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Kwok et al.

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(54) **NASAL MASK AND MASK CUSHION THEREFOR**

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(73) Assignee: **ResMed Limited**, Bella Vista (AU)

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Related U.S. Application Data

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(30) **Foreign Application Priority Data**

Jul. 26, 1996 (AU) PO1265

(51) **Int. Cl.**
A62B 18/02 (2006.01)

(52) **U.S. Cl.** **128/207.13**; 128/205.25; 128/206.18; 128/206.24

(58) **Field of Classification Search** 128/206.24, 128/206.25, 207.11, 207.13, 206.4
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

781,516 A	1/1905	Guthrie
812,706 A	2/1906	Warbasse

(Continued)

FOREIGN PATENT DOCUMENTS

AU	64058/86	4/1987
AU	91/77110 B	11/1991
AU	94/64816 B	12/1994
AU	95/16178 B	7/1995
AU	9459430	2/1996

(Continued)

OTHER PUBLICATIONS

"ResMed Sullivan Mirage—The Mirage is Real—A Perfect Fit—First Time," product brochure © ResMed Limited 1997, 4 pages.

(Continued)

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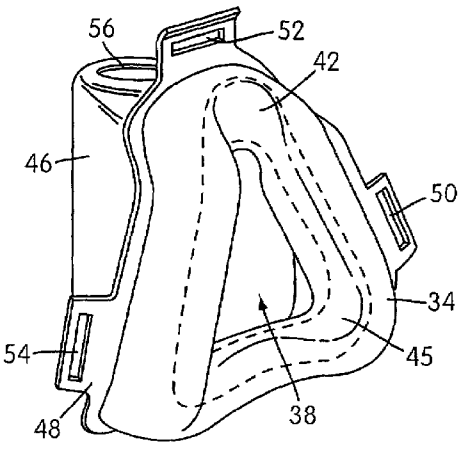
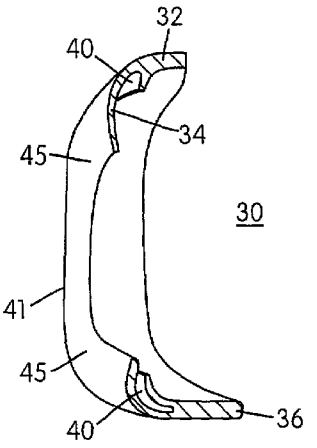
(57) **ABSTRACT**

A nasal cushion (**30**) comprises a substantially triangularly shaped frame (**32**) from which extends a membrane (**34**). The frame (**32**) has a scalloped edge (**36**) by which the cushion (**30**) is affixed to a mask body. The membrane (**34**) has an aperture (**38**) into which the wearer's nose is received. The membrane (**34**) is spaced away from the rim (**40**) of the frame (**32**), and its outer surface (**41**) is of substantially the same shape as the rim (**40**). Respective notches (**42**, **44**) receive the bridge of the wearer's nose. The wearer's nose is received through the aperture (**38**) into the chamber within the mask body (**46**). The seal forming portion (**45**) thus contacts both the surface of the wearer's nose and a portion of the wearer's face in the region between the base of the nose and the upper lip, and around the sides and over the bridge of the nose. The shape of the seal forming portion (**45**) is particularly suited to effectively seal the difficult region of the facial contour that is the crease between between the sides of the nose and the face.

96 Claims, 3 Drawing Sheets





U.S. PATENT DOCUMENTS

902,961	A		11/1908	Goodnow
1,000,706	A		8/1911	Barnum
1,081,745	A		12/1913	Johnston et al.
1,192,186	A		7/1916	Greene
1,206,045	A		11/1916	Smith
1,653,572	A		12/1927	Jackson
1,653,592	A		12/1927	Jackson
1,926,027	A		9/1933	Biggs
2,123,353	A		7/1938	Catt
2,166,164	A		7/1939	Lemberg
2,248,477	A		7/1941	Lombard
2,254,854	A		9/1941	O'Connell
2,317,608	A		4/1943	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
2,465,973	A		3/1949	Bulbulian
2,578,621	A		11/1951	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 et al.
3,189,027	A		6/1965	Bartlett
3,193,624	A		7/1965	Webb et al.
3,227,159	A		1/1966	Borgia et al.
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
3,521,630	A		7/1970	Westberg et al.
3,556,122	A		1/1971	Laerdal
3,580,051	A		5/1971	Blevins
3,680,555	A		8/1972	Warncke
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
4,077,404	A		3/1978	Elam
D250,131	S		10/1978	Lewis et al.
4,167,185	A		9/1979	Lewis
4,174,710	A		11/1979	Pampuch
4,226,234	A		10/1980	Gunderson
4,245,632	A		1/1981	Houston
D262,322	S		12/1981	Mizerak
4,304,229	A		12/1981	Curtin
4,328,797	A		5/1982	Rollins 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
4,414,973	A		11/1983	Matheson et al.
4,454,880	A		6/1984	Muto et al.
4,467,799	A		8/1984	Steinberg
4,522,639	A		6/1985	Ansite et al.
4,558,710	A		12/1985	Eichler
4,574,799	A		3/1986	Warncke
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
H397	H		1/1988	Stark
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.
4,794,921	A		1/1989	Lindkvist
4,799,477	A		1/1989	Lewis
4,803,981	A		2/1989	Vickery
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
4,986,269	A		1/1991	Hakkinen
4,989,596	A		2/1991	Macris et al.
4,989,599	A		2/1991	Carter
5,003,633	A		4/1991	Itoh
5,005,568	A		4/1991	Loescher et al.
5,005,571	A		4/1991	Dietz
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
5,069,205	A		12/1991	Urso
D323,908	S		2/1992	Hollister et al.
5,109,839	A		5/1992	Blasdell et al.
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.
5,140,982	A		8/1992	Bauman
5,148,802	A	*	9/1992	Sanders et al. 128/204.18
5,159,938	A		11/1992	Laughlin
5,178,138	A		1/1993	Walstrom et al.
D334,633	S		4/1993	Rudolph
5,220,699	A		6/1993	Farris
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. 128/205.25
5,265,595	A		11/1993	Rudolph
5,279,289	A		1/1994	Kirk
5,280,784	A		1/1994	Kohler
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
5,372,130	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.
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	Virag et al.	
RE35,339	E	10/1996	Rapoport	
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	
5,647,355	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.	
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	
5,724,965	A	3/1998	Handke et al.	
5,746,201	A	5/1998	Kidd	
5,813,423	A	9/1998	Kirchgeorg	
5,832,918	A	11/1998	Pantino	
5,884,624	A	3/1999	Barnett et al.	
5,921,239	A	7/1999	McCall et al.	
6,082,360	A	7/2000	Rudolph et al.	
6,112,746	A	9/2000	Kwok et al.	
6,119,693	A	9/2000	Kwok et al.	
6,357,441	B1	3/2002	Kwok et al.	
6,412,487	B1	7/2002	Gunaratnam et al.	
6,513,526	B2 *	2/2003	Kwok et al.	128/206.24
6,581,602	B2	6/2003	Kwok et al.	
6,634,358	B2 *	10/2003	Kwok et al.	128/205.25
6,701,927	B2 *	3/2004	Kwok et al.	128/207.13
2004/0094159	A1	5/2004	Kwok et al.	

