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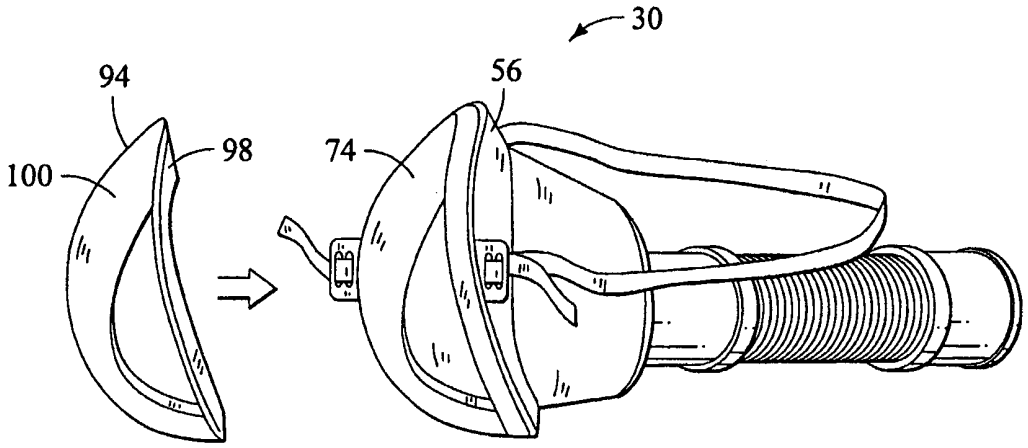
(54) Title: ADHESIVE NASAL MASK ASSEMBLY, SYSTEM AND METHOD OF USING SAME



(57) Abstract

This invention is a nasal mask assembly (30) that selectively secures over the nose of a patient without using a headgear as a primary attachment device to provide a flow of breathing gas to the patient. The nasal mask assembly (30) includes a body member (32) that is maintained over the nose of a patient by adhesively attaching the body member to the patient's face surrounding the nose. The body member includes a nose receiving cavity (34) in which a portion of the patient's nose is positioned during use. The body member (32) is sized, and configured such that the patient's mouth remains exposed when the nasal mask assembly is being worn by the patient. A flange (56) provided on an end of the body member (32) overlies a surface of a patient, and an adhesive layer (74) disposed on the flange secures the flange in a substantially sealed relation on the patient so that the supply of breathing gas can be provided to the patient's airway via the nasal mask assembly (30).

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ADHESIVE NASAL MASK ASSEMBLY, SYSTEM AND METHOD OF USING SAME

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention pertains to a nasal mask that selectively secures over the nose of a patient without the use of a headgear as a primary patient attachment mechanism to provide a flow of breathing gas to the patient, and, in particular, to a nasal mask assembly that is maintained over the nose of a patient by adhesively attaching to the patient's face surrounding the nose, and to a system and method for supplying a gas flow to a patient using such a nasal mask assembly.

2. Description of the Related Art

It is well known to provide positive pressure to a patient's airway to treat a breathing disorder. For example, a patient in respiratory distress may require a respirator, ventilator or other pressure support device to assist their respiratory function by delivering a flow of breathing gas to the patient's airway. Such a flow of breathing gas may be provided to augment the patient's respiratory effort or to replace the patient's respiratory effort entirely. It is also known to provide a flow of breathing gas to a patient to treat sleep apnea syndrome, which is a condition in which the patient suffers from repeated, temporary partial or complete cessation of breathing during sleep.

Conventional approaches for providing positive pressure to a patient's airway to treat a breathing disorder, for example, providing non-invasive ventilation to a patient in respiratory distress and treating sleep apnea, require that the user or caregiver secure a nasal mask over the nose of the patient to provide a patient interface for communicating the flow of breathing gas to the patient's airway. A flexible cushion on the nasal mask contacts the patient's skin to form a seal between the mask and the patient, thereby preventing breathing gas from leaking out between the patient-mask interface.

To ensure a proper substantially leak-free seal at this interface, a relatively large compression force must be applied on the flexible cushion of the nasal mask. This compression force is provided in a conventional patient interface assembly by a headgear assembly attached to the patient's head. Typically, the nasal mask and headgear assembly are

donned by the patient and then straps or other mechanisms on the headgear are tightened to provide the necessary compression force against the patient's face.

It can be appreciated that this conventional approach for providing an interface between the patient and the ventilator or other pressure support device, such as a continuous positive airway pressure (CPAP) device or bilevel airway pressure device, requires a relatively elaborate and complicated headgear assembly and mask attachment mechanism. Such a headgear assembly is relative costly and, for some users, may be difficult to don and tighten properly. In addition, the compressive force applied by the headgear on the face of the patient can be uncomfortable to some patients.

Furthermore, the conventional headgear/nasal mask system generally can not be easily or quickly placed on the patient to provide immediate pressure support. For example, it may be difficult or unsafe for a caregiver to manipulate the patient's head to place the headgear over the patient in its proper location. This is especially true, for example, if a patient is brought into an emergency room with a head or neck injury, in which case any jostling of the head to place the headgear on the patient should be avoided. Also, if the patient's head is immobilized by a backboard and straps, for example, it simply may not be physically possible to attach the conventional headgear to the patient, in which case the caregiver has no option other than to physically hold the nasal mask system in place on the patient or to revert to invasive ventilation.

SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide a nasal mask assembly that overcomes the shortcomings of conventional nasal mask and headgear patient interface systems. This object is achieved according to one embodiment of the present invention by providing a nasal mask assembly that includes a body member that defines a nose receiving cavity and having a first opening and a second opening that provide access to the nose receiving cavity. The first opening is defined in a first end of the body member and receives the nose of the patient such that a portion of the is disposed in the nose receiving cavity while the patient's mouth remains exposed. The second opening, which is defined in a second end of the body member, receives a supply of breathing gas to communicate the breathing gas to the nose receiving cavity. A flange associated with the first opening of the body member is configured and arranged such that a first surface of the flange overlies the patient's skin when the nasal mask assembly is positioned on the patient. An adhesive layer

is provided on the flange. The adhesive layer selectively engages the surface of the patient to maintain the flange in a substantially sealed relation with the patient, thereby adhering the nasal mask assembly to the patient so that positive pressure breathing gas can be administered to the patient without attempting to attach a headgear assembly over the patient's head.

