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(54) **RESPIRATORY MASK ASSEMBLY**

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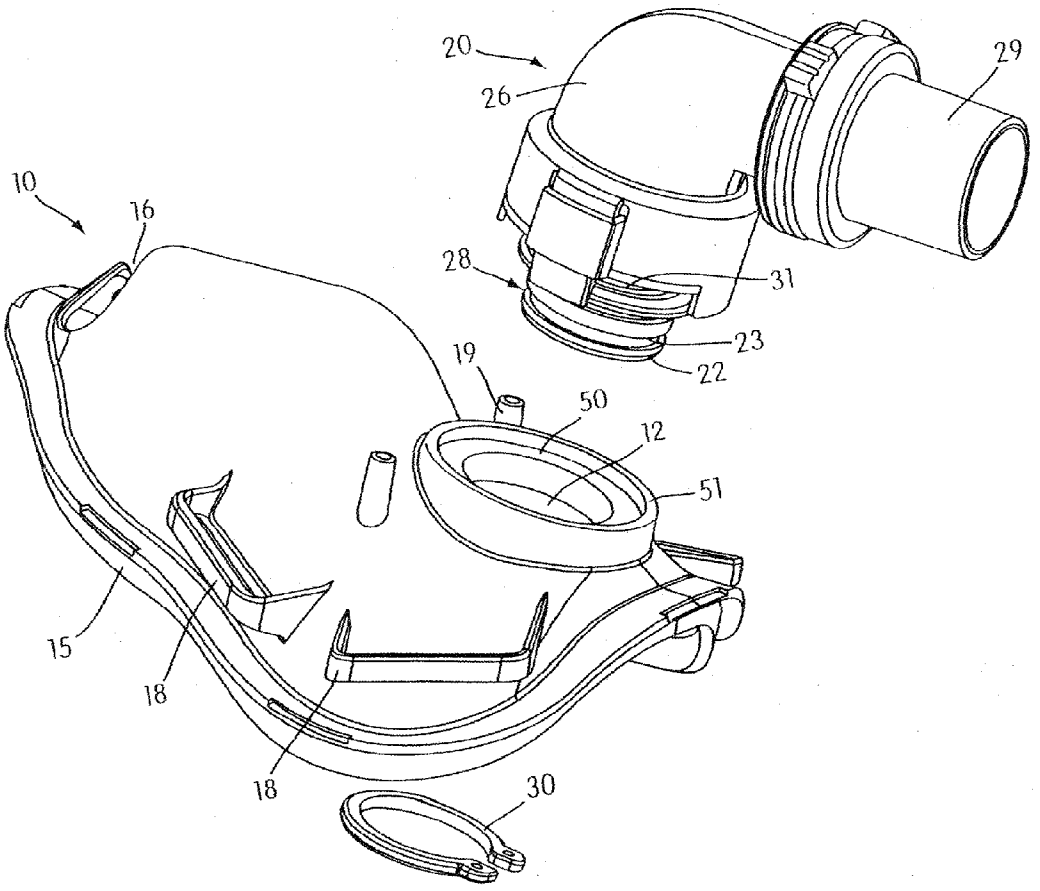
CPC ***A61M 16/20*** (2013.01); ***A61M 16/0816*** (2013.01); ***A61M 16/0057*** (2013.01); ***A61M 16/0622*** (2014.02)

(57) **ABSTRACT**

An elbow assembly includes an elbow with a first portion adapted to be secured to a mask and a second portion adapted to receive pressurized gas. The first and the second portions have a connection structure allowing selective connection and disconnection between the first and second portions. The connection structure includes a pair of resilient arms provided on one of the first and second portions and a flange provided on the other of the first and second portions. Each of the arms include a claw to lock with the flange. The elbow assembly also includes an anti-asphyxia valve (AAV) assembly provided within the elbow and sandwiched between the first and second portions. The AAV assembly has a movable portion that is movable to a closed position at which the movable portion extends across a gas flow path between the first and second portions and substantially prevents a flow of gas between the first and second portions.