FOREIGN PATENT DOCUMENTS

AU	A 32914/95		2/1996
AU	A 41018/97		4/1998
AU	A 89312/98		1/1999
CA	1039144		9/1928
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	195 48 380	A1	12/1994
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		7/1987
EP	0 264 772		10/1987
EP	0 303 090		7/1988
EP	0 386 605	A1	2/1990
EP	0 462 701	A1	5/1991
EP	0427474	A2	5/1991
EP	0 602 424		11/1993
EP	0 608 684	A1	8/1994
EP	0 634 186	A2	1/1995
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	44-16955		7/1969
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

Mirage Spare Parts Brochure, 1997, 2 pages.

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.

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.

U.S. Appl. No. 10/704,754, filed Nov. 2003, Kwok et al.

* cited by examiner

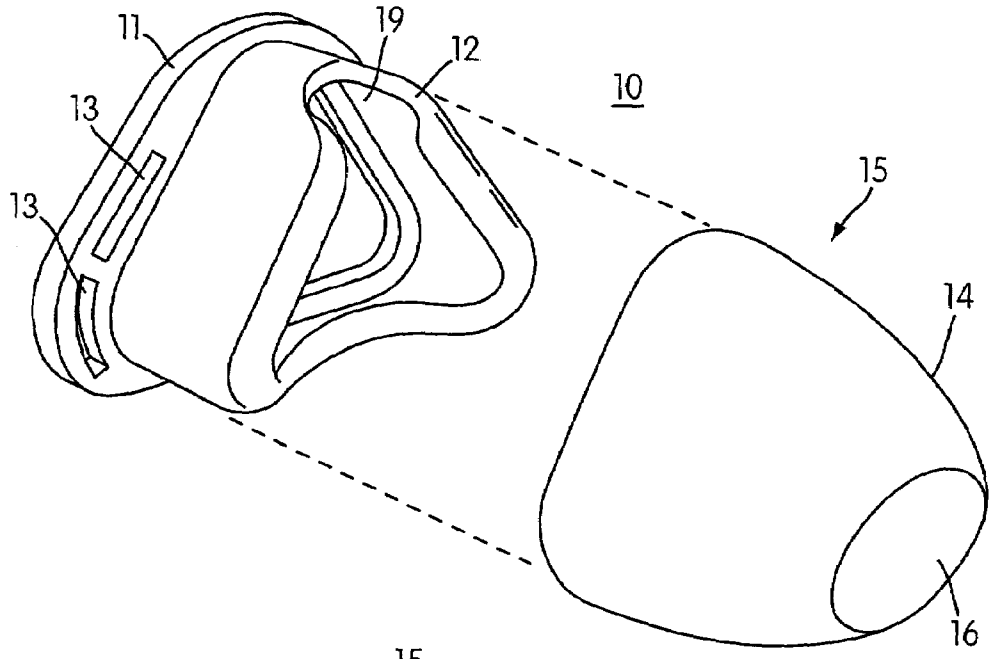


FIG. 1
PRIOR ART

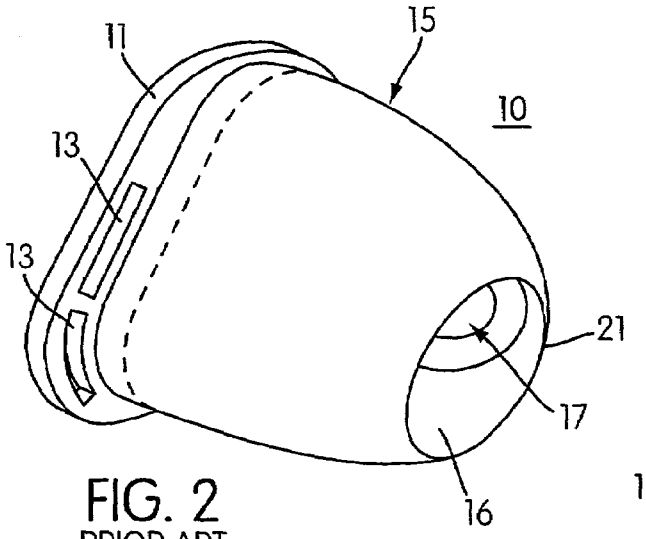


FIG. 2
PRIOR ART

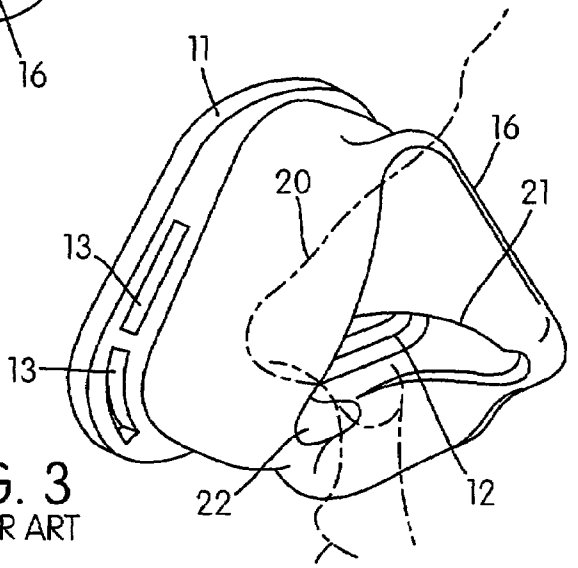
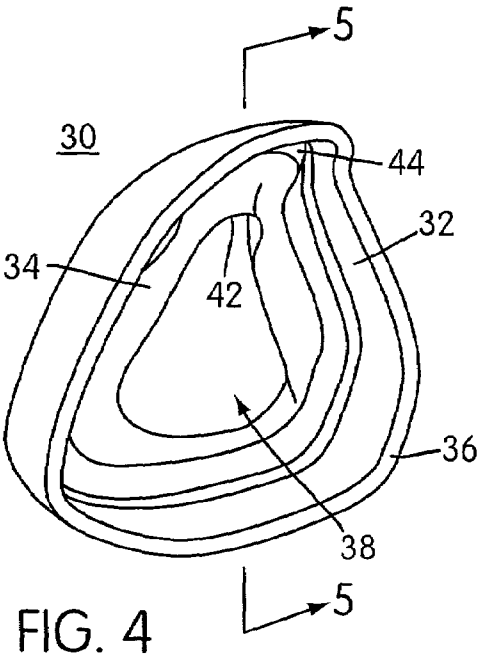


