Abstract:

A patient interface for supplying respiratory therapy to a patient that comprises a vent allowing a leak or bias flow to exit the interface in use, the vent comprising a plurality of apertures, an aperture of the vent extending in a first direction from an interior surface to an exterior surface of the interface, the aperture having a varying cross sectional area along the first direction, the cross section being defined perpendicular to the first direction, the area decreasing moving from the interior surface to a first intermediate location within the aperture, and decreasing moving from the exterior surface to a second intermediate location within the aperture.
"A PATIENT INTERFACE"

FIELD OF THE INVENTION

The present invention relates to patient interfaces for supplying a patient with a flow of breathing gases. In particular, the present invention relates to a gases washout vent for the interface.

SUMMARY OF THE PRIOR ART

A wide variety of patient interfaces have been devised for supplying breathing gases to patients. Many of these interfaces provide sealed communication with the patient airway, such as sealing around parts of the nose or mouth of the wearer or both. In a full ventilation system, breathing gases flow to the interface for breathing by the patient and are withdrawn from the interface for return to the ventilator. This extraction eliminates any build up of carbon dioxide in the interface. Other types of supply lack the active extraction of gases from the patient interface.

For example, most systems for treating obstructive sleep apnea (OSA) using positive airway pressure therapy (PAP) provide a gas supply to the interface but have no return path for gases from the interface. Instead, these systems provide a vent at the interface. The purpose of these systems is to provide breathing gases at a positive pressure, so the vent is sized to provide resistance to flow much greater than the resistance to flow of the supply conduit. Accordingly, a positive pressure can be achieved inside the interface (and therefore the patient airway) despite a constant flow of gases through the vent. The vent can be an opening of fixed size, for example, provided by one or more apertures, or a variable opening, such as an aperture with a pressure-activated valve.

Providing a washout vent at the interface is beneficial, as the PAP therapy can be provided to the patient with only a single conduit connecting between the patient and the flow generator. Reducing the bulk of the connection to the patient improves the comfort and usability of the system. On the other hand, the vent can become a source of noise and a source of discernable draughts. Excessive noise can be irritating for the patient or their bed partner. Depending on their location, draughts can also be annoying to the patient.

A number of approaches have been tried to alleviate these discomforts. US patent 6,581,594 describes vents including a diffusing membrane. The diffusing membrane could be, for example, a very finely perforated foil. US patent 7,207,335 proposes forming one or more vent holes in a resilient insert to be fixed to the mask frame. Figure 12 of US patent 7,207,335 suggests that these holes have a profile that transitions between a smaller hole at the outside and a larger hole inside.
Interfaces produced by Fisher & Paykel Healthcare Limited have included gas washout vents comprising a cluster of holes extending through the frame of the mask, or through the wall of the elbow adjoining mask. These holes have been moulded in the plastic, and the draft for the moulding has been arranged such that the holes narrow moving from the outside surface of the frame to the inside surface of the frame.

SUMMARY OF THE INVENTION

An object of the present invention is to provide a patient interface with an alternative gas washout vent which will at least provide the public with a useful choice.

In one aspect, the present invention may broadly be said to consist in a patient interface for supplying respiratory therapy to a patient that comprises a vent allowing a leak or bias flow to exit the interface in use, the vent comprising a plurality of apertures, an aperture of the vent extending in a first direction from an interior surface to an exterior surface of the interface, the aperture having a varying cross sectional area along the first direction, the cross section being defined perpendicular to the first direction, the area decreasing moving from the interior surface to a first intermediate location within the aperture, and decreasing moving from the exterior surface to a second intermediate location within the aperture.

According to a further aspect the first and second intermediate locations are coincident at a common location.

According to a further aspect the cross sectional area progressively decreases moving toward the common location.

According to a further aspect the cross sectional area decreases between 50% and 95% between the interior surface and the first intermediate location.

According to a further aspect the cross sectional area decreases between 50% and 95% between the exterior surface and the second intermediate location.

According to a further aspect the common location is between 30% and 70% of the distance along the aperture between the interior and exterior surface.

According to a further aspect the aperture has substantially uniform cross sectional shape, and at any point along the first direction has a nominal diameter represented by the perimeter of the cross section divided by pi.

According to a further aspect the nominal diameter decreases at a diminishing rate moving from the interior surface to the first intermediate location.