It is yet another object of the present invention to provide a system and method for delivering a flow of breathing gas to a patient that does not suffer from the disadvantages associated with conventional systems. This object is achieved by providing a system and method of communicating a supply of breathing gas to a patient that includes: (1) providing a nasal mask having a body member defining a nose receiving cavity, with first and second openings providing access to the nose receiving cavity, a flange associated with the first opening, an adhesive layer disposed on the flange, and a protective cover layer disposed on the adhesive layer; (2) removing the protective cover layer to expose the adhesive layer; and (3) attaching the nasal mask over the patient's nose such that a portion of the nose is disposed in the nose receiving cavity with the adhesive maintaining the flange in a substantially sealed relation on the patient while allowing the patient's mouth to remain exposed.

These and other objects, features and characteristics of the present invention, as well as the methods of operation and functions of the related elements of structure and the combination of parts and economies of manufacture, will become more apparent upon consideration of the following description and the appended claims with reference to the accompanying drawings, all of which form a part of this specification, wherein like reference numerals designate corresponding parts in the various figures. It is to be expressly understood, however, that the drawings are for the purpose of illustration and description only and are not intended as a definition of the limits of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a side perspective view of a nasal mask assembly according to the principles of the present invention;

Fig. 2 is a front perspective view of the nasal mask assembly of Fig. 1;

Figs. 3A and 3B are front and rear perspective views, respectively, of a body member portion of the nasal mask assembly of Fig. 1;

Fig. 4 is a perspective view illustrating the attachment of the nasal mask assembly on a patient;

Fig. 5 is a sectional view of a sealing portion of the nasal mask assembly of Fig. 1;

Fig. 6 is an exploded view illustrating the components of the sealing portion of the nasal mask assembly;

Fig. 7 is a side perspective view of a nasal mask assembly including an auxiliary attachment assembly according to the principles of the present invention; and

Fig. 8 is a sectional view of the auxiliary attachment assembly of Fig. 7.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS OF THE INVENTION

Figs. 1 and 2 are side and front perspective views, respectively, of an exemplary embodiment of a nasal mask assembly 30 according to the principles of the present invention. Nasal mask assembly 30 includes a generally frustum shaped body member 32 that defines a nose receiving cavity 34 in which a portion of a patient's nose inserts so that the body member substantially encapsulates the patient's nose. Preferably, body member 32 is an elastomeric shell that flexes to allow or aid in contouring or conforming the nasal mask assembly to the facial features of the patient. Figs. 3A and 3B are front and rear perspective views, respectively, of body member 32, and Fig. 4 is a perspective view illustrating the attachment of nasal mask assembly 30 to a patient with the body member substantially encapsulating the patient's nose.

Body member 32 includes a first opening 36 defined in a first end 37 thereof to allow at least a portion of the patient's nose to be provided in nose receiving cavity 34 so that breathing gas delivered to the nose receiving cavity is communicated to the patient's airway via the nostrils. Body member 32 also includes a second opening 38 defined in a second end 39 thereof to communicate the supply of breathing gas from a ventilator or other pressure support device, such as a continuous positive airway pressure (CPAP) device or bilevel airway pressure device (not shown), to nose receiving cavity 34. A conduit 40 coupled to second opening 38 and the gas flow generating device communicates the flow of breathing gas between these two items.

In an exemplary embodiment of the present invention, second end 39 of body member 32 includes an integrally formed adapter 42 serving as a universal coupling for a variety of conduits. Of course, adapters or other devices can be used with adapted 42 to allow different sized conduits to be coupled to adapter 42. The present invention also contemplates

that adapter 42 can have a variety of shapes, sizes, and configurations to provide a variety of coupling configurations so that the body member can be coupled to a variety of elements.

In the illustrated exemplary embodiment of the present invention, conduit 40 includes a flexible portion 44 generally proximate to body member 32 so that body member 32 can be easily placed and comfortably maintained on the patient. In this illustrated embodiment, flexibility is provided in flexible portion 44 by providing a poppel tube as flexible portion 44. The poppel tube is a tube that includes a series of bellows that allow flexible portion 44 of conduit 40 to expand and contract in an axial direction, i.e., a direction along the length of the conduit. This poppel tube configuration also permits bending of flexible portion 44 so that the body member can move relative to the remaining portions of conduit 40, thereby increasing ease of use and patient comfort.

As shown in Figs. 2 and 4, the free end of flexible portion 44 attaches to the remainder of conduit 40 to couple nasal mask assembly 30 to a ventilator or other pressure support device to communicate a flow of breathing gas between the nose receiving cavity of body member 32, and, hence, the patient's airway, and the ventilator. It is to be understood that additional elements can be coupled to conduit 40 and/or adapter 42. For example, the present invention contemplates coupling an exhaust port member 46 in conduit 40. Exhaust port member 46 includes an exhaust port 48 that allows gas, preferably expired gas from the patient, to pass from the interior of conduit 40 to ambient atmosphere. Suitable exhaust port members are well known. See, for example, U.S. Patent No. 5,002,050 to McGinnis, the contents of which are hereby incorporated by reference into the present application. Another example of suitable exhaust port members are the Whisper Swivel® Exhalation Port and Whisper Swivel® II Exhalation Port manufactured by Respironics, Inc. of Pittsburgh, PA, which are passive exhaust ports that have specific configurations for the exhaust vent to allow gas to vent from the conduit. The Whisper Swivel® Exhalation Port provides a series of slits in the conduit for venting exhaust gasses away from the patient, and the Whisper Swivel® II Exhalation Port provides the exhaust port at a coupling joint so that the point of rotation in the conduit also serves as the exhaust vent. The present invention also contemplates that other elements, including well known elements, such as a pressure port and tubing 50, flow meter, temperature sensor, bacteria filter, heater, and humidifier, can be coupled to or provided in conduit 40.

In the illustrated embodiment, body member 32 includes an exhaust port 52 defined in second end 39. Exhaust port 52, like exhaust port 48, allows gas within the

breathing circuit, which includes conduit 40 and body member 32, to vent into the ambient atmosphere. This is particularly necessary in single-limb ventilation systems that lack a conduit dedicated to carrying exhaust gases from the patient so that these gases can be vended to the ambient atmosphere. It is to be understood, however, that exhaust port 52 can be eliminated if a two-limb breathing circuit is used or if, in a single-limb circuit, a suitable exhaust port, such as exhaust port 48, is provided in conduit 40 or an attachment associated therewith. Likewise, exhaust port 48 can be eliminated if a two-limb breathing circuit is used or if, in a single-limb circuit, exhaust port 52 is configured to function as the sole exhaust port, which may require sizing exhaust port 52 or providing additional exhaust ports in the body member to provide the desired exhaust flow rate. It can be appreciated that more exhaust ports can be provided in the mask or the conduit at a variety of locations to provide additional venting of gases from the nose receiving cavity and/or conduit. In the illustrated embodiment, exhaust port 52 includes a plurality of channels 54 in a protruding portion of the exhaust port to make it difficult for the port to become blocked.