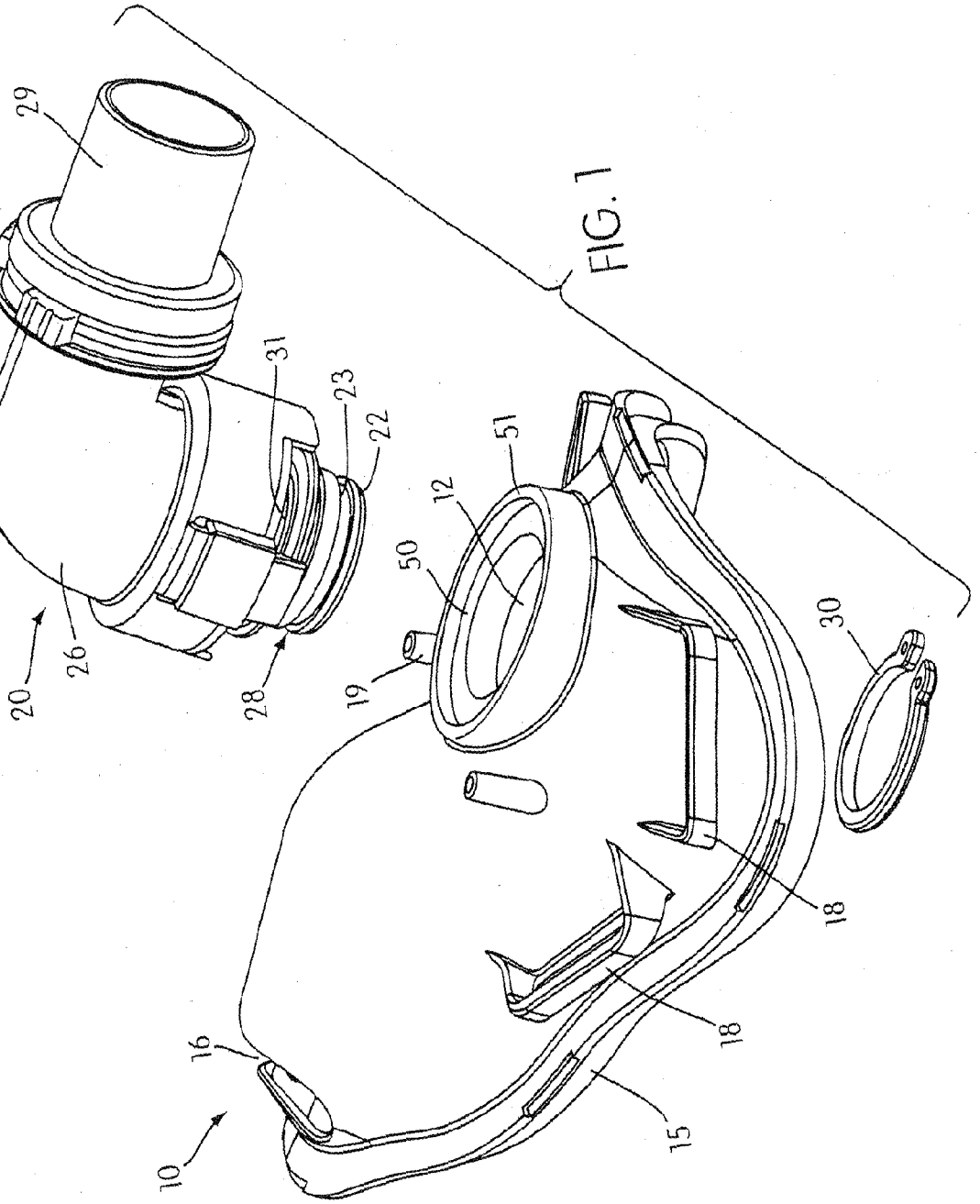


FIG. 1