According to a further aspect the nominal diameter decreases at a diminishing rate moving from the exterior surface to the second intermediate location.
According to a further aspect the portion of the aperture from the interior surface to the first intermediate location is not frustoconical.
According to a further aspect the portion of the aperture from the exterior surface to the second intermediate location is not frustoconical.
According to a further aspect the nominal diameter decreases according to an exponential function.
According to a further aspect the cross sectional area is the same (within 20%) at the exterior surface and at the interior surface.
According to a further aspect the plurality of apertures comprises is in the form of a cluster of apertures.
According to a further aspect the cluster comprises between 10 and 100 apertures.
According to a further aspect each aperture has a minimum cross sectional area of between 0.03mm² and 2.51mm².
According to a further aspect the distance along the first direction from the interior surface to the exterior surface is between 0.8mm and 3.4mm.
According to a further aspect the plurality of apertures is in the form of multiple clusters of apertures.
According to a further aspect each cluster of apertures is within a boundary 60mm long.
According to a further aspect the vent is formed in a wall of the interface with a thickness of the wall at the vent being less than the thickness at areas immediately outside the vent.
According to a further aspect in total the vent comprises between 10 and 100 apertures, the apertures each having a minimum cross sectional area between 0.1mm² and 2mm², and the flow resistance of the vent is such as to provide a resistance of at least 1cmH₂O at a flow of 15LPM and a resistance of less than 20cmH₂O at a flow of 30LPM.
According to a further aspect the interface comprises a seal and a body supporting the seal, and the vent is integrally formed with the body.
According to a further aspect the interface comprises a seal and a body supporting the seal, and the vent is separately formed and inserted into the body.
According to a further aspect the interface comprises a seal and a body supporting the seal, and the vent is provided in the form of a vent insert that is received and retained in a complementary vent aperture provided in the body.
According to a further aspect in the vent area the wall thickness is between 50% and 80% of the average wall thickness of the body.
According to a further aspect the body is made from a rigid plastic such as polycarbonate or polypropylene.
According to a further aspect the body is made from a soft plastic such as urethane or silicone.

According to a further aspect the interface includes an inlet, and a delivery conduit connected to the inlet, and the vent is located on the delivery conduit.

According to a further aspect the interface comprises an inlet, and a delivery conduit connected to the inlet, and the vent is integrally formed with the delivery conduit.

According to a further aspect the interface comprises an inlet, and a delivery conduit connected to the inlet, and the vent is separately formed and inserted into the delivery conduit.

According to a further aspect the interface comprises an inlet, and a delivery conduit connected to the inlet, and the vent is provided in the form of a vent insert that is received and retained in a complementary vent aperture provided in the delivery conduit.

According to a further aspect the delivery conduit comprises an elbow, and the vent is located on the elbow.

According to a further aspect the delivery conduit comprises an elbow, and the vent is integrally formed with the elbow.

According to a further aspect the delivery conduit comprises an elbow, and the vent is separately formed and inserted into the elbow.

According to a further aspect the delivery conduit comprises an elbow, and the vent is provided in the form of a vent insert that is received and retained in a complementary vent aperture provided in the elbow.

According to a further aspect in the vent area the wall thickness is between 50% and 80% of the average wall thickness of the elbow.

According to a further aspect the vent insert is permanently fixed within the vent aperture.

According to a further aspect the vent insert is releasably retained within the vent aperture.

According to a further aspect the vent insert is retained within the vent aperture by a tongue and groove arrangement.

According to a further aspect the vent insert is retained within the vent aperture by clips extending from the underside of the vent insert and which clip into the vent aperture.

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.
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.

**BRIEF DESCRIPTION OF THE DRAWINGS**

**Figure 1** is a perspective view of a portion of an interface including a gas washout vent, viewed from one side.

**Figure 2** is a plan view of the insert of Figure 1.

**Figure 3** is a cross-sectional elevation of the vent of Figure 2, taken through line AA.

**Figure 4** is a plan view of a vent including an alternative arrangement of apertures.

**Figure 5** is a plan view of a vent including a further alternative arrangement of apertures.

**Figure 6** is a plan view of a vent including a further alternative arrangement of apertures.

**Figure 7** is a perspective view of an interface elbow including a vent of Figure 1.

**Figure 8** is a perspective view of an interface elbow including a vent of Figure 1, recessed relative to the surrounding surface of the elbow.

**Figure 9** is a cross-sectional view through the middle of an interface elbow similar to that of Figure 7, which includes an integral vent.

**Figure 10A** is a cross-sectional view of an interface elbow similar to that of Figure 9, except with a vent insert having a clip-in configuration using a tongue and groove arrangement.

**Figure 10B** is a close-up view of region B of Figure 10A.

**Figure 11A** is a cross-sectional view of an interface elbow similar to that of Figure 9, except with a vent insert having a clip-in configuration using clips.