FIG. 3
PRIOR ART



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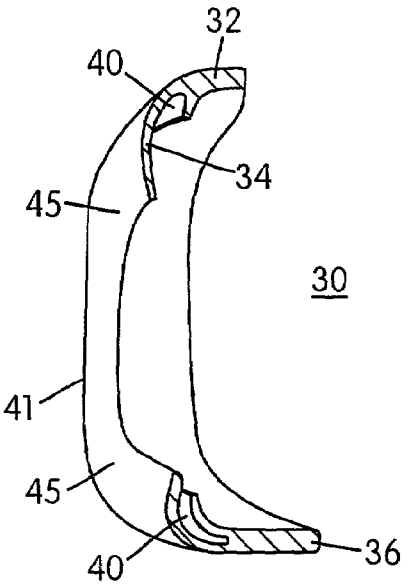

FIG. 5

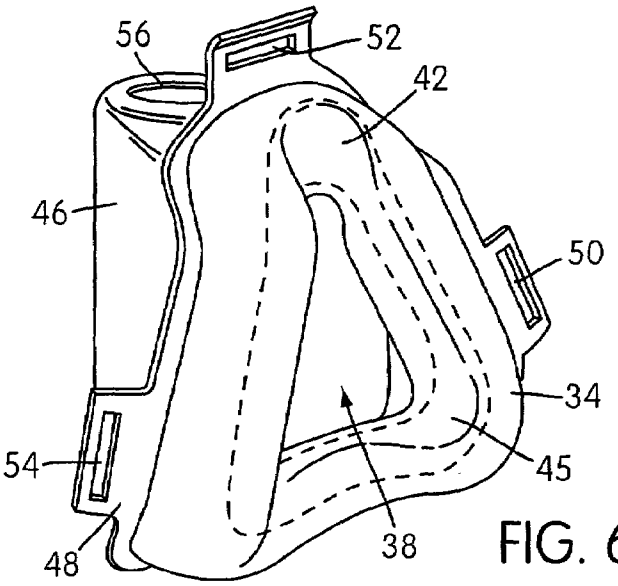

FIG. 6

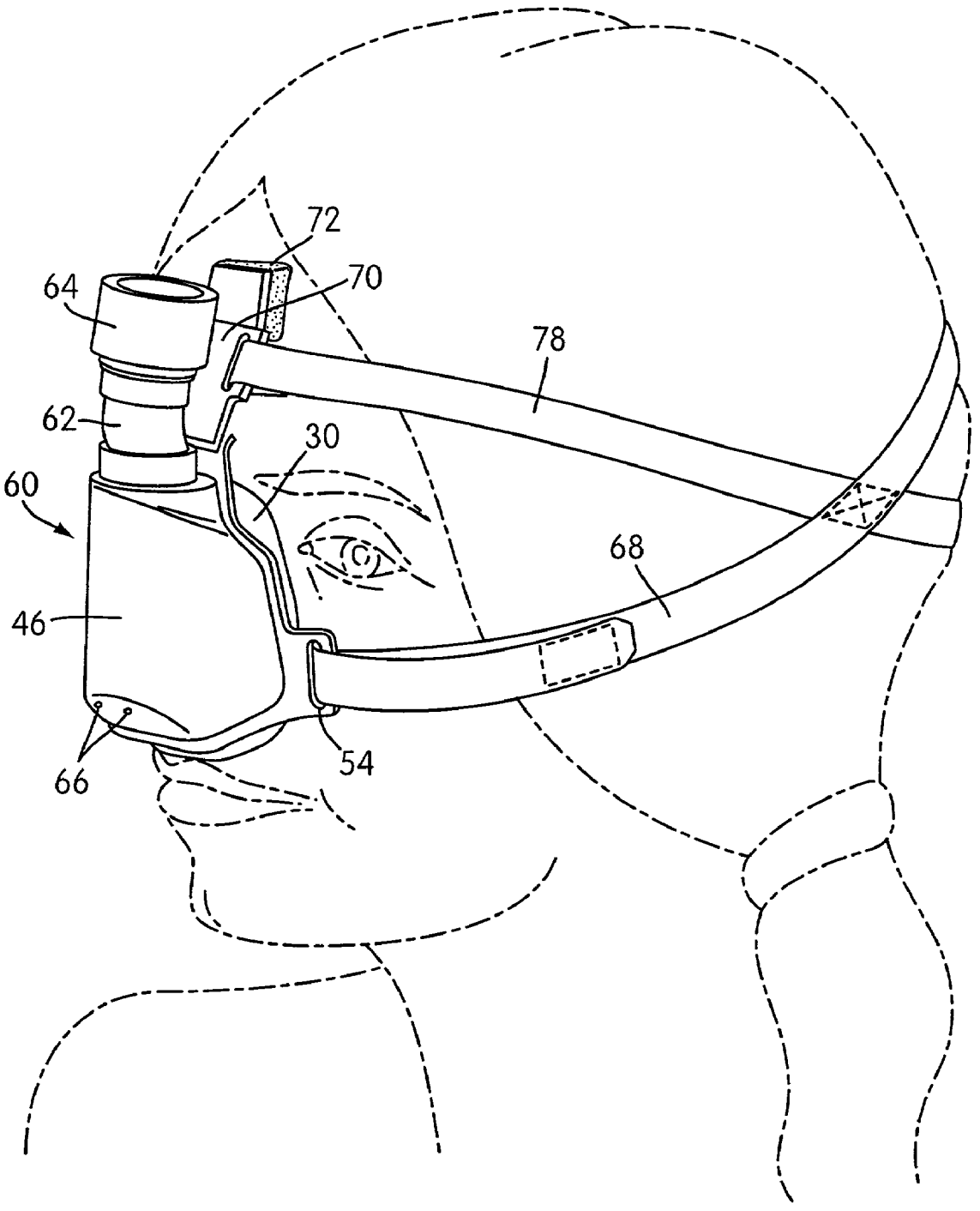

FIG. 7

NASAL MASK AND MASK CUSHION THEREFOR

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. Application Ser. No. 09/230,491, filed Aug. 11, 1999, now U.S. Pat. No. 6,357,441 the specification and drawings of which is incorporated herein by reference. Application Ser. No. 09/230,491 claims priority to Australian Provisional Patent Application No. PO1265, filed Jul. 26, 1996, through 371 PCT Application No. PCT/AU97/00450, filed Jul. 16, 1997 (published as WO 98/04310 on 5 Feb. 1998). This application contains subject matter related to U.S. Application Ser. No. 08/791,212, filed Jan. 31, 1997, now U.S. Pat. No. 6,112,746, incorporated by reference in its entirety, which also claims priority to Australian Provisional Patent Application No. PO1265, filed Jul. 26, 1996.

FIELD OF THE INVENTION

The invention relates generally to a nasal mask and to a cushion therefor, for example, for use in the treatment of respiratory conditions and in assisted respiration.

BACKGROUND OF THE INVENTION

Nasal masks are commonly used in the treatment of respiratory conditions and sleep disorders (e.g., obstructive sleep apnea) by delivering a flow of breathable gas for, or to assist patient respiration. These nasal masks typically receive a gas supply line which delivers gas into a chamber formed by walls of the mask. The walls usually are semi-rigid and have a face contacting portion including an aperture which is aligned with the wearer's nostrils. The face contacting portion can comprise a soft, resilient elastomeric material which may conform to various facial contours. The mask normally is secured to the wearer's head by straps. The straps are adjusted to pull the mask against the face with sufficient force to achieve a gas tight seal between the mask and the wearer's face. Gas is thus delivered to the mask and through the aperture to the wearer's nasal passages.

