

# US Patent & Trademark Office

## Patent Public Search | Text View

---

United States Patent	12390610
Kind Code	B2
Date of Patent	August 19, 2025
Inventor(s)	McAuley; Alastair Edwin et al.

---

### Breathing assistance apparatus

---

#### Abstract

A mask assembly for use as part of an apparatus for supplying a flow of respiratory gases to a user is disclosed. The mask assembly includes a mask body having an inlet through which said flow of respiratory gases are provided to the interior of said mask body. A mask seal assembly comprising a seal of flexible material and a clip of rigid material is attached to the body. The seal has a first side and a second side. The first side of the seal is shaped to approximately match the contours of a user's face and in use substantially seal against a user's face. The second side is attached to the clip. The clip provides an interface extending substantially the full perimeter or periphery of the mask seal assembly for releasably attaching the mask seal assembly to the mask body. The clip comprises a bridging portion spanning outwards from the perimeter or periphery of the mask body to space at least a portion of the second side of the seal outwards from the perimeter or periphery of the mask body.

---

**Inventors:** McAuley; Alastair Edwin (Dallas, TX), Olsen; Gregory James (Auckland, NZ), Patel; Roheet (Auckland, NZ)

**Applicant:** Fisher & Paykel Healthcare Limited (Auckland, NZ)

**Family ID:** 1000008763715

**Assignee:** Fisher & Paykel Healthcare Limited (Auckland, NZ)

**Appl. No.:** 18/468663

**Filed:** September 15, 2023

#### Prior Publication Data

Document Identifier	Publication Date
US 20240115827 A1	Apr. 11, 2024

#### Related U.S. Application Data

continuation parent-doc US 17816275 20220729 US 11766535 20230926 child-doc US 18468663  
continuation parent-doc US 17568186 20220104 US 11559650 20230124 child-doc US 17816275  
continuation parent-doc US 16384218 20190415 US 11247013 20220215 child-doc US 17568186

continuation parent-doc US 15425937 20170206 US 10835702 20201117 child-doc US 16384218  
continuation parent-doc US 14977083 20151221 US 10272218 20190430 child-doc US 16384218  
continuation parent-doc US 13877903 US 9561338 20170207 WO PCT/NZ2011/000211 20111007  
child-doc US 14977083  
division parent-doc US 13877903 US 9561338 20170207 WO PCT/NZ2011/000211 20111007 child-  
doc US 15425937  
us-provisional-application US 61391527 20101008

---

**Publication Classification**

**Int. Cl.:** **A61M16/06** (20060101); **A61M16/00** (20060101); A61M16/10 (20060101); A61M16/16 (20060101)

**U.S. Cl.:**

**CPC**     **A61M16/0622** (20140204); **A61M16/0066** (20130101); **A61M16/0616** (20140204);  
**A61M16/0633** (20140204); **A61M16/0683** (20130101); A61M2016/0039 (20130101);  
A61M16/0069 (20140204); A61M16/024 (20170801); A61M16/109 (20140204);  
A61M16/16 (20130101); A61M2205/3368 (20130101); A61M2205/50 (20130101)

**Field of Classification Search**

**CPC:**     A61M (16/06); A61M (16/0605); A61M (16/0611); A61M (16/0616); A61M (16/0622);  
A61M (16/0627); A62B (18/02); A62B (18/025); A62B (18/04); A62B (18/06)

---

**References Cited**

**U.S. PATENT DOCUMENTS**

Patent No.	Issued Date	Patentee Name	U.S. Cl.	CPC
301111	12/1883	Genese	N/A	N/A
472238	12/1891	Van Orden	N/A	N/A
577926	12/1896	Miller	N/A	N/A
718470	12/1902	Jones	N/A	N/A
751091	12/1903	Moran	N/A	N/A
770013	12/1903	Linn	N/A	N/A
1635545	12/1926	Drager	N/A	N/A
2126755	12/1937	Dreyfus	N/A	N/A
2228218	12/1940	Schwartz	N/A	N/A
2241535	12/1940	Boothby et al.	N/A	N/A
2296150	12/1941	Dockson et al.	N/A	N/A
2353643	12/1943	Bulbulian	N/A	N/A
2359506	12/1943	Battley et al.	N/A	N/A
2388604	12/1944	Eisenbud	N/A	N/A
2415846	12/1946	Francis	N/A	N/A
2452845	12/1947	Fisher	N/A	N/A
2508050	12/1949	Valente	N/A	N/A
2684066	12/1953	Glidden	N/A	N/A
2693800	12/1953	Caldwell	N/A	N/A
2738788	12/1955	Matheson et al.	N/A	N/A
2749910	12/1955	Faulconer	N/A	N/A
2837090	12/1957	Bloom	N/A	N/A

2843121	12/1957	Hudson	N/A	N/A
2859748	12/1957	Hudson	N/A	N/A
2875759	12/1958	Galleher	N/A	N/A
2894506	12/1958	Rose	N/A	N/A
2939458	12/1959	Lundquist	N/A	N/A
3234940	12/1965	Morton	N/A	N/A
3330273	12/1966	Ray	N/A	N/A
3424633	12/1968	Corrigall et al.	N/A	N/A
3490452	12/1969	Greenfield	N/A	N/A
3545437	12/1969	Quackenbush	N/A	N/A
3599635	12/1970	Kenneth	N/A	N/A
3682171	12/1971	Dali et al.	N/A	N/A
3834682	12/1973	McPhee	N/A	N/A
3850171	12/1973	Ball et al.	N/A	N/A
3894562	12/1974	Mosley et al.	N/A	N/A
3972321	12/1975	Proctor	N/A	N/A
3977432	12/1975	Vidal	N/A	N/A
3982532	12/1975	Halldin et al.	N/A	N/A
3992720	12/1975	Nicolinas	N/A	N/A
4090510	12/1977	Segersten	N/A	N/A
D250047	12/1977	Lewis et al.	N/A	N/A
D250131	12/1977	Lewis et al.	N/A	N/A
4127130	12/1977	Naysmith	N/A	N/A
4150464	12/1978	Tracy	N/A	N/A
D252322	12/1978	Johnson	N/A	N/A
4201205	12/1979	Bartholomew	N/A	N/A
4258710	12/1980	Reber	N/A	N/A
4266540	12/1980	Panzik et al.	N/A	N/A
4278082	12/1980	Blackmer	N/A	N/A
4354488	12/1981	Bartos	N/A	N/A
4367735	12/1982	Dali	N/A	N/A
4378011	12/1982	Warncke et al.	N/A	N/A
4437462	12/1983	Piljay	N/A	N/A
4454880	12/1983	Muto et al.	N/A	N/A
4574799	12/1985	Warncke et al.	N/A	N/A
4603602	12/1985	Montesi	N/A	N/A
4621632	12/1985	Bartels et al.	N/A	N/A
4644974	12/1986	Zingg	N/A	N/A
4676241	12/1986	Webb et al.	N/A	N/A
4677977	12/1986	Wilcox	N/A	N/A
D293613	12/1987	Wingler	N/A	N/A
4753233	12/1987	Grimes	N/A	N/A
4773411	12/1987	Downs	N/A	N/A
4782832	12/1987	Trimble et al.	N/A	N/A
4803981	12/1988	Vickery	N/A	N/A
4804160	12/1988	Harbeke	N/A	N/A
4836200	12/1988	Clark et al.	N/A	N/A
4856508	12/1988	Tayebi	N/A	N/A
4907584	12/1989	McGinnis	N/A	N/A
4915104	12/1989	Marcy	N/A	N/A
4915105	12/1989	Lee	N/A	N/A
4919128	12/1989	Kopala et al.	N/A	N/A

4938209	12/1989	Fry	N/A	N/A
4941467	12/1989	Takata	N/A	N/A
4944310	12/1989	Sullivan	N/A	N/A
D310431	12/1989	Bellm	N/A	N/A
4958658	12/1989	Zajac	N/A	N/A
4971051	12/1989	Toffolon	N/A	N/A
4986269	12/1990	Hakkinen	N/A	N/A
5010925	12/1990	Atkinson et al.	N/A	N/A
5016625	12/1990	Hsu et al.	N/A	N/A
5031261	12/1990	Fenner	N/A	N/A
5042478	12/1990	Kopala et al.	N/A	N/A
5046491	12/1990	Derrick	N/A	N/A
D320677	12/1990	Kumagai et al.	N/A	N/A
D321419	12/1990	Wallace	N/A	N/A
5062421	12/1990	Burns et al.	N/A	N/A
5065756	12/1990	Rapoport	N/A	N/A
D322318	12/1990	Sullivan et al.	N/A	N/A
5074297	12/1990	Venegas	N/A	N/A
5094236	12/1991	Tayebi	N/A	N/A
5113857	12/1991	Dickerman et al.	N/A	N/A
5121745	12/1991	Israel et al.	N/A	N/A
5148802	12/1991	Sanders et al.	N/A	N/A
5164652	12/1991	Johnson et al.	N/A	N/A
5231979	12/1992	Rose	N/A	N/A
5243971	12/1992	Sullivan et al.	N/A	N/A
5245995	12/1992	Sullivan et al.	N/A	N/A
D340317	12/1992	Cole	N/A	N/A
5259377	12/1992	Schroeder	N/A	N/A
5267556	12/1992	Feng	N/A	N/A
5269296	12/1992	Landis et al.	N/A	N/A
5315859	12/1993	Schommer	N/A	N/A
5349949	12/1993	Schegerin	N/A	N/A
5353789	12/1993	Schobohm	N/A	N/A
5366805	12/1993	Fujiki et al.	N/A	N/A
D354128	12/1994	Rinehart	N/A	N/A
D355484	12/1994	Rinehart	N/A	N/A
5400776	12/1994	Bartholomew	N/A	N/A
5429683	12/1994	Le Mitouard	N/A	N/A
5438979	12/1994	Johnson et al.	N/A	N/A
5441046	12/1994	Starr et al.	N/A	N/A
5449206	12/1994	Lockwood	N/A	N/A
5449234	12/1994	Gipp et al.	N/A	N/A
5458202	12/1994	Fellows et al.	N/A	N/A
5460174	12/1994	Chang	N/A	N/A
5461932	12/1994	Hall	N/A	N/A
5477852	12/1994	Landis et al.	N/A	N/A
5513634	12/1995	Jackson	N/A	N/A
5518802	12/1995	Colvin et al.	N/A	N/A
5533506	12/1995	Wood	N/A	N/A
5540223	12/1995	Starr et al.	N/A	N/A
5542128	12/1995	Lomas	N/A	N/A
5551419	12/1995	Froehlich et al.	N/A	N/A

5558090	12/1995	James	N/A	N/A
5560354	12/1995	Berthon-Jones et al.	N/A	N/A
5570689	12/1995	Starr et al.	N/A	N/A
5588423	12/1995	Smith	N/A	N/A
5595174	12/1996	Gwaltney	N/A	N/A
5601078	12/1996	Schaller et al.	N/A	N/A
D378610	12/1996	Reischel et al.	N/A	N/A
5649532	12/1996	Griffiths	N/A	N/A
5657752	12/1996	Landis et al.	N/A	N/A
5662101	12/1996	Ogden et al.	N/A	N/A
5664566	12/1996	Mcdonald et al.	N/A	N/A
5687715	12/1996	Landis	N/A	N/A
5690097	12/1996	Howard et al.	N/A	N/A
5724677	12/1997	Bryant et al.	N/A	N/A
5724965	12/1997	Handke et al.	N/A	N/A
5746201	12/1997	Kidd	N/A	N/A
5752510	12/1997	Goldstein	N/A	N/A
5755578	12/1997	Contant et al.	N/A	N/A
5789660	12/1997	Kofoed et al.	N/A	N/A
5806727	12/1997	Joseph	N/A	N/A
5807295	12/1997	Hutcheon et al.	N/A	N/A
5857460	12/1998	Popitz	N/A	N/A
5884624	12/1998	Barnett et al.	N/A	N/A
5904278	12/1998	Barlow et al.	N/A	N/A
5918598	12/1998	Belfer	N/A	N/A
5921239	12/1998	McCall et al.	N/A	N/A
5924420	12/1998	Reischel	N/A	N/A
5941245	12/1998	Hannah et al.	N/A	N/A
5943473	12/1998	Levine	N/A	N/A
5953763	12/1998	Gouget	N/A	N/A
5966745	12/1998	Schwartz et al.	N/A	N/A
6016804	12/1999	Gleason et al.	N/A	N/A
6017315	12/1999	Starr et al.	N/A	N/A
6019101	12/1999	Cotner et al.	N/A	N/A
6021528	12/1999	Jurga	N/A	N/A
6039044	12/1999	Sullivan	N/A	N/A
6050260	12/1999	Daniell et al.	N/A	N/A
6112746	12/1999	Kwok et al.	N/A	N/A
6116235	12/1999	Walters et al.	N/A	N/A
6119693	12/1999	Kwok et al.	N/A	N/A
6119694	12/1999	Correa et al.	N/A	N/A
6127071	12/1999	Lu	N/A	N/A
6135109	12/1999	Blasdell et al.	N/A	N/A
6135432	12/1999	Hebblewhite et al.	N/A	N/A
6192886	12/2000	Rudolph	N/A	N/A
D440302	12/2000	Wolfe	N/A	N/A
6272933	12/2000	Gradon et al.	N/A	N/A
6298850	12/2000	Argaves	N/A	N/A
6302105	12/2000	Wickham et al.	N/A	N/A
6341606	12/2001	Bordewick et al.	N/A	N/A
6347631	12/2001	Hansen et al.	N/A	N/A
6354293	12/2001	Madison	N/A	N/A

D455891	12/2001	Biedrzycki	N/A	N/A
6398197	12/2001	Dickinson et al.	N/A	N/A
6412487	12/2001	Gunaratnam et al.	N/A	N/A
6412488	12/2001	Barnett	N/A	N/A
6418928	12/2001	Bordewick et al.	N/A	N/A
6418929	12/2001	Norfleet	N/A	N/A
6422238	12/2001	Lithgow	N/A	N/A
6427694	12/2001	Hecker et al.	N/A	N/A
6431172	12/2001	Bordewick	N/A	N/A
6435181	12/2001	Jones, Jr. et al.	N/A	N/A
6439234	12/2001	Curti et al.	N/A	N/A
6457473	12/2001	Brostrom et al.	N/A	N/A
6467483	12/2001	Kopacko et al.	N/A	N/A
6470886	12/2001	Jestrabek-Hart	N/A	N/A
6478026	12/2001	Wood	N/A	N/A
6484725	12/2001	Chi et al.	N/A	N/A
6488664	12/2001	Solomon et al.	N/A	N/A
6491034	12/2001	Gunaratnam et al.	N/A	N/A
6497232	12/2001	Fecteau	N/A	N/A
6513526	12/2002	Kwok et al.	N/A	N/A
6526978	12/2002	Dominguez	N/A	N/A
6530373	12/2002	Patron et al.	N/A	N/A
6561188	12/2002	Ellis	N/A	N/A
6561190	12/2002	Kwok	N/A	N/A
6561191	12/2002	Kwok	N/A	N/A
6571798	12/2002	Thornton	N/A	N/A
6581594	12/2002	Drew et al.	N/A	N/A
6581601	12/2002	Ziaee	N/A	N/A
6581602	12/2002	Kwok et al.	N/A	N/A
6584977	12/2002	Serowski	N/A	N/A
6588424	12/2002	Bardel	N/A	N/A
6615832	12/2002	Chen	N/A	N/A
6629531	12/2002	Gleason et al.	N/A	N/A
6631718	12/2002	Lovell	N/A	N/A
6634358	12/2002	Kwok et al.	N/A	N/A
6637434	12/2002	Noble	N/A	N/A
6644315	12/2002	Ziaee	N/A	N/A
6651658	12/2002	Hill et al.	N/A	N/A
6651663	12/2002	Barnett et al.	N/A	N/A
6659102	12/2002	Sico	N/A	N/A
6662803	12/2002	Gradon et al.	N/A	N/A
6668828	12/2002	Figley et al.	N/A	N/A
D485905	12/2003	Moore	N/A	N/A
6679257	12/2003	Robertson et al.	N/A	N/A
6679265	12/2003	Strickland et al.	N/A	N/A
6691707	12/2003	Gunaratnam et al.	N/A	N/A
6712072	12/2003	Lang	N/A	N/A
6736139	12/2003	Wix	N/A	N/A
6769432	12/2003	Keifer	N/A	N/A
6772760	12/2003	Frater et al.	N/A	N/A
6772761	12/2003	Rucker, Jr.	N/A	N/A
6796308	12/2003	Gunaratnam et al.	N/A	N/A

6817362	12/2003	Gelinas et al.	N/A	N/A
6823869	12/2003	Raje et al.	N/A	N/A
6851425	12/2004	Jaffre et al.	N/A	N/A
6851428	12/2004	Dennis	N/A	N/A
6883177	12/2004	Ouellette et al.	N/A	N/A
6892729	12/2004	Smith et al.	N/A	N/A
6895965	12/2004	Scarberry et al.	N/A	N/A
6907882	12/2004	Ging et al.	N/A	N/A
6918390	12/2004	Lithgow et al.	N/A	N/A
6951218	12/2004	Gradon et al.	N/A	N/A
6953354	12/2004	Edirisuriya et al.	N/A	N/A
6997187	12/2005	Wood et al.	N/A	N/A
7004165	12/2005	Salcido	N/A	N/A
7007696	12/2005	Palkon et al.	N/A	N/A
7021311	12/2005	Gunaratnam et al.	N/A	N/A
D520140	12/2005	Chaggares	N/A	N/A
7051765	12/2005	Kelley et al.	N/A	N/A
7066179	12/2005	Eaton et al.	N/A	N/A
7077126	12/2005	Kummer et al.	N/A	N/A
D526094	12/2005	Chen	N/A	N/A
7096864	12/2005	Mayer et al.	N/A	N/A
D533269	12/2005	McAuley et al.	N/A	N/A
7178525	12/2006	Matula, Jr. et al.	N/A	N/A
7178528	12/2006	Lau	N/A	N/A
7201169	12/2006	Wilkie et al.	N/A	N/A
7207333	12/2006	Tohara	N/A	N/A
7210481	12/2006	Lovell et al.	N/A	N/A
7219669	12/2006	Lovell et al.	N/A	N/A
7225811	12/2006	Ruiz et al.	N/A	N/A
7255106	12/2006	Gallem et al.	N/A	N/A
7261104	12/2006	Keifer	N/A	N/A
7287528	12/2006	Ho et al.	N/A	N/A
7290546	12/2006	Sprinkle et al.	N/A	N/A
7296575	12/2006	Radney	N/A	N/A
7318437	12/2007	Gunaratnam et al.	N/A	N/A
7353827	12/2007	Geist	N/A	N/A
7357136	12/2007	Ho et al.	N/A	N/A
7406966	12/2007	Wondka et al.	N/A	N/A
7448386	12/2007	Ho et al.	N/A	N/A
7487772	12/2008	Ging et al.	N/A	N/A
7493902	12/2008	White et al.	N/A	N/A
D589139	12/2008	Guney	N/A	N/A
7523754	12/2008	Lithgow et al.	N/A	N/A
7549420	12/2008	Martinez et al.	N/A	N/A
D595841	12/2008	McAuley et al.	N/A	N/A
7562658	12/2008	Madaus et al.	N/A	N/A
7597100	12/2008	Ging	N/A	N/A
7640934	12/2009	Zollinger et al.	N/A	N/A
7647926	12/2009	Gerder et al.	N/A	N/A
7658189	12/2009	Davidson et al.	N/A	N/A
7665464	12/2009	Kopacko et al.	N/A	N/A
D612933	12/2009	Prentice	N/A	N/A