Although body member 32 is described above and illustrated in the figures as being generally frustum shaped, it is to be understood that the present invention contemplates a wide variety of shapes and configurations for the body member. For example, body member 32 can be semi-circular or egg-shaped. However, the frustum shape for body member 32 is believed to be advantageous in that by providing generally straight walls between first end 37 and second end 39, the strength of the body member, at least in the axial direction, i.e., the direction between first end 37 and second end 39, is maximized. As a result, body member 32 does not tend to collapse when a force is applied on second end 39, which may occur, for example, when the body member is being placed on a patient and the user pushed the mask against the patient using conduit 40 or adapter 42 to seal the mask on the patient. It is preferable that the body member does not collapse in the presence of these relatively small forces.

Nasal mask assembly 30 also includes a flange 56 coupled to body member 32. Flange 56 supports an adhesive for selectively attaching the nasal mask assembly to the face of the patient. Details of suitable adhesives are provided below. In the illustrated embodiment, a first edge 58 of flange 56 is integral with the edge portion of body member 32 defining first opening 36 so that the flange is provided around the entire periphery of first opening 36. As shown in Fig. 4, flange 56 is configured and arranged such that a first surface 60 overlies a surface of a patient when nasal mask assembly 30 is properly positioned on the

patient. The body member and flange are sized and configured such that the mouth of the patient remains exposed while nasal mask assembly 30 is engaged on the patient. It is to be understood, however, that the interior edge of the flange need not be integral with the perimeter of the first opening. On the contrary, the edge of the body member can be joined at other locations on the width of the flange so that a portion of the flange extends into the first opening. Such an embodiment is particularly advantageous in that the inwardly extending portion of the flange is in a position where it can be urged into a sealed relation with the patient's face by the positive pressure provided in the nose receiving cavity, thereby improving the sealing ability of the nasal mask assembly.

In the illustrated embodiment, flange 56 and/or body member 32 are configured such that when the flange and body member are an undeflected state, i.e., prior to being positioned in a sealed relationship on the patient, the shape of the flange and/or body member generally corresponds to the facial contours of the face immediately surrounding the nose for a population of patients. For example, in the exemplary embodiment of the nasal mask assembly shown in the figures, the edge of body member 32 defining first opening 36 is configured such that that lateral sides 62 extend farther from second end 39 than a top portion 66 and a bottom portion 68 of body member 32. This allows the lateral sides of the body member to lie snugly against the sides of the patient's nose while providing a valley 70 at the top of the body member to conform to the bridge of the patient's nose. In addition, bottom portion 68 has a generally concave surface, when viewed from the rear, to accommodate the portion of the patient's face between the upper lip and the nares.

Patient comfort and sealing ability are also maximized in the nasal mask assembly of the present invention by predefining the width of flange 56, which is identified as a distance d between first edge 58 Fig. 3A, to provide greater sealing ability where the sealing function is the most difficult. For example, in the illustrated embodiment, width d is greater at top portion 66 of body member 32 than at bottom portion 68, be forming an effective seal of the mask over the bridge of the nose is generally more difficult than at other locations. Also, it is especially desirable that there be no leakage of gas at the bridge of the nose because such leakage tends to exhaust into the patient's eyes, which is uncomfortable and tends to dry the eyes. Providing a greater width d for flange 56 at this portion of the nasal mask assembly maximizes the sealing function of the flange at the top of the mask. It is to be understood, that offset against the desire that the width d of flange 56 be large enough to provide an effective sealing area with sufficient sealing strength, is the desire to minimize the size of the

mask assembly provided on the patient. Therefore, distance d is preferably kept to a minimum.

As noted above, nasal mask assembly 30 includes an adhesive layer 74 disposed on surface 60 of flange 56. In a preferred embodiment of the present invention, adhesive layer 74 is not disposed directly on flange 56. Instead, a flexible material layer 76 is disposed between adhesive layer 74 and flange 56. In addition, a second adhesive layer 78 is disposed between flexible material layer 76 and flange 56 to attach flexible material layer 76 and adhesive layer 74 to flange 56. Adhesive layer 74 selectively engages the surface of the patient and maintains flange 56 in a substantially sealed relation with the patient, thereby adhering or bonding nasal mask assembly 30 to the patient. Providing flexible material 76 between flange 56 and adhesive layer 74 improves the comfort of the nasal mask assembly because a relatively soft, giving material is adjacent the patient, as opposed to the relatively non-compressible material defining flange 56.

When the nasal mask assembly is not being worn by the patient, a protective cover layer 80 is selectively attached to adhesive layer 74. Protective cover layer 80 prevents items from adhering to adhesive layer 74 and prevents adhesive layer 74 from adhering to undesired items so that the nasal mask assembly can be easily shipped, stored, and handled prior to being placed on a patient. Preferably, protective covering layer 80 includes a tab that can be readily grasped so that the protective cover layer can be easily peeled away from adhesive layer 74. It is to be understood that protective cover layer 80 can be eliminated if other measures are taken to preserve the adhesive integrity of adhesive layer 74. For example, the present invention contemplates that the entire mask assembly be packaged in a container that prevents contact with adhesive layer 74 so that the adhesive layer need not be covered with a protective cover layer. Once the container is opened and the nasal mask assembly removed, it can then be applied to the face of the patient.

Details of the features of the nasal mask assembly, including the presently preferred components thereof, are discussed below with reference to Fig. 6. Fig. 6 also illustrates an example of one embodiment of an assembly process in which the adhesive attachment assembly, which includes adhesive layers 74 and 78 and flexible material layer 76, is fixed to body member 32. As noted above, body member 32 is preferably formed from an elastomeric material that is capable of holding its shape when not deformed by a force, yet capable of some degree of flexation, especially in a lateral direction, i.e., in a radial direction relative toward and away from a central axis of first opening 38, so that it can conform to a

wide variety of patients. In addition, body member 32 is preferably formed to be as light as possible so that it can be comfortably positioned and maintained on the patient. An example of a suitable material for body member 32 is identified as Dynaflex G270, provided by GLS Corp. of Cary, IL.