Problems often arise with masks of the above configuration. For example, the mask may be dislodged, thereby breaking the seal between the mask and wearer. This may occur if the wearer rolls over when sleeping thereby creating a drag force on the gas supply line which is transmitted to the mask, breaking the seal. In the case of a mask being used for the administration of Continuous Positive Airway Pressure (CPAP) treatment for the condition obstructive sleep apnea, such a leak can result in the pressure supplied to the entrance of the wearer's airway being below the therapeutic value, and the treatment becoming ineffective.

Another problem is that the face contacting portion may apply excessive pressure to the wearer's face resulting in discomfort and possibly skin irritation. This excessive forces. In some cases these excessive pressures and forces may cause the face to distort to conform with the face contacting portion to increase wearer discomfort, facial soreness and ulceration.

Other types of devices exist whereby small nostril nosepieces (pillows) are held in place by a harness strapped over the wearer's head, for example as shown in prior art U.S. Pat. No. 4,782,832. While this arrangement may alleviate some problems regarding seal breakage and skin abrasion, the harnesses associated with such devices are quite cumbersome for the wearer, as are the gas supply lines. Also, air 'jetting' into the nostrils can be irritating to the patient making such devices generally uncomfortable to use.

In FIGS. **1**–**3**, a prior art nasal cushion **10**, generally equivalent to that shown in prior art U.S. Pat. No. 5,243,971, is first described.

As shown, the cushion **10** generally includes a base **11** from which depends a semi-rigid cushion frame **12** formed of elastomeric material. Attached over the outside of the frame **12** is a membrane **15**, also of elastomeric material, having at its distal end a face contacting portion **14**. The frame **12** and the membrane **15** generally form a chamber **17** into which the wearer's nose can be received. The frame **12** has a notch **19** to accommodate the bridge of the wearer's nose. The base **11** includes slots **13** to accommodate straps (not shown) to secure the cushion **10** and a mask body (not shown) in combination to the wearer's head.

An aperture **16** is formed at the end of the membrane **15** distal from the frame **12** providing access for a wearer's nose **20** to the chamber **17** as noted. As shown, the aperture **16** in an unflexed state is generally circular (or elliptical) and is large enough to allow partial entry of the wearer's nose. The resilience of the membrane material allows the face contacting portion **14** and the aperture **16** to invert when the nose is received. The inverted membrane arrangement relies upon a positive pressure of supplied gas within the mask to effect a seal to the wearer's face. The seal is characterised as a "rolling edge seal", in that there can be motion of the cushion **10** relative to the patient's face yet the seal is maintained. Even so, a tuck **22** arises in the vicinity of the upper lip due to the circular shape of the aperture, and it is from this tuck that leaks can arise due to head and body movement during sleep.

It is an object of the invention to overcome or at least substantially ameliorate one or more of the foregoing disadvantages.

SUMMARY OF THE INVENTION

In one broad form, the invention discloses a nasal mask cushion to sealingly connect a mask to a wearer's face, the cushion comprising:

a substantially triangularly-shaped frame of resilient material having a rim to surround the wearer's nose;

a membrane also of resilient material, the membrane being relatively more flexible than the frame, and being of the same general shape as said rim and fixed to and extending away from the frame so as to have an outer surface spaced from the rim, a portion of said outer surface forming a face contacting seal; and

a nose-receiving cavity bounded by said frame and said membrane;

and wherein said seal portion is generally coterminous with respect to said rim and is resiliently deformable towards the rim in use of the cushion.

Preferably, the rim and seal portion are shaped to generally match facial contours of the facial tissue around the sides and over the bridge of the nose and between the base of the nose and the top lip.

In one particularly advantageous form, the membrane is substantially saddle-shaped. The membrane further has a centrally located aperture through which the wearer's nose passes to enter said cavity.

It is preferred that the cushion and membrane each include a co-located notch to accommodate the bridge of the nose of the wearer. Typically, the seal portion contacts at least the wearer's nose, and preferably, also the facial tissue

around the sides and over the bridge of the nose and between the base of the nose and the top lip.

The invention further discloses a nasal mask for connection to a wearer's face comprising:

a mask body for connection with a supply of breathable gas; and

a nasal cushion, the body and cushion defining a nose-receiving cavity, the cushion including:

a substantially triangularly-shaped frame of resilient material having a rim to surround the wearer's nose;

a membrane also of resilient material, the membrane being relatively more flexible than the frame, and being of the same general shape as said rim and fixed to and extending away from the frame so as to have an outer surface spaced from the frame, a portion of said outer surface forming a face contacting seal;

and wherein said seal portion is generally coterminous with respect to said rim and is resiliently deformable towards the rim in use of the mask.

The mask body can further include attachment points from which securing straps can be attached, and by which the mask can be secured to the wearer's head. The nasal mask can yet further comprise an arm depending from said body from which a further securing strap(s) can be attached.

The invention further discloses nasal CPAP treatment apparatus comprising a flow generator for the supply of gas at a pressure elevated above atmospheric pressure to a gas delivery conduit, the conduit in turn coupled to a nasal mask as described immediately above.

In one particularly preferred form, a supply of gas can be provided to said cavity, said supply of gas assisting, but not solely causing maintenance of a seal by said seal forming portion of said membrane to the face of the wearer in use of the cushion.

Advantageously, because the membrane and the rim are substantially shaped to the facial contour, and the membrane does not need to turn in on itself, as in the prior art, thus contacting the face without folds or creases. With the cushion/mask secured to the wearer's head, the headstraps need only to be tensioned to balance the force due to mask gas pressure that tends to lift the mask off the face. Such relatively lower mask-to-face pressure results in greater patient comfort, and a reduction in the likelihood of skin irritation.

BRIEF DESCRIPTION OF THE DRAWINGS

An embodiment of the invention will now be described with reference to the accompanying drawings, in which:

FIG. **1** is an exploded perspective view of a prior art nasal mask;

FIG. **2** is a perspective view of the prior art nasal mask of FIG. **1**;

FIG. **3** is a perspective view of the prior art nasal mask attached to a wearer;

FIG. **4** is a rear perspective view of a mask cushion embodying the present invention;

FIG. **5** is a cross-sectional view along line **5**—**5**;

FIG. **6** is a perspective view of a nasal mask including the cushion of FIGS. **4** and **5**; and

FIG. **7** is a perspective view of the nasal mask of FIG. **6** secured to a wearer's head.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. **4** shows a perspective view of a nasal cushion **30** embodying the invention. FIG. **5** shows the cross-sectional view along line **5**—**5**. The cushion **30** comprises a substantially triangularly shaped frame **32** from which extends a membrane **34**. The frame **32** has a scalloped edge **36** by which the cushion **30** is affixed to a mask body, as presently will be described.