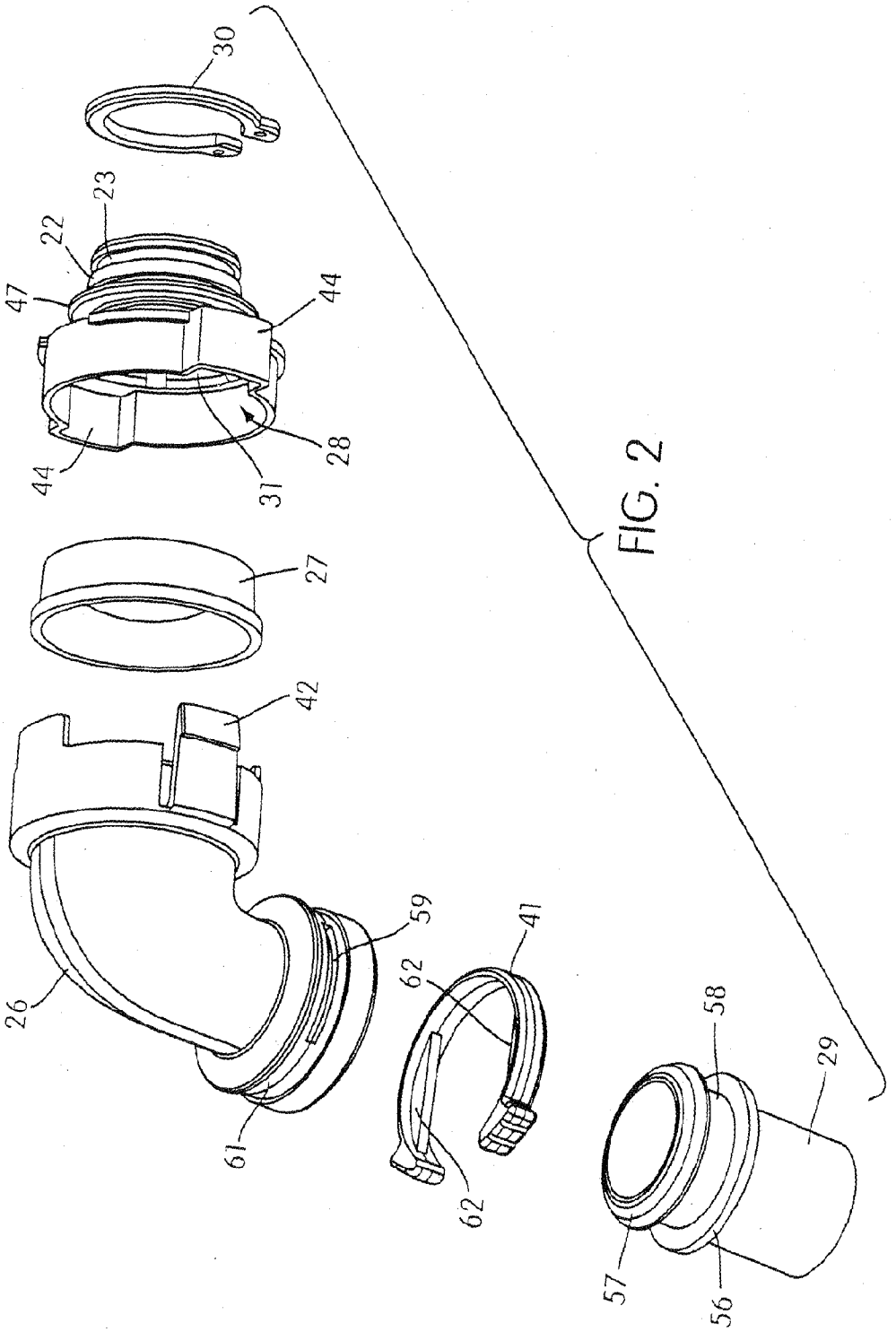
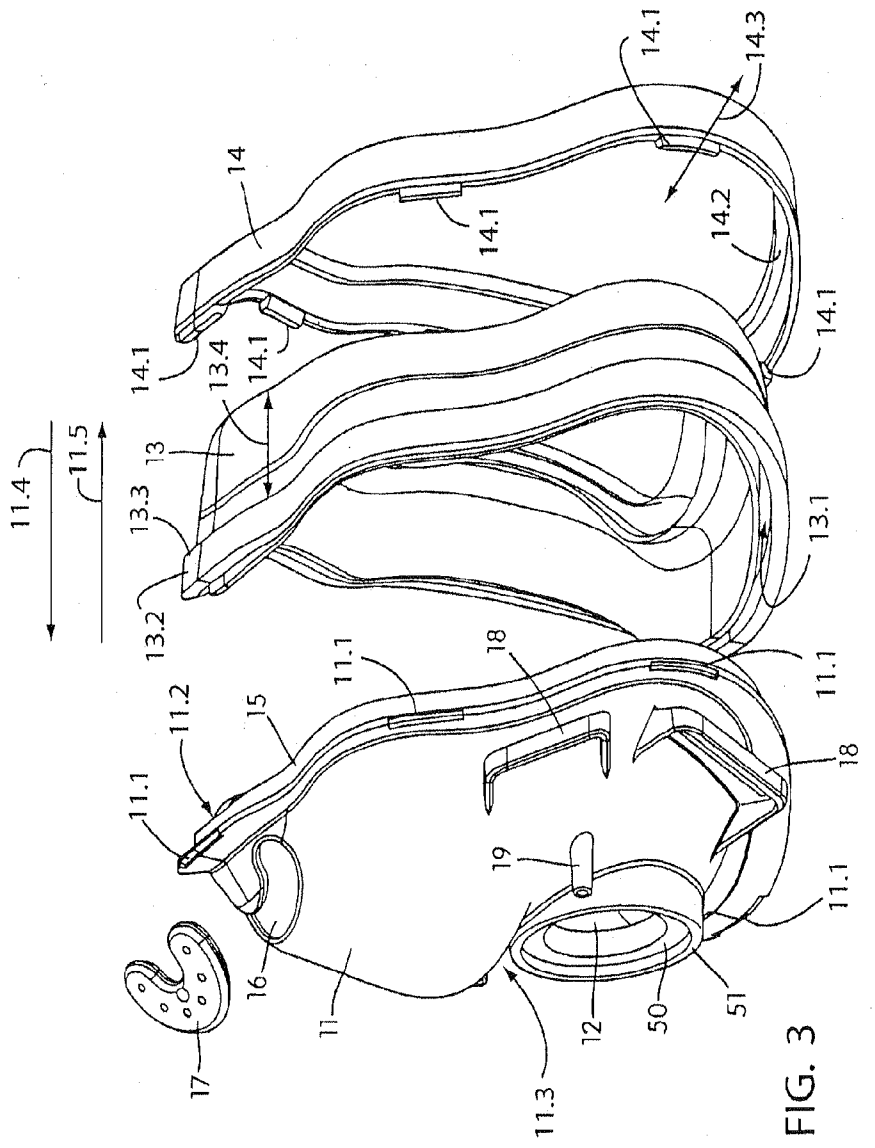