**Figure 11B** is a close-up view of region C of Figure 11A.

**Figure 12** is a front perspective view of a patient interface including a gas washout vent formed by two clusters of apertures in the frame of the mask.

**Figure 13** is a perspective view illustrating an interface with the gas washout vent provided by a combination of clusters of apertures in the mask base and in the interface elbow.

**Figure 14** is a perspective view from one side illustrating a vent including a tight cluster of apertures in the mask frame.

**Figure 15** is a perspective view from one side illustrating a patient interface where the vent is provided as a set of radially aligned groupings of apertures.
**Figure 16** is a perspective view from one side illustrating a patient interface where the vent is provided by a group of apertures distributed around the perimeter of the elbow joint.

**Figure 17** is a perspective view of a patient interface in use on a patient, the patient interface including a washout vent as a cluster of apertures in the interface elbow, the vent facing away from the patient.

**Figure 18** is a chart illustrating the flow resistance of a vent according to the most preferred embodiment of the present invention.

**Figure 19** is a chart comparing sound levels measured for gases flowing through vents with apertures with different cross-sectional profile. Bar 20A represents the sound level with a cross section according to the preferred embodiment of the present invention. Bar 20B represents the sound level where the apertures expand from the inlet side to the outlet side. Bar 20C represents the sound level for a vent where the apertures contract from the inlet side to the outlet side.

**Figure 20** illustrates the three cross aperture cross sections used in the testing of Figure 19.

**DETAILED DESCRIPTION**

Preferred embodiments of the present invention will be described with reference to the figures. According to a first aspect, the invention consists in the shape for an aperture for passing a flow of exhaust gases from the inside of a patient interface to the outside of the patient interface. This shape is best illustrated in the cross section of Figure 3. The shape of each aperture 303 includes a rounded entry 301 at the interior surface 313. The rounded entry has a gradually decreasing cross section. A mid portion 305 gradually tapers toward the mid thickness plane 309 of the wall before gradually expanding. A rounded exit 307 extends between the mid portion 305 and the exterior surface 311.

The preferred apertures have a uniform circular cross-sectional shape (the sectional plane being perpendicular to the flow axis of the aperture).

The aperture could have other sectional shapes, or the aperture may have a non-uniform cross-sectional shape, while still utilising the variation of cross-sectional area that is characteristic of the present invention. In referring to the apertures having a uniform cross-sectional shape, the size of the aperture at each section will vary relative to the size of the aperture at other parallel sections, while the shape remains the same.

With reference to Figure 3, the external diameter 3A of the hole is preferably between 0.7mm and 3.4mm. The diameter 3E of the hole at the interior surface is preferably between 0.7mm and 3.4mm. The smallest internal diameter of the hole, 3B, is preferably between 0.2mm and 1.8mm. The radius 3C at the entrance to the hole and the radius 3F at the exit to the hole are preferably between 0.2mm and 0.7mm.
The most preferred dimensions have the diameter at the interior surface and at the exterior surface about 1.5mm to 2mm, the smallest internal diameter, 3B, about 0.5mm to 1mm and the radius 3C and 3F, about 0.4mm to 0.6mm. The most preferred embodiment has the diameter at the interior surface and the diameter at the exterior surface (3A and 3E) as 1.8mm, the minimum internal dimension 3B at 0.75mm, the radius 3C, 3F at 0.45mm.

The wall thickness 3D of the interface at the location of the apertures is preferably between 0.8mm and 3.4mm, more preferably between 1.5mm and 2.5mm and most preferably about 2mm.

The minimum internal diameter preferably occurs midway from the interior surface to the exterior surface.

The effective flow for each aperture is largely governed by the narrowest portion of the aperture. Having selected a required flow restriction, a preferred number of apertures and hole sizes can be selected based on the cross-sectional area of the narrowest portion. The further shape of the hole can then be developed from the narrowest diameter. So, for example, the hole should exhibit a gradual increase in cross-sectional area, the rate of increase itself increasing, moving toward the surface of the vent. The diameter at the surface should be between two to four times the diameter at the narrowest point.

Referring to Figures 1 to 6, the gas washout vent of the patient interface preferably comprises one or more clusters of apertures. Preferably, each aperture is formed having a shape such as illustrated in Figure 3.