The membrane **34** has an aperture **38** into which the wearer's nose is received in use of the cushion **30**. The membrane **34** is spaced away from the rim **40** of the frame **32**, and its outer surface **41** is of substantially the same shape as the rim **40**. The outer surface **41** of the membrane **34** and the rim **40** of the frame **32** also can be described as generally saddle shaped. The shaping of the outer surface **41** of the membrane **34** and the rim **40** of the frame **32** also include respective notches **42**,**44** that receive the bridge of the wearer's nose in use of the cushion **30**.

As is best seen in FIG. **5**, the frame **32** and the membrane **34** are integrally formed, typically by in a one-shot molding process. The frame **32** and the membrane **34** are fabricated from a resilient material. One suitable such material is Silastic™ silicone elastomer manufactured by Dow Corning. The frame **32**, in one preferred embodiment, has a typical thickness at its rim **40** of 1.5 mm. The membrane **34**, in a preferred embodiment, has a typical thickness of 0.35 mm. In this way, the membrane **34** is relatively more flexible than the rim **40**.

In use of the cushion **30**, a wearer's nose will be inserted in the aperture **38** to engage a seal forming portion **45** (formed between the dashed lines) of the outer surface **41** to cause deformation of the membrane **34**. Depending upon the securing force supplied to the membrane **34**, it may deform to a point where it butts against the rim **40** of the frame **32**. The frame **32** has a rigidity sufficient to withstand usual securing pressures in use of the cushion **30** to tend to retain its shape and resist deformation. It thus acts as a supporting structure.

Referring now to FIG. **6**, the nasal cushion **30** is shown attached to a mask body **46** by the edge **36** of the frame **32**, adhered or otherwise secured to a flange **48** of the mask body **46**. Only the outer surface **41** of the membrane **34** can be seen. The flange **48** includes three slots **50**–**54** from which tensioning straps can be attached to secure the cushion **30** and the mask body **46** (in combination) to the head of a wearer.

The mask body **46** forms a cavity that can receive the nose of the wearer by the aperture **38**. A port **56** is provided at the top of the mask body **46** by which breathable gas can be supplied to the chamber.

Referring now to FIG. **7**, there is shown a nasal mask **60** including the mask body **46** and the mask cushion **30**. A coupling tube **62** is connected at one end with the inlet port **56**, and at the other to a socket **64** into which can be received a gas delivery tube (not shown) for the supply of breathable gas to the chamber internal of the mask body **46**. The mask body **46** also has two vent openings **66** by which expired gas is exhausted. A first fastening strap **68** is fixed between to the lower two slots **50**,**54**. The upper slot **52** receives an arm **70**, the top end of which has a resilient pad **72** to engage the forehead of the wearer. The arm **70** has two slots **74**,**76** along its side edges, by which a second fastening strap **78** is secured.

In fining the nasal mask **60**, the wearer's nose is received through the aperture **38** into the chamber within the mask body **46**. The seal forming portion **45** thus contacts both the surface of the wearer's nose and a portion of the wearer's face in the region between the base of the nose and the upper lip, and around the sides and over the bridge of the nose. The shape of the seal forming portion **45** is particularly suited to

effectively seal the difficult region of the facial contour that is the crease between the sides of the nose and the face. Depending upon the tension applied by the fastening straps **68**,**78**, a seal is formed with the membrane **34** remaining spaced from the rim **40** of the cushion frame **32**. While the provision of pressurised gas to the chamber of the mask body **46** assists in the maintenance of a seal between the membrane **34** and the wearer's nose and face, it is not essential in most cases, and an effective seal will be formed absent any such pressurised gas. The seal formed between the membrane **34** and the wearer's nose and face is not in the nature of a rolling seal in the manner of prior art as shown in FIGS. **1** to **3**, as on relative movement of the mask **60** in relation to the wearer's head, the nose will be restrained by contacting the frame **32**. Thus only limited relative motion between the mask **60** and the wearer's nose and face occurs.

The membrane **34** closely imitates the facial contour, and because of its relatively lesser stiffness than the frame **32**, can conform to particular facial structures with minimum force, and without a tendency to fold or crease.

If the fastening strap **68**,**78** are tensioned to excess, the membrane **34** deforms to abut the rim **40** of the cushion **32**, the frame **32** thus acting as an "end limit". In such a configuration, almost zero relative movement can occur between the mask **60** and the wearer's head.

The nasal cushion **30** and nasal mask **60** has been described with reference to CPAP or assisted respiration treatment, however it is to be understood that the invention generally is applicable to any application where gas and/or atomised liquid is to be supplied to the entrance of the nasal airways. Such applications include nebulisers, gas masks and anaesthetic machines.

The invention claimed is:

1. A nasal mask cushion assembly to sealingly connect a nasal mask to a wearer's face, the cushion assembly comprising:

a generally triangularly shaped frame of resilient material, the frame including an outer surface, an inner surface having an inwardly oriented rim extending along at least a portion of a perimeter of the frame and a notch adapted to receive the bridge of the wearer's nose; and

a generally triangularly shaped membrane of resilient material, the membrane including an aperture adapted to receive the wearer's nose, an outer surface including a seal forming portion adapted to deform and form a seal over a portion of the wearer's face when the mask is in use, an inner surface opposing the rim of the frame, an edge defining the perimeter of the aperture, and a notch in a region of the membrane adapted to receive the bridge of the wearer's nose, wherein

the membrane is more flexible than the frame;

the aperture of the frame is larger than the aperture of the membrane; and

the edge of the membrane, in use, is spaced a distance from the rim in at least the region of the membrane adapted to receive the bridge of the wearer's nose.

2. A nasal mask cushion assembly according to claim **1**, wherein the frame and the membrane are formed in a single piece.

3. A nasal mask cushion assembly to sealingly connect a nasal mask to a wearer's face, the cushion assembly comprising:

a generally triangularly shaped frame of resilient material, the frame including a first side adapted to contact a mask body of the nasal mask, a second side opposite the first side, an aperture extending from the first side to the second side, a rim on the second side extending around at least a portion of the perimeter of the aperture, and a notch in the rim in a region adapted to receive the bridge of the wearer's nose; and

a generally triangularly shaped membrane of resilient material, the membrane including an aperture adapted to receive the wearer's nose, an edge defining the perimeter of the aperture, a notch in a region adapted to receive the bridge of the wearer's nose, a first surface including a seal forming portion disposed around the perimeter of the aperture adapted to deform and form a seal over a portion of the wearer's face in a region between the base of the nose and the upper lip and around the sides and over the bridge of the wearer's nose when the mask is in use, a second surface opposite the first surface that surrounds and is spaced a first distance from the rim of the frame in at least the region adapted to receive the bridge of the wearer's nose when the mask is in use, wherein the membrane is more flexible than the frame.

4. A nasal mask cushion assembly according to claim **3**, wherein the frame and the membrane are formed in a single piece.

5. A nasal mask cushion assembly according to claim **3**, wherein the nasal mask cushion is adapted to fit with a human patient in use.