7681575	12/2009	Wixey et al.	N/A	N/A
7694677	12/2009	Tang	N/A	N/A
7703457	12/2009	Barnett et al.	N/A	N/A
7708017	12/2009	Davidson	N/A	N/A
7753051	12/2009	Burrow et al.	N/A	N/A
D623288	12/2009	Lubke	N/A	N/A
7814911	12/2009	Bordewick et al.	N/A	N/A
7827990	12/2009	Melidis et al.	N/A	N/A
7828990	12/2009	Melidis	N/A	N/A
7856982	12/2009	Matula et al.	N/A	N/A
7861715	12/2010	Jones et al.	N/A	N/A
7877817	12/2010	Ho	N/A	N/A
7896003	12/2010	Matula et al.	N/A	N/A
7931024	12/2010	Ho et al.	N/A	N/A
7934501	12/2010	Fu	N/A	N/A
7942150	12/2010	Guney et al.	N/A	N/A
7992560	12/2010	Burton et al.	N/A	N/A
8042539	12/2010	Chandran et al.	N/A	N/A
8042541	12/2010	Amarasinghe et al.	N/A	N/A
8109271	12/2011	Vandine et al.	N/A	N/A
8136524	12/2011	Ging et al.	N/A	N/A
8136525	12/2011	Lubke et al.	N/A	N/A
8171933	12/2011	Xue et al.	N/A	N/A
D661796	12/2011	Andrews et al.	N/A	N/A
8245711	12/2011	Matula et al.	N/A	N/A
8272382	12/2011	Howard et al.	N/A	N/A
8371302	12/2012	Ging et al.	N/A	N/A
8397727	12/2012	Ng et al.	N/A	N/A
8443807	12/2012	McAuley et al.	N/A	N/A
D686313	12/2012	Matula et al.	N/A	N/A
8479726	12/2012	McAuley	N/A	N/A
8479741	12/2012	McAuley et al.	N/A	N/A
8567404	12/2012	Davidson et al.	N/A	N/A
8631793	12/2013	Omura et al.	N/A	N/A
8631799	12/2013	Davenport	N/A	N/A
8636005	12/2013	Gradon et al.	N/A	N/A
8701667	12/2013	Ho et al.	N/A	N/A
8714157	12/2013	McAuley et al.	N/A	N/A
8720444	12/2013	Chang	N/A	N/A
8757157	12/2013	Price et al.	N/A	N/A
8783257	12/2013	McAuley et al.	N/A	N/A
8869797	12/2013	Davidson et al.	N/A	N/A
8869798	12/2013	Wells et al.	N/A	N/A
8875709	12/2013	Davidson et al.	N/A	N/A
8944061	12/2014	D'Souza et al.	N/A	N/A
8950404	12/2014	Formica et al.	N/A	N/A
8960196	12/2014	Henry	N/A	N/A
8969196	12/2014	Park	N/A	N/A
9010331	12/2014	Lang et al.	N/A	N/A
9027556	12/2014	Ng et al.	N/A	N/A
9032955	12/2014	Lubke et al.	N/A	N/A
9032956	12/2014	Scheiner et al.	N/A	N/A



9072852	12/2014	McAuley et al.	N/A	N/A
9095673	12/2014	Barlow et al.	N/A	N/A
9119929	12/2014	McAuley et al.	N/A	N/A
9119931	12/2014	D'Souza et al.	N/A	N/A
9138555	12/2014	McAuley et al.	N/A	N/A
9149596	12/2014	Valcic et al.	N/A	N/A
9186474	12/2014	Rollins	N/A	N/A
9242062	12/2015	Melidis et al.	N/A	N/A
9292799	12/2015	McAuley et al.	N/A	N/A
9295799	12/2015	McAuley et al.	N/A	N/A
9302065	12/2015	Smith et al.	N/A	N/A
9320566	12/2015	Alston, Jr.	N/A	N/A
9320866	12/2015	McAuley et al.	N/A	N/A
9333315	12/2015	McAuley et al.	N/A	N/A
9339622	12/2015	McAuley et al.	N/A	N/A
9339624	12/2015	McAuley	N/A	N/A
9375545	12/2015	Darkin et al.	N/A	N/A
9381316	12/2015	Ng et al.	N/A	N/A
9439405	12/2015	Brüggemann	N/A	N/A
9457162	12/2015	Ging et al.	N/A	N/A
9486601	12/2015	Stallard et al.	N/A	N/A
9517317	12/2015	McAuley et al.	N/A	N/A
9522246	12/2015	Frater et al.	N/A	N/A
9539405	12/2016	McAuley et al.	N/A	N/A
9550038	12/2016	McAuley et al.	N/A	N/A
9561338	12/2016	McAuley	N/A	A61M 16/0633
9561339	12/2016	McAuley et al.	N/A	N/A
9744385	12/2016	Henry et al.	N/A	N/A
9884160	12/2017	McAuley et al.	N/A	N/A
9901699	12/2017	Veliss et al.	N/A	N/A
9901700	12/2017	McAuley et al.	N/A	N/A
9907925	12/2017	McAuley et al.	N/A	N/A
9974914	12/2017	McAuley	N/A	N/A
10080856	12/2017	McLaren et al.	N/A	N/A
10137271	12/2017	McAuley et al.	N/A	N/A
10201678	12/2018	Guney et al.	N/A	N/A
10252015	12/2018	McAuley et al.	N/A	N/A
10258756	12/2018	Mainusch et al.	N/A	N/A
10258757	12/2018	Allan et al.	N/A	N/A
10272218	12/2018	McAuley et al.	N/A	N/A
10328226	12/2018	Allan et al.	N/A	N/A
10363387	12/2018	Allan et al.	N/A	N/A
10384029	12/2018	McAuley et al.	N/A	N/A
10413694	12/2018	Allan et al.	N/A	N/A
10463825	12/2018	McAuley et al.	N/A	N/A
10742451	12/2019	Tajalli	N/A	N/A
10792451	12/2019	Allan et al.	N/A	N/A
10821251	12/2019	McAuley et al.	N/A	N/A
10835702	12/2019	McAuley et al.	N/A	N/A
10842964	12/2019	McAuley et al.	N/A	N/A
10980962	12/2020	McAuley et al.	N/A	N/A
11179535	12/2020	McAuley et al.	N/A	N/A

11247013	12/2021	McAuley et al.	N/A	N/A
11260194	12/2021	McAuley et al.	N/A	N/A
11291790	12/2021	McAuley et al.	N/A	N/A
11357944	12/2021	McAuley et al.	N/A	N/A
11395894	12/2021	McAuley et al.	N/A	N/A
11471635	12/2021	McAuley et al.	N/A	N/A
11541197	12/2022	McAuley et al.	N/A	N/A
11554234	12/2022	McAuley et al.	N/A	N/A
11559650	12/2022	McAuley	N/A	A61M 16/0633
11660413	12/2022	McAuley et al.	N/A	N/A
11712532	12/2022	McAuley et al.	N/A	N/A
11766535	12/2022	McAuley et al.	N/A	N/A
2001/0017134	12/2000	Bahr	N/A	N/A
2001/0020474	12/2000	Hecker et al.	N/A	N/A
2001/0029952	12/2000	Curran	N/A	N/A
2002/0005198	12/2001	Kwok et al.	N/A	N/A
2002/0014241	12/2001	Gradon et al.	N/A	N/A
2002/0020416	12/2001	Namey	N/A	N/A
2002/0026934	12/2001	Lithgow et al.	N/A	N/A
2002/0029780	12/2001	Frater et al.	N/A	N/A
2002/0039867	12/2001	Curro et al.	N/A	N/A
2002/0046755	12/2001	Voss	N/A	N/A
2002/0053347	12/2001	Ziaee	N/A	N/A
2002/0059935	12/2001	Wood	N/A	N/A
2002/0069467	12/2001	Immediato et al.	N/A	N/A
2002/0092527	12/2001	Wood	N/A	N/A
2002/0096173	12/2001	Berthon-Jones	N/A	N/A
2002/0096176	12/2001	Gunaratnam et al.	N/A	N/A
2002/0096178	12/2001	Ziaee	N/A	N/A
2002/0100474	12/2001	Kellner et al.	N/A	N/A
2002/0100479	12/2001	Scarberry et al.	N/A	N/A
2002/0108613	12/2001	Gunaratnam et al.	N/A	N/A
2002/0117177	12/2001	Kwok	N/A	N/A
2003/0000533	12/2002	Olsen et al.	N/A	N/A
2003/0005509	12/2002	Kelzer	N/A	N/A
2003/0005931	12/2002	Jaffre et al.	N/A	N/A
2003/0005933	12/2002	Izuchukwu	N/A	N/A
2003/0019495	12/2002	Palkon et al.	N/A	N/A
2003/0019496	12/2002	Kopacko et al.	N/A	N/A
2003/0029454	12/2002	Gelinas et al.	N/A	N/A
2003/0047185	12/2002	Olsen et al.	N/A	N/A
2003/0051732	12/2002	Smith et al.	N/A	N/A
2003/0075180	12/2002	Raje	N/A	N/A
2003/0075182	12/2002	Heidmann et al.	N/A	N/A
2003/0079749	12/2002	Strickland et al.	N/A	N/A
2003/0084996	12/2002	Alberg et al.	N/A	N/A
2003/0089373	12/2002	Gradon et al.	N/A	N/A
2003/0094177	12/2002	Smith et al.	N/A	N/A
2003/0121519	12/2002	Estes et al.	N/A	N/A
2003/0145857	12/2002	Sullivan et al.	N/A	N/A
2003/0149384	12/2002	Davis et al.	N/A	N/A
2003/0164170	12/2002	Drew et al.	N/A	N/A

2003/0172936	12/2002	Wilkie et al.	N/A	N/A
2003/0196655	12/2002	Ging et al.	N/A	N/A
2003/0196656	12/2002	Moore	N/A	N/A
2003/0196658	12/2002	Ging et al.	N/A	N/A
2003/0196659	12/2002	Gradon et al.	N/A	N/A
2003/0196664	12/2002	Jacobson	N/A	N/A
2003/0200970	12/2002	Stenzler et al.	N/A	N/A
2003/0217746	12/2002	Gradon et al.	N/A	N/A
2003/0221691	12/2002	Biener	N/A	N/A
2004/0011087	12/2003	Rebouillat et al.	N/A	N/A
2004/0025882	12/2003	Madaus et al.	N/A	N/A
2004/0035427	12/2003	Bordewick et al.	N/A	N/A
2004/0065328	12/2003	Amarasinghe et al.	N/A	N/A
2004/0067333	12/2003	Amarasinghe	N/A	N/A
2004/0092999	12/2003	Lojewski	N/A	N/A
2004/0094157	12/2003	Dantanarayana et al.	N/A	N/A
2004/0107968	12/2003	Griffiths	N/A	N/A
2004/0112377	12/2003	Amarasinghe et al.	N/A	N/A
2004/0112384	12/2003	Lithgow et al.	N/A	N/A
2004/0112385	12/2003	Drew	N/A	N/A
2004/0118212	12/2003	Orr et al.	N/A	N/A
2004/0118406	12/2003	Lithgow	N/A	N/A
2004/0118412	12/2003	Piletti-Reyes	N/A	N/A
2004/0133604	12/2003	Ging	N/A	N/A
2004/0139973	12/2003	Wright	N/A	N/A
2004/0149280	12/2003	Semeniuk	N/A	N/A
2004/0182398	12/2003	Sprinkle et al.	N/A	N/A
2004/0211427	12/2003	Jones et al.	N/A	N/A
2004/0221850	12/2003	Ging et al.	N/A	N/A
2004/0226566	12/2003	Gunaratnam et al.	N/A	N/A
2004/0255949	12/2003	Lang et al.	N/A	N/A
2004/0261797	12/2003	White et al.	N/A	N/A
2005/0011521	12/2004	Sprinkle et al.	N/A	N/A
2005/0011524	12/2004	Thomlinson et al.	N/A	N/A
2005/0016532	12/2004	Farrell	N/A	N/A
2005/0016544	12/2004	Thornton	N/A	N/A
2005/0028822	12/2004	Sleeper et al.	N/A	N/A
2005/0028833	12/2004	Vena et al.	N/A	N/A
2005/0033247	12/2004	Thompson	N/A	N/A
2005/0045182	12/2004	Wood et al.	N/A	N/A
2005/0051171	12/2004	Booth	N/A	N/A
2005/0051177	12/2004	Wood	N/A	N/A
2005/0066976	12/2004	Wondka	N/A	N/A
2005/0076913	12/2004	Ho et al.	N/A	N/A
2005/0092327	12/2004	Fini et al.	N/A	N/A
2005/0098183	12/2004	Nash et al.	N/A	N/A
2005/0121030	12/2004	Bateman et al.	N/A	N/A
2005/0121037	12/2004	Wood	N/A	N/A
2005/0133038	12/2004	Rutter	N/A	N/A
2005/0150497	12/2004	Eifler et al.	N/A	N/A
2005/0155604	12/2004	Ging et al.	N/A	N/A
2005/0172969	12/2004	Ging	N/A	N/A

2005/0199239	12/2004	Lang et al.	N/A	N/A
2005/0199241	12/2004	Ging et al.	N/A	N/A
2005/0199242	12/2004	Matula et al.	N/A	N/A
2005/0205096	12/2004	Matula	N/A	N/A
2005/0235999	12/2004	Wood et al.	N/A	N/A
2005/0241644	12/2004	Guney et al.	N/A	N/A
2006/0027237	12/2005	Sleeper	N/A	N/A
2006/0032504	12/2005	Burton et al.	N/A	N/A
2006/0042629	12/2005	Geist	N/A	N/A
2006/0042632	12/2005	Bishop et al.	N/A	N/A
2006/0054169	12/2005	Han et al.	N/A	N/A
2006/0060200	12/2005	Ho et al.	N/A	N/A
2006/0076019	12/2005	Ho	N/A	N/A
2006/0081250	12/2005	Bordewick et al.	N/A	N/A
2006/0081256	12/2005	Palmer	N/A	N/A
2006/0096598	12/2005	Ho et al.	N/A	N/A
2006/0102185	12/2005	Drew et al.	N/A	N/A
2006/0107958	12/2005	Sleeper	N/A	N/A
2006/0118117	12/2005	Berthon-Jones et al.	N/A	N/A
2006/0124131	12/2005	Chandran	N/A	N/A
2006/0130844	12/2005	Ho et al.	N/A	N/A
2006/0137690	12/2005	Gunaratnam et al.	N/A	N/A
2006/0169286	12/2005	Eifler et al.	N/A	N/A
2006/0174887	12/2005	Chandran et al.	N/A	N/A
2006/0178645	12/2005	Peppel	N/A	N/A
2006/0196511	12/2005	Lau et al.	N/A	N/A
2006/0201514	12/2005	Jones et al.	N/A	N/A
2006/0207599	12/2005	Busch	N/A	N/A
2006/0213516	12/2005	Hoffman	N/A	N/A
2006/0225740	12/2005	Eaton et al.	N/A	N/A
2006/0231103	12/2005	Matula et al.	N/A	N/A
2006/0237017	12/2005	Davidson et al.	N/A	N/A
2006/0237018	12/2005	McAuley et al.	N/A	N/A
2006/0249159	12/2005	Ho	N/A	N/A
2006/0254593	12/2005	Chang	N/A	N/A
2006/0266361	12/2005	Hernandez	N/A	N/A
2006/0283456	12/2005	Geiselhart et al.	N/A	N/A
2006/0283458	12/2005	Woodard	N/A	N/A
2006/0283459	12/2005	Geiselhart et al.	N/A	N/A
2006/0283461	12/2005	Lubke et al.	N/A	N/A
2007/0000492	12/2006	Hansel et al.	N/A	N/A
2007/0010786	12/2006	Casey et al.	N/A	N/A
2007/0044804	12/2006	Matula et al.	N/A	N/A
2007/0062536	12/2006	McAuley	N/A	N/A
2007/0089749	12/2006	Ho et al.	N/A	N/A
2007/0107733	12/2006	Ho	N/A	N/A
2007/0125384	12/2006	Zollinger et al.	N/A	N/A
2007/0125385	12/2006	Ho et al.	N/A	N/A
2007/0125387	12/2006	Zollinger et al.	N/A	N/A
2007/0137653	12/2006	Wood	N/A	N/A
2007/0142785	12/2006	Lundgaard et al.	N/A	N/A
2007/0157353	12/2006	Guney et al.	N/A	N/A

2007/0163594	12/2006	Ho et al.	N/A	N/A
2007/0163600	12/2006	Hoffman	N/A	N/A
2007/0174952	12/2006	Jacob	N/A	N/A
2007/0175480	12/2006	Gradon et al.	N/A	N/A
2007/0209663	12/2006	Marque et al.	N/A	N/A
2007/0215158	12/2006	Kroupa et al.	N/A	N/A
2007/0215161	12/2006	Frater et al.	N/A	N/A
2007/0221227	12/2006	Ho	N/A	N/A
2007/0227541	12/2006	Van Den	N/A	N/A
2007/0267022	12/2006	Chiam	N/A	N/A
2007/0272247	12/2006	Porat	N/A	N/A
2007/0272249	12/2006	Chandran	N/A	N/A
2007/0295335	12/2006	Nashed	N/A	N/A
2008/0035152	12/2007	Ho et al.	N/A	N/A
2008/0041388	12/2007	McAuley et al.	N/A	N/A
2008/0041393	12/2007	Bracken	N/A	N/A
2008/0047560	12/2007	Veliss et al.	N/A	N/A
2008/0053446	12/2007	Sleeper et al.	N/A	N/A
2008/0053450	12/2007	Van Kerkwyk et al.	N/A	N/A
2008/0060648	12/2007	Thornton et al.	N/A	N/A
2008/0060653	12/2007	Hallett et al.	N/A	N/A
2008/0060657	12/2007	McAuley et al.	N/A	N/A
2008/0066745	12/2007	Janbakhsh	N/A	N/A
2008/0066755	12/2007	Janbakhsh	N/A	N/A
2008/0078387	12/2007	Vandine	N/A	N/A
2008/0078396	12/2007	Janbakhsh	N/A	N/A
2008/0083412	12/2007	Henry et al.	N/A	N/A
2008/0092905	12/2007	Gunaratnam	N/A	N/A
2008/0099024	12/2007	Gunaratnam et al.	N/A	N/A
2008/0105257	12/2007	Klasek et al.	N/A	N/A
2008/0110464	12/2007	Davidson et al.	N/A	N/A
2008/0127978	12/2007	Rubin et al.	N/A	N/A
2008/0135050	12/2007	Hitchcock et al.	N/A	N/A
2008/0142019	12/2007	Lewis	N/A	N/A
2008/0149104	12/2007	Eifler	N/A	N/A
2008/0171737	12/2007	Fensome	N/A	N/A
2008/0178875	12/2007	Henry	N/A	N/A
2008/0178886	12/2007	Lieberman et al.	N/A	N/A
2008/0190432	12/2007	Blochlinger et al.	N/A	N/A
2008/0190436	12/2007	Jaffe et al.	N/A	N/A
2008/0196728	12/2007	Ho	N/A	N/A
2008/0210241	12/2007	Schulz et al.	N/A	N/A
2008/0223370	12/2007	Kim	N/A	N/A
2008/0230068	12/2007	Rudolph	N/A	N/A
2008/0236586	12/2007	McDonald et al.	N/A	N/A
2008/0245369	12/2007	Matula et al.	N/A	N/A
2008/0257354	12/2007	Davidson	N/A	N/A
2008/0264422	12/2007	Fishman	N/A	N/A
2008/0271739	12/2007	Facer et al.	N/A	N/A
2008/0276937	12/2007	Davidson et al.	N/A	N/A
2008/0302366	12/2007	McGinnis et al.	N/A	N/A
2008/0314388	12/2007	Brambilla et al.	N/A	N/A