The cluster of apertures may be formed directly in the wall of the patient interface, for example, in the wall of a mask frame or swivel elbow (as will be explained with reference to Figure 9), or may be formed in an insert fitted into an aperture in the wall of the patient interface (as will be explained with reference to Figures 10A-11B). The insert may be permanently fixed in the aperture or replaceable. Permanent fixing, or moulding directly into the wall of the interface is preferred, however, a removable insert has a benefit that the total area of the bias flow outlet can be selected to match a required flow resistance. For example, a patient requiring lower treatment pressures but desiring high flow could have a vent with larger or more apertures.

Figures 1 to 6 illustrate arrangements of apertures in a cluster. These are illustrated on an oval disk portion of a wall of the interface. This is for illustrative purposes only, and the oval shape has no significance.

In the arrangement of Figures 1 and 2, the apertures of the cluster 201 are provided in a grid arrangement. The holes are symmetrically aligned with each other and patterned to provide the closest possible, or nearly closest possible spacing. Preferably the distance 2A between rows of holes is between 0.6mm and 3.3mm. This distance refers to the distance between hole centres.

The most preferred distance is about 1.7mm. The distance 2B between adjacent holes in a row is
slightly larger than the hole diameter at the surface, and is preferably between 0.9mm and 3.6mm. Most preferably this distance is about 2mm.

A hole arrangement where the holes are entirely separated, so that the holes do not interfere at the surface is preferred. In moulding the vent from a plastic material, the holes can be formed by replaceable prongs in the mould tool. For holes of this profile, the moulding tools may include prongs from each mould half meeting at a approximately the mid thickness of the part, so that the parting line is mid way through each aperture. As individual prongs are occasionally damaged during manufacture, the tool may be constructed so that the individual prongs can be removed and replaced readily. Individual prongs will be easier to manufacture if they have a rotationally symmetric external profile. If the holes are made to overlap at the surface, the contoured individual prongs would be more complex.

Furthermore, it is believed that overlapping holes, at the exterior surface, would lead to converging flows, which might lead to more noise.

Where the vent is made as an insert, the insert could be made as a laminate structure comprising two parts, each manufactured with holes formed from one side, with these parts joined back to back. The parts might be joined, for example, by a very finely applied adhesive or by an adhesive tape having complimentary apertures, with the tape sandwiched between the two portions.

An alternative arrangement of holes is illustrated in Figure 4. In this version, a large number of holes are arranged in a similar layout to the arrangement in Figure 2. The arrangement in Figures 1 and 2 has 36 holes with an internal diameter of approximately 0.75mm. The arrangement of Figure 4 has 46 holes of equivalent size.

Figure 5 illustrates another variation with fewer holes than Figure 2, but a similar arrangement. The arrangement of Figure 5 has 32 holes.

Figure 6 shows a further alternative arrangement in which the holes are arranged in a separated layout. In this layout, the holes are arranged in a matrix of rings. This more open configuration may offer better dispersion of the exiting flow. The illustrated cluster in Figure 6 includes 29 holes.

Figures 7 to 16 illustrate different arrangements of bias holes relative to the patient interface. In particular, Figures 7, 8, 9, 10A, 10B, 11A, 11B and 13 illustrate interface arrangements in which the bias flow holes are provided on an elbow extending from the mask. Figures 12 to 16 illustrate arrangements where the bias flow holes are provided on the mask. Figure 13 illustrates an arrangement in which a cluster 1010 of bias flow hole is provided on the connector 1009 extending from the mask and additional clusters 1001 are provided on the body 1005 of the mask.
Referring to Figure 7, a cluster 701 of bias holes are provided in the wall of a connector 703 that in use is connected to the body of the mask. The preferred connector is an elbow that extends between a first opening 705 proximal to the mask in use and a second opening 706 to which conduit or tubing typically connects in use. The elbow may turn the gases flow through an angle of up to 90°. Preferably the elbow turns the gases flow through an angle between 30° and 60°. The bias flow holes are preferably located toward the outside of the bend of the elbow. Preferably the portion of the wall of the elbow where the bias flow holes are located essentially faces the mask opening 705 of the elbow, such that exhalation flow into the elbow through the mask opening (in the direction of arrows 707) is directed by the portion of the elbow connector adjacent the mask, directly toward the bias flow holes 701. The elbow may include a funnel, tube or passage extending from the mask opening 705 to the bias flow vent.

The same basic arrangement is illustrated in Figure 8.

In the arrangement illustrated in Figure 7, the exterior surface 709 of the vent is substantially flush with the exterior surface 711 of the elbow. In the arrangement of Figure 8, the exterior surface 801 of the vent is recessed relative to the exterior surface 803 of the elbow connector 805. The thickness of the wall at the vent may be substantially the same as the thickness of the wall of the elbow or connector, or may be reduced relative to the thickness of the wall of the elbow or connector.