6. A nasal mask cushion assembly according to claim **3**, wherein the nasal mask cushion comprises a CPAP cushion including a breathing chamber subject to above ambient pressure in use.

7. A nasal mask cushion assembly to sealingly connect a nasal mask to a wearer's face, the cushion assembly comprising:

a generally triangularly shaped frame of resilient material, the frame including an inner surface including an inwardly oriented rim extending along at least a portion of a perimeter of the frame, an outer surface, an aperture, and a notch in a region adapted to receive the bridge of the wearer's nose; and

a generally triangularly shaped membrane of resilient material, the membrane including an aperture adapted to receive the wearer's nose, an outer surface including a seal forming portion adapted to deform and form a seal over a portion of the wearer's face in a region between the base of the nose and the upper lip and around the sides and over the bridge of the wearer's nose when the mask is in use, an inner surface opposing the rim and spaced a first distance from the rim of the frame in at least the region of the frame adapted to receive the bridge of the wearer's nose when the mask is in use, an edge defining the perimeter of the aperture, and a notch in a region of the membrane adapted to receive the bridge of the wearer's nose, wherein

the membrane is more flexible than the frame;

the aperture of the frame is larger than the aperture of the membrane; and

the edge of the membrane is spaced a second distance from the rim, the second distance being variable.

8. A nasal mask cushion assembly according to claim **7**, wherein the frame and the membrane are formed in a single piece.

9. A nasal mask cushion assembly to sealingly connect a nasal mask to a wearer's face, the cushion assembly comprising:

a generally triangularly shaped frame of resilient material, the frame including a first side adapted to contact a mask body of the nasal mask, a second side opposite the first side, an aperture extending from the first side

to the second side, an inwardly oriented rim extending along at least a portion of a perimeter of the frame and a notch in a region adapted to receive the bridge of the wearer's nose; and

a generally triangularly shaped membrane of resilient material, the membrane including an aperture adapted to receive the wearer's nose, an edge defining the perimeter of the aperture, a notch in a region adapted to receive the bridge of the wearer's nose, a first surface including a seal forming portion disposed around the perimeter of the aperture adapted to deform and form a seal over a portion of the wearer's face in a region between the base of the nose and the upper lip and around the sides and over the bridge of the wearer's nose when the mask is in use, a second surface opposite the first surface that is spaced a first distance from the rim in at least the region adapted to receive the bridge of the wearer's nose when the mask is in use, wherein

the membrane is more flexible than the frame;

the aperture of the membrane is smaller than the aperture of the frame; and

the edge of the membrane is spaced a second distance from the rim, the second distance being variable.

10. A nasal mask cushion assembly according to claim **9**, wherein the frame and the membrane are formed in a single piece.

11. A nasal mask for connection to a wearer's face comprising:

a mask body for connection with a supply of breathable gas; and

a nasal cushion secured to said mask body, the body and cushion forming a nose-receiving cavity, said cushion including:

a nasal bridge region, a cheek region and a lip region;

a first membrane of resilient material having a first molded inwardly curved rim; and

a saddle-shaped second membrane also of resilient material, said second membrane having a second molded inwardly curved rim, said second molded rim being fixed to and extending away from said first membrane so as to have a second membrane inner surface spaced a distance from an outer surface of said first molded rim, said distance greater than a thickness of the first molded inwardly curved rim, said first distance measured when the mask is not in use, a portion of said second molded rim forming a face contacting seal;

wherein said face contouring, seal is substantially coterminous with respect to said second molded rim and is resiliently deformable towards said first membrane in use of said mask and,

the first and second molded inwardly curved rims are curved generally towards the nose-receiving cavity.

12. The nasal mask of claim **11**, further comprising an arm coupled to and extending above the nasal bridge region of the mask, the arm including an oblong slot positioned on each lateral side of the arm to receive a strap.

13. The nasal mask of claim **12**, further comprising a single resilient pad mounted on the arm and centered above the nasal bridge region of the mask.

14. The nasal mask of claim **13**, wherein the second membrane is conformable, in use, to various facial structures with minimum force.

15. The nasal mask of claim **14**, wherein a maximum deformation position of the second membrane is defined by the first membrane.

16. The nasal mask of claim **15**, wherein the maximum deformation position is not reached under normal tightening force of the mask to the wearer's face.

17. The nasal mask of claim **11**, wherein the first and second membranes are formed as a one-piece unit.

18. The nasal mask of claim **11**, wherein the first membrane is thicker than the second membrane.

19. The nasal mask of claim **11**, wherein the mask body includes a plurality of vent openings.

20. The nasal mask of claim **11**, wherein an edge of the frame interengages with the mask body, the edge being non-planar, the edge including a nasal bridge edge region and a lip edge region that diverge away from each cheek edge region and towards the mask body.

21. A nasal CPAP treatment apparatus comprising:

a flow generator for the supply of gas at a pressure elevated above atmospheric pressure;

a gas delivery conduit coupled to said flow generator; and

a nasal mask in turn coupled to said conduit, said nasal mask including:

a mask body for connection with a supply of breathable gas; and

a nasal cushion secured to said mask body, the body and cushion forming a nose-receiving cavity, the cushion including:

a nasal bridge region, a cheek region and a lip region;

a first membrane of resilient material having a first membrane having a first molded inwardly curved rim; and

a saddle-shaped second membrane having a second molded inwardly curved rim also of resilient material, said second membrane being fixed to and extending away from said first membrane so as to have an inner surface spaced a distance from said first molded rim, said distance greater than a thickness of the first inwardly curved rim, said distance measured when the mask is not in use, a portion of said second molded rim forming a face contacting seal;

wherein said seal portion is generally coterminous with respect to said second molded rim and is resiliently deformable towards said first membrane in use of said mask, and

wherein the seal portion fully covers the first molded inwardly curved rim so that the second inwardly curved rim is positioned to provide the only seal with the wearer's face in use.

22. The apparatus of claim **21**, further comprising an arm coupled to and extending above the nasal bridge region of the mask, the arm including an oblong slot positioned on each lateral side of the arm to receive a strap.

23. The apparatus of claim **22**, further comprising a single resilient pad mounted on the arm and centered above the nasal bridge region of the mask.

24. The apparatus of claim **23**, wherein the second membrane is conformable, in use, to various facial structures with minimum force.

25. The apparatus of claim **24**, wherein a maximum deformation position of the second membrane is defined by the first membrane.

26. The apparatus of claim **25**, wherein the maximum deformation position is not reached under normal tightening force of the mask to the wearer's face.