2008/0314390	12/2007	Kwok et al.	N/A	N/A
2008/0319334	12/2007	Yamamori	N/A	N/A
2009/0014007	12/2008	Brambilla et al.	N/A	N/A
2009/0032024	12/2008	Burz et al.	N/A	N/A
2009/0044808	12/2008	Guney et al.	N/A	N/A
2009/0078267	12/2008	Burz et al.	N/A	N/A
2009/0090364	12/2008	Daugaard et al.	N/A	N/A
2009/0107504	12/2008	McAuley et al.	N/A	N/A
2009/0114227	12/2008	Gunaratnam et al.	N/A	N/A
2009/0120442	12/2008	Ho	N/A	N/A
2009/0126739	12/2008	Ng et al.	N/A	N/A
2009/0133697	12/2008	Kwok et al.	N/A	N/A
2009/0139527	12/2008	Ng et al.	N/A	N/A
2009/0145429	12/2008	Ging et al.	N/A	N/A
2009/0151729	12/2008	Judson et al.	N/A	N/A
2009/0173349	12/2008	Hernandez et al.	N/A	N/A
2009/0183734	12/2008	Kwok et al.	N/A	N/A
2009/0183739	12/2008	Wondka	N/A	N/A
2009/0188507	12/2008	Lacava	N/A	N/A
2009/0211583	12/2008	Carroll et al.	N/A	N/A
2009/0223519	12/2008	Eifler et al.	N/A	N/A
2009/0223521	12/2008	Howard	N/A	N/A
2009/0320842	12/2008	Doherty	N/A	N/A
2009/0320851	12/2008	Selvarajan et al.	N/A	N/A
2010/0000538	12/2009	Edwards et al.	N/A	N/A
2010/0000539	12/2009	Woodard	N/A	N/A
2010/0000543	12/2009	Berthon-Jones et al.	N/A	N/A
2010/0006101	12/2009	McAuley	128/206.24	A61M 16/0633
2010/0037897	12/2009	Wood	N/A	N/A
2010/0051031	12/2009	Lustenberger et al.	N/A	N/A
2010/0051034	12/2009	Howard	N/A	N/A
2010/0083969	12/2009	Crumblin	N/A	N/A
2010/0108072	12/2009	D'Souza	N/A	N/A
2010/0132717	12/2009	Davidson et al.	N/A	N/A
2010/0154798	12/2009	Henry et al.	N/A	N/A
2010/0170516	12/2009	Grane	N/A	N/A
2010/0199992	12/2009	Ho	N/A	N/A
2010/0229868	12/2009	Rummery et al.	N/A	N/A
2010/0229872	12/2009	Ho	N/A	N/A
2010/0258132	12/2009	Moore	N/A	N/A
2010/0258136	12/2009	Doherty et al.	N/A	N/A
2010/0294281	12/2009	Ho	N/A	N/A
2010/0307502	12/2009	Rummery et al.	N/A	N/A
2010/0313891	12/2009	Veliss et al.	N/A	N/A
2010/0319700	12/2009	Ng et al.	N/A	N/A
2010/0326445	12/2009	Veliss et al.	N/A	N/A
2011/0067704	12/2010	Kooij	N/A	N/A
2011/0072553	12/2010	Ho	N/A	N/A
2011/0088699	12/2010	Skipper	128/206.26	A61M 16/06
2011/0126838	12/2010	Alberici	N/A	N/A
2011/0146675	12/2010	Chen	N/A	N/A
2011/0162654	12/2010	Carroll et al.	N/A	N/A

2011/0232649	12/2010	Collazo et al.	N/A	N/A
2011/0253156	12/2010	Sweeney	N/A	N/A
2011/0259337	12/2010	Hitchcock et al.	N/A	N/A
2011/0265796	12/2010	Amarasinghe et al.	N/A	N/A
2011/0290253	12/2010	McAuley	N/A	N/A
2012/0125339	12/2011	Ho et al.	N/A	N/A
2012/0132208	12/2011	Judson et al.	N/A	N/A
2012/0132209	12/2011	Rummery	N/A	N/A
2012/0138061	12/2011	Dravitzki et al.	N/A	N/A
2012/0204879	12/2011	Cariola et al.	N/A	N/A
2012/0285457	12/2011	Mansour et al.	N/A	N/A
2012/0304999	12/2011	Swift et al.	N/A	N/A
2012/0318265	12/2011	Amirav et al.	N/A	N/A
2013/0133659	12/2012	Ng et al.	N/A	N/A
2013/0133664	12/2012	Startare	N/A	N/A
2013/0152918	12/2012	Rummery et al.	N/A	N/A
2013/0160769	12/2012	Ng et al.	N/A	N/A
2014/0026888	12/2013	Matula	N/A	N/A
2014/0083428	12/2013	Rothermel et al.	N/A	N/A
2014/0083430	12/2013	Matula, Jr. et al.	N/A	N/A
2014/0137870	12/2013	Barlow et al.	N/A	N/A
2014/0261432	12/2013	Eves et al.	N/A	N/A
2014/0290669	12/2013	Ngo	N/A	N/A
2014/0311492	12/2013	Stuebiger et al.	N/A	N/A
2014/0338672	12/2013	D'Souza et al.	N/A	N/A
2014/0373834	12/2013	Gunaratnam et al.	N/A	N/A
2015/0033457	12/2014	Tryner et al.	N/A	N/A
2015/0090266	12/2014	Melidis et al.	N/A	N/A
2015/0246198	12/2014	Bearne et al.	N/A	N/A
2015/0335846	12/2014	Romagnoli et al.	N/A	N/A
2015/0352308	12/2014	Cullen et al.	N/A	N/A
2015/0374944	12/2014	Edwards et al.	N/A	N/A
2016/0001028	12/2015	McAuley et al.	N/A	N/A
2016/0008558	12/2015	Huddart et al.	N/A	N/A
2016/0015922	12/2015	Chodkowski et al.	N/A	N/A
2016/0038707	12/2015	Allan et al.	N/A	N/A
2016/0051786	12/2015	McAuley et al.	N/A	N/A
2016/0213873	12/2015	McAuley et al.	N/A	N/A
2016/0213874	12/2015	Davidson et al.	N/A	N/A
2016/0296720	12/2015	Henry et al.	N/A	N/A
2017/0246411	12/2016	Mashal et al.	N/A	N/A
2017/0296770	12/2016	Gunaratnam et al.	N/A	N/A
2017/0368288	12/2016	Stephens et al.	N/A	N/A
2018/0221615	12/2017	Sevincli	N/A	N/A
2018/0250483	12/2017	Olsen et al.	N/A	N/A
2018/0256844	12/2017	Galgali et al.	N/A	N/A
2019/0001095	12/2018	Rose et al.	N/A	N/A
2020/0046928	12/2019	Allan et al.	N/A	N/A
2020/0171260	12/2019	McLaren	N/A	N/A
2020/0197644	12/2019	McAuley et al.	N/A	N/A
2021/0228829	12/2020	McAuley et al.	N/A	N/A
2022/0105294	12/2021	McAuley et al.	N/A	N/A

2022/0249794	12/2021	McAuley et al.	N/A	N/A
2022/0331539	12/2021	McAuley et al.	N/A	N/A
2023/0084024	12/2022	McAuley et al.	N/A	N/A
2023/0086085	12/2022	McAuley et al.	N/A	N/A
2023/0256188	12/2022	McAuley et al.	N/A	N/A
2023/0381440	12/2022	Allan et al.	N/A	N/A

#### FOREIGN PATENT DOCUMENTS

Patent No.	Application Date	Country	CPC
2009321054	12/2014	AU	N/A
1311662	12/1991	CA	N/A
2648690	12/2006	CA	N/A
000966064-0001	12/2007	CD	N/A
000966064-0002	12/2007	CD	N/A
000966064-0003	12/2007	CD	N/A
000966064-0004	12/2007	CD	N/A
000966064-0017	12/2007	CD	N/A
2172538	12/1993	CN	N/A
1780265	12/2004	CN	N/A
1750854	12/2005	CN	N/A
1784250	12/2005	CN	N/A
1901961	12/2006	CN	N/A
101991897	12/2010	CN	N/A
895692	12/1952	DE	N/A
29723101	12/1997	DE	N/A
19603949	12/1997	DE	N/A
102005041717	12/2005	DE	N/A
102006011151	12/2006	DE	N/A
0 281 275	12/1987	EP	N/A
0 350 322	12/1989	EP	N/A
0 427 474	12/1990	EP	N/A
0 462 701	12/1990	EP	N/A
0 747 078	12/1995	EP	N/A
1 099 452	12/2000	EP	N/A
0 830 180	12/2001	EP	N/A
1 258 266	12/2001	EP	N/A
1 306 098	12/2002	EP	N/A
1 488 820	12/2003	EP	N/A
1 582 231	12/2004	EP	N/A
2 042 209	12/2008	EP	N/A
2 130 563	12/2008	EP	N/A
2 145 645	12/2009	EP	N/A
1 753 495	12/2009	EP	N/A
1 481 702	12/2011	EP	N/A
2 749 176	12/2013	EP	N/A
1 646 910	12/2014	EP	N/A
2 022 528	12/2015	EP	N/A
1 841 482	12/2015	EP	N/A
2 451 518	12/2016	EP	N/A
2658725	12/1990	FR	N/A
2749176	12/1996	FR	N/A
2823122	12/2001	FR	N/A



190224431	12/1901	GB	N/A
880824	12/1960	GB	N/A
979357	12/1964	GB	N/A
1467828	12/1976	GB	N/A
2133275	12/1983	GB	N/A
2173274	12/1985	GB	N/A
2186801	12/1986	GB	N/A
2385533	12/2002	GB	N/A
2408459	12/2004	GB	N/A
2406797	12/2004	GB	N/A
62-024721	12/1986	JP	N/A
H09-010311	12/1996	JP	N/A
2000-325481	12/1999	JP	N/A
2004-016488	12/2003	JP	N/A
2005-529687	12/2004	JP	N/A
2005-537906	12/2004	JP	N/A
2007-516750	12/2006	JP	N/A
531332	12/2003	NZ	N/A
534606	12/2003	NZ	N/A
528029	12/2004	NZ	N/A
548575	12/2005	NZ	N/A
551103	12/2005	NZ	N/A
567740	12/2008	NZ	N/A
WO 82/003548	12/1981	WO	N/A
WO 97/00092	12/1996	WO	N/A
WO 97/32494	12/1996	WO	N/A
WO 97/45154	12/1996	WO	N/A
WO 98/04310	12/1997	WO	N/A
WO 98/04311	12/1997	WO	N/A
WO 98/018514	12/1997	WO	N/A
WO 98/024499	12/1997	WO	N/A
WO 98/048878	12/1997	WO	N/A
WO 98/57691	12/1997	WO	N/A
WO 99/04842	12/1998	WO	N/A
WO 99/43375	12/1998	WO	N/A
WO 99/058181	12/1998	WO	N/A
WO 99/058198	12/1998	WO	N/A
WO 00/050122	12/1999	WO	N/A
WO 00/057942	12/1999	WO	N/A
WO 00/069497	12/1999	WO	N/A
WO 00/74509	12/1999	WO	N/A
WO 00/074758	12/1999	WO	N/A
WO 00/078384	12/1999	WO	N/A
WO 01/00266	12/2000	WO	N/A
WO 01/32250	12/2000	WO	N/A
WO 01/041854	12/2000	WO	N/A
WO 01/058293	12/2000	WO	N/A
WO 01/062326	12/2000	WO	N/A
WO 01/89381	12/2000	WO	N/A
WO 01/94721	12/2000	WO	N/A
WO 01/097892	12/2000	WO	N/A
WO 01/97892	12/2000	WO	N/A

WO 01/097893	12/2000	WO	N/A
WO 02/005883	12/2001	WO	N/A
WO 02/011804	12/2001	WO	N/A
WO 02/047749	12/2001	WO	N/A
WO 02/074372	12/2001	WO	N/A
WO 03/035156	12/2002	WO	N/A
WO 03/076020	12/2002	WO	N/A
WO 03/082406	12/2002	WO	N/A
WO 03/092755	12/2002	WO	N/A
WO 04/007010	12/2003	WO	N/A
WO 04/096332	12/2003	WO	N/A
WO 04/012803	12/2003	WO	N/A
WO 04/022146	12/2003	WO	N/A
WO 04/022147	12/2003	WO	N/A
WO 04/030510	12/2003	WO	N/A
WO 04/030736	12/2003	WO	N/A
WO 04/041341	12/2003	WO	N/A
WO 04/041342	12/2003	WO	N/A
WO 04/052438	12/2003	WO	N/A
WO 04/071565	12/2003	WO	N/A
WO 04/073777	12/2003	WO	N/A
WO 04/073778	12/2003	WO	N/A
WO 04/079066	12/2003	WO	N/A
WO 05/010608	12/2004	WO	N/A
WO 05/016403	12/2004	WO	N/A
WO 05/018523	12/2004	WO	N/A
WO 05/021075	12/2004	WO	N/A
WO 05/051468	12/2004	WO	N/A
WO 05/063326	12/2004	WO	N/A
WO 05/063328	12/2004	WO	N/A
WO 05/076874	12/2004	WO	N/A
WO 05/079726	12/2004	WO	N/A
WO 05/086943	12/2004	WO	N/A
WO 05/086946	12/2004	WO	N/A
WO 05/097247	12/2004	WO	N/A
WO 05/123166	12/2004	WO	N/A
WO 06/000046	12/2005	WO	N/A
WO 06/050559	12/2005	WO	N/A
WO 06/069415	12/2005	WO	N/A
WO 06/074513	12/2005	WO	N/A
WO 06/074514	12/2005	WO	N/A
WO 06/074515	12/2005	WO	N/A
WO 06/096924	12/2005	WO	N/A
WO 06/130903	12/2005	WO	N/A
WO 06/138346	12/2005	WO	N/A
WO 06/138416	12/2005	WO	N/A
WO 07/006089	12/2006	WO	N/A
WO 07/009182	12/2006	WO	N/A
WO 07/021777	12/2006	WO	N/A
WO 07/022562	12/2006	WO	N/A
WO 07/041751	12/2006	WO	N/A
WO 07/041786	12/2006	WO	N/A

WO 07/045008	12/2006	WO	N/A
WO 07/048174	12/2006	WO	N/A
WO 07/053878	12/2006	WO	N/A
WO 07/114492	12/2006	WO	N/A
WO 07/147088	12/2006	WO	N/A
WO 08/007985	12/2007	WO	N/A
WO 08/011682	12/2007	WO	N/A
WO 08/014543	12/2007	WO	N/A
WO 08/030831	12/2007	WO	N/A
WO 08/036625	12/2007	WO	N/A
WO 08/043134	12/2007	WO	N/A
WO 08/060295	12/2007	WO	N/A
WO 08/068966	12/2007	WO	N/A
WO 08/070929	12/2007	WO	N/A
WO 08/106716	12/2007	WO	N/A
WO 08/148086	12/2007	WO	N/A
WO 09/026627	12/2008	WO	N/A
WO 09/022248	12/2008	WO	N/A
WO 09/052560	12/2008	WO	N/A
WO 09/059353	12/2008	WO	N/A
WO 09/092057	12/2008	WO	N/A
WO 09/109005	12/2008	WO	N/A
WO 09/133561	12/2008	WO	N/A
WO 09/139647	12/2008	WO	N/A
WO 10/066004	12/2009	WO	N/A
WO 10/073142	12/2009	WO	N/A
WO 10/131189	12/2009	WO	N/A
WO 10/135785	12/2009	WO	N/A
WO 10/148453	12/2009	WO	N/A
WO 11/014931	12/2010	WO	N/A
WO 11/059346	12/2010	WO	N/A
WO 11/060479	12/2010	WO	N/A
WO 11/077254	12/2010	WO	N/A
WO 12/040791	12/2011	WO	N/A
WO 12/045127	12/2011	WO	N/A
WO 12/052902	12/2011	WO	N/A
WO 12/143822	12/2011	WO	N/A
WO 14/015382	12/2013	WO	N/A
WO 14/020469	12/2013	WO	N/A
WO 14/109749	12/2013	WO	N/A
WO 14/175752	12/2013	WO	N/A
WO 14/175753	12/2013	WO	N/A
WO 15/033287	12/2014	WO	N/A
WO 16/000040	12/2015	WO	N/A
WO 17/049356	12/2016	WO	N/A
WO 17/049357	12/2016	WO	N/A
WO 18/007966	12/2017	WO	N/A
WO 18/064712	12/2017	WO	N/A

## OTHER PUBLICATIONS

Opponent's outline of submissions in the matter of Australian patent applications Nos. 20223628, 2021201838, 2021201840, 2021201841, 2021201842 and 2021201843, dated Mar. 13, 2024, 51 pp. cited by

applicant

Applicant's Outline of Submissions in the matter of Australian Patent Application Nos. 2020223628, 2021201838, 2021201840, 2021201841, 2021201842, 2021201843 dated Mar. 20, 2024, 72 pp. cited by applicant

Australian Examination Report for Patent Application No. 2012265597 dated Dec. 19, 2013, in 5 pages. cited by applicant

Australian Examination Report in patent application No. 2010241390, dated Jan. 9, 2015, 4 pages. cited by applicant

Australian Examination Report in patent application No. 2015201920, dated Jul. 20, 2015, 3 pages. cited by applicant

Australian examination report in patent application No. 2016202801, dated Jun. 20, 2016, 2 pages. cited by applicant

Australian Examination Report in patent application No. 2010241390, dated Sep. 28, 2016, 4 pages. cited by applicant

Australian Examination Report in patent application No. 2010246985, dated Mar. 4, 2014, 5 pages. cited by applicant

Australian Examination Report in patent application No. 2015202814, dated Aug. 14, 2015, 8 pages. cited by applicant

Australian Examination Report in patent application No. 2016202799, dated May 31, 2016, 2 pages. cited by applicant

Australian Examination Report No. 1, in patent application No. AU 2013300237, dated Jun. 8, 2017, in 4 pages. cited by applicant

Australian Examination Report No. 2 for patent application No. 2018217307, dated Mar. 3, 2020, 4 pp. cited by applicant

Australian Examination Report; Application No. 2007273324; dated May 22, 2012; 4 pages. cited by applicant

Brazilian office action dated Jul. 11, 2019 in patent application No. BR11201211420-4. cited by applicant

Canadian Examination Report for Application No. 2655839 dated Oct. 4, 2013, in 2 pages. cited by applicant

Canadian Examination Report for patent application No. 2880749, dated Feb. 28, 2020, 4 pp. cited by applicant

Canadian Examination Report in patent application No. 2998247, dated Jan. 8, 2019, 4 pages. cited by applicant

Canadian Examination Report in patent application No. 2780310, dated Jul. 26, 2016, 4 pages. cited by applicant