The bias flow holes in the cluster 701 or 801 may be aligned with their flow axis perpendicular to the wall of the elbow, or aligned to the direction of exhalation flow passing through the portion 708 of the elbow that is proximal to the mask. For example, the flow axis may be aligned to the direction of arrows 707.

As mentioned above, the vent may be integrally formed in the wall of a patient interface or may be formed as a vent insert that is permanently or releasably fixed into a corresponding vent aperture of the patient interface. Figures 9-11B show examples of such configurations in which the vent is provided in the wall of the elbow connector of the patient interface and these will now be described, although it will be appreciated that the vent or vents may be similarly provided at other suitable locations in the wall of the interface, including but not limited to the mask frame or body, connector, or in another part or portion of the delivery conduit of the interface.

Figure 9 is an elbow connector 750 similar to that shown in Figure 7, and like reference numerals represent like components or parts. Like in Figure 7, the connector 750 is provided with a vent in the form of a cluster of bias flow holes 752 (only a selection shown for clarity) formed in a portion of the wall 754 toward the outside bend of the elbow. As shown, the bias flow holes 752 are formed integrally and directly through the portion of the wall 754 of the connector.
Figures 10A and 10B show an elbow connector 760 similar to that shown in Figure 9, and like reference numerals represent like components or parts. Elbow connector 760 also comprises a vent in the form of a cluster of bias flow holes 752 (only a selection shown for clarity), but the vent is provided as vent insert 756 that is received and retained within a complementary vent aperture formed in the wall portion 754. The vent insert 756 may be a component having a have a disc or oval shape when viewed in plan like the vent portion shown in Figure 2, although this shape is not essential. The vent aperture provided in the wall portion 754 of the connector 760 has a complementary size and shape to the vent insert. In this configuration, the vent insert 756 is received and retained in place in the wall of the connector by a tongue and groove arrangement.

As shown in Figure 10B, the vent insert 756 is provided with a tongue 758 or protrusion extending about the periphery of the outer surface of the insert that engages securely into a complementary shaped groove 759 or recess extending about the peripheral surface of the vent aperture in the wall portion 754 of the connector. It will be appreciated that the arrangement may be reversed if desired with the tongue being provided on the vent aperture and the groove being provided on the vent insert. As shown, the tongue and groove arrangement extends continuously about the entire periphery of vent insert and complementary vent aperture, but it will be appreciated that the arrangement may be discontinuous in other forms with a plurality of spaced apart pairs of individual protrusions and complementary recesses being provided about the periphery of the vent insert and vent aperture. It will be appreciated that the vent insert may be either permanently fixed within the vent aperture by virtue of a tongue and groove arrangement alone or in combination with other fixing mechanisms, sealing or adhesives, or alternatively the tongue and groove arrangement may be configured to allow for the vent insert to be releasable from the vent aperture such that it can be replaced by another vent insert if desired in particular applications. For example, the vent insert may be configured to snap-out of the vent aperture by the application of a suitable external force.

Figures 11A and 11B show an elbow connector 770 similar to that shown in Figures 10A and 10B with a clip-in vent insert 756 received and retained in a complementary vent aperture formed in the wall portion 754 of the connector, and like reference numerals represent like components or parts. Again, the vent insert 756 may be a component having a disc or oval shape when viewed in plan like the vent portion shown in Figure 2, although this shape is not essential. The vent aperture provided in the wall portion 754 of the connector 770 also has a complementary size and shape to the vent insert. In this configuration, the vent insert 756 is received and retained in place within the vent aperture of the wall portion 754 of the connector by two opposed cantilevered resilient clips 772 extending from the underside of the vent insert at opposite sides of the periphery of the vent insert and which lock, engage or latch with complementary engagement
or catch surfaces 774 associated with the vent aperture. In this configuration, the clips 772 are each provided with latching portions having angled latching surfaces 776 that engage with complementary angled catch surfaces 774 associated with the vent aperture. The latching portions of the clips protrude outwardly relative to the periphery of the vent insert and vent aperture. In this example, the catch surfaces 774 are formed on the inner surface of the wall portion 754 of the connector adjacent the vent aperture edge. During installation, the vent insert 756 is inserted or pushed into the vent aperture such that the clips 772 bend inwardly relative to their rest position during partial engagement and then upon full engagement snap outwardly toward their rest position into a locked or latched engagement position with their complementary catch surfaces to secure the vent insert within the vent aperture. It will be appreciated that more than two clips could be used about the periphery of the vent insert in alternative forms of the clip-in configuration. It will also be appreciated that the vent insert may be either permanently fixed within the vent aperture by virtue of the clips alone or in combination with other fixing mechanisms, sealing or adhesives, or alternatively the clips may be configured to allow for the vent insert to be releasable from the vent aperture such that it can be replaced by another vent insert if desired in particular applications. For example, the vent insert may be configured to snap-out of the vent aperture by the application of a suitable external force while manipulating the clips into an unlocked or unlatched position.