FIG. 2


11.4
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14.1
14.3
14.2
13.4
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51
11.3

FIG. 3

RESPIRATORY MASK ASSEMBLY

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. application Ser. No. 13/396,002, filed Feb. 14, 2012, now allowed, which is a continuation of U.S. application Ser. No. 12/419,442, filed Apr. 7, 2009, now U.S. Pat. No. 8,113,197, which is a continuation of U.S. application Ser. No. 11/322,237, filed Jan. 3, 2006, now U.S. Pat. No. 7,861,714, which is a continuation of U.S. application Ser. No. 10/164,370, filed Jun. 10, 2002, now U.S. Pat. No. 7,207,334, which is a divisional of U.S. application Ser. No. 09/498,705, filed Feb. 7, 2000, now U.S. Pat. No. 6,491,034, and related to the following applications: U.S. application Ser. No. 09/985,457, filed Nov. 2, 2001, now U.S. Pat. No. 7,185,652, and U.S. application Ser. No. 09/985,458, filed Nov. 2, 2001, now U.S. Pat. No. 7,089,939, and U.S. application Ser. No. 11/285,077, now U.S. Pat. No. 7,174,893, each incorporated herein by reference in its entirety.

FIELD OF THE TECHNOLOGY

[0002] The present technology relates to improvements in patient gas delivery apparatus of the kind used in the analysis and treatment of respiratory disorders. The invention will be described with particular reference to patient gas delivery apparatus used in the treatment of respiratory disorders such as Obstructive Sleep Apnea (OSA) but it is not intended to be limited thereto.

