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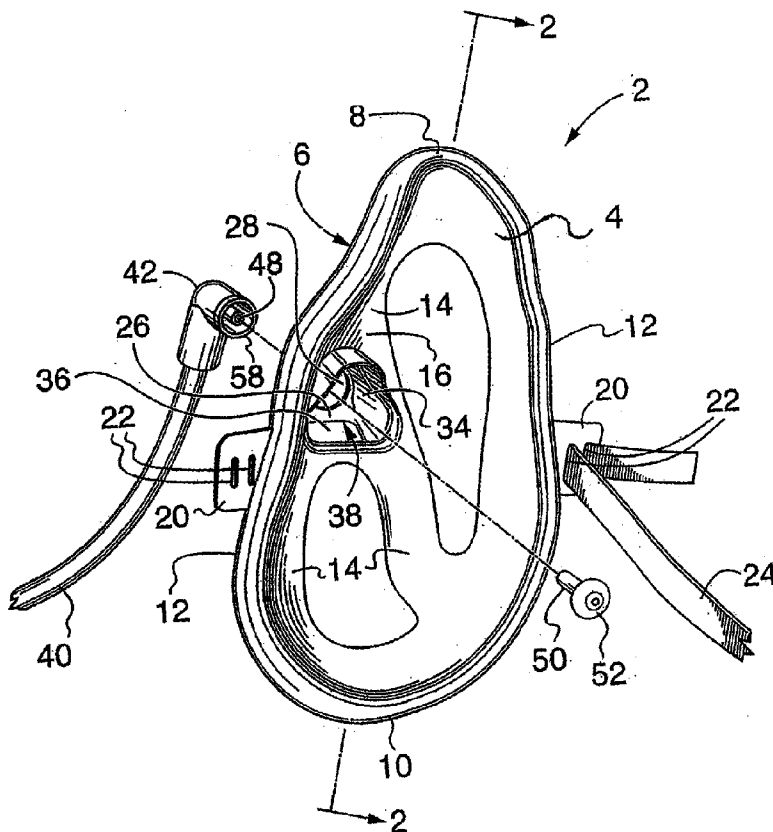
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(54) **Title:** PATIENT OXYGEN DELIVERY MASK



(57) **Abstract:** A mask for delivery of oxygen to a patient, includes a body having a rim to sit comfortably on a patient's face, a central portion, and webs extending between the central portion and the peripheral portion and integral therewith. The webs define open areas that make up at least 30% of the mask body. The central portion includes a gas diffuser shaped to direct a turbulent gas plume over the patient's nose and mouth. The dimensions of the diffuser permit formation of a suitable gas plume over a range of oxygen delivery rates.

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— *with amended claims*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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TITLE OF THE INVENTION**PATIENT OXYGEN DELIVERY MASK****RELATED APPLICATIONS**

The present application is a continuation-in-part of application
no. 11/038,816 filed on January 20, 2005, which is a continuation-in-part of
5 application number 10/966,920 filed on October 15, 2004.

FIELD OF THE INVENTION

The present invention relates to medical equipment, namely a novel
mask for delivery of oxygen to a patient, and more particularly to a mask
10 which can be used to replace conventional oxygen masks and nasal
cannulae oxygen delivery systems.

BACKGROUND OF THE INVENTION

Conventional oxygen masks comprise tent like structures which are
15 strapped over the nose and mouth of the patient, often using an elastic
band or bands behind the patient's ears or head. Oxygen is fed from a
supply through a tube into the bottom portion of the mask at the front of
the patient. Many problems exist with such masks, including the fact that
many patients find them claustrophobic, the mask must be removed for the
20 patient to speak or eat, thereby discontinuing therapy, and the face mask
creates irregular and inefficient infusion of oxygen by the patient since
exhaled air from the patient is mixed with oxygen in the mask. Oxygen
masks can only be used for oxygen flows greater than 4 litres/minute
because exhaled gas accumulates in the mask, and, at lower flow rates
25 interferes with delivery of oxygen-enriched air to the patient.

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Conventional nasal cannulae oxygen delivery systems employ an oxygen delivery tube with tubular, open ended nasal prongs at the delivery end of the tube for insertion into a patient's nasal passages. The oxygen delivery tube and nasal cannulae are supported in position by a tube
5 wrapped about the patient's ears or head, making the system both difficult to handle and uncomfortable since it applies downward pressure on the patient's ears when the patient is in a seated position. As well, patients often get nose bleeds from the dryness of the oxygen supplied through the nasal cannulae. Patients also get sores on the ears, face and nose due to
10 the direct contact of the oxygen tubing with the skin. Nasal cannulae can only deliver flows of 0.5 to 4 litres/minute.

Of background interest is Ketchedjian, U.S. Patent No. 6,247,470 issued June 19, 2001 which describes and illustrates an oxygen delivery apparatus comprising a headset to which is pivotally attached, for rotation in
15 one plane, a flexible arm carrying tubular members for passing oxygen to a patient's mouth. The apparatus is also provided with a carbon dioxide monitoring system.

McCombs et al., U.S. Patent No. 6,065,473 issued May 23, 2000 describes a somewhat similar apparatus, for non-medical purposes,
20 intended to dispense concentrated oxygen to users, the apparatus comprising an oxygen delivery nozzle attached by an arm extending from a flexible head band, to bathe the user's nose and mouth with oxygen, when in use. Laid-open German Application DE 43 07 754 A1, published April 7, 1994, teaches a system for controlled supply or removal of respiratory air
25 from a user, which system incorporates a mask body held by a rigid air tube over the mouth and/or nose of the user, the air tube being pivotally adjustable in one plane, to enable proper positioning of the mask.

U.S. Patent No. 3,683,907 of Cotabish issued August 15, 1972 describes and illustrates a fresh air respirator, for use for example by
30 miners, which comprises a cup, supported by pivotable arms in front of the

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face of the user, a stream of air being conducted to the cup to provide fresh air around the user's nose and mouth.

The applicant has developed a number of lightweight oxygen delivery systems for patients, as described for example in U.S. Patents Nos. 5 6,675,796 issued January 13, 2004, 6,595,207 issued July 22, 2003 and 6,450,166 issued September 17, 2002. Also, applicant's U.S. Design Patent Nos. D449,376 issued August 16, 2003 and D449,883 issued October 30, 2001 illustrate designs for such devices. All of these references feature oxygen diffuser devices, designed to create a turbulent oxygen flow, to be 10 situated during use in front of the nose and mouth of a patient, and being held in that area by means of a mount such as a head band, to which is secured a rigid, but bendable oxygen delivery tube. The subject matter of each of these references is incorporated herein by reference.