27. The apparatus of claim **21**, wherein the first and second membranes are formed as a one-piece unit.

28. The apparatus of claim **21**, wherein the first membrane is thicker than the second membrane.

29. A mask cushion for sealingly connecting a mask to a wearers face, comprising:

a frame defining at least a portion of a breathing chamber, said frame being of resilient material and having a first membrane, the first membrane including a first molded inwardly curved rim disposed within the breathing chamber and extending along at least a portion of an inner perimeter of the frame, said frame having a front portion with an edge structured to be coupled to a body portion of the mask; and

a saddle-shaped second membrane of resilient material, said second membrane having a second molded inwardly curved rim, said second membrane curved rim spaced a distance from said first membrane curved rim, said distance greater than a thickness of the first molded inwardly curved rim, said distance measured when the mask is not in use, a portion of said second membrane curved rim forming a face contacting seal, wherein

a substantially full perimeter of the second molded inwardly curved rim is curved towards the front portion of the frame opposite the wearer's face, and

the substantially full perimeter of the second molded inwardly curved rim is provided in covering yet spaced relation to each portion of the first molded inwardly curved rim.

30. The nasal mask cushion of claim 29, wherein the second membrane is conformable, in use, to various facial structures with minimum force.

31. The mask cushion of claim 30, wherein a maximum deformation position of the second membrane is defined by the first membrane.

32. The mask cushion of claim 31, wherein the maximum deformation position is not reached under normal tightening force of the mask to the wearer's face.

33. The mask cushion of claim 29, wherein the first and second membranes are formed as a one-piece unit.

34. The mask cushion of claim 29, wherein the first membrane is thicker than the second membrane.

35. A nasal mask cushion according to claim 29, wherein the nasal mask cushion comprises a CPAP cushion including a breathing chamber subject to above ambient pressure in use.

36. A cushion and mask assembly comprising:

a mask including a mask shell constructed to receive a supply of breathable air, an arm extending away from the mask shell and including at least one oblong slot to receive a strap, and a resilient pad provided to the arm above a nasal bridge region of the mask; and

a cushion having a main upstanding wall, the wall having a first end removably coupleable to the mask and a second end defining an opening into a nasal cavity formed by the mask and the cushion, at least a portion of the wall including a first membrane positioned between the first and second ends and extending inwardly onto the nasal cavity, the second end of the wall defining a saddle-shaped second membrane adapted to form a seal over a portion of the wearer's face in a region between the base of the nose and the upper lip and around the sides and over the bridge of the wearer's nose when the mask is in use, the second membrane being spaced from the first membrane a distance that is greater than a thickness of the first membrane, the first membrane having a width that is less than a distance from an intersection of the first membrane and the wall to an edge of the second membrane defining an aperture of the nasal cavity, the second membrane overhanging and covering substantially all portions of the first membrane, the first membrane acting to define a maximum deformation position of the second membrane in use.

37. The assembly of claim 36, wherein the second membrane is conformable, in use, to various facial structures with minimum force.

38. The assembly of claim 36, wherein the first and second membranes are formed as a one-piece unit.

39. The assembly of claim 36, wherein the first membrane is thicker than the second membrane.

40. A mask cushion to sealingly connect a mask to a wearer's face, the cushion comprising:

a substantially triangularly-shaped frame of resilient material having an inwardly oriented rim to surround at least a portion of the wearer's nose;

a membrane also of resilient material, the membrane being relatively more flexible than the frame, and being of the same general shape as said rim and fixed to and extending away from the frame so as to have an outer surface spaced from the rim, a portion of said outer surface forming a face contacting seal portion; and

a nose-receiving cavity bounded by said frame and said membrane;

wherein:

said face contacting seal portion is generally coterminous with respect to said rim and is resiliently deformable towards the rim in use of the cushion,

the membrane has a radius of curvature oriented towards the nose-receiving cavity, and

a substantially full perimeter of the membrane is provided in covering yet spaced relation to each portion of the rim.

41. The cushion as claimed in claim 40, wherein said membrane and said rim each has a co-located notch to accommodate the bridge of a nose.

42. The cushion as claimed in claim 41, wherein said membrane is shaped so that said seal portion, in use, contacts at least a wearer's nose.

43. The cushion as claimed in claim 41, wherein said membrane and said rim are substantially saddle-shaped.

44. The cushion as claimed in claim 40, wherein said membrane is shaped so that said seal portion, in use, contacts at least a wearer's nose.

45. The cushion as claimed in claim 44, wherein said seal portion, in use, contacts the facial tissue around the sides and over the bridge of the nose, and between the base of the nose and the top lip.

46. The cushion as claimed in claim 40, wherein said rim and said seal portion are shaped to generally match facial contours of the facial tissue around the sides and over the bridge of the nose, and between the base of the nose and the top lip.

47. The cushion as claimed in claim 40, wherein only the membrane is adapted to contact the wearer's face in use.

48. The cushion as claimed in claim 40, wherein only a single seal is provided about the wearer's face in use.

49. The cushion as claimed in claim 40, wherein the mask cushion is adapted to fit with a human patient in use.

50. A mask cushion according to claim 40, wherein the mask cushion comprises a CPAP cushion including a breathing chamber subject to above ambient pressure in use.

51. A nasal mask cushion to sealingly connect a mask to a wearer's face, the cushion comprising:
a nasal bridge region, a cheek region and a lip region;
a first membrane comprising a frame of resilient material having a side wall and a first molded inwardly curved rim extending from said side wall; and
a saddle-shaped second membrane of resilient material, said second membrane having a second molded inwardly curved rim, said second membrane curved rim spaced a distance from said first molded inwardly curved rim, said distance being greater than a thickness of the first molded inwardly curved rim, said distance measured when the mask is not in use, a portion of said second membrane curved rim forming a face contacting seal,
wherein the second molded inwardly curved rim has a curvature oriented to present a generally convex sealing surface to the wearer's face in use.

52. The nasal mask cushion of claim 51, wherein the second membrane is conformable, in use, to various facial structures with minimum force.

53. The nasal mask cushion of claim 52, wherein a maximum deformation position of the second membrane is defined by the first membrane.

54. The nasal mask cushion of claim 53, wherein the maximum deformation position is not reached under normal tightening force of the mask to the wearer's face.

55. The nasal mask cushion of claim 51, wherein the first and second membranes are formed as a one-piece unit.

56. The nasal mask cushion of claim 51, wherein the first membrane is thicker than the second membrane.

57. The nasal mask cushion of claim 51, wherein an edge of the frame is adapted to interengage with the mask, the edge being non-planar, the edge including a nasal bridge edge region and a lip edge region that diverge away from each cheek edge region.

58. A mask cushion according to claim 51, wherein the nasal mask cushion is adapted to fit with a human patient in use.

59. A nasal mask cushion according to claim 51, wherein the nasal mask cushion comprises a CPAP cushion including a breathing chamber subject to above ambient pressure in use.

60. A nasal mask cushion to sealingly connect a mask to a wearer's face, the cushion comprising:
a nasal bridge region, a cheek region and a lip region;
a first membrane comprising a frame of resilient material having a side wall including an edge molded to a mask body and a first molded inwardly curved rim extending from the side wall; and
a saddle-shaped second membrane of resilient material, said second membrane having a second molded inwardly curved rim, a portion of said second membrane curved rim forming a face contacting seal, said second membrane curved rim spaced a sufficient distance from said first membrane curved rim such that under a normal tightening force of the mask to the wearer's face, at least a portion of the second membrane curved rim remains spaced from the first membrane curved rim,
wherein each of the first and second molded inwardly curved rims has a radius of curvature generally oriented in a direction towards the side wall.