Canadian Examination Report in patent application No. 2918167, dated Oct. 3, 2016, 4 pages. cited by applicant

Canadian Examination Report in patent application No. 2780310, dated Jan. 25, 2018 4 pages. cited by applicant

Canadian Examination Report in patent application No. 2780310, dated Oct. 9, 2018, 3 pp. cited by applicant

Canadian Examination Report in patent application No. 2880749, dated May 16, 2019, 5 pages. cited by applicant

Canadian Examination Report in patent application No. 2890556, dated Nov. 28, 2016, 4 pages. cited by applicant

Canadian Examination Report in patent application No. 3010066, dated Dec. 19, 2019, 4 pages. cited by applicant

Canadian Examination Report in patent application No. 3010066, dated May 3, 2019, 4 pages. cited by applicant

Canadian Examination Report in patent application No. 3017161, dated Apr. 22, 2020. 4 pp. cited by applicant

Canadian Examination Report in patent application No. 3017161, dated Aug. 21, 2019, 3 pp. cited by applicant

Chinese Examination Report in patent application No. 201080028029.0, dated Mar. 27, 2014, 16 pages. cited

by applicant  
Chinese Examination Report in patent application No. 2007800266164, dated Feb. 17, 2011, 18 pages. cited by applicant  
Chinese Examination Report in patent application No. 201080061122.1, dated Jul. 17, 2015, 10 pages. cited by applicant  
Chinese examination report in patent application No. 201210080441.8, dated Dec. 1, 2014, 1 pp. (English translation). cited by applicant  
Chinese examination report in patent application No. 201210080441.8, dated Mar. 4, 2014, 11 pp. (English translation). cited by applicant  
Chinese Examination Report in patent application No. 201610114706.X, dated Jul. 30, 2018, 9 pp., with translation. cited by applicant  
Chinese Examination Report; dated Sep. 14, 2015; Application No. 201080028029.0; 3 pages. cited by applicant  
Chinese Examination Report; dated Sep. 3, 2014; Application No. 201080061122.1; 7 pages. cited by applicant  
Chinese First Office Action in patent application No. 201710824612.6, dated Sep. 30, 2019, 25 pp. cited by applicant  
Chinese Fourth Office Action in patent application No. 201610116121.1, dated Sep. 30, 2019, 12 pages. cited by applicant  
Chinese Office Action in patent application No. 201610116121.1, dated Sep. 28, 2017, 5 pages. cited by applicant  
Chinese Second Examination Report in patent application No. 201610114706.X, dated Apr. 24, 2019 8 pp., with translation. cited by applicant  
Chinese Second Office Action in patent application No. 201710824612.6, dated May 25, 2020. 19 pages. cited by applicant  
Chinese Second Office Action; dated Jan. 19, 2015; Application No. 201080028029.0; 30 pages. cited by applicant  
Chinese Third Examination Report in patent application No. 201610114706.X, dated Jan. 16, 2020, with translation. 32 pages. cited by applicant  
Chinese Third Office Action in patent application No. 201810116121.1, dated Apr. 28, 2019, 16 pages. cited by applicant  
Decision Denying Institute of Inter Partes Review dated Jul. 16, 2019 in IRP2019-00179, 32 pp. cited by applicant  
Decision to Institute dated Jul. 16, 2019 in IPR2019-00180, 34 pp. cited by applicant  
English Translation of JP Examination Report; dated Feb. 10, 2014; Application No. 2012-510418; 8 pages. cited by applicant  
European examination report dated Jun. 16, 2020 in patent application No. 18163847.9, 5 pp. cited by applicant  
European Examination Report dated Mar. 16, 2020 in patent application No. 18195537.8. 7 pages. cited by applicant  
European examination report dated Sep. 5, 2019 in patent application No. 18163847.9, 5 pp. cited by applicant  
European Examination Report in patent application No. 09746823.5, dated Apr. 3, 2017, 2 pages. cited by applicant  
European Examination Report in patent application No. 07808683.2, dated May 9, 2018, 5 pages. cited by applicant  
European Examination Report, European Application 13828380.9, dated Apr. 7, 2017, 8 pp. cited by applicant  
U.S. Appl. No. 60/493,515, filed Aug. 8, 2002, Sleeper et al. cited by applicant  
U.S. Appl. No. 60/496,059, filed Aug. 18, 2003, Ho et al. cited by applicant  
U.S. Appl. No. 60/529,696, filed Dec. 16, 2003, Lithgow et al. cited by applicant  
U.S. Appl. No. 61/064,406, filed Mar. 4, 2008, Wehbeh. cited by applicant

U.S. Appl. No. 61/071,893, filed May 22, 2008, Wehbeh et al. cited by applicant

U.S. Appl. No. 61/136,617, filed Sep. 19, 2008, Wehbeh et al. cited by applicant

Resmed Mirage Swift™ II Nasal Pillows System product page ([http://www.resmed.com/en-us/products/masks/mirage\\_swift\\_II\\_nasal\\_pillows\\_system/Mirage-Swift-II-Nasal-Pillows-System.html?menu=products](http://www.resmed.com/en-us/products/masks/mirage_swift_II_nasal_pillows_system/Mirage-Swift-II-Nasal-Pillows-System.html?menu=products)); archived Jul. 21, 2008, 2 pp. cited by applicant

Resmed Mirage Swift™ II user brochure (<http://www.resmed.com/en-us/products/masks/mirage-swift-II-np-brochure-patient-english-usa.pdf>) copyright 2007, 4 pp. cited by applicant

ResMed Mirage Swift II Fitting guide ([http://www.resmed.com/en-us/products/masks/mirage\\_swift\\_II\\_nasal\\_pillows\\_system/documents/mirage-swift\\_ii\\_np-fitting\\_English.pdf](http://www.resmed.com/en-us/products/masks/mirage_swift_II_nasal_pillows_system/documents/mirage-swift_ii_np-fitting_English.pdf)) copyright 2006, 2 pp. cited by applicant

ResMed Mirage Swift II comparison to older Swift patient interface ([http://www.resmed.com/en-us/products/masks/mirage\\_swift\\_II\\_nasal\\_pillows\\_system/documents/mirage-swift-ii-np-comparison-guide.pdf](http://www.resmed.com/en-us/products/masks/mirage_swift_II_nasal_pillows_system/documents/mirage-swift-ii-np-comparison-guide.pdf), 2007, 6 pp. cited by applicant

ResMed Mirage Swift II user guide ([http://www.resmed.com/en-us/products/service\\_and\\_support/documents/60893rl\\_mirage\\_swiftII\\_nasal\\_userglide\\_us\\_multi.pdf](http://www.resmed.com/en-us/products/service_and_support/documents/60893rl_mirage_swiftII_nasal_userglide_us_multi.pdf)) copyright 2006, 1 p. cited by applicant

ResMed Mirage Swift II component card ([http://www.resmed.com/en-us/products/masks/mirage\\_swift\\_II\\_nasal\\_pillows\\_system/documents/mirage-swift-ii-np-cc-USA.pdf](http://www.resmed.com/en-us/products/masks/mirage_swift_II_nasal_pillows_system/documents/mirage-swift-ii-np-cc-USA.pdf)); copyright 2006, 2 pp. cited by applicant

Resmed Swift™ LT Nasal Pillows System, product page, ([http://www.resmed.com/en-us/products/masks/mirage\\_swift\\_II\\_nasal\\_pillows\\_system/Mirage-Swift-II-Nasal\\_Pillows-System.html?menu=products](http://www.resmed.com/en-us/products/masks/mirage_swift_II_nasal_pillows_system/Mirage-Swift-II-Nasal_Pillows-System.html?menu=products)), Jul. 3, 2008, 2 pp. cited by applicant

Resmed Swift LT user brochure, ([http://www.resmed.com/en-us/products/masks/mirage\\_swift\\_II\\_nasal\\_pillows\\_system/documents/mirage-swift-ii-np-brochure-patient-english-usa.pdf](http://www.resmed.com/en-us/products/masks/mirage_swift_II_nasal_pillows_system/documents/mirage-swift-ii-np-brochure-patient-english-usa.pdf)), copyright 2008, 4 pp. cited by applicant

Resmed Swift™ LT component card ([http://www.resmed.com/en-us/assets/documents/product/swift\\_It/components\\_card/1012463\\_swift-It\\_components-card\\_usa\\_eng.pdf](http://www.resmed.com/en-us/assets/documents/product/swift_It/components_card/1012463_swift-It_components-card_usa_eng.pdf)) copyright 2008, 46 pp. cited by applicant

Resmed Swift™ LT fitting guide, ([http://www.resmed.com/en-us/assets/documents/product/swift-II/clinical\\_fact\\_sheet/1012406\\_swift-ii\\_fact-sheet\\_usa\\_eng.pdf](http://www.resmed.com/en-us/assets/documents/product/swift-II/clinical_fact_sheet/1012406_swift-ii_fact-sheet_usa_eng.pdf)), 2008, 2 pp. cited by applicant

Resmed Swift™ LT fact sheet ([http://www.resmed.com/en-us/assets/documents/product/swift-It/clinical\\_fact\\_sheet/1012406\\_swiftIt\\_fact-sheet\\_usa\\_eng.pdf](http://www.resmed.com/en-us/assets/documents/product/swift-It/clinical_fact_sheet/1012406_swiftIt_fact-sheet_usa_eng.pdf), copyright 2008, 4 pp. cited by applicant

Resmed Swift™ LT image gallery ([http://www.resmed.com/en-us/products/masks/swift\\_It\\_nasal\\_pillows\\_system/imagegallery.html?menu=products](http://www.resmed.com/en-us/products/masks/swift_It_nasal_pillows_system/imagegallery.html?menu=products), Apr. 25, 2008, 2 pp. cited by applicant

Resmed Swift™ LT interactive fitting guide—screenshot from troubleshooting part (<http://www.resmed.com/en-us/assets/multimedia/product/swift-It/flash/swift-It-fitting-eng.swf>), Jul. 3, 2008, 2 pp. cited by applicant

Puritan Bennett Breeze® SleepGear® CPAP Interface, product page (<http://puritanbennett.com/prod/product.aspx?id=233>); archived Oct. 19, 2007, 2 pp. cited by applicant

Bennett Breeze® SleepGear® User's Guide ([http://puritanbennett.com/\\_catalog/pdf/dfu/107598a00\[I\].pdf](http://puritanbennett.com/_catalog/pdf/dfu/107598a00[I].pdf)); copyright 2007, 18 pp. cited by applicant

Bennett Breeze® SleepGear® sales sheet ([http://www.puritanbennett.com/\\_Catalog/PDF/Product/BreezeSleepGear.pdf](http://www.puritanbennett.com/_Catalog/PDF/Product/BreezeSleepGear.pdf)) copyright 2016, 7 PP. cited by applicant

Bennett mask coding matrix ([http://www.puritanbennett.com/\\_Catalog/PDF/Product/BreezeSlpGear\(ST03700\).pdf](http://www.puritanbennett.com/_Catalog/PDF/Product/BreezeSlpGear(ST03700).pdf)) copyright 2006, 3 pp. cited by applicant

Puritan Bennett Breeze fitting guide ([http://www.puritanbennett.com/\\_Catalog/PDF/Product/BreezeFittingPoster.pdf](http://www.puritanbennett.com/_Catalog/PDF/Product/BreezeFittingPoster.pdf), Oct. 19, 2007, 1 p. cited by applicant

Respironics Optilife Pillows mask product page (<http://optilife.respironics.com:80/>); archived Nov. 21, 2007, 2 pp. cited by applicant

Respironics Optilife Pillows mask part numbers page (<http://optilife.respironics.com:80/Parts.aspx>); archived Nov. 23, 2007, 4 pp. cited by applicant

Respironics Optilife Pillows mask FAQ (<http://optilife.respironics.com:80/fags.aspx>); archived Nov. 23, 2007, 6 pp. cited by applicant

Respironics Optilife Pillows mask feature page (<http://optilife.respironics.com:80/features.aspx>); archived Nov. 23, 2007, 4 pp. cited by applicant

Respironics Optilife Pillows mask fitting guide screen shot (<http://optilife.respironics.com:80/fittingGuide.aspx>); archived Aug. 7, 2008, 1 p. cited by applicant

Respironics Optilife Pillows mask adjustment video screenshots, <https://www.youtube.com/watch?v=shjcNmvvcbA>; uploaded Aug. 3, 2008, 2 pp. cited by applicant

Puritan Bennett Breeze description; copyright 2000 by Mallinckrodt Inc., 4 pp. cited by applicant

Fisher & Paykel Opus product page, archived Sep. 3, 2009, 2 pp. cited by applicant

Fisher & Paykel Opus patient interface product photographs, Jul. 2007, 6 pp. cited by applicant

Photographs of Opus 360 nasal pillows mask patient instructions RevB, Jul. 2007, 4 pp. cited by applicant

Respironics Optilife brochure detailing updates; copyright 2008; dated Mar. 26, 2008, 3 pp. cited by applicant

Fisher & Paykel Opus product page, archived Sep. 7, 2009, 2 pp. cited by applicant

Fisher & Paykel Opus “Off-the-lips” pillows explanation page, archived Aug. 23, 2009, 2 pp. cited by applicant

Fisher & Paykel Opus “Off-the-lips” patient interface brochure, archived Oct. 14, 2009, 6 pp. cited by applicant

Fisher & Paykel Opus user-guide, archived Nov. 17, 2009, 2 pp. cited by applicant

Fisher & Paykel HC200 Series Nasal CPAP Blower & Heated Humidifier User Manual, 17 pp., May 1998. cited by applicant

Fisher & Paykel Healthcare, FlexiFit® 431 Full Face Mask instructions, 2010, 4 pp. cited by applicant

Fisher & Paykel Healthcare, FlexiFit™ 431 Full Face Mask, specification sheet, 2004, 2 pp. cited by applicant

Fisher & Paykel Healthcare, Interface Solutions Product Profile, 2006, 12 pp. cited by applicant

Fisher & Paykel MR810 Manual, Rev. C, 2004, 43 pp. cited by applicant

HomeDepot.com—Ring Nut Sales Page (Retrieved Oct. 16, 2015 from <http://www.homedepot.com/p/Everbilt-1-2-in-Galvanized-HexNut-804076/20464-7893>), 4 pp. cited by applicant

Malloy, 1994, Plastic Part Design for Injection Molding, Hanser Gardner Publications, Inc, Cincinnati, OH, 14 pp. cited by applicant

Merriam-Webster's Collegiate Dictionary, Eleventh Edition, 2004, pp. 703, 905, 1074, 1184. cited by applicant

Philips Respironics ‘System One Heated Humidifier—User Manual’, 2011, pp. 1-16, [retrieved on Nov. 25, 2013] from the internet: URL: <http://www.cpapxchange.com/cpap-machines-biap-machines/system-one-60-seri-es-cpap-humidifier-manual.pdf> front cover, pp. 3-4 and 6. cited by applicant

ResMed FlexiFit brochure. cited by applicant

ResMed Exhibit, FlexiFit™ 431, product brochure, web pages (Wayback Machine), 2006, 23 pp. cited by applicant

ResMed Origins Brochure (Retrieved Apr. 17, 2016 from <http://www.resmed.com/us/dam/documents/articles/resmedorigins.pdf>), 64 pp. cited by applicant

ResMed Ultra Mirage™ Full Face Mask, product brochure, 2004, 2 pp. cited by applicant

ResMed Ultra Mirage™ Full Face Mask, product brochure, web pages (Wayback Machine), 2006, 9 pp. cited by applicant

ResMed, Jun. 29, 1997, Mask Frames (Source: Wayback Machine Internet Archive); <http://web.archive.org/web/19970629053430/http://www.resmed.com-/maskframes/mask.htm>, 2 pp/. cited by applicant

ResMed, Mirage Swift™ Nasal Pillows System from ResMed, product brochure, 2004, 6 pp. cited by applicant

ResMed, Mirage Swift™ Nasal Pillows System: User's Guide, product brochure, 2004, 11 pp. cited by applicant

ResMed, Mirage Vista™ Nasal Mask: Components Card, product brochure, 2005, 1 p. cited by applicant

The American Heritage Dictionary of the English Language, Fourth Edition, 2006, pp. 1501, 1502, 1650. cited by applicant

WeddingBands.com—Men's Wedding Ring Shopping Page (Retrieved Oct. 16, 2015 from <http://www.weddingbands.com/ProductPop.sub.--wedding.sub.--band-s.sub.--metal/48214W.html>), 3 pp. cited by applicant

ResMed, Oct. 1999, Mirage® Full Face Mask Update, Product Bulletin No. 161, 3 pp. cited by applicant

ResMed, Dec. 6, 1998, Mirage Full Face Cushion—Medium, drawing, 1 p. cited by applicant

ResMed, Jun. 20, 2000, Brochure, Mirage Full Face Mask, 5 pp. cited by applicant

ResMed, Oct. 4, 2000, Mirage® Full Face Mask, User's Guide, 3 pp. cited by applicant

U.S. Appl. No. 61/064,406, 34 pages, provided by USPTO on Feb. 23, 2009. cited by applicant

U.S. Appl. No. 61/071,893, 43 pages, provided by USPTO on Feb. 23, 2009. cited by applicant

U.S. Appl. No. 61/136,617, 82 pages, provided by USPTO on Feb. 23, 2009. cited by applicant

Petition for Inter Partes Review of U.S. Pat. No. 8,479,741 Pursuant to 35 U.S.C. §§ 311-19, 37 C.F.R. § 42, IPR2016-01714, dated Sep. 7, 2016. cited by applicant

Patent Owner Preliminary Response to Petition for Inter Partes Review of U.S. Pat. No. 8,479,741, IPR2016-01714, filed Dec. 14, 2016. cited by applicant

Decision Denying Institution of Inter Partes Review of U.S. Pat. No. 8,479,741 Pursuant to 37 C.F.R. § 42.108, IPR2016-01714, entered Mar. 10, 2017. cited by applicant

Declaration of Dr. John Izuchukwu, Ph.D., P.E., U.S. Pat. No. 8,443,807, IPR Nos. 2016-1726 & 2016-1734, dated Sep. 7, 2016. cited by applicant

Declaration of Dr. John Izuchukwu, Ph.D., P.E., U.S. Pat. No. 8,479,741, IPR Nos. 2016-1714 & 2016-1718, dated Sep. 7, 2016. cited by applicant

Patent Owner Preliminary Response to Petition for Inter Partes Review of U.S. Pat. No. 8,479,741, IPR2016-01718, filed Dec. 16, 2016. cited by applicant

Decision Denying Institution of Inter Partes Review of U.S. Pat. No. 8,479,741 Pursuant to 37 C.F.R. § 42.108, IPR2016-01718, entered Mar. 13, 2017. cited by applicant

Petition for Inter Partes Review of U.S. Pat. No. 8,479,741 Pursuant to 35 U.S.C. §§ 311-19, 37 C.F.R. § 42, IPR2016-01718, dated Sep. 7, 2016. cited by applicant

Petition for Inter Partes Review of U.S. Pat. No. 8,443,807 Pursuant to 35 U.S.C. §§ 311-19, 37 C.F.R. § 42, IPR2016-01726, dated Sep. 7, 2016. cited by applicant

Patent Owner Preliminary Response to Petition for Inter Partes Review of U.S. Pat. No. 8,443,807, IPR2016-01726, filed Dec. 13, 2016. cited by applicant

Decision Denying Institution of Inter Partes Review of U.S. Pat. No. 8,443,807 Pursuant to 37 C.F.R. § 42.108, IPR2016-01726, entered Mar. 6, 2017. cited by applicant