Other references of general background interest include U.S. Patent 15 No. 4,282,869 of Zidulka issued August 11, 1981, U.S. Patent No. 4,018,221 of Rennie issued April 19, 1977, U.S. Patent No. 5,687,715 of Landis et al. issued November 18, 1997, U.S. Patent No. 4,465,067 of Koch et al. issued August 4, 1984 and U.S. Patent No. 5,697,363 of Hart issued December 16, 1977, all of which describe and illustrate different types of 20 head mounted apparatus for delivering oxygen or other gases to a patient.

Most of these prior art devices intended for delivery of oxygen to a patient do not provide the ease of usage, both by health care workers and the patient, and reliability against unintended removal or dislodgement from position, as is required to permit widespread use by the health care 25 profession.

It is desirable to provide an oxygen delivery mask system that provides a suitably high oxygen concentration over a wide range of O₂ flow rates. This would permit the use of a single mask for a variety of applications, wherein different flow rates are desirable. It is particularly 30 desirable to provide a mask capable of application as a high flow mask, for

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use with highly compromised patients. It is desirable to provide a range of flow rates in an open mask that does not trap the exhaled air. It is further desirable to provide a mask that may be readily collapsed into a more compact structure for storage and transport, but which easily snaps back into its use position.

It is an object of the present invention to provide a more versatile, reliable and practical system for delivery of oxygen to patients.

SUMMARY OF INVENTION

According to a first aspect the present invention consists in a mask for delivery of gas to a patient comprising a central portion, a rim configured for contacting the patient's face around the patient's nose and mouth region, a web joining said central portion to said rim and comprising openings within said mask, a gas nozzle configured for connection to a source of gas for delivering gas into said mask, and a gas diffuser protruding from said central portion, said diffuser comprising a baffle positioned over said nozzle for obstructing the flow of gas from said nozzle and a wall fully surrounding said nozzle and protruding inwardly towards said patient from said central portion such that the entirety of the wall protrudes inwardly from the central portion of the mask by between about 3 mm and 25 mm.

Preferably said mask in combination with an oxygen delivery tube releasably securable to the outer surface of the central portion of the mask so as to communicate with the gas connection.

Preferably said baffle comprises a stem mounted adjacent to said nozzle and a head having a curved surface facing said nozzle for generating turbulence within said gas flow.

Preferably said head includes a curled back conical lip facing said nozzle.

Preferably said stem includes a passageway open to the interior of said mask body and communicating with the exterior of said mask for permitting measurement of exhaled gas from within said mask body.

Preferably said wall is generally cup-shaped comprising a free edge contoured so as to conform, when the mask is in position on a patient, generally to the shape of a patient's nose and mouth area but spaced apart therefrom when in use.

Preferably said wall has a maximum top to bottom distance when said mask is vertical of 40 mm above and below said nozzle and a maximum side to side distance of 20 mm on either side of said nozzle, when said mask is positioned in an upright position.

Preferably said diffuser is positioned so as to maintain a spacing of between 12 and 40 mm between said diffuser and said user's face as measured from the skin surface between nose and mouth.

Preferably said openings comprise between 30 and 80 per cent of the total surface area of said body, said surface area comprising open and covered areas.

Preferably said openings comprise between 50 and 75 per cent of the total surface area of said body.

Preferably said diffuser is positioned so as to be centered over a point about halfway between the user's nose and upper lip.

Preferably at least one of said openings provides access from the mask exterior to the user's nostrils.

Preferably said mask further comprising a sensor for monitoring exhaled gases within the interior of said mask.

Preferably said wall protrudes inwardly from said central portion by between about 13 mm and 20 mm.

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Preferably said web comprises an array of bridges between said central portion and said rim radiating from said central portion, said web further comprising at least one stiffening rib protruding inwardly from at least one of said bridges, joining with said diffuser.

Preferably said mask further comprising an elbow-shaped connector engaged to said nozzle for providing a passageway for delivery of said gas into the interior of said mask body.

Preferably said mask configured to deliver an FIO₂ concentration to a patient within a range of 21% to 90%, by controlling the flow of O₂ to said diffuser within a range of 1.5 LPM and 15 LPM.

Preferably said mask configured to deliver an FIO₂ concentration to patient within a range of about 21% to about 92%, by controlling the flow of O₂ to said diffuser within a range of 1.5 LPM and 40 LPM.

Preferably said mask configured to deliver an FIO₂ concentration to patient within a range of about 21% to about 92%, by controlling the flow of O₂ to said diffuser within a range of 1.5 LPM and 30 LPM.

In accordance with the present invention there is provided an improved mask for delivery of oxygen to a patient. The mask comprises a body having a peripheral portion that forms the mask rim, which when in use sits comfortably on a patient's face. The mask body is generally concave, opening towards the patient's face. The mask body is open in configuration and is further defined by a central portion, and bridge portions extending between the central portion and the peripheral portion and integral therewith. The central portion has an inner surface and an outer surface. The inner surface is oriented towards the patient's face, when the mask is in position, and is contoured so as to sit at a location spaced over the patient's nose and mouth.

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An oxygen diffuser extends from the inner surface of the central portion towards the patient's face. The diffuser includes an outer tubular structure formed from a wall circumscribing a base. The term "wall" is used herein for convenience of description and refers to a structure that extends upwardly when the mask is face down. Obviously, when the mask is upright, this component will extend in a generally horizontal orientation. The diffuser wall has a generally concave configuration and circumscribes a centrally positioned oxygen delivery aperture which extends through the central portion between the inner surface and the outer surface. A baffle positioned within the oxygen flow path within the interior of the tubular diffuser wall disrupts the inflowing gas stream to generate turbulence. The diffuser structure directs the flow of oxygen generally towards the patient's nose and mouth when the mask is in use. Acting together, the diffuser wall and baffle generate an oxygen plume which surrounds the patient's nose and mouth. Attachments are provided on opposite sides of the peripheral portion, for securing a flexible strap means to extend behind the patient's head or ears to hold the mask in position when in use. Also, means are associated with the aperture and of the central portion releasably to secure in position an oxygen delivery tube. The bridge portion consists of an array of webs that are arranged to maintain the convex shape of the mask while permitting a substantial open structure, with preferably about half or more of the mask body being open. As will be seen, the open structure has several benefits. For patient comfort, it is less restrictive and permits the patient to eat, talk, etc. As well, the open structure permits exhaled air to readily dissipate.

In a further embodiment of the present invention, the mask additionally includes the oxygen delivery tube. This delivery tube is attached to an elbow, so designed as to swivel in at the attachment point, so that the oxygen supply tube can easily be directed to either side of the patient. It is releasably securable to the outer surface of the central portion of the mask so as to communicate with the oxygen delivery aperture. As well, a baffle is provided, the baffle being constructed so as to be releasably seated over the oxygen delivery aperture on the inner surface of the central portion of the mask. The inner surface of the baffle is configured so as to assist, during use of the mask, in creating turbulence in an oxygen flow leaving the

oxygen delivery aperture and assist in mixing oxygen with ambient air and thereby avoid a direct flow of oxygen towards the patient's face.