In the examples of Figures 10A-11B, the vent insert may be formed from the same material as the surrounding body of the elbow connector, such as rigid plastic material including, but not limited to, polycarbonate and polypropylene, or any other suitable material. Alternatively, the vent insert 754 may be formed from a material that is different to that of the surrounding body of the elbow connector, if desired.

Figures 12 to 16 illustrate an assembled patient interface including an elbow connector and a mask. The mask includes a body portion and a seal portion. Typically the body portion is formed from a rigid plastic material such as polycarbonate or polypropylene. Typically the seal portion is formed from a soft and resilient material such as silicone or kraton. However, the body portion may also be formed from a soft, resilient material, but typically of a higher stiffness due to a combination of material and form. The illustrated mask is only illustrative. The bias flow hole profile of the present invention may be used in a wide range of interface products.

In the embodiment of Figures 12 and 14, the gas washout vent is provided by clusters 901, 903 of apertures in the body 905 of the mask. Preferably a pair of clusters are arranged on either side of the gas flow connector. However on other interfaces, such as nasal masks or full face masks, or nasal pillows interfaces, other locations for clusters of apertures may be available and preferred.
In the embodiment of Figure 15, a plurality of groups 1201 of apertures are provided, arranged in a radiating pattern either side of the swivel elbow 1203. Again, these apertures are provided in the body 1205 of the mask.

In the embodiment of Figure 16, the holes are arranged and distributed around the perimeter of the socket 1305 that holds the swivel elbow 1303 on the mask body 1307.

In all of the arrangements of Figures 7 to 16, each of the apertures of the bias flow vent is formed with a shape according to the present invention, as has been described earlier with reference to Figure 3.

Figure 17 illustrates a complete patient interface that might incorporate the bias flow holes according to the present invention. This interface includes a mask 1401 with a mask body 1403 and inflating nasal seal 1405. A strap 1407 extends from either lateral portion of the mask body 1405. A swivel elbow 1409 extends from a front portion of the mask body and a flexible conduit 1411 depends from the swivel elbow 1409. The flexible conduit 1411 is supported from a collar 1413 which can be fitted around the neck of the patient and adjusted to size.

The bias flow vent 1415 is located on the exterior of the swivel elbow 1409, on the outside of the bend of the swivel elbow. This location directs the gas flowing from the bias flow holes away from the face of the patient as illustrated by arrows 1417.

Figure 18 illustrates the pressure response of a prototype vent incorporating bias flow holes according to the present invention. The prototype vent was as illustrated in Figure 1, with the most preferred dimensions described earlier. This confirms that the vent exhibits a linear increase of exhaust flow relative to increasing air pressure. The test confirms a bias flow exceeding 15 litres per minute at 4 cmH₂O, rising to approximately 42 litres per minute at 20 cm H₂O. This range is suitable for use with existing CPAP therapy devices.

Figure 19 is a chart providing a comparison of the sound levels of vents with different bias flow geometries. The bias flow hole geometries subject of the tests illustrated in Figure 19 are illustrated in Figure 20. In relation to geometry 20A the vent included an arrangement of holes arranged as illustrated in Figure 1. A vent of a Fisher & Paykel Healthcare OPUS interface included holes of geometry 20B. A vent of a ResMed Swift LT interface included holes of geometry 20C. The vents were tested to ensure that each vent provided the same bias flow (26 to 27 litres per minute) during the sound test. The sound pressure level was measured for each vent using a sound meter configured to apply the dBA weighting. The sound pressure level was measured at the same distance from the vent for each test. This distance was approximately 15 cm.

Hole type 20A is of the form discussed above in relation to Figures 1 to 3. This used the most preferred hole geometry described in relation to those Figures. Hole type 20B had a
frustoconical shape, with diameter steadily increasing from the inside surface of the wall to the outside surface of the wall. The inside diameter was 0.65mm and the outside diameter was 1.0mm.

Hole type 20C was of a frustoconical shape with the diameter steadily decreasing from the inside surface of the vent to the outside surface of the vent.