BACKGROUND OF THE TECHNOLOGY

[0003] Patient gas delivery apparatus of the kind having a mask worn by a patient and a gas delivery conduit attached to the mask are commonly used in the analysis and treatment of respiratory disorders. The gas conduit delivers a gas under pressure to the patient. It is necessary that the gas conduit is detachable from the mask to facilitate cleaning.

[0004] Patient gas delivery apparatus typically includes at a minimum, a gas delivery conduit and a nose or full face mask. In some cases it is a clinical requirement that additional components be included, such as means for CO_2 washout, for example, vents, anti-asphyxia valves and the like. In some cases, these additional components must be assembled in between the gas delivery conduit and the mask. Problems with prior art assemblies include: (a) they may be inadvertently assembled without the additional components; (b) they may be incorrectly assembled, for example, incorrectly aligned; (c) during the course of treatment, the patient may inadvertently remove or dismantle the assembly and incorrectly reassemble it.

[0005] Further, known mask cushions are usually molded from a relatively soft, resilient, elastic material and they are shaped during manufacture to match the facial contours of an average intended wearer. However, a problem with the known types of masks is that, because individuals vary so much from the average, the masks must be forced against their inherent resiliency to deform and so adapt to the shapes of the users in order to avoid gas leakage. This requires that the masks be secured firmly by retaining straps or harnesses in order to prevent air leakage.

[0006] Flow generators are typically utilized to deliver a breathable gas (i.e., air) to a patient wearing the mask. In CPAP treatment, gas is delivered to the patient's airways at about 2-30 cm H_2O above atmospheric pressure. The flow generator is generally connected to flexible tubing which is secured to the mask worn by the patient. If the flow generator's operation is interrupted as a result of a power outage or other mechanical or electrical failure, there may be a significant build up of carbon dioxide in the mask as the patient's exhaled air is not washed out of outlet vents which are usually contained in the mask. This may present a health problem to the patient.

[0007] There have been numerous patents which have addressed some sort of safety valve for gas or air delivery masks. An example of such a patent is U.S. Pat. No. 5,438,981. This patent discloses a counter balanced, rigid valve element which depending on the gas flow, either covers an opening to the ambient air or covers the gas flow airway such that the air or breathing gas is forced out into the ambient air opening. However, this system suffers from being a fairly complicated and expensive system whose correct operation relies on a counter balanced moving part moving relative to its housing. Further, if any condensation from the air gets on or around the balanced valve element, the operation of this valve element can be compromised. This valve is also difficult to clean.

[0008] Applicant's International Application PCT/AU97/00849 discloses a valve having a single valve element. However, whilst being simpler than preceding valves of this type, the valve shown in PCT/AU97/00849 still relies on the use of a rigid valve element moving relative to its housing and biased by magnets.

SUMMARY OF THE INVENTION

[0009] One aspect of the present invention is directed towards solving or ameliorating one or more of these problems. One aspect of the invention will be described with reference to a full face mask, though other forms of mask and additional components may be used.

[0010] According to one example, a respiratory mask assembly for delivering breathable gas to a patient comprises a mask frame having a first cooperating interlocking structure; a mask cushion provided to the frame and adapted to form a seal on the patient's face; a cushion clip to retain the mask cushion on the mask frame, the cushion clip having a second cooperating interlocking structure and being selectively attachable to and detachable from the mask frame, the first and second cooperating interlocking structures interlocking with one another in a cooperating relationship to secure the cushion clip on the mask frame; and an elbow joint provided to the frame and having a swivel tube adapted to connect to a gas delivery conduit, wherein the first and second cooperating interlocking structures are provided to at least a bottom and left and right sides of the mask frame and cushion clip, and include a tab-recess arrangement in which a plurality of tabs are engageable within respective recesses in interlocking relation to secure the clip to the frame.