In yet a further embodiment of the present invention, the mask is further provided with an oxygen/carbon dioxide monitor tube releasably securable to the outer surface of the central portion of the mask, so as to communicate through the oxygen delivery aperture with an area above the inner surface of the central portion during use of the mask for passage of air within the mask to an oxygen/carbon dioxide monitor. The baffle is constructed so as to be releasably seated over the oxygen delivery aperture on the inner surface of the central portion of the mask. The baffle has a concave shaped wall and is configured and positioned so as to assist during use of the mask in creating turbulence in an oxygen flow leaving the oxygen delivery aperture and assist in mixing oxygen with ambient air and thereby avoid a direct flow of oxygen toward a patient's face. A carbon dioxide intake is positioned within the concave shaped wall of the baffle, the carbon dioxide intake communicating with the carbon dioxide monitor tube.

The bridge portions of the mask, from a top of the mask to a bottom of the mask, may be configured in an inverted "Y" shape so that openings are provided towards the bottom and on both sides of the mask for unobstructed access to, and viewing of a patient's mouth and others parts of the patient's face. The bridge portions comprise a web which is spaced apart from the patient's face so as to maintain a sense of openness and lack of confinement for the patient. A suitable spacing is between 12 and 40 mm from the patient's face, for example when measured from the region between the patient's nose and upper lip.

According to another aspect, the bridge portions include a pair of opposing transverse webs, radiating horizontally outwardly from the central portion, when the mask is held in a vertical position, defining openings both above and below each of

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the transverse webs. It is believed that the use of transverse webs provide improved oxygen concentrations within the mask, across a range of oxygen flow rates being introduced into the mask. Without wishing to be tied to any theory, it is believed that this is accomplished by partially blocking the inflow of entrained ambient air, as oxygen enters the mask, and is particularly effective at relatively high O₂ flow rates. The structure still permits the use of substantial openings within the mask body, so as to easily permit exhaled air to be discharged.

According to another aspect, the diffuser wall structure extending from the central portion of the mask extends outwardly by a specified amount so as to generate a plume of oxygen-enriched air surrounding the user's face and nose, across a wide range of flow rates. The diffuser wall has a generally triangular shape when viewed in plan, from the perspective of the user. Preferably, in this version the diffuser wall ranges in height between about 3 and 25 mm, with the wall increasing in height from bottom to top. More particularly, the wall may range in height between 8 and 16 mm. The exposed rim of the wall is generally vertical when the mask is upright, and since the mask body itself angles upwardly and inwardly towards the user, the wall is tapered to accommodate this angle and thus increases in height towards the bottom of the mask. The diffuser wall structure has a maximum width (left to right when the mask is upright) of about 40 mm at its widest point and a maximum height (top to bottom when the mask is upright) of about 80 mm. More preferably, the width is 20-30 mm and height is 17-27 mm. As well, the exposed rim of the wall is curvilinear so as to protrude somewhat more towards the user towards the top of the mask.

According to another aspect, at least some and preferably all of the bridge portions include a rib that extends inwardly towards the user's face. The rib joins with the wall portion of the central portion, and extends generally parallel to the orientation of the corresponding bridge. The rib is at its thickest when it joins with the wall, and tapers as it extends towards the rim. The ribs serve a stiffening function to help maintain the shape of the mask while permitting relatively thinner materials for the webs. Further, if the mask body, including the ribs, is fabricated from a suitable resilient material,

the ribs permit the mask to be compressed into a relatively flat structure for transport and storage, and to snap back into a suitable concave "use" position. For this purpose, the mask may be stored in a suitable container, such as a bag or ridged or semi-ridged container, such that when opened and the mask removed therefrom, it will snap resiliently into its suitable concave position for use by a patient.

In a further aspect, the oxygen delivery system comprises in general terms a mask for covering a portion of the user's face, having a peripheral rim for contacting the user's face to substantially surround only his mouth and nose region, a web-like mask body and an oxygen diffuser. A fastener such as an elastic strap holds the mask firmly against the user's face so as to cover the nose and mouth region. The body is semi-rigid or more preferably rigid and shaped so as to protrude outwardly away from the user's face to be spaced apart from the user's face. The body supports a gas diffuser and a baffle or other gas obstructing member positioned in the path of the discharged gas so as to direct a turbulent stream of gas towards the user, such as oxygen or an oxygen-rich gas. The diffuser is positioned so as to direct the gas flow towards the user's mouth and nose region at a non-oblique angle so as to generate a plume covering or substantially covering this portion of the user's face. Thus, if the user is upright the gas flow is substantially horizontal. The mask body consists of a web having at least one and preferably a plurality of openings to permit access to the user's face, for example an opening directly opposed to the user's mouth to permit the user to eat, drink and converse normally while wearing the mask, while also permitting medical personnel to easily administer medicines or a thermometer or the like to the patient's mouth.

According to this aspect, a plurality of relatively large openings (together comprising at least about 30% of the surface area of the mask body and preferably at least 50%) also permits rapid discharge and dispersal of exhaled gases to the exterior of the mask. The location, size, number and shape of the openings is dictated at least in part by the desired use of the mask, keeping in mind the comfort and convenience of the user and the needs of medical staff for potential access to the user's mouth or

nose. For example, a mask for use by an infant may include openings which permit the feeding of the infant, wiping of his face and other functions. Medical staff may also need to have quick access to the user's nose or mouth, and it is convenient that this may be accomplished without removal of the mask. Another important aspect which dictates the opening size etc. relates to psychological factors, to minimize the anxiety felt by users. This can be particularly the case with infants, the elderly and those suffering from diminished mental capacity. Thus, a variety of different configurations of the openings is contemplated. The mask has a size and shape so as to provide an oxygen-enriched zone surrounding the user's nose and mouth.

The open structure of the mask body permits the generation of an effective gas plume during use, even with the supply of a relatively wide range of gas deliver rates. The characteristics of the plume are determined at least in part by the configuration of the openings and the webs which define the mask body. The open structure also permits exhaled gases to be easily dissipated. However, unlike a fully open mask, the web-like bridges effectively obstruct at least some of the inflowing ambient air so as to enhance the generation of plume of enriched gas around the user's nose and mouth.

The openings within the mask body can take on any convenient and suitable shape such as square, triangular or rectangular or other polygonal, or round or oval. The openings have a size range of between .25 square inches in area and 6.0 square inches and preferably between 0.25 and 3.0 square inches.