It is to be understood that body member 32 can be formed from two or more individual elements that are joined together to define the body member. However, body member 32 is preferably formed from a unitary piece of material, such as from a single extrusion. In addition, many of the components associated with the body member, such as all those shown in Figs. 3A and 3B, are preferably formed from the same extrusion so that the body member and associated elements are a unitary piece. It is to be understood that if body member 32 and/or the associated components, are not formed as a unitary piece, the separate components can be formed from different materials. For example, the present invention contemplates that second end portion 39 of body member 32 be formed from a material different from that used to form wall 82 so that wall 82 is, for example, more flexible than second end portion 39. Flange 56 can also be formed from a material or a variety of materials that are the same as or different from the material or materials defining body member 32 to provide a wide variation in the flexibility and contouring characteristics of the nasal mask assembly depending on the materials selected.

As shown in Fig. 6, the assembly of the nasal mask assembly includes applying a first primer coat layer 84 on surface 60 of flange 56 prior to applying second adhesive layer 78 to facilitate bonding of second adhesive layer 78 to flange 56. In addition, a second primer coat layer 86 is provided on flexible material layer 76 to facilitate bonding of second adhesive layer 78 thereto. First and second primer coat layers 84 and 86 are preferably the #94 primer provided by 3M Corp. of St. Paul, Minnesota. It is to be understood, however, that other types of primer coat layers can be used or that the primer coat layers can be eliminated depending on the materials selected for flange 56, second adhesive layer 78, and flexible material layer 76. In addition, the present invention contemplates that different types of primer coats can be used for first and second primer coat layers.

Second adhesive 78 is any adhesive that is suitable for bonding flange 56 to flexible material layer 76. An example of a suitable adhesive is the Acrylic Tape w/VHB 9469 sold by 3M Corp. of St. Paul, MN. It can be appreciated, however, that other types of adhesives may be used for second adhesive 78 depending on the materials selected for flange 56 and flexible material layer 76 to which it is bonded.

Flexible material layer 76 is preferably a foam that is capable of flexing to conform to the features of the patient's face. In one embodiment of the present invention, flexible material layer 76 is a foam that is gas permeable to allow the skin underlying the flexible material layer to breathe. It is to be understood, that flexible material layer 76 alone preferably does not provide the entire contouring function of the nasal mask assembly that allows it to conform comfortably to a wide variety of patients. This ability is provided by the combination of the flexible material layer, the flexible flange and the flexible body member. An example of a foam suitable for use as flexible material layer 76 is the Volara foam provided by Volteck, a Division of Sekisui America Corp., of Lawrence, Massachusetts.

Adhesive layer 74, also referred to as the first adhesive layer, is an adhesive specifically suited for boding to human skin while providing a sufficient bonding strength to prevent pull-off of the nasal mask assembly from the patient even in the presence of positive pressure applied in the nose receiving cavity by the ventilator system and/or patient exhalation. As such, adhesive layer 74 must be relatively impervious to skin oils and perspiration. It is also preferable for adhesive layer 74 to be removable from the patient without damaging the patient's skin. Furthermore, it is preferable for adhesive layer 74 to retain enough adhering ability even after being removed so that it can be reapplied to the patient and provide a suitable seal for the nasal mask assembly. This allows the mask to be positioned, removed, and repositioned, if necessary, in the event the first positioning attempt was not successful. An example of a material suitable for use as adhesive layer 74 is the skin adhesive MTC611 provided by H&N Chemical Co. of Totowa, New Jersey.

The components of the sealing system shown in Fig. 6 can be joined together in a sequential manner beginning with first primer coat 84 and ending with protective cover layer 80. However, the present invention contemplates that other techniques can be used to assemble the nasal mask assembly. For example, the present invention contemplates pre-assembling adhesive layer 74, flexible material layer 76, and second adhesive layer 76 as an adhesive seal assembly, with first adhesive layer 74 being covered by protective cover layer 80 and second adhesive layer 78 being protected by a second protective cover layer (not shown) that serves the same function as protective cover layer 80. The adhesive seal assembly is applied to flange 56 by removing the second protective cover layer from second adhesive layer 78, applying primer coat layer 84, if necessary, to flange 56, and attaching second adhesive layer 78 to flange 56. Preferably, a grippable tab is provided on the second protective cover layer to simplify its removal from second adhesive layer 78.

Referring again to Figs. 1 and 2, in the illustrated exemplary embodiment of the present invention, nasal mask assembly 30 includes a headgear assembly 88 that assists in placing and maintaining the nasal mask assembly with the patient. Headgear assembly includes a pair of attachment assemblies 90 associated with flange 56 for coupling a headstrap 92 to the nasal mask. In the illustrated exemplary embodiment, each attachment assembly 90 is an attachment tab integral with flange 56 on opposing sides of the nasal mask generally at a midline thereof. As shown, each attachment tab engages a portion of headstrap 92 such that the headstrap can be tightened at either tab. Preferably, headstrap 92 is a light weight elastomeric strap made from an elastic material. During use, the headstrap wraps around the patient's head to hold the mask on or near the patient in the event the adhesive fails so that the nasal mask assembly does not fall off the patient.

It is to be understood, that the primary means for securing nasal mask assembly 30 to the patient remains the adhesive attachment of flange 56. The strapping force provided by headgear assembly 88 at best serves a secondary role in securing the body member to the patient and does not replace that provided by the adhesive. In addition, the strapping forces provided by headgear assembly 88 are preferably kept to a minimum so that the mask does not exert a substantial force on the face of the patient, thereby making the mask comfortable to wear.

While the illustrated embodiments show attachment assemblies 90 provided on flange 56, it is to be understood that the attachment assemblies can be provided at other locations, such as on body member 32. In addition, more than two attachment assemblies can be provided and more than one headstrap can be employed in a variety of configurations and at other locations to provide the above-described supplemental attachment function. In addition, the headstrap can be made from a variety of materials so long as the headstrap serves to keep the mask on the patient should the adhesive fail.