Petition for Inter Partes Review of U.S. Pat. No. 8,443,807 Pursuant to 35 U.S.C. §§ 311-19, 37 C.F.R. § 42, IPR2016-01734, dated Sep. 7, 2016. cited by applicant

Patent Owner Preliminary Response to Petition for Inter Partes Review of U.S. Pat. No. 8,443,807, IPR2016-01734, filed Dec. 22, 2016. cited by applicant

Decision Denying Institution of Inter Partes Review of U.S. Pat. No. 8,443,807 Pursuant to 37 C.F.R. § 42.108, IPR2016-01734, entered Mar. 13, 2017. cited by applicant

File History of U.S. Pat. No. 8,479,741 to McAuley et al, published Oct. 1, 2009. cited by applicant

File History of U.S. Pat. No. 8,443,807 to McAuley et al, published Jan. 7, 2010. cited by applicant

Patent Owner's Complaint for *Fisher & Paykel Healthcare Ltd. v. ResMed Corp.*, Case No. 2:16-cv-06099-R-AJW (C.D. Cal.), dated Aug. 15, 2016. cited by applicant

Patent Owner's Notice of Voluntary Dismissal Without Prejudice for *Fisher & Paykel Healthcare Ltd. v. ResMed Corp.*, Case No. 2:16-cv-06099-R-AJW (C.D. Cal.), dated Aug. 16, 2016. cited by applicant

Patent Owner's Complaint for *Fisher & Paykel Healthcare Ltd. v. ResMed Corp.*, Case No. 3:16-cv-02068-



GPC-WVG (S.D. Cal.), dated Aug. 16, 2016. cited by applicant

Petitioners' Complaint for *ResMed Inc., et al. v. Fisher & Paykel Healthcare Corp. Ltd., et al.*, Case No. 3:16-cv-02072-JAH-MDD (S.D. Cal.), dated Aug. 16, 2016. cited by applicant

Petitioners' Notice of Voluntary Dismissal Without Prejudice for *ResMed Inc., et al. v. Fisher & Paykel Healthcare Corp. Ltd., et al.*, Case No. 3:16-cv-02072-JAH-MDD (S.D. Cal.) , dated Aug. 18, 2016. cited by applicant

Statutory Declaration made by Alistair Edwin McAuley, Apr. 9, 2015, in the matter of an Opposition by Fisher & Paykel Healthcare Limited of Australian patent application 2009221630 in the name of ResMed Limited. cited by applicant

Statutory Declaration made by Alistair Edwin McAuley, Apr. 14, 2015, in the matter of an Opposition by Fisher & Paykel Healthcare Limited of Australian patent application 2009221630 in the name of ResMed Limited. cited by applicant

Statutory Declaration made by Alistair Edwin McAuley, Apr. 17, 2015, in the matter of an Opposition by Fisher & Paykel Healthcare Limited of Australian patent application 2009221630 in the name of ResMed Limited. cited by applicant

Statutory Declaration made by Alistair Edwin McAuley, Sep. 16, 2015, in the matter of an Opposition by Fisher & Paykel Healthcare Limited of Australian patent application 2009221630 in the name of ResMed Limited. cited by applicant

First Affidavit of Alistair Edwin McAuley, Dec. 5, 2016, in the matter of *Fisher and Paykel Healthcare Limited v. ResMed Limited* filed in the Federal Court of Australia. cited by applicant

Second Affidavit of Alistair Edwin McAuley, Dec. 21, 2016, in the matter of *Fisher and Paykel Healthcare Limited v. ResMed Limited* filed in the Federal Court of Australia. cited by applicant

Third Affidavit of Alistair Edwin McAuley, Jan. 31, 2017, in the matter of *Fisher and Paykel Healthcare Limited v. ResMed Limited* filed in the Federal Court of Australia, 284 pp. cited by applicant

Declaration of Anthony Michael Ging in IPR 2019-000172, IPR 2019-000173, IPR 2019-000177, IPR 2019-000178, dated Nov. 8, 2018, 329 pp. cited by applicant

McGraw-Hill Dictionary of Scientific and Technical Terms, Sixth Edition, 2003, Tube, p. 2200. cited by applicant

Claim Chart for AirFit P10, U.S. Pat. No. 9,333,315, dated Nov. 7, 2018, 3 pp. cited by applicant

Affidavit of Martina Elise Muellers regarding the purchase of a sample of the “Respironics ComfortClassic nasal mask”. cited by applicant

An extract of parallel infringement proceedings on the basis of the opposed patent that a reinforcing member necessarily limits the lateral expansion of the cushion, dated Sep. 16, 2016, 3 pp. cited by applicant

Cleaning Instruction for the “Respironics ComfortClassic nasal mask” dated 2002, 4 pp. cited by applicant

A submission of Jan. 2, 2018 in parallel proceedings in New Zealand. cited by applicant

Declaration of Greg Olsen regarding the “Respironics ComfortClassic nasal mask”. cited by applicant

Excerpt from a notice of Sep. 6, 2017 in parallel proceedings pending in Germany. cited by applicant

Excerpt from a notice of Sep. 8, 2018 in parallel proceedings pending in Australia, 3 pp. cited by applicant

Excerpt from a submission of Jan. 31, 2017 in parallel proceedings pending in New Zealand, 2 pp. cited by applicant

Expert opinion of Mr. Herbert T. Bauer, dated Sep. 4, 2017, 18 pp. cited by applicant

Extract of patentee's submission of Oct. 24, 2016 made in preliminary injunction proceedings based on the opposed patent. cited by applicant

FDA Home Medical Devised Databases, 510(k) Premarket Notification, 3 pp., Decision Date Jan. 31, 1996. cited by applicant

Feature analysis of claim 1 of EP 1 841 482 B1. cited by applicant

ResMed, Instruction manual of the “MAP Papillon mask”, 2005. cited by applicant

Instructions for Use for the “Respironics ComfortClassic Nasal Mask” (English and German version), 7 pp. cited by applicant

Invoice for a Respironics ComfortClassic nasal mask, dated Jun. 13, 2003. cited by applicant

Letter of May 16, 2018 from the procedure of European patent No. EP 1 841 482 B1 with enclosures. cited by applicant

Opposition Division preliminary opinion in EP 1 841 482 B1 (with enclosures), filed Aug. 22, 2019. cited by applicant

Overview table regarding the auxiliary requests filed by the patentee, submitted May 16, 2018, 1 p. cited by applicant

Respironics Inc, Securities and Exchange Commission Form 10-K Annual Report, Jun. 30, 1998, 79 pp. cited by applicant

Respironics Monarch Mini, 1 p. with 7 pp. of photos dated Jul. 20, 2005. cited by applicant

Respironics, Inc, Sep. 30, 1997, Solo™ CPAP System, User Instructions, 33 pp. cited by applicant

Respironics ComfortCurve, 1 p. with 7 pp. of photos dated Nov. 4, 2005. cited by applicant

Affidavit of Christopher Bryn Sparks regarding European patent No. EP1841482B1, dated Nov. 12, 2018, 5 pp. cited by applicant

Affidavit of Christopher Earl Nightingale regarding European patent No. EP1841482B1, dated May 15, 2018, 16 pp. cited by applicant

Affidavit of Christopher Earl Nightingale regarding European patent No. EP1841482B1, dated May 9, 2018, 22 pp. cited by applicant

Affidavit of Richard Joseph Lordo regarding European patent No. EP1841482B1, dated Nov. 26, 2019, 3 pp. cited by applicant

Affidavit of Richard Joseph Lordo regarding European patent No. EP1841482B1, dated Nov. 29, 2018, 5 pp. cited by applicant

Department of Health and Human Services, May 7, 1997, Premarket Notification [501(k)] review, Appendix 2, ResMed Operating Manual, Autoset Home System, 7 pp. cited by applicant

Resmed, Aug. 26, 1997, Mask frames, nasal cushions and headgear, web page, <http://web.archive.org/web/199806111424/http://www.resmed.com:80/maskframes/standar.htm>, 3 pp. cited by applicant

Resmed, Feb. 12, 2001, Modular mask components and part numbers, [https://web.archive.org/web/20010212075443/http://www.resmed.com:80/products/modular\\_components.htm](https://web.archive.org/web/20010212075443/http://www.resmed.com:80/products/modular_components.htm), 1 p. cited by applicant

Photos of the Fisher and Paykel Healthcare Aclaim Mask, photos taken Oct. 6, 2023, 133 pp. (uploaded in 4 parts) The Fisher & Paykel Aclaim Mask has been publicly displayed, offered for sale and sold by the Applicant since at least 200. cited by applicant

Photos of the Healthdyne Soft Series Mask, photos taken Oct. 6, 2023, 45 pp. The Healthdyne Soft Series Mask has been publicly displayed, offered for sale and sold since at least 1993. cited by applicant

Letter to IP Australia dated Jun. 14, 2023 in Australian patent application No. 2021240146, 1 pp. cited by applicant

Opposition—Statement of Grounds and Particulars dated Jul. 18, 2023 in Australian patent application No. 2021240146, 20 pp. cited by applicant

Photos of the ResMed Activa Mask and Associated Packaging, photos taken Feb. 3, 2023, 120 pp. cited by applicant

The ResMed Mirage Activa Nasal Mask has been publicly displayed, offered for sale and sold by ResMed Pty Ltd since at least 2003 (Uploaded in 2 parts). cited by applicant

Photos of the ResMed Activa LT Mask and Associated Packaging, photos taken Feb. 3, 2023, 75pp. (uploaded in 5 parts) The ResMed Mirage Activa LT Nasal Mask has been publicly displayed, offered for sale and sold by ResMed Pty Ltd since at least 2008 (Uploaded in 5 parts). cited by applicant

Photos of the Respironics Comfort Curve and Associated Packaging, photos taken Feb. 3, 2023, 143 pp. The Respironics Comfort Curve has been publicly displayed, offered for sale and sold by Respironics since at least 2005. cited by applicant

Photos of the Respironics Monarch Mini and Associated Packaging, photos taken Feb. 3, 2023, 152 pp. The Respironics Monarch Mini has been publicly displayed, offered for sale and sold by Respironics since at least 2000. cited by applicant

Statement of Grounds and Particulars dated Jun. 9, 2023 in Australian patent application No. 2021240146, 16 pp. cited by applicant

Statement of Grounds and Particulars dated Jul. 12, 2023 in Australian patent application No. 202173595, 19

pp. cited by applicant  
Statutory Declaration for David John Palkon dated Sep. 7, 2023 in Australian patent application Nos. 2021240146 and 2021273595, 1879 pp. (uploaded in 4 parts). cited by applicant  
Statutory Declaration for Melody Crinion dated Sep. 7, 2023 in Australian patent application Nos. 2021240146 and 2021273595, 98 pp. cited by applicant  
Statutory Declaration of Robynne Lyndsay Sanders dated Sep. 7, 2023 in Australian patent application Nos. 2021240146 and 2021273595, 6566 pp (uploaded in 54 parts). cited by applicant  
Photos of the Sullivan Bubble Mask, photos taken Feb. 3, 2023, 49 pp. (uploaded in 2 parts) TheSullivan Bubble Mask has been publicly displayed, offered for sale and sold by ResMed Pty Ltd (or its predecessor in title) since at least 1996. cited by applicant  
Declaration of Jason Eaton dated Dec. 11, 2023 in the matter of Australian Patent ApplicationsNo. 2021240146 and 2021273595 in the name of Fisher & Paykel Healthcare Limited and Opposition by ResMed Pty Ltd, 227 pp. cited by applicant  
European Examination Report, European Application 13828380.9, dated Jul. 27, 2018, 8 pp. cited by applicant  
European Examination Report, European Application 13828380.9, dated Mar. 3, 2020, 8 pp. cited by applicant  
European Extended Search Report dated Feb. 14, 2019 in patent application No. 18195537.8. cited by applicant  
European extended search report dated Oct. 31, 2018 in patent application No. 18171619.2, 9 pp. cited by applicant  
European Extended Search Report in patent application No. 10830251.4, dated Sep. 4, 2015, 7 pages. cited by applicant  
European Extended Search Report in patent application No. 17179765.7, dated Dec. 11, 2017, 8 pages. cited by applicant  
European Extended Search Report; dated Apr. 2, 2014; Application No. 09819444.2; 8 pages. cited by applicant  
European Patent Office, Extended European Search Report, Application No. 18163847.9-1122, dated Jul. 23, 2018, in 7 pages. cited by applicant  
European Search Report and Written Opinion in patent application No. 09746823.5, dated May 12, 2016, 12 pages. cited by applicant  
European Search Report in patent application No. 11830981.4, dated Aug. 24, 2015; 6 pages. cited by applicant  
European Search Report in patent application No. 191976761.1, dated Mar. 3, 2020, 10 pages. cited by applicant  
European Summons to Attend Oral Proceedings and Written Opinion in patent application No. 09746823.5, dated Dec. 13, 2017, 7 pages. cited by applicant  
Extended European Search Report in EP patent application No. 18178220.2, dated Sep. 21, 2018, 8 pp. cited by applicant  
Extended Search Report; European Application No. 10774623.2; dated Sep. 8, 2015; 7 pages. cited by applicant  
Great Britain combined search and examination report dated May 11, 2018 in patent application No. GB1805606.9. 3 pp. cited by applicant  
Great Britain Combined Search and Examination Report in patent application No. GB1406401.8, dated May 7, 2014, 4 pages. cited by applicant  
Great Britain Combined Search and Examination Report in patent application No. GB1406402.6, dated May 7, 2014, 6 pages. cited by applicant  
Great Britain Combined Search and Examination Report in patent application No. GB1719334.3, dated Nov. 30, 2017, in 9 pages. cited by applicant  
Great Britain examination report dated Jul. 20, 2018 in patent application No. GB1719334.3, 3 pp. cited by applicant  
Great Britain examination report dated Jul. 5, 2018 in patent application No. GB1805606.9, 3 pp. cited by

applicant

Great Britain examination report dated May 11, 2018 in patent application No. GB1805605, 1, 7 pp. cited by applicant

Great Britain examination report dated May 30, 2018 in patent application No. GB1719334.3, 4 pp. cited by applicant

Great Britain Examination Report in patent application No. GB1119385.1, dated May 9, 2013, 4 pages. cited by applicant

Great Britain examination report in patent application No. GB1501499.6, dated Jun. 1, 2017, in 8 pages. cited by applicant

Indian Examination Report dated Mar. 14, 2019 in patent application No. 8767/CHENP/2011. 6 pages. cited by applicant

Indian Examination Report in patent application No. 1431/KOLNP/2012. 7 pages. cited by applicant

Intention to Grant dated Nov. 22, 2021, in EP Application No. 18171619.2; in 55 pages. cited by applicant

International Preliminary Report on Patentability (IPRP), International application No.

PCT/NZ2009/000219, dated Apr. 12, 2011, 9 pages. cited by applicant

International Preliminary Report on Patentability and Written Opinion of the ISA; International Application No. PCT/ NZ2010/000229; dated May 22, 2012; 14 pages. cited by applicant

International Search Report and Written Opinion received for PCT Patent Application No.

PCT/NZ2009/000072, mailed on Jul. 28, 2009, 12 pages. cited by applicant

International Search Report for application No. PCT/NZ2005/000062 dated May 27, 2005. 3 pages. cited by applicant

International Search Report for International Application No. PCT/NZ2007/000185, dated Oct. 31, 2007 in 3 pages. cited by applicant

International Search Report for International application No. PCT/NZ2014/000021, filed Feb. 21, 2014, 10 pages. cited by applicant

International Search Report, International Application No. PCT/NZ2009/000219, mailed Feb. 2, 2010, 3 pages. cited by applicant

International Search Report, PCT/NZ2010/000229, dated Mar. 18, 2011, 8 pages. cited by applicant

International Search Report, PCT/NZ2011/000211, dated Feb. 17, 2012, 4 pages. cited by applicant

International Search Report; Application No. PCT/NZ2013/000138; dated Nov. 1, 2013; 7 pp. cited by applicant

Japanese Decision for Final Rejection dated Jul. 1, 2019 in patent application No. 2017-238259, 2 pp. cited by applicant

Japanese Examination Report in patent application No. 2012-510418, dated Feb. 10, 2014, 4 pages. cited by applicant

Japanese Examination Report in patent application No. 2012-538784, dated Aug. 25, 2014, 7 pages. cited by applicant

Japanese Examination Report in patent application No. 2015-098324, dated Jul. 22, 2015, 8 pages. cited by applicant

Japanese examination report in patent application No. 2015-526496, dated Apr. 17, 2017, in 13 pages. cited by applicant

Japanese Examination Report in patent application No. 2015-526496, dated Feb. 28, 2018, 2 pp. cited by applicant

Japanese Examination Report in patent application No. 2017-040092, dated Feb. 5, 2018. 4 pages. cited by applicant

Japanese Examination Report; dated Jul. 22, 2015; Application No. 2015-098324; 8 pages. cited by applicant

Japanese notification of reason for rejection in patent application No. 2012-538784, dated Aug. 5, 2015, 10 pp. cited by applicant

Japanese office action dated Sep. 1, 2019 in patent application No. 2018-188040. 10 pages. cited by applicant

Japanese Office Action; Application No. 2012-538784; dated Jul. 25, 2016; 4 pages. cited by applicant

Japanese Official Action dated Sep. 3, 2018 in patent application No. 2017-238259. 8 pages. cited by

applicant

Japanese Pretrial Examination Report dated Jan. 7, 2020 in patent application No. 2017-238259. 4 pages. cited by applicant

Office Action in corresponding Indian Patent Application No. 5250/KOLNP/2008, dated May 23, 2017, in 8 pages. cited by applicant

Office Action; Canadian Application No. 2890556; dated Jan. 27, 2016; 3 pages. cited by applicant

Office Action; European Application No. 07808683.2; dated Jul. 8, 2015; 8 pages. cited by applicant

Scheduling Order dated Jul. 16, 2019 in IPR2019-00180, 12 pp. cited by applicant

Third Office Action; Chinese Application No. 201080061122.1; dated Apr. 1, 2016; 5 pages. cited by applicant

UK Search and Examination Report; Mar. 14, 2013; Application No. GB1210075.6; 2 pages. cited by applicant

Written Opinion of the international Searching Authority, PCT/NZ2013/000139, dated Nov. 1, 2013. 5 pages. cited by applicant

Written Opinion, PCT/NZ2011/00021, dated Feb. 17, 2012, 7 pages. cited by applicant

Written Opinion; PCT/NZ2011/000211; dated Feb. 17, 2012; 7 pages. cited by applicant

---

*Primary Examiner:* Boecker; Joseph D.

*Attorney, Agent or Firm:* VIA LLP

---

## **Background/Summary**

**PRIORITY, INCORPORATION BY REFERENCE** (1) This application is a continuation of U.S. patent application Ser. No. 17/816,275, filed Jul. 29, 2022 and issuing as U.S. Pat. No. 11,766,535, which is a continuation of U.S. patent application Ser. No. 17/568,186, filed Jan. 4, 2022, now U.S. Pat. No. 11,559,650, which is a continuation of U.S. patent application Ser. No. 16/384,218, filed Apr. 15, 2019, now U.S. Pat. No. 11,247,013, which is a continuation of both U.S. patent application Ser. No. 14/977,083, filed Dec. 21, 2015, now U.S. Pat. No. 10,272,218, and of U.S. patent application Ser. No. 15/425,937, filed Feb. 6, 2017, now U.S. Pat. No. 10,835,702. Both U.S. patent application Ser. Nos. 14/977,083 and 15/425,937 claim priority to U.S. patent application Ser. No. 13/877,903, filed May 30, 2013, now U.S. Pat. No. 9,561,338, which claims priority to international Patent App. No. PCT/NZ2011/000211, filed Oct. 7, 2011, which claims benefit of U.S. Provisional Patent App. No. 61/391,527, filed Oct. 8, 2010. All of the above, and any and all applications for which a foreign or domestic priority claim is identified in the Application Data Sheet as filed with the present application, are hereby incorporated by reference under 37 CFR § 1.57, for all that each contains, for all purposes.