[0011] According to another example, a respiratory mask assembly for delivering breathable gas to a patient comprises a mask frame having a first cooperating interlocking structure; a cushion clip having a second cooperating interlocking structure and being selectively attachable to and detachable from the mask frame, the first and second cooperating interlocking structures interlocking with one another in a cooperating relationship to secure the cushion clip on the mask frame; and a mask cushion adapted to form a seal on the patient's face and having an outer peripheral portion posi-

tioned between the mask frame and the cushion clip so as to seal the mask cushion on the mask frame.

[0012] According to yet another example, a respiratory mask assembly for delivering breathable gas to a patient comprises a mask frame; a mask cushion adapted to form a seal with the patient's face; and a clip member engaged with the mask cushion and structured to interlock with the mask frame, wherein the mask frame and the clip member include a tab-recess arrangement in which a plurality of securing tabs engage with a corresponding one of a plurality of recesses so as to retain the mask cushion on the mask frame, the tab-recess arrangement provided to at least a bottom and left and right sides of the mask frame and clip member.

[0013] These and other aspects of the invention will be described in or apparent from the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] Further examples of the present technology will now be described by way of example only with reference to the accompanying drawings in which:

[0015] FIG. **1** is a perspective view showing the mask, anti-asphyxia valve housing and conduit connection assembly;

[0016] FIG. **2** is an exploded view of the anti-asphyxia valve and conduit connection assembly shown in FIG. **1**; and

[0017] FIG. **3** is an exploded view of the mask assembly shown in FIG. **1**.

DETAILED DESCRIPTION

[0018] In FIG. **1** a mask frame is shown generally at **10**. The mask is designed to be worn on a patient's face and is secured by means of straps (not shown) received by attachment points **18**.

[0019] A conduit end assembly is shown generally at **20**, including an elbow part **26** having at one end thereof a combined vent/connector piece **28**. The elbow and vent/connector piece together form a housing for an anti-asphyxia valve (as will be further discussed) or other internal components (not shown). At the other end of the elbow is a detachable swivel tube **29** for connection of the gas delivery conduit (not shown).

[0020] The mask **10** includes a circular aperture **12** sized to receive a mating portion **22** of the vent/connector piece **28**. The mating portion **22** has an annular groove **23** formed therein that receives a locking means **30** in the form of a C-shaped clip attached after mating to the mask. The clip **30** has an outside diameter greater than the width of the aperture **12** and an inner diameter adapted to ensure a snug fit within the annular groove **23**. The clip **30** is resilient and can expand sufficiently to allow the clip to be fitted into and removed from the groove **23**. As shown in FIG. **1**, the clip **30** is located onto the mating portion **22** on the inside of the mask **10**. In this position, the clip **30** is inaccessible while the mask is being worn by a patient. Once the mating portion **22** of the vent/connector piece **28** has been inserted through the aperture **12** and the locking clip placed in the annular groove, the conduit end assembly **20** and the mask **10** cannot be separated without first removing the mask from the patient.

[0021] An exploded view of one embodiment of the anti-asphyxia valve and conduit connector assembly is shown in FIG. **2**.

[0022] As illustrated in FIG. **2**, the end of the elbow **26** adjacent the mask **10** is fitted with an anti-asphyxia valve arrangement that provides an air passage to the patient in the event of failure of the gas delivery apparatus, consisting of a valve membrane **27** fitted into the end of elbow **26** and vents **31** in the vent/connector piece **28**. During proper operation of the gas delivery system, the valve membrane remains in the orientation shown in FIG. **2**, closing off the vents **31**. In the event of a drop in pressure below a predetermined level, the valve membrane **27** flips to a reverse orientation, opening the vents **31**. The construction and operation of the anti-asphyxia valve is described in more detail in the Applicant's Australian Patent Application No. 65527/99, the contents of which are incorporated herein by reference and described herein.

[0023] Resilient detents **42** on the elbow **26** pass through and engage behind slot-forming formations **44** in the vent/connector piece **28** to provide releasable engagement of the two parts.