An additional embodiment of the present invention is discussed below with reference to Figs. 7 and 8. In this embodiment, nasal mask assembly 30 is the same as that discussed above except for the addition of an auxiliary attachment assembly 94. Auxiliary attachment assembly 94, the details of which are illustrated in Fig. 8, which is a cross-section of a portion of the auxiliary attachment assembly, includes a substrate 96, an adhesive layer 98 disposed on a first side of the substrate, and an adhesive layer 100 disposed on a second side of the substrate. The auxiliary attachment assembly allows for reusing of the nasal mask assembly by being selectively attachable to the exposed surface of adhesive 74. More

specifically, adhesive layer 98 attaches to adhesive layer 74, thereby attaching the auxiliary attachment assembly to the remainder of the nasal mask so that adhesive layer 100 provides an adhesive layer for contacting the skin of the patient. Protective cover layers 102 overlie adhesive layers 98 and 100 prior to the auxiliary attachment assembly being disposed on the nasal mask.

According to a preferred embodiment of the present invention, substrate 96 is a paper or cloth material that is coated on opposing sides with adhesive layers 98 and 100. In addition, substrate 96 is configured to generally match the shape of flange 56. To apply the auxiliary attachment assembly, the user removes the protective cover layer overlying adhesive 98 and attaches that side of the auxiliary attachment assembly to the used/non-sticky face contacting layer on flange 56. The protective cover layer overlying adhesive layer 100 can then be removed to provide a new adhesive layer to again bond the nasal mask assembly to the patient. It can be appreciated that the auxiliary attachment assembly can be removed and reapplied or discarded in favor of a new auxiliary attachment assembly so that he same nasal mask can be reattached to a patient a number of times.

It can thus be appreciated that the above-described nasal mask assembly provides a patient interface device for communicating a flow of breathing gas from a source thereof to the airway of the patient without using a headstrap to provide the primary force for securing the mask to the patient. Instead, an adhesive provided around the perimeter of the mask attaches the mask to the patient. Using an adhesive allows the mask to be quickly placed on the user so that the ventilation therapy can be initiated faster than conventional systems. In addition, the simplified structure for the nasal mask assembly minimizes the number of parts, and, hence, the manufacturing complexity and costs so that the nasal mask assembly is relatively inexpensive. Also, the entire assembly is made from light weight materials to enhance patient comfort. Moreover, because an adhesive is used to attach the nasal mask assembly to the patient, the mask does not exert any significant pressure on the patient's face, thereby making it more comfortable for the patient to wear than conventional masks, and, perhaps, safer, because the patient's head does not need to be moved to place the mask on the patient. In addition, if the patient has a facial trauma, it is preferable to avoid applying a force on the patient's face.

Although the invention has been described in detail for the purpose of illustration based on what is currently considered to be the most practical and preferred embodiments, it is to be understood that such detail is solely for that purpose and that the

invention is not limited to the disclosed embodiments, but, on the contrary, is intended to cover modifications and equivalent arrangements that are within the spirit and scope of the appended claims.

What is Claimed is:

1. A nasal mask assembly comprising:

a body member defining a nose receiving cavity, said body member having a first opening defined in a first end and adapted to receive a nose of a patient such that a portion of a nose of such a patient is disposed in said nose receiving cavity and such that a mouth of such a patient remains exposed responsive to said nasal mask assembly being positioned on such a patient, and said body member having a second opening defined in a second end and adapted to receive a supply of breathing gas to communicate such breathing gas to said nose receiving cavity;

a flange associated with said first opening of said body member, said flange being configured and arranged such that a first surface is adapted to overlie a surface of a patient responsive to said nasal mask assembly being positioned on such a patient; and

a first adhesive layer disposed on said first surface of said flange, said first adhesive layer selectively engaging a surface of a patient and maintaining said first surface of said flange in a substantially sealed relation with such a patient so as to adhere said nasal mask assembly to a surface of a patient responsive to said nasal mask assembly being positioned on such a patient.

2. A nasal mask assembly according to claim 1, wherein said body member is generally frustum shaped with said first opening being defined in a base thereof and said second opening being defined in an apex thereof.

3. A nasal mask assembly according to claim 1, wherein at least one of said body member and said flange is defined by a flexible elastomeric material.

4. A nasal mask assembly according to claim 1, wherein a configuration of at least one of said first end of said body member and said flange is predefined so as to generally correspond to facial contours of a region surrounding a nose of a population of patients.

5. A nasal mask assembly according to claim 1, wherein said flange includes a first edge and a second edge, and wherein said first edge of said flange is fixed to an edge of said body member defining said first opening.

6. A nasal mask assembly according to claim 5, wherein a distance between said first edge and said second edge of said flange is greater in a portion of said flange adapted to be positioned proximate to a bridge and a side of a nose of a patient than in a portion of said flange adapted to be positioned proximate a patient's upper lip.

7. A nasal mask assembly according to claim 1, further comprising:

a flexible material layer disposed between said first adhesive layer and said flange; and

a second adhesive layer disposed between said flexible material layer and said flange.

8. A nasal mask assembly according to claim 1, further comprising:

a headgear assembly; and

an attachment assembly associated with at least one of said body member and said flange, said attachment assembly providing at least one contact point for coupling said headgear assembly to said nasal mask assembly.

9. A nasal mask assembly according to claim 1, further comprising a conduit coupled to said second opening such that an interior of said conduit communicates with said nose receiving cavity.

10. A nasal mask assembly according to claim 9, wherein at least one of said body member and said conduit includes an exhaust port defined therein to communicate an interior of an associated one of said nose receiving cavity and an interior of said conduit to atmosphere.

11. A nasal mask assembly according to claim 9, wherein said conduit includes a flexible portion generally proximate to said body member.

12. A nasal mask assembly according to claim 1, further comprising a protective cover layer selectively attachable to said first adhesive layer, said protective cover layer preventing attachment of said first adhesive layer in said substantially sealed relation

responsive to said protective cover layer being affixed to said first adhesive layer, and permitting said first adhesive layer to be attached to a patient in said substantially sealed relation responsive to said protective cover layer being removed from said first adhesive layer.

13. A nasal mask assembly according to claim 1, further comprising an auxiliary attachment assembly comprising:

a substrate having a first side and a second side;

a second adhesive layer disposed on said first side of said substrate; and

a third adhesive layer disposed on said second side of said substrate, said auxiliary attachment assembly being selectively attachable to said first adhesive layer such that said second adhesive layer contacts said first adhesive layer and such that said third adhesive layer is adapted to engages a surface of a patient and maintain said flange in said substantially sealed relation.