## **BACKGROUND**

### **Field**

(1) The present invention generally relates to patient interfaces. More particularly, the present invention relates to such interfaces particularly though not solely for use in delivering CPAP therapy to patients suffering from obstructive sleep apnoea (OSA).

### **Related Art**

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

(3) Such respiratory masks should provide an effective seal against the user's face to reduce the likelihood of leakage of the gas being supplied. Commonly, in prior mask configurations, a good mask-to-face seal has been attained in many instances only with considerable discomfort for the user. This

problem is prevalent in those applications, especially medical applications, in which the user wears a mask or patient interface continuously for hours or perhaps even days. In such situations, the user may not tolerate the mask for long durations and optimum therapeutic or diagnostic objectives thus will not be achieved, or will be achieved with great difficulty and considerable user discomfort.

(4) To aid with user comfort, masks can be provided in a range of different sizes. A user will find one particular size in the available range of sizes most suitable for providing an effective seal and a comfortable fit. A single mask frame can be provided to which a range of different sized seals may be fitted. A user chooses the most suitably sized seal from the available range (e.g., the user chooses one size from small, medium, large and extra large) and attaches that seal to the mask frame for use.

(5) A further example of a way in which differently sized users are accommodated is the nasal mask range disclosed in US2010/0006101, the entire contents of which are hereby incorporated by reference herein. As shown in FIG. 1 of this application, three different sized mask bodies **430** and correspondingly sized seal assemblies **440** are provided. A user may select the most suitably sized frame and corresponding seal assembly for use. Various components of the nasal mask disclosed in US2010/0006101 are described below with reference to FIGS. 2 to 6.

(6) The mask assembly **402** comprises a mask body **430** and a mask seal assembly **440**. The mask body **430** provides the overall structural support for the mask assembly, and provides a clip type fitting **433** for attaching the mask assembly **402** to headgear **421**. The mask body includes a forehead support **431** to which the headgear is also attached.

(7) A rear side of the mask body **430** interfaces to the seal assembly **440**. The seal assembly **440** provides a sealing interface against a user's face in use.

(8) The mask body **430** has an inlet for receiving a flow of respiratory gases and exhaust holes **425** to allow exhaled breath to be vented from the mask assembly. The mask body forms an internal cavity to which respiratory gases are supplied via the inlet. The inlet comprises a tubular projection **422** extending from a front side **471** of the mask body **430**. A connector **423** connects to the inlet and swivels with respect to the mask body **430**, for connecting a supply conduit to the mask body.

(9) The seal assembly **440** comprises a flexible seal **443** attached to a relatively rigid plastic clip **442**. The flexible seal **443** is over-moulded to the plastic clip **442** so that the seal assembly **440** forms a single item of the mask assembly **402**. The plastic clip has a series of holes **446** around its perimeter. During manufacture, overmoulding of the seal to the clip causes the seal material to flow through the series of holes **446**. During manufacture, the seal material is cured. Once cured, the seal **443** is mechanically linked to the plastic clip **442** via holes **446**, providing a mechanical joint between the clip and the seal. The holes **446** are located through a raised ridge **445** running around the inside perimeter of the clip.

(10) The clip **442** releasably attaches to the mask body in a 'clip' or 'snap' type engagement. A series of bumps **448**, or raised portions, on the mask body **430** interact with corresponding recesses **447** on the clip **442**, to hold the clip **442** in place on the body **430**. As the clip **442** attaches to the mask body, interference between the clip and each mask body bump **448** causes the clip or the mask body, or both, to deflect to a deflected condition until each bump **448** reaches a corresponding recess **447**. Once the clip has been fully engaged with the body, each bump **448** locates within a corresponding recess **447**, and the clip or body, or both un-deflect from the deflected condition to an un-deflected or partially deflected condition, the parts being clipped or snapped together in a fully engaged position.

(11) The clip **442** preferably has a relatively long lead in, or ramped profile **449**, leading to the clip recess **447**. This lead in section extends the full inside perimeter length of the clip **442**. The lead-in section assists with the attachment of the clip to the mask body. The clip **442** or mask body **430**, or both, are gradually deflected over the length of the lead-in section until the apex of the lead-in section and each mask body bump **448** pass each other. Once the bumps **448** have passed over the lead-in section, the bumps **448** locate within each corresponding recess **447**, such that there is little or no interference between the two parts **430** and **442**. The two parts un-deflect in a relatively sudden snap action compared to the gradual deflection caused by the lead in section **449** during engagement.

(12) The face seal assembly **440** includes at least one wing portion **444** to assist a user to disengage the face seal assembly from the mask body. The wing portions **444** provide a gripping flange to pull the

clip **442** away from the mask body **430**.

(13) The nasal mask includes a cushion **441**. Cushion **441** is provided around the periphery of the mask, and is surrounded by the seal assembly **440**. The cushion **441** provides support to the seal **443** to achieve an effective seal onto the face of the user to reduce the likelihood of leakage.

(14) One end **462** of the mask cushion is shaped to match the shape of the seal in contact with the user's face, and an opposite end **463** is shaped to match the mask body. The cushion includes a raised bridge **465** in the nasal bridge region. The raised bridge **465** can also be described as a cut out section made in the cushion, the cut out being on the mask body end **463** of the cushion. As the raised bridge **465** is unsupported by the mask body **430**, it is much more flexible and results in less pressure on the nasal bridge of the patient.

(15) The cushion **441** is located around the outer periphery of the mask body, contacting the mask body except for in the raised bridge portion **465** of the cushion. The cushion is located in a generally triangular cavity **466**, the cavity continuing around the periphery of the body, terminating at each side of the nose bridge region **467** of the mask, where the raised bridge portion **465** of the cushion does not contact the mask body **430**. The cavity **466** is generally formed by two spaced apart walls **476** and **477**. The cushion **441** is a separate item, the seal assembly **440** fitting in place over the cushion to hold it in place within the mask assembly **402**.

(16) In this specification where reference has been made to patent specifications, other external documents, or other sources of information, this is generally for the purpose of providing a context for discussing the features of the invention. Unless specifically stated otherwise, reference to such external documents is not to be construed as an admission that such documents, or such sources of information, in any jurisdiction, are prior art, or form part of the common general knowledge in the art.

#### SUMMARY

(17) An object of the present invention is to provide a patient interface which goes some way to overcoming disadvantages in the prior art or which will at least provide the users with a useful choice.

(18) In one aspect, the present invention broadly consists in a mask assembly for use as part of an apparatus for supplying a flow of respiratory gases to a user, comprising: a mask body having an inlet through which said flow of respiratory gases are provided to the interior of said mask body, the inlet adapted to be connected to a gases conduit, a mask seal assembly comprising a seal of flexible material and a clip of rigid material, the seal having a first side and a second side, the first side of the seal being shaped to approximately match the contours of a user's face and in use substantially seal against a user's face, the second side attached to said clip, the clip providing an interface extending substantially the full perimeter or periphery of the mask seal assembly for releasably attaching the mask seal assembly to the mask body, and wherein the clip comprises a bridging portion spanning outwards from the perimeter or periphery of the mask body to space at least a portion of the second side of the seal outwards from the perimeter or periphery of the mask body.

(19) Preferably the mask assembly comprises an inner cushion located between the clip and the first side of the seal.

(20) Preferably the inner cushion is located between the bridging portion of the clip and the first side of the seal.

(21) Preferably the clip comprises a channel in the bridging portion, a first side of the inner cushion in use supporting the first side of the seal, and a second side of the inner cushion being received in the channel.

(22) Preferably the seal is attached to a first side of the clip and a second side of the clip releasably attaches to the mask body, and the bridging portion spans between the first and second sides of the clip.

(23) Preferably the seal assembly comprises a second seal of flexible material attached to the second side of the clip for forming a seal between the mask seal assembly and the mask body.

(24) Preferably the bridging portion and the seal are sized according to one of a series of sizes, each one of the series of sizes suitable for sealing against a differently sized user's face.

(25) Preferably the mask body is adapted for use with a plurality of the seal assemblies, at least one said seal assembly having a said bridging portion, each said seal assembly having a said seal sized according to one of a series of sizes, each one of the series of sizes suitable for sealing against a

differently sized user's face, and the second side of the clip of each said seal assembly being the same or similar to be releasably attached to the mask body.

(26) Preferably the seal and the second seal are integrally formed and joined together across the bridging portion.

(27) Preferably the seal and the second seal are integrally formed and joined together across the bridging portion via a runner across or through the bridging portion.

(28) Preferably the mask assembly comprises an inner cushion located between the mask body and the first side of the seal.

(29) Preferably the mask assembly comprises a channel in the mask body, a first side of the inner cushion in use supporting the first side of the seal, and a second side of the inner cushion being received in the channel in the mask body.

(30) Preferably the bridging portion has an outward dimension that is the same or similar around the perimeter or periphery of the mask body.

(31) Preferably the bridging portion has an outward dimension that varies around the perimeter or periphery of the clip.

(32) Preferably the outward dimension of the bridging portion is larger at a bottom portion of the seal assembly and smaller at an upper portion or nasal bridge region of the seal assembly.

(33) Preferably the bridging portion tapers from a first outward dimension in the bottom portion of the mask assembly to a second outward dimension in the upper portion or nasal bridge region of the mask assembly.

(34) Preferably each said seal assembly in the said plurality of seal assemblies has a bridging portion with a first outward dimension in the bottom of the mask assembly and a second outward dimension in the upper portion of the mask assembly and the first outward dimension is greater than the second outward dimension, and the second outward dimension of each said seal assembly is the same or similar, and the first outward dimension of each said seal assembly is different to the first outward dimension of the other said seal assemblies in said plurality of seal assemblies, the first outward dimension of each said seal assembly sized to be suitable for sealing against a differently sized user's face.

(35) Preferably the bridging portion extends rearward away from a front of the mask body towards a user's face in use.

(36) Preferably the mask body is adapted for use with a plurality of the seal assemblies, at least one said seal assembly having a said bridging portion, each said seal assembly having a seal of a different type comprising one of a cannula seal, a nasal seal, a mouth seal and a full face seal, and the second side of the clip of each said seal assembly being the same or similar to be releasably attached to the mask body.

(37) Preferably the mask seal assembly releasably attaches to a rear perimeter of the mask body.

(38) Preferably the rear perimeter of the mask body defines an area being more than ten times the area of the mask body inlet.

(39) Preferably the bridging portion spaces the second side of the seal outwards from the perimeter or periphery of the mask body by at least 10 mm.

(40) Preferably the mask body defines a hollow space for receiving or covering a user's nose or mouth or both.

(41) In another aspect, the present invention broadly consists in a mask package comprising: a mask body having an inlet through which a flow of respiratory gases are provided to the interior of the mask body, the inlet adapted to be connected to a gases conduit, a first seal assembly comprising: a first seal of a flexible material and a first clip of a rigid material, the first seal having a first side and a second side, the first side of the first seal being shaped to approximately match the contours of a user's face and in use substantially seal against a user's face, said second side of said first seal attached to said first clip, the first clip providing an interface extending substantially the full perimeter or periphery of the first seal assembly, the second side of the first seal attached to a first side of the first clip and a second side of the first clip for releasably attaching the first seal assembly to the mask body, a second seal assembly comprising: a second seal of a flexible material and a second clip of a rigid material, the



second seal having a first side and a second side, the first side of the second seal being shaped to approximately match the contours of a user's face and in use substantially seal against a user's face, said second side of said second seal attached to said second clip, the second clip providing an interface extending substantially the full perimeter or periphery of the second seal assembly, the second side of the second seal attached to a first side of the second clip and a second side of the second clip for releasably attaching the second seal assembly to the mask body, wherein the first clip or the second clip or both comprises a bridging portion spanning outwards from the perimeter or periphery of the mask body to space at least a portion of the second side of the first or second seal outwards from the perimeter or periphery of the mask body when the first or second seal assembly is attached to the mask body, and the first side of the first clip being comparatively different to the first side of the second clip, and the first seal being comparatively different to the second seal.

(42) Preferably the mask package comprises a first inner cushion for use with the first seal assembly and a second inner cushion for use with the second seal assembly.

(43) Preferably the first seal assembly attached to the mask body, the first inner cushion is located between the first clip and the first side of the first seal, or with the second seal assembly attached to the mask body, the second inner cushion is located between the second clip and the first side of the second seal.

(44) Preferably the first seal assembly attached to the mask body, the first inner cushion is located between the bridging portion of the first clip and the first side of the first seal, or with the second seal assembly attached to the mask body, the second inner cushion is located between the bridging portion of the second clip and the first side of the second seal.

(45) Preferably the bridging portion of the first clip of the first seal assembly has a channel for receiving the first inner cushion, or/and the bridging portion of the second clip of the second seal assembly has a channel for receiving the second inner cushion.

(46) Preferably the bridging portion of the first clip of the first seal assembly has an outward dimension that varies around the perimeter of the first clip, or the bridging portion of the second clip of the second seal assembly has an outward dimension that varies around the perimeter of the first clip.

(47) Preferably the bridging portion of the first clip of the first seal assembly has a larger outward dimension at the bottom of the first seal assembly compared to the outward dimension at the top or nasal bridge region of the first seal assembly, and/or the bridging portion of the second clip of the second seal assembly has a larger outward dimension at the bottom of the second seal assembly compared to the outward dimension at the top or nasal bridge region of the second seal assembly.

(48) Preferably the bridging portion of the second clip of the second seal assembly has a larger outward dimension at the bottom of the second seal assembly compared to the bridging portion of the first clip of the first seal assembly, the second seal of the second seal assembly being larger than the first seal of the first seal assembly.

(49) Preferably the bridging portion of the first clip of the first seal assembly and the bridging portion of the second clip of the second seal assembly have the same or a similar outward dimension in the nasal bridge region of the clip.

(50) Preferably the first side of the second seal has a longer perimeter length than the first side of the first seal.

(51) Preferably a mask assembly comprising the mask body and the first seal assembly has an internal cavity having a first depth, and a mask assembly comprising the mask body and the second seal assembly has an internal cavity having a second depth, the second depth being greater than the first depth.

(52) Preferably the bridging portion of the second clip of the second seal assembly extends rearward away from the general plane of the mask body when the second seal assembly is attached to the mask body.

(53) Preferably the first seal assembly comprises a seal of flexible material attached to the second side of the first clip for forming a seal between the first mask seal assembly and the mask body, and/or the second seal assembly comprises a seal of flexible material attached to the second side of the second clip for forming a seal between the second mask seal assembly and the mask body.

- (54) Preferably the first seal of the first seal assembly and the seal on the second side of the first clip of the first seal assembly are integrally formed and joined together across the bridging portion of the first clip, and/or the second seal of the second seal assembly and the seal on the second side of the second clip of the second seal assembly are integrally formed and joined together across the bridging portion of the second clip.
- (55) Preferably a mask assembly comprising the mask body and the first seal assembly or the second seal assembly is a nasal mask or a full face mask.
- (56) Preferably the first side of the second clip has a longer perimeter length than the first side of the first clip, the second seal being larger than the first seal.
- (57) Preferably the first side of the second seal has a longer perimeter length than the first side of the first seal.
- (58) Preferably the first and second seals are different types of seals, the first and second seals being one of a cannula seal, a nasal seal, a mouth seal and a full face seal.
- (59) Preferably the first mask seal assembly and the second mask seal assembly releasably attach to a rear perimeter of the mask body.
- (60) Preferably the rear perimeter of the mask body defines an area being more than ten times the area of the mask body inlet.
- (61) Preferably the bridging portion of the first clip spaces the second side of the first seal outwards from the perimeter or periphery of the mask body by at least 10 mm, or the bridging portion of the second clip spaces the second side of the second seal outwards from the perimeter or periphery of the mask body by at least 10 mm.
- (62) Preferably the mask body defines a hollow space for receiving or covering a user's nose or mouth or both.
- (63) In another aspect, the present invention broadly consists in a mask assembly for use as part of an apparatus for supplying a flow of respiratory gases to a user, comprising: a mask body having an inlet through which said flow of respiratory gases are provided to the interior of said mask body, the inlet adapted to be connected to a gases conduit, a mask seal assembly comprising a seal of a flexible material and a clip of a rigid material, said seal having a first side and a second side, the first side of said seal being shaped to approximately match the contours of a user's face and in use substantially seal against a user's face, said second side attached to said clip, said clip providing an interface extending substantially the full perimeter or periphery of the mask seal assembly for releasably attaching the mask seal assembly to the mask body, and an inner cushion located between the clip and said first side of the seal.
- (64) Preferably the clip comprises a bridging portion spanning outwards from the perimeter or periphery of the mask body to space at least the second side of the seal outwards from the perimeter or periphery of the mask body.
- (65) Preferably the inner cushion is located between the bridging portion and the first side of the seal.
- (66) Preferably the clip comprises a channel in the bridging portion, a first side of the inner cushion in use supporting the first side of the seal, and a second side of the inner cushion being received in the channel.
- (67) Preferably the seal is attached to a first side of the clip and a second side of the clip releasably attaches to the mask body, and the bridging portion spans between the first and second sides of the clip.
- (68) Preferably the seal assembly comprises a second seal of flexible material attached to the second side of the clip for forming a seal between the mask seal assembly and the mask body.
- (69) Preferably the bridging portion and said seal are sized according to one of a series of sizes, each one of the series of sizes suitable for sealing against a differently sized user's face.
- (70) Preferably the mask body is adapted for use with a plurality of said seal assemblies, at least one said seal assembly having a said bridging portion, each said seal assembly having a said seal sized according to one of a series of sizes, each one of the series of sizes suitable for sealing against a differently sized user's face, and said second side of the clip of each said seal assembly being the same or similar to be releasably attached to the mask body.
- (71) Preferably the seal and the second seal are integrally formed and joined together across the

bridging portion.

(72) Preferably the seal and the second seal are integrally formed and joined together across the bridging portion via a runner across or through the bridging portion.

(73) Preferably the mask assembly comprises an inner cushion located between the mask body and said first side of the seal.

(74) Preferably the mask assembly comprises a channel in the mask body, a first side of the inner cushion in use supporting the first side of the seal, and a second side of the inner cushion being received in the channel in the mask body.

(75) Preferably the bridging portion has an outward dimension that is the same or similar around the perimeter or periphery of the mask body.

(76) Preferably the bridging portion has an outward dimension that varies around the perimeter or periphery of the clip.

(77) Preferably the outward dimension of the bridging portion is larger at a bottom portion of the seal assembly and smaller at an upper portion or nasal bridge region of the seal assembly.

(78) Preferably the bridging portion tapers from a first outward dimension in the bottom portion of the mask assembly to a second outward dimension in the upper portion or nasal bridge region of the mask assembly.