The size and shape of the mask is preferably optimized to minimize the surface area of the mask body and maximize the open area so as to enhance the user's comfort. This is accomplished by providing a relatively large area of the mask body being open, for example by providing a plurality of relatively large openings within the body. It has been found that the mask body may comprise a relatively open structure if the gas diffuser mounted to the mask is positioned generally directly opposed to the user's nose and mouth region and spaced apart from the user's face so as to

generate a plume of turbulent gas flow which covers the mouth and nose region of the user. In order to generate this plume of turbulent flow, the diffuser comprises a rear wall which fixedly receives a gas delivery tube, the mouth or nozzle of the tube discharging into the interior of the diffuser towards the user's face. A gas flow disrupter is positioned between the nozzle and the user's face. The rear portion is surrounded by a peripheral wall or flange extending towards the interior of the mask and the user's face so as to form a generally concave structure to assist in directing the gas flow towards the user. Preferably the rear portion is a wall which may be flat or curved, with the gas outlet entering the wall, for example at a generally central location. The peripheral wall may comprise a generally triangular shape as in the above-described embodiment, or any other convenient shape. A turbulent flow pattern is generated by providing one or more obstructions associated with the diffuser in the path of the gas flow after it exits the gas delivery tube. For example, a baffle may be provided within the interior of the diffuser, which may comprise a mushroom-shaped structure which partly obstructs the path of the discharged gas.

The diffuser conforms to dimensional and positional constraints in order to provide a gas plume having sufficient size to substantially cover the user's nose and mouth. It has been found that the diffuser should comprise a width of no more than 40 mm at its widest point and a maximum height of 80 mm and preferably smaller than this in both dimensions. The diffuser is positioned within the mask such that no part of the diffuser is outside of a region defined in relation to a point between the base of the user's nose and his upper lip, the region comprising a space 40 mm above and below this point in the vertical plane when the mask is vertical and 20 mm on either side of this point in the side-to-side direction. Preferably the diffuser is centered in side to side and vertical dimensions relative to this point. Further, the diffuser is preferably mounted so as to leave a gap between the diffuser and the user's face of between 12 and 40 mm as measured from the user's skin surface between upper lip and nose. Preferably, the diffuser is generally triangular in shape with base downwardly, and preferably the width and height are between 20-30 mm and 17-27 mm respectively.

It has been found that a mask which is provided with a diffuser that conforms to the dimensional requirements described above, and which is positioned within the mask as described, and wherein the mask body includes a plurality of openings or cut-outs, provides an optimal level of comfort, with minimal coverage of the face while still permitting an oxygen-enriched zone fully covering the user's nose and mouth. Preferably the cut-outs within the mask body should comprise at least 30 per cent of the total surface area of the body when measured as if the body were considered to comprise a plane surface, and still more preferably the cut-outs comprise between 30 and 80 per cent of the total surface area. In a still more preferred version the range is more narrowly defined as being between 50 and 80 per cent, and yet more narrowly as between 60 and 75 per cent.

An oxygen delivery mask permits an efficient delivery of oxygen-enriched gas in a comfortable fashion if it includes a combination of an oxygen diffuser opposed to the user's nose and mouth region and directed so as to direct a turbulent gas plume directly at the nose and mouth, and at least one opening within the mask body. Without intending to be restricted to a theory, it is believed that the user's breath inspiration generates negative pressure within the mask interior thereby creating a mixing effect whereby exterior air is drawn through the mask openings into the turbulent gas plume via a venturi effect. Upon exhaling, a positive pressure is generated within the mask and the exhaled air is exhausted through the openings. This maintains within the mask interior an oxygen-rich and CO₂-poor environment, which enhances the user's comfort level and is more medically effective.

Positioning of the diffuser opposed to the nose and mouth region so as to direct a turbulent plume directly towards the user's nose and mouth also permits an oxygen-enriched gas plume which is of generally equal gas makeup over both the mouth and nose. Thus, user inhales the same gas mixture whether breathing through mouth or nose. The diffuser is suitable shaped and positioned so as to cover both the nose and mouth of a typical user.

Preferably the mask body is semi-rigid, for example fabricated from a molded plastic such as PVC, ABS, polypropylene, silicone polycarbonate or other suitable inert resilient material. The mask body is thus able to retain its shape when in use and to maintain the diffuser in its appropriate position, but being flexible for patient comfort and also to permit the mask to be flattened for storage, transport and the like. The ribs described above associated with the webs assist the flattened mask to spring back into shape when released.

The oxygen delivery mask of the present invention provides an easy to use, comfortable, reliable and efficient mask for delivery of oxygen to a patient. As well, since this mask construction does not provide complete enclosure over the patient's nose and mouth, there is less chance of claustrophobia.

In a further aspect, although the invention has been described for use for delivering oxygen or an oxygen-enriched gas it will be seen that with modifications it may be used for other medical applications such as delivery of anesthetic or other gases to a patient.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other advantages of the invention will become apparent upon reading the following detailed description and upon referring to the drawings in which :

FIGURE 1 is an exploded perspective view from the rear of one embodiment of the oxygen delivery mask according to the present invention;

FIGURE 2 is an elevational section view of the mask of Figure 1, along lines 2-2 of Figure 1;

FIGURE 3 is a perspective view from the front of the mask of Figure 1;

FIGURE 4 is an elevational section view of a second embodiment of an oxygen delivery mask in accordance with the present invention, including a carbon dioxide monitoring function; and

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16 sits spaced over the nose and mouth of the patient when the mask 2 is in position. A circular aperture 28 extends through central portion 16 from outer surface 30 to inner surface 32.

Integrally formed on inner surface 32 of central portion 16, is a
5 triangular wall 34, extending about a base 36 which circumscribes circular aperture 28. This wall 34 and base 36 together form a shape which is of generally concave configuration, with one of the apexes of the triangle formed by wall 34 being oriented towards top 8 of mask 2 and the other two apexes oriented towards bottom 10. Thus, a generally triangular shape is
10 formed by the mask, albeit generally with rounded corners, which approximates the human nose and mouth region, so as to generate an oxygen enriched region within the mask which substantially covers the user's nose and mouth. This wall and base form a diffuser 38 which has a similar function to the diffuser construction described and illustrated in
15 applicant's earlier patents and applications referred to previously herein. The diffuser 38 has a maximum width of about 25 mm and a maximum height of about 22 mm.