[0024] The vent/connector piece has a collar **47** that abuts a corresponding surface of the mask **10** to limit the distance that the vent/connector piece can be inserted into the mask aperture **12** (FIG. **1**). The corresponding surface is an annulus **50** having a protruding rim **51** the outer circumference of which preferably engages the inner surface of the detents **42** on insertion of the mating portion **22** into the aperture **12**. This engagement prevents the detents from being pushed radially inwards sufficiently for the detents to disengage from behind the slot-forming formations **44**, thus preventing the elbow **26** and vent/connector piece **28** from separating whilst still attached to the mask frame **11**, for example during patient treatment. The result of this is that the anti-asphyxia valve arrangement cannot be disassembled without first removing the elbow and vent/connector piece assembly from the mask. However, once disconnected from the mask, the assembly may be readily separated for cleaning and then reassembled.

[0025] The other, distal end of elbow **26** has an enlarged diameter portion which receives the swivel tube **29**, onto which a flexible gas conduit (not shown) may be fitted. The swivel tube **29** has a pair of flanges **56** and **57** defining an annular groove **58** therebetween. The end of swivel tube **29** is inserted into the elbow **26** until the end flange **57** abuts an inner surface (not shown) within elbow **26**. In this position the annular groove **58** is at least partially aligned with an annular groove **61** in the exterior of the elbow, which receives a swivel clip **41**.

[0026] The swivel clip **41** has an inner diameter only slightly greater than the diameter of the groove **61**, to ensure a snug fit within the groove. The clip **41** is resilient to permit sufficient expansion for attachment and removal of the clip from the groove. The groove **61** has slots **59** which receive lugs **62** on the clip. These lugs rotatably engage in the groove **58** between flanges **56** and **57** of the swivel tube. The swivel tube arrangement thus acts as a rotatable coupling between the conduit and the elbow whilst allowing quick attachment and removal of the gas conduit from the elbow regardless of whether the assembly is attached to the mask at the time.

[0027] As shown in FIG. **3**, the mask includes a mask frame **11**, cushion **13** and cushion clip **14**. The cushion is received on a rib **15** extending around the periphery of the mask frame **11**. The cushion is held to the rib by the cushion clip **14**. The mask frame includes attachment points **18** that receive straps (not shown) for attaching the mask to the patient, an aperture **16** for receiving an air vent **17**, and measurement ports **19**.

[0028] The mask frame **11** includes a plurality of recesses **11.1** that provide a first cooperating interlocking structure and the cushion clip **14** includes a plurality of tabs **14.1** that is equal to a number of recesses in the mask frame **11** and provides a second cooperating interlocking structure. The plurality of tabs **14.1** engage a respective recess **11.1** to secure the cushion clip **14** on the mask frame **11**.

[0029] The mask assembly, in the example shown in FIG. **3**, is a full face mask. As shown in FIG. **3**, the frame includes top and bottom recesses, two left side recesses and two right side recesses (not shown). The cushion clip **14** includes corresponding top and bottom tabs **14.1** as well as two right side tabs (both shown) and two left side tabs (only one shown).

[0030] The mask cushion includes a groove **13.1** extending around the periphery thereof and the groove of the cushion receives the rib **15** of frame **11**.

[0031] The cushion **13** includes an outwardly extending portion **13.2** that provides the groove **13.1** on one side thereof. An opposite side of the outwardly engaging portion **13.2** provides a shoulder **13.3** that engages a flange **14.2** on the cushion clip **14** to retain the cushion **13** on frame **11**.

[0032] The cushion includes a rearwardly extending portion designated by reference number **13.4**. The cushion serves to seal the mask assembly on the patient's face, and is structured to space the mask frame **11** from the patient's face.

[0033] The frame **11** includes a first side **11.2** structured to accommodate cushion **13**, and a second side **11.3**. The cushion clip **14** and frame **11** are configured to cooperate with one another such that the cushion clip **14** is selectively attachable to the frame **11** in a first direction **11.4** defined generally from the first side **11.2** to the second side **11.3** of the frame, to thereby secure the cushion **13** between the cushion clip **14** and the frame **11**.

[0034] The cushion clip **14** and frame **11** are configured to cooperate with one another such that the cushion clip is selectively detachable from the frame **11** in a second direction **11.5**, opposite to the first direction **11.4**, defined generally from the second side **11.3** to the first side **11.2** of the frame **11**, to thereby allow removal of the cushion **13** from frame **11**.