14. A system according to claim 1, further comprising a headstrap having a first end portion and a second end portion adapted to attach to one of said body member and said flange.

15. A system for providing breathing gas to a patient, comprising:

a pressure generator that generates a flow of breathing gas;

a conduit coupled to said pressure generator to carry said flow of breathing gas from said pressure generator to a patient; and

a nasal mask assembly comprising:

a body member defining a nose receiving cavity, said body member having a first opening defined in a first end adapted to receive a nose of a patient such that a portion of a nose of such a patient is disposed in said nose receiving cavity and such that a mouth of such a patient remains exposed responsive to said nasal mask assembly being positioned on such a patient, and said body member having a second opening defined in a second end, said second opening being coupled to said conduit to communicate said flow of breathing gas to said nose receiving cavity;

a flange associated with said first opening, said flange being configured and arranged such that a first surface is adapted to overlie a surface of a patient responsive to said nasal mask assembly being positioned on such a patient; and

a first adhesive layer disposed on said first surface of said flange, said first adhesive layer selectively engaging a surface of a patient and maintaining said first surface of said flange in a substantially sealed relation with such a patient so as to adhere said nasal mask assembly to a surface of a patient responsive to said nasal mask assembly being positioned on such a patient.

16. A nasal mask assembly comprising:

nose encapsulating means for encapsulating a nose of a patient such that a portion of a nose of such a patient, including a patient's nostrils, is disposed in an interior of said nose encapsulating means and such that a mouth of such a patient is not disposed in said interior of said nose encapsulating means responsive to nose encapsulating means being positioned on such a patient; and

adhesive means for maintaining said nose encapsulating means in a substantially sealed relation with a surface of a patient responsive to said nasal mask assembly being positioned on such a patient.

17. A nasal mask assembly according to claim 16, further comprising means for providing a supply of breathing gas to said interior of said nose encapsulating means so that said supply of breathing gas enters a patient's nostrils.

18. A nasal mask assembly according to claim 16, further comprising means for exhausting breathing gas from said interior of said nose encapsulating means.

19. A nasal mask assembly according to claim 16, further comprising means for selectively attaching said nose encapsulating means to a head of a patient to provide a secondary constraint to maintain said nose encapsulating means in proximity to a patient.

20. A method of communicating a supply of breathing gas to a patient, comprising:

providing a nasal mask including:

a body member defining a nose receiving cavity, said body member having a first opening and a second opening,

a flange associated with said first opening,

an adhesive layer disposed on a first surface of said flange, and

a protective cover layer disposed on said adhesive layer;

removing said protective cover layer to expose said adhesive layer; and

attaching said nasal mask over a nose of a patient such that a portion of a nose of such a patient is disposed in said nose receiving cavity with said adhesive layer maintaining said flange in a substantially sealed relation with respect to such a patient with a mouth of such a patient remaining exposed.

21. A method according to claim 20, further comprising a step of providing a supply of breathing gas to said nose receiving cavity via said second opening.

22. A method according to claim 21, wherein said nasal mask assembly includes a strap having a first end portion and a second end portion adapted to attach to one of said body member and said flange, further comprising a step of attaching said strap around a head of a patient.

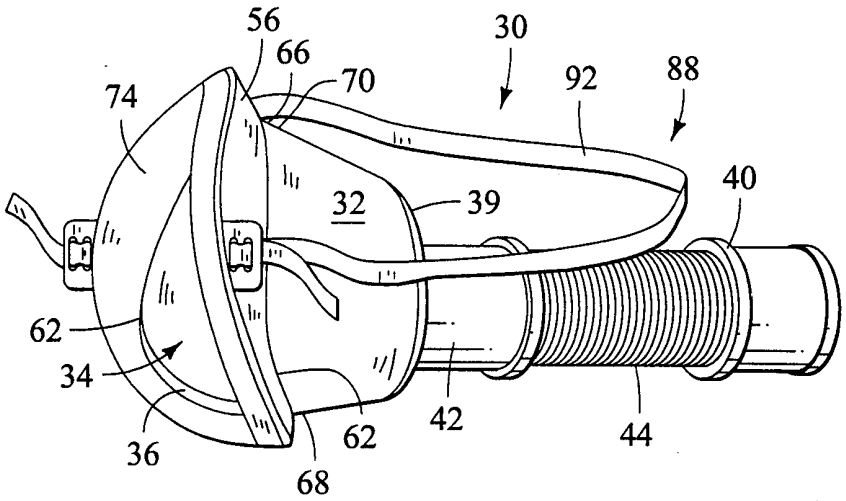
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FIG.1

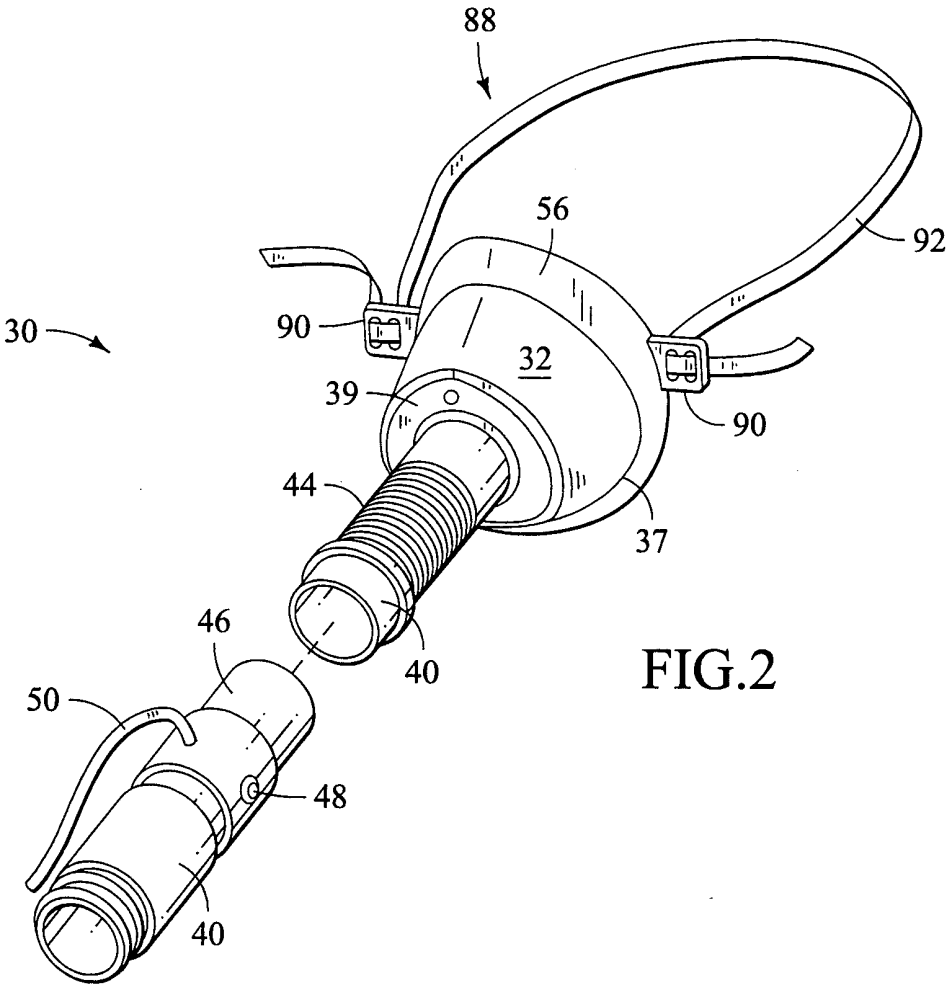
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FIG.2