In the embodiment of mask illustrated in Figures 1 to 3, an oxygen delivery tube 40 is secured in a rigid elbow 42, elbow 42 being rotatably
20 secured by an appropriate, conventional securing means such as frictional engagement in aperture 28 or its snapping into an undercut 44 about aperture 28 on the outer surface 30, so that it can pivot about the circumference of aperture 28 (Figures 3 and 5). Elbow 42 provides a passageway 46 for delivery of oxygen, during operation of the device, into
25 diffuser 38 on the inner surface 32 of central portion 16. The diffuser 38 and associated baffle are shaped so as to generate a plume of turbulent flow of oxygen-enriched gas which surrounds the user's nose and preferably also his mouth. The generation of this plume requires a suitable discharge velocity of gas through the nozzle. This may be accomplished by providing
30 a gas discharge rate between 1- 15 Litres/min) Formation of the plume is related to the physical design of the nozzle, diffuser and baffle. The blending of the oxygen and atmospheric oxygen is related to the gas

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velocity. Without wishing to be tied to any particular theory of operation, the physical properties of the divide required to generate a plume include the shape, size and positioning of the baffle which serves to deflecting the gas flow back down, then bounce of sidewalls to create this plume-so the walls would have to be no closer than half the diameter of the pin top. The direction of the gas flow exiting the diffuser is substantially directly towards the user's face so as to strike the user at an angle generally perpendicular to the user's face. The gas flow is thus non-oblique in relation to the user's face. The diffuser 38 is positioned so as to direct the flow most strongly at the user's nose and mouth region. It has been found that the configuration described herein efficiently provides an oxygen-enriched zone in the region surrounding the user's mouth and nose, while permitting relatively large cut-outs within the mask.

The baffle 50 is positioned within the path of the gas exiting the nozzle and has a shape and size which is suitable for interrupting the linear gas flow exiting the nozzle so as to generate turbulence. It will be seen that a variety of sizes and shapes will achieve this function. In the illustrated example, the baffle comprises an upstanding stem 48 within elbow 42 which provides a means for releasable attachment thereto of post 50 of mushroom shaped baffle 52. As can be seen in Figure 2, the inner end of baffle 52 has a curled back conical lip 54 on its head 56, the underside of this lip being in line with oxygen passing from aperture 26 at the inner end 58 of elbow 42. This curled back conical lip 54 is of a size and configuration, with respect to wall 34 of diffuser 38, such that turbulence is generated in the stream of oxygen passing from elbow inner end 58 and aperture 28, creating a plume of oxygen enriched air at the patient's nose and mouth when the mask is in position.

In the alternative embodiment of mask 2 illustrated in Figure 4, while mask body 4 and integral diffuser 38 are of a similar configuration to those of Figures 1, 2 and 3, in addition to an oxygen delivery tube 40 passing into elbow 42, elbow 42 is configured to have an oxygen/carbon dioxide monitor tube 60 secured to it, which tube communicates with a separate

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oxygen/carbon dioxide monitor passageway 62 extending within elbow 42 to its inner end 58. Oxygen/carbon dioxide monitor tube 60 and passageway 62 are separate and independent from oxygen delivery tube 40 and oxygen delivery passageway 46. Oxygen from delivery tube 40 is again delivered
5 through elbow 42 to aperture 28 and the inside of mask 2 and the wall 34 of diffuser 38 circumscribes this aperture 28 and directs the flow of oxygen generally outwardly from diffuser 38.

In this embodiment, baffle 64 has a hollow post 66, the hollow center communicating with an opening 68 on the inside of baffle 64, and with the
10 oxygen/carbon dioxide monitor passageway 62 and tube 60.

Head 70 of the baffle 64 circumscribes the opening 68, the head being of a concave shape formed by wall 72. This head 70 fills a significant part of the interior of diffuser 38. Wall 72 extends outwardly beyond the edges of wall 34, and generates the necessary oxygen turbulence to provide
15 an effective plume of oxygen for delivery to the nose and mouth area of the patient when the mask 2 is in position. At the same time however, an effective oxygen/carbon dioxide monitoring of the patient's exhaled breath is permitted through the oxygen/carbon dioxide monitor opening 68 within head 70.

In further embodiments shown in Figures 6A, 6B and 6C, a mask 2
20 comprises a body 4 having a peripheral rim 6. The rim 6 comprises a material such as PVC or Silicone which provides sufficient rigidity to permit the mask to maintain its shape while permitting a degree of resiliency to permit the mask to comfortably conform to a user's face. The rim is
25 provided with an outer surface for contacting the user's face of a material which is soft and pliable plastic with a Durometer range of 20-100 Shore A. The rim preferably has a roughly triangular shape to generally conform to a human nose and mouth region, namely a broad base and a narrow apex, with rounded corners. The rim 6 may alternatively comprise a bendable
30 material such as aluminum which retains its shape when flexed, which may be provided to the user in a shape which roughly follows the contours of a

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typical human face. The mask may be provided in a plurality of rim sizes to fit different classes of users, for example infants and small, medium and large adults.

The body 4 comprises a web of shaped substantially rigid material.
5 This may comprise a semi-rigid material such as that described above in connection with the first embodiment. However, if the body 4 is provided with a more lace-like structure defined by a large number of cut-outs, described below, a more rigid material will be desired such as TPE-
"thermoplastic elastomer". In general, the body has sufficient rigidity to
10 maintain its generally cup-like configuration and to support the diffuser 38 which is fastened to and supported by the body, at a position spaced apart from the user's face. Because the relative position of the diffuser 38 is important to the functioning of this version, the body should have sufficient rigidity to maintain the central position of the diffuser 38 during normal use
15 of the mask. The body 4 may possess a degree of resiliency to enhance user comfort and daily functions and to permit the mask to better conform to the user's face. The body comprises a plurality of cut-outs 60 which may be of any shape and size suitable to serve several desired functions. These functions include permitting the user to speak, eat and drink with a
20 minimum of obstruction, wipe or blow his nose, scratch or otherwise touch his face, kiss and other normal activities. As well, it is contemplated that others such as health professionals may rely on the cut-outs 60 to feed or provide fluid to the user or for other functions. Thus, it is contemplated that relatively large openings are provided in the region of the user's nose and
25 mouth. However, other arrangements of openings are possible such a larger number of smaller openings. The openings must not be so many or large as limit the ability of the web to fixedly support the diffuser 38.

The diffuser 38 is mounted within the mask body 4 so as to be centered vertically and horizontally (side-to-side) above a point which when
30 the mask is worn by a person, is about halfway between the base of the nose and the upper lip.

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Preferably, the cut-outs 60 comprise at least 50 per cent of the total surface area of the body 6 (when measured with the surface area including both open and closed areas) and still more preferably the cut-outs comprise between 50 and 80 per cent of the total surface area. In a still more preferred version the range is more narrowly defined as being between 60 and 75 per cent.