The average sound level recorded for the vent using hole geometry 20A was 30.5dba. The average sound pressure level for the vent including the holes with geometry 20B was 35dba. The average sound pressure level for the vent having holes with the geometry 20C was 31.5dba. While these differences are not numerically large, small differences in sound pressure level equate to large increases in perceived volume. This is exacerbated in the sleep setting in which these products are used.
CLAIMS

1. A patient interface for supplying respiratory therapy to a patient that comprises a vent allowing a leak or bias flow to exit the interface in use, the vent comprising a plurality of apertures, an aperture of the vent extending in a first direction from an interior surface to an exterior surface of the interface, the aperture having a varying cross sectional area along the first direction, the cross section being defined perpendicular to the first direction, the area decreasing moving from the interior surface to a first intermediate location within the aperture, and decreasing moving from the exterior surface to a second intermediate location within the aperture.

2. A patient interface as claimed in claim 1 wherein the first and second intermediate locations are coincident at a common location.

3. A patient interface as claimed in claim 2 wherein the cross sectional area progressively decreases moving toward the common location.

4. A patient interface as claimed in any one of claims 1 to 3 wherein the cross sectional area decreases between 50% and 95% between the interior surface and the first intermediate location.

5. A patient interface as claimed in any one of claims 1 to 4 wherein the cross sectional area decreases between 50% and 95% between the exterior surface and the second intermediate location.

6. A patient interface as claimed in claim 3 wherein the common location is between 30% and 70% of the distance along the aperture between the interior and exterior surface.

7. A patient interface as claimed in any one of claims 1 to 6 wherein the aperture has substantially uniform cross sectional shape, and at any point along the first direction has a nominal diameter represented by the perimeter of the cross section divided by pi.

8. A patient interface as claimed in claim 7 wherein the nominal diameter decreases at a diminishing rate moving from the interior surface to the first intermediate location.

9. A patient interface as claimed in claim 7 or claim 8 wherein the nominal diameter decreases at a diminishing rate moving from the exterior surface to the second intermediate location.
10. A patient interface as claimed in any one of claims 1 to 9 wherein the portion of the aperture from the interior surface to the first intermediate location is not frustoconical.

11. A patient interface as claimed in any one of claims 1 to 10 wherein the portion of the aperture from the exterior surface to the second intermediate location is not frustoconical.

12. A patient interface as claimed in any one of claims 7 to 9 wherein the nominal diameter decreases according to an exponential function.

13. A patient interface as claimed in any one of claims 1 to 12 wherein the cross sectional area is the same (within 20%) at the exterior surface and at the interior surface.

14. A patient interface as claimed in any one of claims 1 to 13 wherein the plurality of apertures is in the form of a cluster of apertures.

15. A patient interface as claimed in claim 14 wherein the cluster comprises between 10 and 100 apertures.

16. A patient interface as claimed in claim 14 or claim 15 wherein each aperture has a minimum cross sectional area of between 0.03mm$^2$ and 2.51mm$^2$.

17. A patient interface as claimed in any one of claims 1 to 16 wherein the distance along the first direction from the interior surface to the exterior surface is between 0.8mm and 3.4mm.

18. A patient interface as claimed in any one of claims 1 to 17 wherein the plurality of apertures is in the form of multiple clusters of apertures.

19. A patient interface as claimed in any one of claims 14 to 16 or claim 18 wherein each cluster of apertures is within a boundary 60mm long.

20. A patient interface as claimed in any one of claims 1 to 19 wherein the vent is formed in a wall of the interface with a thickness of the wall at the vent being less than the thickness at areas immediately outside the vent.
21. A patient interface as claimed in any one of claims 1 to 20 wherein in total the vent comprises between 10 and 100 apertures, the apertures each having a minimum cross sectional area between 0.1mm² and 2mm², and the flow resistance of the vent is such as to provide a resistance of at least 1cmH₂O at a flow of 15LPM and a resistance of less than 20cmH₂O at a flow of 30LPM.

22. A patient interface as claimed in any one of claims 1 to 21 wherein the interface comprises a seal and a body supporting the seal, and the vent is integrally formed with the body.

23. A patient interface as claimed in any one of claims 1 to 21 wherein the interface comprises a seal and a body supporting the seal, and the vent is separately formed and inserted into the body.

24. A patient interface as claimed in any one of claims 1 to 21 wherein the interface comprises a seal and a body supporting the seal, and the vent is provided in the form of a vent insert that is received and retained in a complementary vent aperture provided in the body.

25. A patient interface as claimed in any one of claims 22 to 24 wherein in the vent area the wall thickness is between 50% and 80% of the average wall thickness of the body.