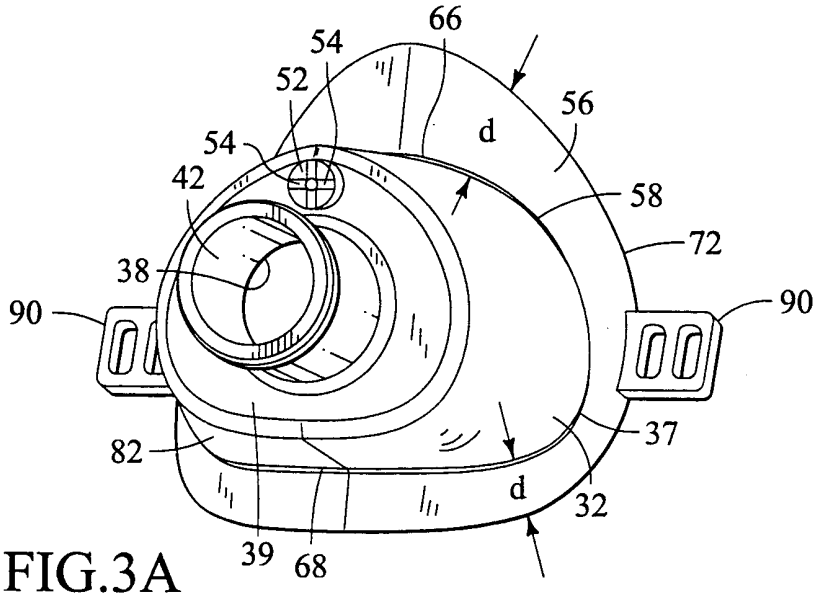
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FIG.3A

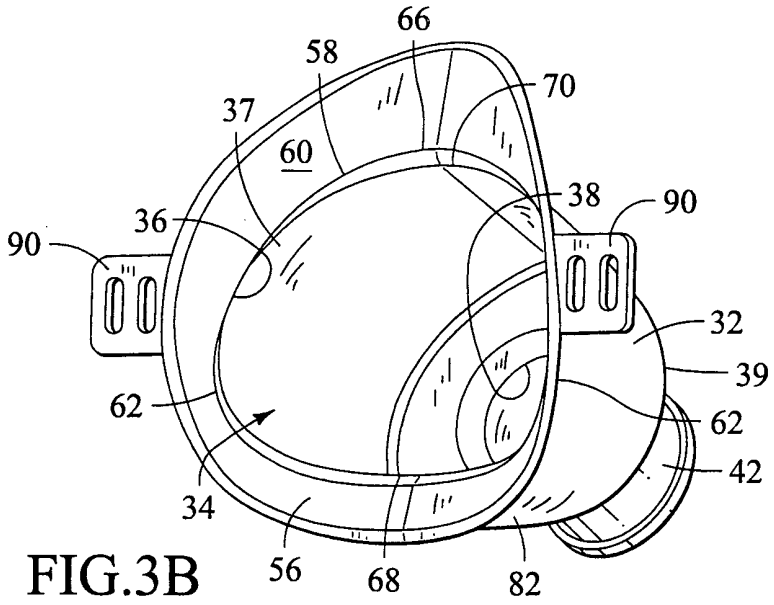
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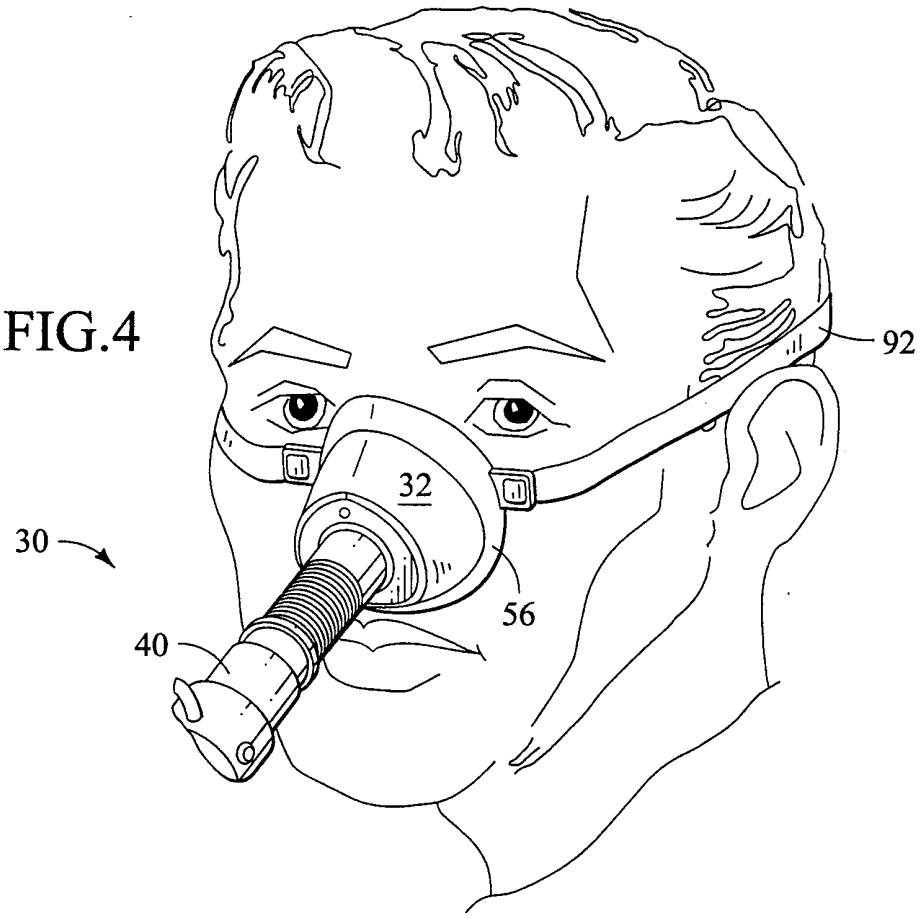
FIG.3B

