert against a correspondingly sized rim of the mask opening.

30. A mask assembly as in claim **22**, wherein the insert is selected from a shape consisting of substantially circular, triangular, cross or peanut shaped.

31. A mask assembly as in claim **22**, wherein a portion of the orifice near an atmosphere side of the mask is smaller than a portion of the orifice near a side of the mask on the patient's side.

32. A mask assembly as in claim **22**, wherein a central portion of the orifice has a constant diameter.

33. A mask assembly as in claim **22**, wherein a shape of the orifice is symmetrical between a side on the mask or the patient's side and an atmosphere side of the mask.

34. A mask assembly as in claim **22**, wherein a shape of the orifice is asymmetrical between a side of the mask on the patient's side and an atmosphere side of the mask.

35. A mask assembly for use with a system for supplying breathable gas pressurized above atmospheric pressure to a human patient's airways, the mask assembly including:

a) a mask which is adapted for fluid communication with a gas supply conduit, said mask including an opening therein; and

b) an insert formed of an elastomeric material at least partially positioned within said opening, said insert having at least one orifice therethrough for gas washout in a first direction,

wherein said mask adjacent said opening has a first thickness in said first direction and said insert adjacent said orifice has a second thickness in said first direction which is greater than said first thickness.

36. A mask assembly as in claim **35**, wherein the mask is formed from an elastomeric material.

37. A mask assembly as in claim **35**, wherein the mask is formed from a relatively rigid material.

38. A mask assembly as in claim **37**, wherein the rigid material is polycarbonate and the insert is formed from a material selected from the group consisting of Silastic™ and Santoprene™.

39. A mask as in claim **35**, wherein the insert is attachable to the mask.

40. A mask as in claim **39**, wherein the mask includes a plurality of said inserts.

41. A mask assembly as in claim **35**, wherein the insert is substantially crescent-shaped and includes a plurality of orifices therethrough.

42. A mask assembly as in claim **35**, wherein the insert comprises a groove around a periphery of the insert, the groove being adapted to locate the insert against a correspondingly sized rim of the mask opening.

43. A mask assembly as in claim **35**, wherein the insert is selected from a shape consisting of substantially circular, triangular, cross or peanut shaped.

44. A mask assembly as in claim **36**, wherein a portion of the orifice near an atmosphere side of the mask is smaller than a portion of the orifice near a side of the mask on the patient's side.

45. A mask assembly as in claim **35**, wherein a central portion of the orifice has a constant diameter.

46. A mask assembly as in claim **35**, wherein a shape of the orifice is symmetrical between a face side of the mask and an atmosphere side of the mask.

47. A mask assembly as in claim **35**, wherein a shape of the orifice is asymmetrical between a side of the mask on the patient's side and an atmosphere side of the mask.

48. a mask assembly for use with a system for supplying breathable gas pressurized above atmospheric pressure to a human patient's airways, the mask assembly including:

a) a mask including an interior chamber which is adapted for fluid communication with a gas supply conduit, said mask including an opening therein between the interior chamber and atmosphere and having a thickness in a direction substantially normal to a surface of said mask adjacent said opening; and

b) an insert of an elastomeric material, the insert at least partially positioned within said opening having at least one orifice therethrough for gas washout,

wherein the orifice has a length which is greater than said thickness.

49. A mask assembly as in claim **48**, wherein the mask is formed from an elastomeric material.

50. A mask assembly as in claim **48**, wherein the mask is formed from a material that is relatively rigid compared to the elastomeric material of the insert.

51. A mask assembly as in claim **50**, wherein the relatively rigid material is polycarbonate and the insert is formed from a material selected from the group consisting of Silastic™ and Santoprene™.

52. A mask assembly as in claim **48**, wherein the insert is attachable to the mask.

53. a mask assembly as in claim **52**, wherein the mask includes a plurality of said inserts.

54. A mask assembly as in claim **48**, wherein the insert is substantially crescent-shaped and includes a plurality of orifices therethrough.

55. A mask assembly as in claim **48**, wherein the insert comprises a groove around a periphery of the insert, the groove being adapted to locate the insert against a correspondingly sized rim of the mask shell opening.

56. A mask assembly as in claim **48**, wherein the insert is selected from a shape consisting of substantially circular, triangular, cross or peanut shaped.

57. A mask assembly as in claim **48**, wherein a portion of the orifice near an atmosphere side of the mask is smaller than a portion of the orifice near a side of the mask on the patient's side.

58. A mask assembly as in claim **48**, wherein a central portion of the orifice has a constant diameter.

59. A mask assembly as in claim **48**, wherein a shape of the orifice is symmetrical between a side of the mask on the patient's side and an atmosphere side of the mask.

60. A mask assembly as in claim **48**, wherein a shape of the orifice is asymmetrical between a side of the mask on the patient's side and an atmosphere side of the mask.