The diffuser 38 protrudes through and is supported by the body 4 at a position generally opposed to the user's nose and mouth region. The diffuser and associated baffle are substantially as described in connection with the embodiments. However, it has been found that if the diffuser body conforms to particular size and positioning limits, it effectively generates a zone or region of oxygen-enriched gas in the region of the patient's nose and mouth, regardless of the number, size and shape of the cut-outs 60. For this purpose it is desirable to fabricate the body 4 from a relatively rigid material such as polystyrene, thermoplastic elastomer or polycarbonate. The diffuser 38 receives a gas supply from supply line 40, via elbow 42 in the same manner as described above. A mushroom-shaped baffle within the interior of the diffuser 38 assists in the dispersal of gas. It will be further apparent to those skilled in the art that the diffuser 38 may comprise a range of sizes and shapes. However, in order to generate the desired region of oxygen enriched gas the diffuser comprises a cup-like body opening towards the user. It should have a maximum size and positioning within the mask that permits the diffuser to fit entirely within a region of the mask defined by reference to an imaginary point on the user's face between the base of the nose and upper lip, in the midline of the face, with the diffuser entirely fitting within the space defined by 20 mm on either side of this line horizontally and 40 mm above and below the this point vertically (when the user is upright). Preferably the diffuser is sufficiently small so as to permit some slippage of the mask while still remaining within this region, for example as described above a generally triangular configuration about 25 mm wide at its base and about 22 mm high. The diffuser is also positioned within the mask such that the gas discharge nozzle is between 12 and 40 mm displaced forwardly of the user's face measured from the area

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between the upper lip and below the nose of a users face. The body 6 must have sufficient forward protrusion so as to position the rear rim of the diffuser so that it does not contact the nose of the typical user. The spacing thus required will vary somewhat with different sizes of masks. For
5 example, the diffuser may protrude rearwardly into the interior of the body 4 by about 2 mm, and the body thus has an overall depth of about 15 mm.

According to another embodiment, illustrated in Figures 7 and 8, the mask body 4 is similar in overall configuration to the embodiments described previously, including a rim 6 for contacting the patient's face, a
10 central diffuser structure 34 spaced apart from the user's face, and an array of web-like bridges 102, 110 and 112, described below, radiating outwardly from the central portion 16 to join the central portion 16 to the rim 6. The bridges have a generally curved shape so as to define the concave structure of the mask body 4. The bridges define a generally open structure to the
15 mask body, including preferably a relatively large opening 100 in the central lower region approximately opposite to the patient's mouth. The bridges include first and second opposing lateral bridges 102, which when the mask is upright radiate outwardly in a substantially horizontal direction, on either opposing side of the central region. The horizontal bridges 102 define upper
20 and lower lateral openings 106, 108 within the mask body. Preferably, the bridges further include opposing downwardly angling bridges 110, with the space 100 therebetween defining the central lowermost opening facing the user's mouth. The remaining bridge 112 extends vertically upwardly between the central portion 16 and the rim 6.

25 Within the present example, the lateral bridges 102 have curved side edges 114, such that these bridges 102 are at their narrowest in the central portions thereof, tapering outwardly towards either end in a symmetric fashion. The approximate width of each bridge 102 at its narrowest is 11 mm. The central vertical bridge 112 is approximately 7 mm at its
30 narrowest, and the opposing left and right lower bridges 110 are approximately 11 mm wide.

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The central diffuser structure includes an oxygen inlet 116 with a mushroom-shaped baffle (as shown in Figure 2 and here removed for clarity) partially obstructing the inlet 116 to generate a turbulent gas plume. The baffle is surrounded by the wall 34 extending horizontally towards the user's face, when the mask is upright, with the wall having a generally triangular shape when viewed in front elevation from the perspective of the user. The diffuser region defined by the height of the wall from its base to its top (referenced now to the mask being horizontal) is deeper than in the embodiments described above so as to extend closer to the user's face. In the previous embodiments described above, the wall ranges from being generally flush with the central part of the mask body, to an outward protrusion of about 12 mm. In this embodiment, the wall has a minimum protrusion of about 13 mm and a maximum protrusion of about 20 mm. It is contemplated that these may range plus or minus by about 5 mm. As is seen in the Figures, the wall varies in protrusion to accommodate the inward and upward tilt of the mask, such that the exposed rim of the wall is generally vertical when the mask is upright. As well, the exposed rim 117 is angled such that it protrudes more towards the user at its upper region relative to its lower region. For example, the rim may have a generally curvilinear shape as seen in the Figures, such that when seen from the side, the rim has in general a backwards "S" shape.

The embodiment further includes an array of stiffening ribs 120, which are integral with the webs, and serve to stiffen the webs for maintaining their shape with the use of relatively thinner material. The ribs 120 extend longitudinally substantially the length of each web 102, 110, 112, and extend approximately centrally along the interior of each web. The ribs 120 are tapered, such that their tallest portion joins with the wall of the diffuser, tapering to a minimal height adjacent the rim. Preferably, the ribs and webs are molded together and comprise the same material, which preferably is resilient. As described above, the mask is preferably molded or otherwise formed from a suitably resilient material, such that the mask may be stored in a substantially flattened position, and when released the ribs

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assist the mask to snap back into their concave position suitable for patient use.

In a further aspect, the mask rim 6 comprises an array of attachments for attaching different selected straps, bands, or the like for fastening the mask to the user's head. Thus, the rim includes opposing outwardly extending tabs 124, each of which includes an opening 126 for fastening a band or the like. The tabs 124 preferably are positioned at about the middle region of the mask. Additional openings 128, 130 are provided through the rim 6, including opposed openings 128 slightly above the tabs and two opposed openings 130 below the tabs, near the lower end of the mask. A single band (not shown) may be fastened to the tabs, and/or the openings slightly above the tabs, for extending around the back of the user's head. Alternatively, a pair of opposing looped fastenings (not shown) may be attached on either side of the mask, with a first end of the loop attaching to the tab and the second end of the loop attaching to the lower opening. The loops are preferably elasticized for extending around the user's ears, as a convenient way to hold the mask snugly against the user's face, without the need for a band extending fully around the backside of the user's head.

It has been found that masks within the scope of the present invention, and in particular the final embodiment described herein, are acceptable with a relatively high oxygen flow rate, with relatively high oxygen concentrations within the mask interior.

In a study, a mask according to the last embodiment described above was tested using live participants with a range of oxygen flow rates. The dilution rate X of the gas plume within the mask was determined according to the following equations:

$$V_2 = V_1 * d_1^2 / d_2^2 = V_3 \quad (\text{Concentration of Mass, Continuity})$$

$$X \approx Q / 2\pi K V_2 R r^2 \exp(-2r^2 / 2Rr^2) \quad (\text{Concentration of Mass, Gaussian Model})$$

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The sampling tube for the monitor was taped at the same location on all participants, at the center of the lower lip area. Oxygen flow rates were adjusted from 1.5 LPM to 30 LPM. In the experiment, the participants were seated upright in order to simulate field conditions.