26. A patient interface as claimed in any one of claims 22 to 25 wherein the body is made from a rigid plastic.

27. A patient interface as claimed in claim 26 wherein the rigid plastic is selected from either polycarbonate or polypropylene.

28. A patient interface as claimed in any one of claims 22 to 25 wherein the body is made from a soft plastic.

29. A patient interface as claimed in claim 28 wherein the soft plastic is selected from either urethane or silicone.

30. A patient interface as claimed in any one of claims 1 to 29 wherein the interface comprises an inlet, and a delivery conduit connected to the inlet, and the vent is integrally formed with the delivery conduit.
31. A patient interface as claimed in any one of claims 1 to 29 wherein the interface comprises an inlet, and a delivery conduit connected to the inlet, and the vent is separately formed and inserted into the delivery conduit.

32. A patient interface as claimed in any one of claims 1 to 29 wherein the interface comprises an inlet, and a delivery conduit connected to the inlet, and the vent is provided in the form of a vent insert that is received and retained in a complementary vent aperture provided in the delivery conduit.

33. A patient interface as claimed in any one of claims 30 to 32 wherein the delivery conduit comprises an elbow, and the vent is integrally formed with the elbow.

34. A patient interface as claimed in any one of claims 30 to 32 wherein the delivery conduit comprises an elbow, and the vent is separately formed and inserted into the elbow.

35. A patient interface as claimed in any one of claims 30 to 32 wherein the delivery conduit comprises an elbow, and the vent is provided in the form of a vent insert that is received and retained in a complementary vent aperture provided in the elbow.

36. A patient interface as claimed in any one of claims 33 to 35 wherein in the vent area the wall thickness is between 50% and 80% of the average wall thickness of the elbow.

37. A patient interface as claimed in any one of claims 24, 32 or 35 wherein the vent insert is permanently fixed within the vent aperture.

38. A patient interface as claimed in any one of claims 24, 32 or 35 wherein the vent insert is releasably retained within the vent aperture.

39. A patient interface according to claim 37 or claim 38 wherein the vent insert is retained within the vent aperture by a tongue and groove arrangement.

40. A patient interface according to claim 37 or claim 38 wherein the vent insert is retained within the vent aperture by clips extending from the underside of the vent insert and which clip into the vent aperture.
FIGURE 18
Comparison of sound levels for different bias hole geometries

FIGURE 19
A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.
A61M 16/06 (2006.0 1)  A62B 18/02 (2006.0 1)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Electronic data base consulted during the international search (name of database and, where practicable, search terms used)
EPDOC, WPI: IPC/EC A61 M, A62B and keywords: mask, vent, aperture, profile, shape, noise, exhaust; and like terms

GOOGLE PATENTS: mask, vent, orifice, noise, hourglass; and like terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td>EP 2027880 A1 (RESMED LIMITED) 25 February 2009 See abstract; paragraphs [0002], [01 20], [01 19]-[01 39], [02 10]-[03 12]; figs. 2-2-1 , 2-2-2, 2-4, 2-6, 2-10-1, 2-18-1, 2-1 8-2, 2-2 1-1 to 2-2 1-3, 4-7 A to 4-D</td>
<td>1-40</td>
</tr>
</tbody>
</table>

Further documents are listed in the continuation of Box C X See patent family annex

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referred to in an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"K" document member of the same patent family

Date of the actual completion of the international search
12 August 2011

Date of mailing of the international search report
16.08.2011

Name and mailing address of the ISA/AU
AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606, AUSTRALIA
E-mail address: pct@ipaustralia.gov.au
Facsimile No. +61 2 6283 7999

Authorized officer
E. W. SOO
AUSTRALIAN PATENT OFFICE
(ISO 9001 Quality Certified Service)
Telephone No: +61 2 6283 2138
This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>EP 2027880</td>
<td>CN 101380497 JP 2009050707 NZ 570796</td>
</tr>
<tr>
<td>US 20090050 156</td>
<td></td>
</tr>
<tr>
<td>US 20080276937</td>
<td>NZ 568159 NZ 579280</td>
</tr>
<tr>
<td>WO 9834665</td>
<td>AU 53019/98 AU 58476/98 EP 0968022</td>
</tr>
<tr>
<td>JP 200151035</td>
<td>JP 200434467 1 JP 2008119538</td>
</tr>
<tr>
<td>JP 2011019922</td>
<td>US 6561190 US 6561191</td>
</tr>
<tr>
<td>US 20030116160</td>
<td>US 7207335 US 2003007975 1</td>
</tr>
<tr>
<td>us 7845354</td>
<td>US 20070101998</td>
</tr>
</tbody>
</table>

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.