FIG.4



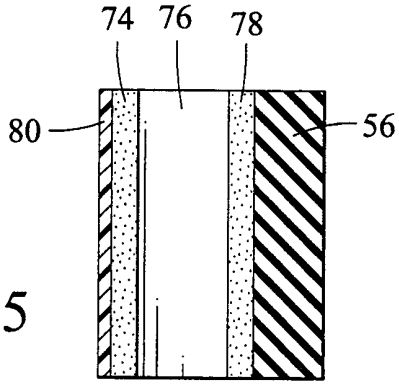


FIG.5

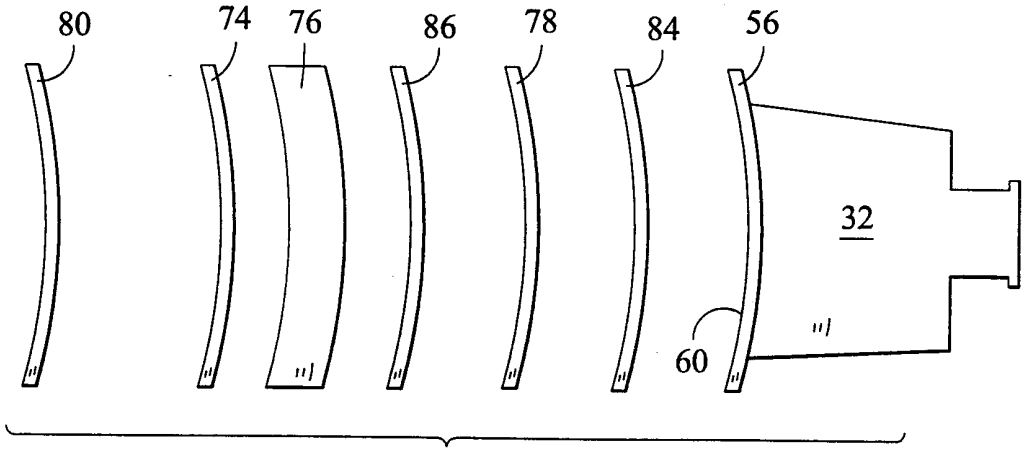


FIG.6

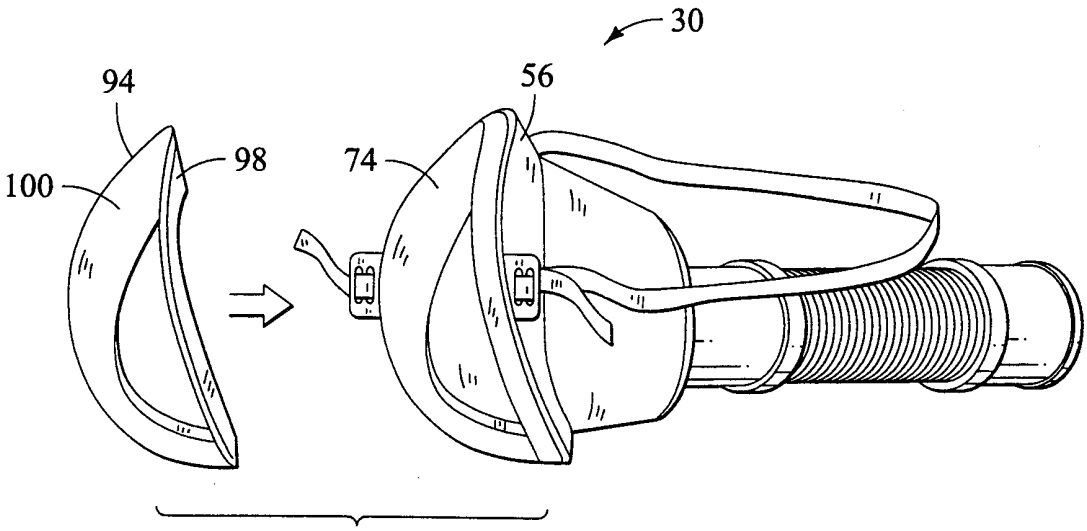


FIG.7

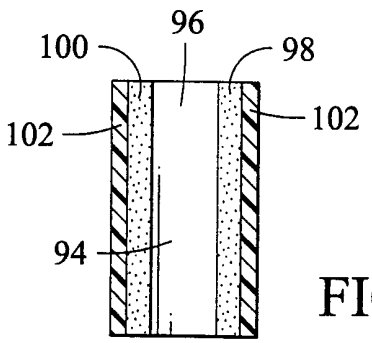


FIG.8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/04628

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A62B 18/02, 08

US CL : 128/206.21, 206.24, 206.25, 206.27, 207.11, 207.13

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)

U.S. : 128/206.21, 206.24, 206.25, 206.27, 207.11, 207.13

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,918,598 A (BELFER et al.) 06 July 1999, Figs. 1-6B, and cols. 9 and 10.	1-7, 9-13, 15-18, 20, 21 --- 14, 19, 20
Y	US 6,019,101 A (COTNER et al.) 01 February 2000, Fig.1.	14, 19, 22
Y	US 5,647,357 A (BARNETT et al.) 15 July 1997, Fig. 1-5.	14, 19, 22

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

* Special categories of cited documents:

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"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

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"&" document member of the same patent family

Date of the actual completion of the international search

04 MAY 2000

Date of mailing of the international search report

25 MAY 2000

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Form PCT/ISA/210 (second sheet) (July 1998) ★