(79) Preferably each said seal assembly in the said plurality of seal assemblies has a bridging portion with a first outward dimension in the bottom of the mask assembly and a second outward dimension in the upper portion of the mask assembly and the first outward dimension is greater than the second outward dimension, and the second outward dimension of each said seal assembly is the same or similar, and the first outward dimension of each said seal assembly is different to the first outward dimension of the other said seal assemblies in said plurality of seal assemblies, the first outward dimension of each said seal assembly sized to be suitable for sealing against a differently sized user's face.

(80) Preferably the bridging portion extends rearward away from a front of the mask body towards a user's face in use.

(81) Preferably the mask body is adapted for use with a plurality of the seal assemblies, at least one said seal assembly having a said bridging portion, each said seal assembly having a seal of a different type comprising one of a cannula seal, a nasal seal, a mouth seal and a full face seal, and the second side of the clip of each said seal assembly being the same or similar to be releasably attached to the mask body.

(82) Preferably the mask seal assembly releasably attaches to a rear perimeter of the mask body.

(83) Preferably the rear perimeter of the mask body defines an area being more than ten times the area of the mask body inlet.

(84) Preferably the bridging portion spaces the second side of the seal outwards from the perimeter or periphery of the mask body by at least 10 mm.

(85) Preferably the mask body defines a hollow space for receiving or covering a user's nose or mouth or both.

(86) In another aspect, the present invention broadly consists in a mask seal assembly for use as part of an apparatus for supplying a flow of respiratory gases to a user, comprising: a seal of flexible material and a clip of rigid material, the seal having a first side and a second side, the first side of the seal being shaped to approximately match the contours of a user's face and in use substantially seal against a user's face, the second side attached to said clip, the clip providing an interface extending substantially the full perimeter or periphery of the seal assembly, the clip having a first side and a second side, the second side of the seal being attached to the first side of the clip, and the second side of the clip for releasably attaching the mask seal assembly to a mask body, wherein the clip comprises a bridging portion spanning between the first and second sides of the clip to space at least a portion of the second side of the seal outwards from the perimeter or periphery of the second side of the clip.

(87) Preferably the clip comprises a channel in the bridging portion for receiving an inner cushion for supporting the first side of the seal in use.

(88) Preferably the seal assembly comprises a second seal of flexible material attached to the second

side of the clip for forming a seal between the mask seal assembly and a mask body.

(89) Preferably the bridging portion and the seal are sized according to one of a series of sizes, each one of the series of sizes suitable for sealing against a differently sized user's face.

(90) Preferably the seal and the second seal are integrally formed and joined together across the bridging portion.

(91) Preferably the seal and the second seal are integrally formed and joined together across the bridging portion via a runner across or through the bridging portion.

(92) Preferably the bridging portion has an outward dimension that is the same or similar around the perimeter or periphery of the mask seal assembly.

(93) Preferably the bridging portion has an outward dimension that varies around the perimeter or periphery of the clip.

(94) Preferably the outward dimension of the bridging portion is larger at a bottom portion of the seal assembly and smaller at an upper portion or nasal bridge region of the seal assembly.

(95) Preferably the bridging portion tapers from a first outward dimension in the bottom portion of the mask assembly to a second outward dimension in the upper portion or nasal bridge region of the mask assembly.

(96) Preferably the bridging portion extends rearward away from a front of a mask body to which the mask assembly is attached in use and towards a user's face in use.

(97) Preferably the mask seal assembly is adapted to releasably attach to a rear perimeter of a mask body defining a hollow space for receiving or covering a user's nose or mouth or both and having an inlet through which the flow of gases are provided to the interior of the mask body.

(98) Preferably the rear perimeter of the mask body defines an area being more than ten times the area of the mask body inlet.

(99) Preferably the bridging portion spaces the second side of the seal outwards from the perimeter or periphery of the second side of the clip by at least 10 mm.

(100) The term "comprising" is used in the specification and claims, means "consisting at least in part of." When interpreting a statement in this specification and claims that includes "comprising", features other than that or those prefaced by the term may also be present. Related terms such as "comprise" and "comprises" are to be interpreted in the same manner. The invention consists in the foregoing and also envisages constructions of which the following gives examples.

(101) For purposes of summarizing the invention and the advantages achieved over the prior art, certain objects and advantages of the invention have been described above and as further described below. Of course, it is to be understood that not necessarily all such objects or advantages may be achieved in accordance with any particular embodiment of the invention. Thus, for example, those skilled in the art will recognize that the invention may be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other objects or advantages as may be taught or suggested herein.

(102) All of these embodiments are intended to be within the scope of the invention herein disclosed. These and other embodiments of the present invention will become readily apparent to those skilled in the art from the following detailed description of the preferred embodiments having reference to the attached figures, the invention not being limited to any particular preferred embodiment(s) disclosed.

---

## Description

### BRIEF DESCRIPTION OF THE DRAWINGS

(1) Preferred forms of the present invention will now be described with reference to the accompanying drawings. The appended drawings are schematic, not necessarily drawn to scale, unless otherwise indicated, and are meant to illustrate and not to limit embodiments of the invention.

(2) FIG. 1 illustrates three differently sized prior art mask frames and corresponding seal assemblies.

(3) FIG. 2 is a perspective view of the nasal mask of FIG. 1.

(4) FIG. 3 is an exploded view of the nasal mask of FIG. 1.

- (5) FIG. 4a is a perspective view of the mask seal assembly of the nasal mask of FIG. 1.
- (6) FIG. 4b is a perspective view of the seal clip of the mask seal assembly of the nasal mask of FIG. 1.
- (7) FIG. 5 is a perspective view showing the mask body and the mask seal assembly of the nasal mask of FIG. 1, with the mask seal assembly removed from the mask body.
- (8) FIG. 6 is a sectional view on line X-X of the nasal mask of FIG. 2.
- (9) FIG. 7 is a block diagram of a humidified continuous positive airway pressure system as might be used in conjunction with the mask assembly of the present invention.
- (10) FIG. 8 is a cross sectional view of a mask assembly according to one embodiment of the present invention.
- (11) FIGS. 9A to 9C are part sectional views of a lower portion of a series of three differently sized mask assemblies.
- (12) FIGS. 10A to 10C are part sectional views of a lower portion of three alternative mask assemblies each having a 'large' sized seal assembly.
- (13) FIGS. 11A to 11C are part sectional views of a lower portion of three alternative mask assemblies each having a 'medium' sized seal assembly.
- (14) FIG. 12 is a diagram showing part sectional views of a common mask body and a range of mask seal assemblies for attachment to the common mask base.
- (15) FIG. 13 is a perspective view of a mask assembly comprising the present invention with section cut away to show a lower portion of the mask assembly in cross section.
- (16) FIGS. 14A to 14D show cross sections of alternative seal arrangements for forming a seal between a seal assembly and a mask body of a mask assembly comprising the present invention.
- (17) FIGS. 15A and 15B are part sectional views of a lower portion of two alternative mask assemblies each with a first seal and a second seal joined together across a bridging portion of a seal clip.

#### DETAILED DESCRIPTION

- (18) It will be appreciated that the mask assembly as described in the preferred embodiment of the present invention can be used in respiratory care generally or with a ventilator, but will now be described below with reference to use in a humidified Continuous Positive Airway Pressure (CPAP) system. It will also be appreciated that the present invention can be applied to various forms of mask assembly including, but not limited to, nasal masks and full face masks that cover both the user's nose and mouth.
- (19) With reference to FIG. 7 a humidified CPAP system is shown in which a patient 1 is receiving humidified and pressurised gases through a patient interface 2 connected to a supply conduit 3. It should be understood that CPAP is used generically and includes a range of variants including VPAP (Variable Positive Airway Pressure) and BiPAP (Bi-level Positive Airway Pressure) and numerous other forms of respiratory therapy.
- (20) Supply conduit 3 is connected to the outlet 4 of a humidification chamber 5 that contains a volume of water 6. Supply conduit 3 may contain a heater or heater wires (not shown) which heat the walls of the conduit or the gases in the conduit to reduce condensation of humidified gases within the conduit. Humidification chamber 6 is preferably formed from a plastics material. The contents of the chamber are heated by a heater. For example the chamber may have a highly heat conductive base (for example an aluminium base) which is in direct contact with a heater plate 7 of humidifier 8. Humidifier 8 is provided with control means or electronic controller 9 which may comprise a microprocessor based controller executing computer software commands stored in associated memory.
- (21) Controller 9 receives input from sources such as a user interface or dial 10 through which a user of the device may, for example, set a value (e.g., a preset or predetermined value) of humidity or temperature of the gases to be supplied. The controller may also receive input from other sources; for example temperature and/or flow velocity sensors 11 and 12 through connector 13 and heater plate temperature sensor 14. In response to the user set humidity or temperature value input via dial 10 and the other inputs, controller 9 determines when (or to what level) to energise heater plate 7 to heat the water 6 within humidification chamber 5. As the volume of water 6 within humidification chamber 5 is heated, water vapour begins to fill the volume of the chamber above the water's surface and is passed out of the humidification chamber 5 outlet 4 with the flow of gases (for example air) provided from a

gases supply means or blower **15** which enters the chamber through inlet **16**. Exhaled gases from the patient's mouth are passed directly to ambient surroundings in FIG. **1**.

(22) Blower **15** is provided with variable pressure regulator or a variable speed fan **21**. The fan draws air or other gases through blower inlet **17**. The speed of the variable speed fan **21** is controlled by electronic controller **18** (or alternatively the function of controller **18** could be carried out by controller **9**) in response to inputs from controller **9**.

(23) Mask Assembly

(24) A mask assembly **2** according to the present invention is described with reference to FIGS. **8** to **13**. FIG. **8** shows a mask comprising a mask body **30**. The mask body includes an inlet **22** for receiving a flow of gases into the mask assembly. The mask body preferably includes features for securing the mask assembly in position on the user's face. For example, the embodiment of FIG. **8** includes a forehead rest **31** to assist with correct placement of the mask assembly against the user's face, and a clip **33** for attachment to headgear. Headgear may also be attached to features of the forehead rest. The mask body may include other known features, for example vent holes **25** for venting expired gases and air, and a channel **66** for receiving an inner cushion (not shown) for supporting the seal **43**.

(25) A seal assembly **40** comprising a seal **43** of a flexible material and clip **42** of a rigid material is attached to a rear side of the mask body. A first side of the flexible seal contacts a user's facial features in use. A second side of the flexible seal is attached to the clip. The seal assembly is releasably attached to the mask body **30** by the clip. Preferably the clip extends substantially the full perimeter of the mask seal assembly. The clip is rigid compared to the seal material and provides a convenient interface for releasably attaching the flexible seal to the mask body. For example, the clip is manufactured from polycarbonate, ABS, nylon, acetyl or other similar rigid plastic. Alternatively the clip may be made from a high Shore A hardness silicone. For example, a silicone with a Shore A hardness of 90 may provide sufficient rigidity. The clip and mask body may be manufactured from the same material type. The seal is formed from rubber or other suitable flexible, resilient material. Preferably the seal is formed from silicone with a Shore-A hardness of less than 60. Preferably the seal is made from silicone with a Shore A hardness of 20-40.

(26) From the above mentioned materials, the difference in rigidity of the clip material (rigid) and the seal material (flexible) will be appreciated. For example, polycarbonate has a Young's modulus of approximately 2 GPa, whereas the Young's modulus of a rubber or other suitable material for use as the flexible seal is in the order of 1 to 5 MPa.

(27) The seal generally provides a flexible perimeter about the perimeter or periphery of the mask body. The seal surrounds an opening to the inside of the mask assembly. A nasal mask assembly seals against a user's face around the user's nose, the seal opening covering the user's nose. A full face mask seals against a user's face around the user's nose and mouth, the seal opening covering both the user's nose and mouth.

(28) The clip has a bridging portion **50** that spans outwards from the perimeter or periphery of the mask body **30**. The bridging portion spaces at least a portion of the second side of the flexible seal **43** outwards from the perimeter or periphery of the mask body to which the clip is attached.

(29) The mask body **30** may be used with a conventional seal assembly as disclosed in the prior art, for example as illustrated in FIG. **4A**. Where a larger mask may be used by a larger user, the same mask body **30** useable with the conventional seal assembly may be used together with a seal assembly comprising a clip with a bridging portion **50**. The bridging portion **50** allows a larger flexible seal **43** to be attached to the mask body **30**, as illustrated in FIG. **8**.

(30) The present invention allows a single mask body **30** to be used for a range of differently sized users. For example, a range of differently sized seal assemblies may be provided. Each seal assembly may have a clip including a bridging portion **50**. The bridging portion of each seal assembly may be a different size and each clip may be attached to a different size flexible seal. A smallest seal assembly in a range of differently sized seal assemblies may not include a bridging portion, the smallest seal assembly being a standard or conventional type seal assembly, for example as illustrated in FIG. **4A**.

(31) For supply to a user, a packaged interface product may include a single mask body, and a plurality of these seal assemblies, each of a different size with at least one of the seal assemblies having a

bridging portion. The package may include instructions for selection and assembly of the seal assemblies to the mask body **30**. The plurality of different size seal assemblies may be varied according to their size, by the size and arrangement of the bridging portion, the placement of an inner cushion and other aspects of variation described in this specification.

(32) The range of seal assemblies for use with a single mask body preferably each have an identical or at least similar connection portion or side for attaching to the single mask body.

(33) The clip with bridging portion expands a mask body to a larger size for use with a larger flexible seal. The mask body may be used with a first seal assembly comprising a flexible seal and clip without a bridging portion, for example as shown in FIG. **9C**. The same mask body may be used with one or more seal assemblies each comprising a flexible seal and clip with a bridging portion to expand the mask body for use with a larger seal. A series of seal assemblies may be provided, each seal assembly in the series having a clip with a progressively larger bridging portion and corresponding larger flexible seal. A plurality of seal assemblies with clips each having differently sized bridging portions may be provided to achieve a range of mask assemblies, for appropriate selection by a user, as illustrated in FIGS. **9A** and **9B**.

(34) As shown in FIG. **8**, preferably the bridging portion of the clip has an outward dimension **D** that varies around the perimeter or periphery of the mask body. As shown in FIG. **8**, preferably the outward dimension of the bridging portion is larger at a bottom portion of the clip and smaller at an upper portion of the clip. Alternatively, the bridging portion may have an outward dimension the same or similar around the periphery of the mask body.

(35) The outward dimension of the bridging portion of a number of different seal assemblies may be the same in a particular portion of the mask body perimeter or periphery to which the clips are attached. For example, a range of different seal assemblies each may comprise a clip with bridging portion having a similar or the same outward dimension in the nasal bridge region, and each clip having a different outward dimension outside the nasal bridge region.

(36) A mask according to the present invention may include a mask body having a forehead rest, for example as shown in FIG. **8**. It can be advantageous for a mask having a forehead rest to have a range of different seal assemblies each comprising a clip with bridging portion having a similar or the same outward dimension in the nasal bridge region. With each clip in the range of seal assemblies having a similar outward dimension in the nasal bridge region, the distance between the top of the seal assembly and the forehead rest remains the same across the range of different sized seal assemblies. This is preferred as the distance the forehead rest is above the top of the mask body can be sized to be suitable for use with a range of different sized seal assemblies. By comparison, in a less preferred embodiment of the present invention, each seal assembly has a clip with bridging portion having a substantially constant outward dimension around the full parameter of the seal assembly. For larger seals, the distance between the top of the seal and the forehead rest therefore decreases.

(37) The distance between the top of the seal and the forehead rest ideally should increase for increasing sized users. With each seal in a range of seals having the same bridging portion outward dimension in the nasal bridge region, the distance between the forehead rest and the top of each seal is the same, which is preferred to the previously described less preferred embodiment.

(38) Preferably the clip has a bridging portion that tapers from a first outward dimension in a lower section of the seal to a second outward dimension in the nasal bridge region, the first dimension being greater than the second dimension.

(39) The embodiment of FIG. **8** is illustrated without an inner cushion between the mask body **30** and the flexible seal **43**. Preferably the mask assembly comprises an inner cushion between the mask body **30** and the flexible seal **43**, or an inner cushion between the clip and the flexible seal.

(40) FIGS. **10A** to **10C** illustrate alternative clips with a bridging portion in the lower portion of the seal assembly for providing a 'large' sized seal **43** compared to other sealing assemblies. In each embodiment of FIGS. **10A** to **10C**, an inner cushion is located between the clip and the first side of the flexible seal **43**. Preferably the inner cushion is located between the clip bridging portion and the first side of the flexible seal.

(41) Preferably the bridging portion comprises a channel **67** for receiving and locating a side of the

inner cushion at the clip. The channel may extend around a full circumference of the clip, or the channel may extend around a portion of a circumference of the clip. For example, the channel may extend around the clip outside the nasal bridge region only for use with a cushion having a raised nasal bridge region similar to the configuration of the inner cushion described in US2010/0006101.

(42) In the embodiment of FIG. 10B, the bridging portion extends outwardly from the mask body 30 and also rearward, away from the general plane of the mask body, towards the user in use. The mask body and seal assembly combine to provide a cavity for surrounding the user's nose, or mouth or both. The rearward extension of the clip bridging portion increases the depth of the cavity provided by the mask assembly. For example, the depth D.sub.B of the cavity provided by the assembly of FIG. 10B with a rearward extension of the clip bridging portion is deeper than the depth D.sub.A of the cavity of the assembly of FIG. 10A with a clip bridging portion that does not extend rearward. The rearward extension of the bridging portion 50 of the embodiment of FIG. 10B spaces the second side of the seal 43 rearward from the perimeter or periphery of the mask body. For larger sized users, for example a user with a larger nose, a deeper internal cavity provided by the mask body and seal clip may reduce the likelihood of the user's nose touching an inside surface of the mask body compared to a mask assembly comprising a smaller seal 43. Extending the second side of the flexible seal 43 rearwards by providing a clip with a rearward extending bridging portion provides a deeper cavity to receive the user's nose compared to a mask assembly having a clip without a rearward extending bridging portion.

(43) In the alternative embodiment of FIG. 10C, a deeper mask cavity is created compared to the embodiment of FIG. 10A by providing a deeper inner cushion and flexible seal for sealing against the user's face. The embodiments of FIGS. 10A and 10C each have the same shaped clip with bridging portion.

(44) FIGS. 11A to 11C illustrate alternative clips with a bridging portion in the lower portion of the seal assembly for providing a 'medium' sized seal compared to other sealing assemblies. For example, the bridging portions 50 of the embodiments of FIGS. 11A to 11C have a smaller outward dimension compared to the bridging portions 50 of the embodiments of FIGS. 10A to 10C so that the seal 43 of the embodiments of FIGS. 11A to 11C are smaller than the seals of the embodiments of FIGS. 10A to 10C. And the bridging portions 50 of the embodiments of FIGS. 11A to 11C each provide a seal 43 that is larger than the seal of the illustrative embodiment comprising a clip with a bridging portion having a smaller outward dimension, or an embodiment comprising a clip without a bridging portion, for example the illustrative embodiment of FIG. 9C.

(45) In the embodiment of FIG. 11A, an inner cushion 41 is located between the mask body 30 and the first side of the flexible seal 43, similar in concept to the aforementioned nasal mask illustrated in FIGS. 1-6. A channel 66 is formed in the mask body by two spaced apart members 76 and 77. A side of the inner cushion 41 in contact with the mask body is received in the channel 66.

(46) FIGS. 11B and 11C illustrate embodiments similar to the embodiment of FIG. 10A described above, with the inner cushion located between the clip 42 and the flexible seal 43. However the outward dimension of the clip bridging portion of the 'medium' seal assemblies of FIGS. 11B and 11C is smaller than the outward dimension of the 'large' clip of the embodiment of FIG. 10A.