61. The nasal mask cushion of claim 60, wherein the second membrane is conformable, in use, to various facial structures with minimum force.

62. The nasal mask cushion of claim 61, wherein a maximum deformation position of the second membrane is defined by the first membrane.

63. The nasal mask cushion of claim 62, wherein the maximum deformation position is not reached under normal tightening force of the mask to the wearer's face.

64. The nasal mask cushion of claim 60, wherein the first and second membranes are formed as a one-piece unit.

65. The nasal mask cushion of claim 60, wherein the first membrane is thicker than the second membrane.

66. A nasal mask cushion according to claim 60, wherein the nasal mask cushion is adapted to fit with a human patient in use.

67. A nasal mask cushion according to claim 60, wherein the nasal mask cushion comprises a CPAP cushion including a breathing chamber subject to above ambient pressure in use.

68. A nasal mask for connection to a wearer's face comprising:
a mask body for connection with a supply of breathable gas; and
a nasal cushion secured to said mask body, the body and cushion forming a nose-receiving cavity, said cushion including:
a nasal bridge region, a cheek region and a lip region;
a substantially triangularly-shaped first membrane of resilient material having a first molded inwardly curved rim; and
a saddle-shaped second membrane also of resilient material, said second membrane having a second molded inwardly curved rim, said second molded rim being fixed to and extending away from said first membrane so as to have a second membrane inner surface spaced a distance from an outer surface of said first molded rim, a portion of said second molded rim forming a face contacting seal;
wherein said seal portion is substantially coterminous with respect to said second molded rim and is resiliently deformable towards said first membrane in use of said mask, at least a portion of the second molded rim remaining spaced from the first molded rim when the mask is connected to the wearer's face, and
wherein the first and second molded inwardly curved rims are generally curved towards the nose-receiving cavity.

69. The nasal mask of claim 68, further comprising an arm coupled to and extending above the nasal bridge region of the mask, the arm including at least one oblong slot to receive a strap.

70. The nasal mask of claim 69, further comprising at least one pad provided to the arm above the nasal bridge region of the mask.

71. The nasal mask of claim 70, wherein the second membrane is conformable, in use, to various facial structures with minimum force.

72. The nasal mask of claim 71, wherein a maximum deformation position of the second membrane is defined by the first membrane.

73. The nasal mask of claim 72, wherein the maximum deformation position is not reached under normal tightening force of the mask to the wearer's face.

74. The nasal mask of claim 68, wherein the first and second membranes are formed as a one-piece unit.

75. The nasal mask of claim 68, wherein the first membrane is thicker than the second membrane.

76. A nasal mask according to claim 68, wherein the nasal mask cushion is adapted to fit with a human patient in use.

77. A nasal mask according to claim 68, wherein the nasal mask cushion comprises a CPAP cushion including a breathing chamber subject to above ambient pressure in use.

78. A nasal CPAP treatment apparatus comprising:

a flow generator for the supply of gas at a pressure elevated above atmospheric pressure;

a gas delivery conduit coupled to said flow generator; and

a nasal mask in turn coupled to said conduit to said nasal mask including:

a mask body for connection with a supply of breathable gas; and

a nasal cushion secured to said mask body, the body and cushion forming a nose-receiving cavity, the cushion including:

a nasal bridge region, a cheek region and a lip region;

a frame of resilient material having a first membrane with an inwardly oriented rim extending along at least a portion of the frame; and

a saddle-shaped second membrane having a molded inwardly curved rim also of resilient material, said second membrane being fixed to and extending away from said first membrane so as to have an inner surface spaced a distance from said first membrane, a portion of said molded rim forming a face contacting seal portion with the wearer's face in use;

wherein said seal portion is generally coterminous with respect to said molded rim and is resiliently deformable towards said first membrane in use of said mask, at least a portion of the molded rim remaining spaced from the membrane when the mask is connected to a wearer's face.

79. The apparatus of claim 78, further comprising an arm coupled to and extending above the nasal bridge region of the mask, the arm including an oblong slot positioned one each lateral side of the arm to receive a strap.

80. The apparatus of claim 79, further comprising a single resilient pad mounted on the arm and centered above the nasal bridge region of the mask.

81. The apparatus of claim 80, wherein the second membrane is conformable, in use, to various facial structures with minimum force.

82. The apparatus of claim 81, wherein a maximum deformation position of the second membrane is defined by the first membrane.

83. The apparatus of claim 78, wherein the maximum deformation position is not reached under normal tightening force of the mask to the wearer's face.

84. The apparatus of claim 78, wherein the first and second membranes are formed as a one-piece unit.

85. The apparatus of claim 78, wherein the first membrane is thicker than the second membrane.

86. The apparatus of claim 78, wherein the mask body includes a plurality of vent openings.

87. The apparatus of claim 78, wherein an edge of the frame interengages with the mask body, the edge being non-planar, the edge including a nasal bridge edge region and a lip edge region that diverge away from each cheek edge region and towards the mask body.

88. A nasal CPAP treatment apparatus according to claim 78, wherein the nasal mask cushion is adapted to fit with a human patient in use.

89. A mask cushion for sealingly connecting a mask to a wearer's face, comprising:

a frame defining at least a portion of a breathing chamber, said frame being of resilient material and having a first membrane, at least a portion of the first membrane including a first molded inwardly curved rim disposed within the breathing chamber; and

a saddle-shaped second membrane of resilient material, said second membrane having a second molded inwardly curved rim forming a boundary of said breathing chamber, said second membrane curved rim spaced a distance from said first membrane curved rim, measured when the mask is not in use, a portion of said second membrane curved rim forming a face contacting seal, said second membrane curved rim spaced a sufficient distance from said first membrane curved rim such that under a normal tightening force of the mask to the wearer's face, the second membrane curved rim remains spaced from the first membrane curved rim around at least a portion of the first membrane curved rim, wherein;

the second molded inwardly curved rim is curved in a direction towards a front portion of the frame opposite the face contacting seal, and

a substantially full perimeter of the second membrane curved rim is provided in covering yet spaced relation to each portion of the first membrane curved rim.

90. The mask cushion of claim 89, wherein the second membrane is conformable, in use, to various facial structures with minimum force.

91. The mask cushion of claim 90, wherein a maximum deformation position of the second membrane is defined by the first membrane.

92. The mask cushion of claim 91, wherein the maximum deformation position is not reached under normal tightening force of the mask to the wearer's face.

93. The mask cushion of claim 89, wherein the first and second membranes are formed as a one-piece unit.

94. The mask cushion of claim 89, wherein the first membrane is thicker than the second membrane.

95. A mask cushion according to claim 89, wherein the mask cushion is adapted to fit with a human patient in use.

96. A mask cushion according to claim 89, wherein the mask cushion comprises a CPAP cushion including a breathing chamber subject to above ambient pressure in use.

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