[0035] Each tab **14.1** is resiliently movable in a third direction **14.3** that is substantially transverse to the first and second directions **11.4** and **11.5**. Tab portions **14.1** move in the direction indicated by arrows **14.3** when the tab portions are snapped or flexed into place within recesses **11.1**, and when they are removed therefrom.

[0036] While particular embodiments of this invention have been described, it will be evident to those skilled in the art that the present invention may be embodied in other specific forms without departing from the essential characteristics thereof. The present embodiments and examples are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

What is claimed is:

1. An elbow assembly comprising:

an elbow having a first portion adapted to be secured to a mask and a second portion adapted to receive pressurized gas, the first and the second portions having a connection structure allowing selective connection and disconnection between the first and second portions, the connection structure including a pair of resilient arms provided on one of the first and second portions and a flange provided on the other of the first and second portions, each of the arms including a claw to lock with the flange; and

an anti-asphyxia valve (AAV) assembly provided within the elbow and sandwiched between the first and second portions, the AAV assembly having a movable portion that is movable to a closed position at which the movable portion extends across a gas flow path between the first and second portions and substantially prevents a flow of gas between the first and second portions.

2. The elbow assembly of claim **1**, wherein the AAV assembly is separable from both the first and second portions.

3. The elbow assembly of claim **2**, wherein at least a portion of the AAV assembly forms an outer wall of the elbow assembly.

4. The elbow assembly of claim **3**, wherein the connection structure secures the AAV assembly to the elbow.

5. The elbow assembly of claim **1**, wherein the connection structure encloses the AAV assembly.

6. A respiratory mask assembly configured to deliver pressurized breathable gas to a patient, the respiratory mask assembly comprising:

a respiratory mask; and

the elbow assembly of claim **1**, the elbow assembly being removably connected to the respiratory mask.

7. The respiratory mask assembly of claim **6**, wherein the respiratory mask comprises:

a cushion configured to engage the patient's face; and

a frame configured to support the cushion and configured to receive the elbow assembly.

8. The respiratory mask assembly of claim **7** further comprising a cushion clip configured to secure the cushion to the frame.

9. An elbow assembly comprising:

a first portion adapted to be secured to a mask;

a second portion adapted to receive pressurized gas, the first and the second portions together defining a first flow path;

a connection structure configured to selectively connect the first portion to the second portion;

an opening in a sidewall of the elbow assembly, the opening in the sidewall defining a second flow path; and

an anti-asphyxia valve (AAV) assembly provided within the elbow assembly and sandwiched between the first and second portions, the AAV assembly having a movable portion that is movable to a closed position at which the movable portion extends across the second flow path and substantially prevents a flow of gas through the second flow path.

10. The elbow assembly of claim **9**, wherein the connection structure comprises a pair of resilient arms provided on one of the first and second portions and a flange provided on the other of the first and second portions, each of the arms including a claw to lock with the flange.

11. The elbow assembly of claim **9**, wherein the opening in the sidewall of the elbow assembly is located in a sidewall of the first portion.

12. The elbow assembly of claim **9**, wherein the AAV is configured to be in the closed position when pressurized gas is flowing from the second portion to the first portion through the first flow path.

13. The elbow assembly of claim **9**, wherein the AAV assembly is separable from both the first and second portions.

14. The elbow assembly of claim **9**, wherein at least a portion of the AAV assembly forms an outer wall of the elbow assembly.

15. The elbow assembly of claim **9**, wherein the connection structure secures the AAV assembly to the first and second portions.

16. The elbow assembly of claim **9**, wherein the connection structure encloses the AAV assembly.

17. A respiratory mask assembly configured to deliver pressurized breathable gas to a patient, the respiratory mask assembly comprising:

a respiratory mask; and

the elbow assembly of claim **9**, the elbow assembly being removably connected to the respiratory mask.

18. The respiratory mask assembly of claim **17**, wherein the respiratory mask comprises:

a cushion configured to engage the patient's face; and

a frame configured to support the cushion and configured to receive the elbow assembly.

19. The respiratory mask assembly of claim **18** further comprising a cushion clip configured to secure the cushion to the frame.

* * * * *