- 5 A Datex-Ohmeda AS/5 multigas monitor had a sampling flow rate of 200 mL/min, and a delay time of approx.2.5 s with this configuration. Alveolar gas equilibrium was achieved before stabilized waveforms were noted.

10 Reported mean oxygen concentrations and associated standard deviations (SD) in the individuals are the results of at least 5 individual readings collected over 90 sec. Intervals. Oxygen was supplied to the participants at 1.5, 2, 2.5, 3, 5, 10, 15, 20, 25 and 30 Litres per minute (LPM). Flow rates were recorded as indicated by the Chemetron 09990-62050 oxygen regulator needle valve. No attempt was made to accurately determine flow rates, since this device is typical to those used in the field.

- 15 A measurement was taken from the edge of the diffuser to the participant's lips, in mm. These to later verify for the CFD study and establish the constant (K).

20 By comparing the published existing Oxygen Flow Setting Table (Table 1) to the newly designed mask (Table 2) the results indicate significant oxygen concentrations at higher flow rate settings.

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| Flow (Litres/min) | O2 Concentration (%) |
|-------------------|----------------------|
| 2 | 28 - 31 |
| 4 | 32 - 35 |
| 6 | 36 - 39 |
| 8 | 40 - 43 |
| 10 | 42 - 47 |
| 12-15 | 48 - 50 |

- Table 1

| Flow (Litres/min) | O2 Concentration (%) |
|-------------------|----------------------|
| 1.5 LPM | 21%-35% |
| 2 LPM | 23%-47% |
| 2.5 LPM | 26%-63% |
| 3.0 LPM | 29%-68% |
| 5.0 LPM | 41%-84% |
| 10 LPM | 57%-88% |
| 15 LPM | 64%-90% |

- Table 2

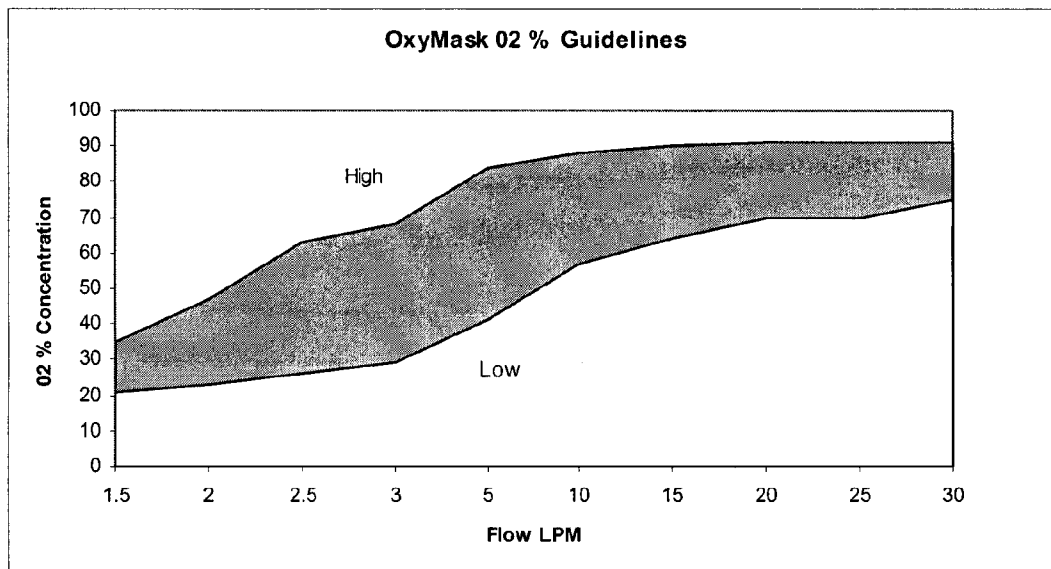
The data relating to the embodiments of Figures 7 and 8 thus shows
 5 that the parameters (good oxygen concentration and varied flow rates) can
 be achieved.

Low flow systems deliver 100% oxygen at flows that are less than the
 patient's inspiratory flow rate (i.e., the delivered oxygen is diluted with
 room air) and thus the oxygen concentration (FI_{O2}) may be high or low
 10 depending on a specific device and the patient's rate.

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In contrast, nasal cannula can provide 24-40% oxygen with flow rates up to 6 L/min but should be humidified at rates above 4 L/min.

At rates higher than 6 to 10 LPM and 40-70% oxygen require a partial re-breathing mask. This is considered a low flow system; a non re-breathing mask is similar to the partial re-breathing mask, except that it has a series of one-way valves. This requires a minimum flow of 10 L/min. The delivered FI_{O_2} of this system is 60-80%.



10 Figures 9 through 13 illustrate schematically the gas plume formed, at different flow rates, by the mask according to the final embodiment described herein. The simulations indicate how the shape of the oxygen enriched plume changes in concentration and distance from the diffuser at various flow rates, 1.5, 5.0 10.0 20.0 and 40 LPM (Liters/Minute).

15 Figure 14 is a graph showing the gas velocity, at different flow rates, plotted against the distance from the end of the mushroom-shaped central baffle, in the embodiment described lastly herein. Figure 15 is a graph showing the mass fraction, namely of the oxygen percentage which at i.e. 2.29 E-01 is 22.9%, plotted against the distance from the baffle towards the

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user's face, for different flow rates. In both cases, flow rates between 1.5 and 40 LPM were tested.

As well, the mask design of the present invention allows a patient to drink, eat, be suctioned and speak, without removal of the mask. Also, exhaled air does not collect in the area in front of the patient's nose and mouth and interfere with the mask's operation, as in the case of conventional oxygen masks, since exhaled air easily passes to the surrounding environment through the spaces between the bridge portions and the peripheral portion of the mask.

In tests which have been done and proven the efficacy of the mask designs according to the present invention, it has been determined that patients find the mask according to the present invention to be far more comfortable than conventional oxygen masks. Unlike conventional masks, users cannot feel oxygen being delivered to their nose and mouth area, and enjoy the compactness of the mask. Technically, lower flow rates of oxygen to a patient through the mask of the present invention can be achieved, with as much or greater oxygen concentration in the air being delivered to the patient, as compared to conventional oxygen masks. In this manner, the mask according to the present invention provides both comfort and efficiency to patients which providing optimal blood oxygen saturation in a cost effective manner. Flow rates ranging from .5 Litres to 15 Litres per minute have proven suitable providing a far greater range of possible flow rates than available through conventional oxygen delivery devices. The following examples describe tests performed with the mask.

Example 1

A study was conducted, comprising a randomized, cross-over, single-blind study of patients having the following inclusion criteria:

- chronic pulmonary disease requiring supplemental oxygen therapy;

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- stable oxygen requirement (unchanging over a three hour period);
- 18-80 years of age.