61. A mask assembly for use with a system for supplying breathable gas pressurized above atmospheric pressure to a human or animal patient's airways, the mask assembly comprising:

(a) a gas supply conduit,

(b) a mask which is in fluid connection with the gas supply conduit,

(c) a region of the gas supply conduit defining a first venting orifice adapted for gas washout, and

(d) an insert formed of an elastomeric material positioned within said first venting orifice, said insert having at least one orifice therethrough for gas washout, said at least one orifice having a cross-sectional contour from a side of the orifice on the patient's side of the mask to an atmosphere side of the orifice, the cross-sectional contour remaining substantially constant in size as gas is passed therethrough.

62. A mask assembly as in claim **61**, wherein the mask is formed from an elastomeric material.

63. A mask assembly as in claim **61**, wherein the mask is formed from a material that is relatively rigid compared to the elastomeric material of the insert.

64. A mask assembly as in claim **63**, wherein the relatively rigid material is polycarbonate and the insert is formed from a material selected from the group consisting of Silastic™ and Santoprene™.

65. A mask assembly as in claim **61**, wherein the insert is substantially crescent-shaped and includes a plurality of orifices therethrough.

66. A mask assembly as in claim **61**, wherein the insert comprises a groove around a periphery of the insert, the groove being adapted to locate the insert against a correspondingly sized rim of the first venting orifice.

67. A mask assembly as in claim **61**, wherein the insert is selected from a shape consisting of substantially circular, triangular, cross or peanut shaped.

68. A mask assembly as in claim **61**, wherein the conduit includes a plurality of said inserts.

69. A mask assembly as in claim **61**, wherein the mask also includes at least one venting orifice and a further and said insert positioned therein.

70. A mask assembly in claim **61**, wherein a portion of the cross-sectional contour of the orifice near the atmosphere side of the orifice is smaller than a portion of the cross-sectional contour of the orifice near the side of the orifice on the patient's side of the mask.

71. A mask assembly as in claim **61**, wherein a central portion of the orifice contour has a constant diameter.

72. A mask assembly as in claim **61**, wherein the orifice contour is symmetrical between the face side of the orifice and the atmosphere side of the orifice.

73. A mask assembly as in claim **61**, wherein the orifice contour is asymmetrical between the face side of the orifice and the atmosphere side of the orifice.

74. A mask assembly for use with a system for supplying breathable gas pressurized above atmospheric pressure to a human's airways, the mask assembly comprising:

(a) a mask formed of a relatively rigid material, the mask being adapted for fluid connection with a gas supply conduit,

(b) a region of the mask defining a first venting orifice adapted for gas washout, and

(c) an insert formed of an elastomeric material positioned within said first venting orifice, said insert having two orifices therethrough for gas washout, each said orifice having an asymmetrical cross-sectional contour from a side of the orifice on the patient's side of the mask to an atmosphere side of the orifice, the cross-sectional contour remaining substantially constant in size as gas is passed therethrough, the insert also including a groove around a periphery of the insert, the groove being adapted to locate the insert against a correspondingly sized rim of the first venting orifice.

75. A mask assembly for use with a system for supplying breathable gas pressurized above atmospheric pressure to a patient's airways, the mask assembly comprising:

a) a mask having an inlet tube adapted for fluid connection with a gas supply conduit;

b) a first venting orifice for gas washout formed in the mask; and

c) an insert formed of an elastomeric material positioned within the first venting orifice, said insert having at least one orifice formed therethrough for gas washout, said at least one orifice having a cross-sectional contour from a first side of the orifice of the patient's side of the mask to a second side of the orifice on the atmospheric side, the cross-sectional contour remaining substantially constant in size as gas is passed therethrough, wherein:

the mask is formed from a material that is relatively rigid compared to the elastomeric material of the insert,

the insert includes a groove around a periphery of the insert, the groove being adapted to locate the insert against a correspondingly sized rim of the first venting orifice,

a size of first side of the orifice is different from a size of the second side of the orifice, the first side of the orifice being larger than the second side of the orifice, a portion of the orifice between the first and second sides varying in size along a length thereof, and

the mask has a first thickness adjacent the mask orifice that is less than a second thickness of the insert.

76. A mask assembly as claimed in claim **75**, wherein the mask includes one of a face mask, a nose mask, a mouth mask and nasal pillows.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,561,190 B1 Page 1 of 1
APPLICATION NO. : 09/021541
DATED : May 13, 2003
INVENTOR(S) : Kwok et al.

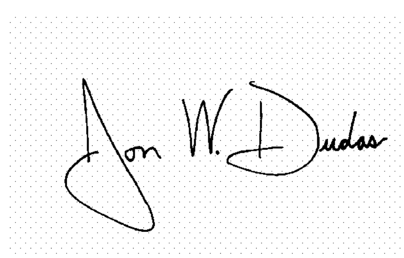
It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 3, line 53, after "rim 28." insert:

As seen in Figure 8, orifice 22 has a cross-sectional contour from a face side of the orifice to an atmosphere side of the orifice. In Figure 8, the contour is shown as being symmetrical between the face side of the orifice and the atmosphere side of the orifice with a central portion of the orifice contour being of constant diameter. After the insert 20 is positioned in opening 26 of mask shell 12, the contour remains substantially constant in size as gas is passed therethrough.

Signed and Sealed this

Twenty-fourth Day of October, 2006



JON W. DUDAS
Director of the United States Patent and Trademark Office