(47) Due to the smaller bridging portion of the clip of the medium seal assembly of FIG. 11B, the side of the inner cushion in contact with the clip may be reduced in cross section compared to the inner cushion of the large seal assemblies of FIGS. 10A to 10C. In the alternative embodiment of FIG. 11C, a channel for receiving the cushion in the seal assembly is formed by material of the flexible seal that contacts a user's face in use, and material of a second flexible seal 44 on the other side of the bridging portion 50. The second flexible seal 44 is discussed below.

(48) One embodiment of the present invention comprises a packaged mask assembly product including a single mask body and a plurality of seal assemblies of different sizes for use with the single mask body. For example, a mask package may include a single mask body 30 and a first seal assembly 540, a second seal assembly 640, and a third seal assembly 740, as shown in FIG. 12. The first seal assembly has a clip 542 and seal 543. The clip 542 does not have a bridging portion, the second side 5432 of the seal attached to the clip is not spaced outwards of the mask body when the seal assembly is attached to the mask body. For example, a portion of the material forming the seal 543 also forms a seal against



the mask body. The mask assembly comprising the mask body **30** and the first seal assembly **540** may also include an inner cushion **541** located between the first side **5431** of the seal **542** and the mask body **30**. The inner cushion is received in the channel **66** of the mask body **30**. The mask assembly comprising the first seal assembly **540** is most suited to users with smaller facial features compared to other users.

(49) Where the first seal assembly is not large enough for a particular user, that user may chose to use the second seal assembly **640**. The second seal assembly has a clip **642** and seal **643**. The clip **642** has a bridging portion **650** to space the second side **6432** of the seal attached to the clip outwards of the mask body when the seal assembly is attached to the mask body. The bridging portion has an outward dimension  $D_{sub.m}$  to space the second side of the seal outwards from the mask body by a distance. The bridging portion **650** of clip **642** allows a larger seal to be used with the body **30** by comparison with the seal of the first seal assembly **540**. For example, the seal **643** attached to clip **642** of the second seal assembly **640** may be taller and wider in places compared to the seal **543** of the first seal assembly **540**.

(50) The mask assembly comprising the mask body **30** and the second seal assembly **640** may also include an inner cushion **641**. In the illustrated example, the inner cushion **641** is located between the first side **6431** of the seal **643** and clip **642**. The inner cushion **641** is received in the channel **667** of the clip **642**.

(51) Where the second seal assembly is not large enough for a particular user, that user may chose to use the third seal assembly **740**. The third seal assembly has a clip **742** and seal **743**. The clip **742** has a bridging portion **750** to space the second side **7432** of the seal attached to the clip outwards of the mask body when the seal assembly is attached to the mask body. The bridging portion has an outward dimension  $D_{sub.L}$  to space the second side of the seal outwards from the mask body by a distance. By comparison, the outward dimension of the bridging portion **750** of the third seal assembly **740** is larger than the outward dimension of the bridging portion **650** of the second seal assembly **640**. The bridging portion **750** of clip **742** allows a larger seal to be used with the body **30** by comparison with the seal of the second seal assembly **640**. For example, the seal **743** attached to clip **742** of the third seal assembly **740** may be taller and wider in places compared to the seal **643** of the second seal assembly.

(52) The mask assembly comprising the mask body **30** and the third seal assembly **740** may also include an inner cushion **741**. In the illustrated example, the inner cushion **741** is located between the first side **7431** of the seal **743** and clip **742**. The inner cushion **741** is received in the channel **767** of the clip **742**.

(53) It can be seen from FIG. **12** that incorporating a bridging portion into the clip of a plurality of seal assemblies, each one with a different sized bridging portion, provides for a series of differently sized seal assemblies for use with a common mask body. A series of seal assemblies, each with a bridging portion with an increased outward dimension provides a series of increasing sized seal assemblies for use with a common mask body.

(54) The seal of a seal assembly generally provides a flexible perimeter about the perimeter or periphery of the mask assembly. The seal surrounds an opening to the inside of the mask assembly. A second seal described as being larger than a first seal has a larger perimeter and opening than the first smaller seal. For example, the present invention may comprise a nasal mask package comprising a common mask body and a series of differently sized seal assemblies, each having a perimeter adapted to seal about a user's nose, the user's nose being received in an opening of the seal. Alternatively, the present invention may comprise a full face mask package comprising a common mask body and a series of differently sized seal assemblies, each having a perimeter adapted to seal about a user's nose and mouth, the user's nose and mouth being received in an opening of the seal.

(55) Furthermore, a second seal described as being larger than a first seal not only has a larger perimeter and opening than the first smaller seal, but preferably also has a deeper seal assembly depth. The depth of a seal assembly is indicated in FIG. **12** by dimensions  $D_{sub.1}$ ,  $D_{sub.2}$  and  $D_{sub.3}$  for the three different sized seals illustrated. As shown, the depth of the seal assemblies increases for increasing seal sizes.

(56) A large range of users can be accommodated by providing three different size mask seals for use

with a common body. The three different size seals may conveniently be labeled as small, medium and large. A nasal mask suitable for a range of smaller users may have a seal height from the bridge of the nose to the philtrum area of around 45 mm. A nasal mask suitable for a range of medium sized users may have a seal height from the bridge of the nose to the philtrum area of around 54 mm. According to the present invention, the difference in height between the small seal and the medium seal is accommodated by the outward dimension of the bridging portion of the clip of the medium seal assembly. A nasal mask suitable for a range of larger sized users may have a seal height from the bridge of the nose to the philtrum area of around 58 mm. Similarly, according to the present invention, the difference in height between the small seal and the large seal is accommodated by the outward dimension of the bridging portion of the clip of the large seal assembly, the outward dimension of the bridging portion of the clip of the large seal assembly being greater than the outward dimension of the bridging portion of the clip of the medium seal assembly.

(57) A series of differently sized seal assemblies may comprise a feature or features that are common to more than one seal assembly in the series. For example, a plurality of seal assemblies in a series of seal assemblies may each have the same or a similarly shaped nasal bridge region.

(58) The present invention allows for a range of different types of seals to be used with a common mask body. For example, a common mask body may be used with a nasal seal assembly comprising a clip and seal for sealing around the nose of a user. The same mask body may also be used with a full face seal assembly comprising a clip and a seal for sealing around the nose and mouth of a user.

(59) The seal of each seal assembly is attached to a first side of the seal assembly clip. A second side of the clip attaches to the common mask body. Each seal assembly clip has an identical or at least similar connection portion or second side for attaching to the common mask body. The clip of each seal assembly has a different first side to allow different types of seals to be used with the common mask body. The portion of the clip spanning between the first and second sides of the clip allows a different size or type of seal to be used with the common mask body. For example, the seal and first side of the clip of a full face seal assembly has a longer perimeter length than the seal and first side of the clip of a nasal seal assembly. The difference in perimeter lengths of the first sides of the clips of the full face and nasal seal assemblies is achieved by the clip of the full face seal assembly having bridging portion spanning between the first and second sides of the clip with a larger outward dimension than the clip of the nasal seal assembly. For example, the clip of the nasal seal assembly may have a bridging portion with a smaller outward dimension than the clip of the full face seal assembly, or the clip of the nasal seal assembly may not have a bridging portion, the second side of the seal of the nasal seal assembly not being spaced outwardly from the perimeter of the common mask body.

(60) A range of different types of seals, each with a clip having a different first side allows many different types of seals to be used with a common mask body. For example the common mask body may be used with a cannula seal assembly, a nasal seal assembly, a mouth seal assembly and a full face assembly.

(61) As described above, a sealing assembly according to one embodiment of the present invention comprises a rigid clip having a bridging portion for spacing the second side of the flexible seal in contact with a user's face outwards from the perimeter of the mask body. The flexible seal is attached to a first side of the clip. A second side of the clip attaches to the mask body. The bridging portion of the clip spans between the first and second sides of the clip.

(62) Preferably the seal assembly further comprises a second flexible seal **44** attached to the second side of the clip for forming a seal between the seal assembly **40** and the mask body **30**, as shown in FIGS. **10A** to **14B**. The bridging portion **50** spans between a first seal **43** for forming a seal against a user's face, and a second seal **44** for forming a seal between the seal assembly and the mask body **30**.

(63) The first and second seals may be integrally formed, for example in an injection moulding process, the first and second seals integrally formed and joined together via a runner across or through the bridging portion. Alternatively, the first and second seals may be joined by overmoulding the seal material from the first flexible seal to the second flexible seal across the bridging portion as illustrated in FIGS. **15A** and **15B**. Alternatively, the first and second seals may be separately formed, for example by providing multiple insertion points, a multiple stage moulding process, or by a runner subsequently

removed.

(64) Various second seal configurations for sealing between the seal assembly and the mask body are illustrated in FIGS. 14A to 14D. As illustrated in FIG. 14A, the second seal 44 has a bearing surface 51 extending around the perimeter of the clip. The second seal bearing surface 51 faces a corresponding bearing surface 52 on the mask body. The seal bearing surface and the mask bearing surface are in contact when the seal assembly is attached to the mask body in a butting engagement. When the seal assembly 40 is attached to the mask body 30, the second seal 44 at the bearing interface is compressed so that a sealing interface is formed between the seal assembly and the mask body.

(65) Preferably, the clip has a raised ridge 45 running around the inside perimeter of the clip. The second seal 44 is compressed when the clip is attached to the mask body by being squashed between the raised ridge 45 and the mask body bearing surface 52 when the seal assembly 40 is attached to the mask body 30.

(66) To assist with creating a good seal between the seal assembly and the mask body, a continuous rim 53 may be provided on the seal bearing surface 51. The rim provides a small contact area in contact with the mask body bearing surface 52. The small contact area allows a relatively high compression of the rim, and therefore effective seal, for a relatively small seal assembly to mask body engagement force.

(67) The alternative sealing arrangement illustrated in FIG. 14B comprises a seal that slides against a corresponding lateral member of the mask body during engagement of the seal assembly to the mask body. For example, a wall 77 forming a side of a channel 66 in the mask body for receiving the inner cushion as shown in FIG. 11A extends rearward to contact the second seal 44 when the seal assembly 40 is attached to the mask body 30. Preferably the second seal 44 comprises a raised rim 53 on the surface 51 that contacts the lateral member 77. The rim provides a small contact area in contact with the mask body bearing surface 52 in contact with the seal. The small contact area allows a relatively high compression of the rim, and therefore effective seal, for a relatively small seal assembly to mask body engagement force.

(68) The alternative sealing arrangement illustrated in FIG. 14C comprises a lip 54 that bears against an end of a lateral member of the mask body 30. For example, a wall 77 forming a side of a channel 66 in the mask body for receiving the inner cushion as shown in FIG. 11A extends rearward to contact the lip 54 of the second seal 44 when the seal assembly 40 is attached to the mask body 30.

(69) The alternative sealing arrangement illustrated in FIG. 14D is similar to the arrangement of FIG. 14B but includes two sealing rims 53 in sealing contact with a surface of the mask body.

(70) The present invention has been described with reference to a nasal mask assembly. However, the present invention may equally be applied to other mask assemblies, for example full face masks that cover a user's nose and mouth.

(71) Although certain preferred embodiments and examples have been discussed herein, it will be understood by those skilled in the art that the present invention extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the invention and obvious modifications and equivalents thereof. In addition, while a number of variations of the invention have been shown and described in detail, other modifications, which are within the scope of this invention, will be readily apparent to those of skill in the art based upon this disclosure. It is also contemplated that various combinations or sub-combinations of the specific features and aspects of the embodiments may be made and still fall within the scope of the invention. Accordingly, it should be understood that various features and aspects of the disclosed embodiments can be combined with or substituted for one another in order to form varying modes of the disclosed invention. Thus, it is intended that the scope of the present invention herein disclosed should not be limited by the particular disclosed embodiments described above, but should be determined only by a fair reading of the present disclosure, including the appended claims.

## Claims

1. A mask seal assembly for use as part of an apparatus for supplying a flow of respiratory gases to a user, the mask seal assembly comprising: a first seal and a second seal, each of flexible material, and a clip of rigid material, the first seal having a first side and a second side, the first side of the first seal being shaped to approximately match contours of a face of the user and in use substantially seal against the face of the user, the second side attached to said clip, the clip providing an interface extending substantially a full perimeter or periphery of the mask seal assembly, the clip having a first side and a second side, the second side of the first seal being attached to the first side of the clip, and the second side of the clip for releasably attaching the mask seal assembly to a mask body by way of direct engagement with the mask body, the second seal attached to the second side of the clip for forming a seal between the mask seal assembly and the mask body, wherein the clip comprises a bridging portion spanning between the first side and the second side of the clip to space at least a portion of the second side of the first seal outwards from a perimeter or periphery of the second side of the clip, wherein the first seal and the second seal are integrally formed and joined together across the bridging portion via a runner across or through the bridging portion.
2. The mask seal assembly of claim 1, wherein the first seal and the second seal are joined by overmoulding the flexible material of the first seal to the second seal across the bridging portion.
3. The mask seal assembly of claim 1, wherein the first seal and the second seal are separately formed by: providing multiple insertion points, a multiple stage moulding process, or a second runner which is subsequently removed.
4. The mask seal assembly of claim 1, wherein the second seal comprises a lip.
5. The mask seal assembly of claim 4, wherein the lip is configured to bear against an end of a lateral member of the mask body.
6. The mask seal assembly of claim 1, wherein the bridging portion has an outward dimension (D) that is approximately the same around the perimeter or periphery of the mask seal assembly.
7. The mask seal assembly of claim 1, wherein the bridging portion has an outward dimension (D) that varies around the perimeter or periphery of the second side of the clip.
8. The mask seal assembly of claim 1, wherein the bridging portion extends rearward away from a front of the mask body to which the mask seal assembly is configured to be attached to in use and towards the face of the user in use.
9. The mask seal assembly of claim 1, wherein the mask seal assembly is adapted to releasably attach to a rear perimeter of the mask body defining a hollow space for receiving or covering a nose or a mouth of the user, or both, and having an inlet through which the flow of respiratory gases is provided to an interior of the mask body.
10. The mask seal assembly of claim 1, wherein the clip is manufactured from polycarbonate, ABS, nylon, acetyl or other similar rigid plastic, and the first seal is formed from silicone with a Shore-A hardness of less than 60.
11. A mask assembly for supplying a flow of respiratory gases to a user, the mask assembly comprising: a mask seal assembly according to claim 1, and the mask body.
12. The mask assembly of claim 11, wherein the mask body includes an inlet for receiving a flow of gases into the mask assembly.
13. A packaged interface product comprising: a single mask body, and a plurality of mask seal assemblies each of a different size and comprising a connection portion or side configured to attach to the single mask body, wherein at least one of the plurality of mask seal assemblies is as claimed in claim 1.
14. The packaged interface product of claim 13, wherein: two or more of the plurality of mask seal assemblies are as claimed in claim 1, and an outward dimension (D) of the bridging portion of each of the two or more of the plurality of mask seal assemblies are the same in a particular portion of the mask body perimeter or periphery to which the clips are attached.
15. A mask seal assembly for use as part of an apparatus for supplying a flow of respiratory gases to a user, the mask seal assembly comprising: a first seal and a second seal, each of flexible material, and a clip of rigid material, the first seal having a first side and a second side, the first side of the first seal

being shaped to approximately match contours of a face of the user and in use substantially seal against the face of the user, the second side attached to said clip, the clip providing an interface extending substantially a full perimeter or periphery of the mask seal assembly, the clip having a first side and a second side, the second side of the first seal being attached to the first side of the clip, and the second side of the clip for releasably attaching the mask seal assembly to a mask body, the second seal attached to the second side of the clip for forming a seal between the mask seal assembly and the mask body, wherein the clip comprises a bridging portion spanning between the first side and the second side of the clip to space at least a portion of the second side of the first seal outwards from a perimeter or periphery of the second side of the clip, wherein the first seal and the second seal are integrally formed and joined together across the bridging portion via a runner across or through the bridging portion, wherein the bridging portion spaces the second side of the first seal outwards from the perimeter or periphery of the second side of the clip by at least 10 mm.

16. A packaged interface product comprising: a single mask body, and a plurality of mask seal assemblies each of a different size and comprising a connection portion or side configured to attach to the single mask body, wherein at least one of the plurality of mask seal assemblies comprises: a first seal and a second seal, each of flexible material, and a clip of rigid material, the first seal having a first side and a second side, the first side of the first seal being shaped to approximately match contours of a face of the user and in use substantially seal against the face of the user, the second side attached to said clip, the clip providing an interface extending substantially a full perimeter or periphery of the mask seal assembly, the clip having a first side and a second side, the second side of the first seal being attached to the first side of the clip, and the second side of the clip for releasably attaching the mask seal assembly to a mask body, the second seal attached to the second side of the clip for forming a seal between the mask seal assembly and the mask body, wherein the clip comprises a bridging portion spanning between the first side and the second side of the clip to space at least a portion of the second side of the first seal outwards from a perimeter or periphery of the second side of the clip, wherein the first seal and the second seal are integrally formed and joined together across the bridging portion via a runner across or through the bridging portion, wherein the bridging portion and the first seal is one of a series of sizes, each one of the series of sizes suitable for sealing against a differently sized user's face.

17. A mask seal assembly for use as part of an apparatus for supplying a flow of respiratory gases to a user, the mask seal assembly comprising: a clip of rigid material providing an interface extending substantially a full perimeter or periphery of the mask seal assembly, the clip comprising: a first side; a second side including a connection portion configured to releasably engage the mask seal assembly to a mask body assembly; and a bridging portion spanning between the first side and the second side of the clip; a first seal of flexible material, the first seal having a first side and a second side, the first side of the first seal being shaped to approximately match contours of a face of the user and in use substantially seal against the face of the user, the second side of the first seal being attached to the first side of the clip; a second seal of flexible material, the second seal attached to the second side of the clip, wherein the first seal and the second seal are integrally formed and joined together across the bridging portion via a runner across or through the bridging portion; wherein the bridging portion spaces at least a portion of the second side of the first seal outwards from a perimeter or periphery of the second side of the clip.

18. The mask seal assembly of claim 17, wherein the first seal and the second seal are joined by overmoulding the flexible material of the first seal to the second seal across the bridging portion.

19. The mask seal assembly of claim 17, wherein the second seal comprises a lip.

20. The mask seal assembly of claim 19, wherein the lip is configured to bear against an end of a lateral member of the mask body assembly.

21. The mask seal assembly of claim 17, wherein the bridging portion has an outward dimension (D) that varies around the perimeter or periphery of the second side of the clip.

22. The mask seal assembly of claim 17, wherein the bridging portion extends rearward away from a front of the mask body assembly to which the mask seal assembly is configured to be attached to in use and towards the face of the user, in use.

23. The mask seal assembly of claim 17, wherein the mask seal assembly is adapted to releasably

attach to a rear perimeter of the mask body assembly defining a hollow space for receiving or covering a nose or a mouth of the user, or both, and having an inlet through which the flow of respiratory gases is provided to an interior of the mask body assembly.

24. The mask seal assembly of claim 17, in combination with the mask body assembly, the mask body assembly comprising an inlet configured to connect with a respiratory gas supply.

25. A mask assembly for supplying a flow of respiratory gases to a user, the mask assembly comprising: the mask seal assembly according to claim 17, and the mask body assembly.

---