5 Excluded were patients whose oxygen requirement is unstable (i.e. changing hourly) or who could not tolerate being deprived of supplemental oxygen for five minutes or less.

Protocol

Continuous monitoring of minute ventilation (Respirace), SaO₂, HR, nasal/oral flow, PO₂ and PCO₂ at the lip, O₂ flow and TcPCO₂:

- 10
- 5-10 min washout / 5 min baseline (room air);
 - Mask #1 (supplemental oxygen; referred to herein as "OxyMask™" or "OM" and comprising an embodiment of the invention);
 - 15-30 min at 4-5% above baseline SaO₂;
 - 15-30 min at 8-9% above baseline SaO₂;
- 15
- 5-10 min washout / 5 min baseline (room air);
 - Mask #2 (supplemental oxygen; referred to herein as "venturi" or "V", comprising a prior art mask);
 - 15-50 min at 4-5% above baseline SaO₂;
 - 15-30 min at 8-9% above baseline SaO₂.

20 Data analyzed using two-way analysis of variance (ANOVA) and paired t-test:

- p values <0.05 were considered statistically significant.

Patient Demographics

25 N=13 patients with chronic pulmonary disease using supplemental oxygen via nasal cannula.

4 male, 9 female.

age: 56 ± 16 (range: 28-79).

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BMI: 35.0 ± 12.3.

O2 requirement: 2.3 ± 1.3 Lpm (rest), 3.4 ± 1.6 Lpm (exercise).

Pulmonary Function Tests

| Spirometry | | |
|-------------------|---------------|---------------|
| | Measured | % Predicted |
| FVC, L | 1.87 ± 0.66 | 57.38 ± 13.20 |
| FEV1, L | 1.22 ± 0.56 | 51.54 ± 21.50 |
| FEV1/FVC | 65.06 ± 19.29 | - |
| V50, L/sec | 1.38 ± 1.23 | 42.15 ± 34.71 |
| V25, L/sec | 0.40 ± 0.32 | 25.23 ± 18.66 |
| VC, L | 2.00 ± 0.80 | 60.20 ± 15.05 |

| Arterial Blood Gases | |
|------------------------------------|--------------|
| pH | 7.38 ± 0.05 |
| H ion, nmol/L | 41.63 ± 5.01 |
| pCO ₂ , mmHg | 47.50 ± 6.65 |
| pO ₂ , mmHg | 50.88 ± 7.92 |
| Bicarbonate, mmol/L | 29.13 ± 4.70 |
| Measured O ₂ Saturation | 0.85 ± 0.06 |
| Base Excess, mmol/L | 2.26 ± 4.29 |

5 *Results*

| | Low Saturation | | High Saturation | | ANOVA | | |
|-----------------------------|-----------------------|------------|------------------------|------------|------------------|-------|--------------|
| | OxyMask | Venturi | OxyMask | Venturi | Saturation Level | Mask | Inter-action |
| SaO ₂ , % | 92.0 ± 3.6 | 91.7 ± 3.4 | 94.8 ± 3.2 | 94.9 ± 3.6 | - | NS | NS |
| Flow O ₂ , L/min | 0.9 ± 0.3 | 4.8 ± 1.5 | 2.1 ± 0.9 | 12.2 ± 3.9 | <0.01 | <0.01 | <0.01 |

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| | | | | | | | |
|--|-----------------|-----------------|------------------|---------------------|-------|-------|-------|
| Ve, L/min | 9.1 ± 5.0 | 7.4 ± 4.2 | 10.6 ± 5.9 | 8.0 ± 4.4 | NS | <0.05 | NS |
| tPCO ₂ , mmHg | 51.9 ± 8.9 | 51.4 ± 7.6 | 51.3 ± 9.1 | 52.4 ± 8.0 | NS | NS | <0.05 |
| P _i O ₂ , mmHg | 229.7 ± 44.5 | 192.6 ± 11.9 | 459.5 ± 167.5 | 330.0 ± 126.6 | <0.01 | <0.01 | <0.05 |
| P _E O ₂ , mmHg | 164.4 ± 16.9 | 181.7 ± 12.2 | 209.2 ± 39.2 | 266.9 ± 52.4 | <0.05 | <0.01 | <0.05 |
| P _i CO ₂ , mmHg | 3.9 ± 1.5 | 1.6 ± 0.9 | 3.2 ± 0.6 | 1.4 ± 0.8 | <0.05 | <0.01 | NS |
| P _E CO ₂ , mmHg | 33.5 ± 8.9 | 11.3 ± 5.6 | 27.2 ± 8.9 | 11.6 ± 8.0 | <0.01 | <0.01 | <0.05 |
| HR, b/min | 77.9 ± 18.0 | 78.2 ± 17.9 | 78.9 ± 18.9 | 77.3 ± 17.7 | <0.05 | NS | NS |
| Nasal:Oral Flow | 1.20 ± 0.32 | 1.01 ± 0.26 | 1.11 ± 0.22 | 1.07 ± 0.26 | NS | NS | NS |

Summary

O₂ flow rate significantly lower with OM vs. V.

P_iO₂ significantly higher and P_EO₂ significantly lower with OM. vs. V

- 5 Ve significantly higher with OM vs. V while TcPCO₂ similar between masks.

P_iCO₂ and P_ECO₂ significantly higher with OM vs. V.

Difference in O₂ flow remained significant when comparing patients whose Ve increased by >=10% with OM vs. V to those whose did not.

- 10 It is evident that many alternatives, modifications and variations will be apparent to those skilled in the art in light of the foregoing description.

- 30 -

Accordingly, it is intended to embrace all such alternatives, modifications and variations as fall within the spirit and broad scope of the invention.

Editorial Note
2007247797

There is no Claim 16 for the following claims

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CLAIMS

1. A mask for delivery of gas to a patient comprising a central portion, a rim configured for contacting the patient's face around the patient's nose and mouth region, a web joining said central portion to said rim and comprising openings within said mask, a gas nozzle configured for connection to a source of gas for delivering gas into said mask, and a gas diffuser protruding from said central portion, said diffuser comprising a baffle positioned over said nozzle for obstructing the flow of gas from said nozzle and a wall fully surrounding said nozzle and protruding inwardly towards said patient from said central portion such that the entirety of the wall protrudes inwardly from the central portion of the mask by between about 3 mm and 25 mm.
2. A mask according to claim 1 in combination with an oxygen delivery tube releasably securable to the outer surface of the central portion of the mask so as to communicate with the gas connection.
3. A mask as defined in claim 1 wherein said baffle comprises a stem mounted adjacent to said nozzle and a head having a curved surface facing said nozzle for generating turbulence within said gas flow.
4. A mask as defined in claim 3 wherein said head includes a curled back conical lip facing said nozzle.
5. A mask as defined in claim 3 wherein said stem includes a passageway open to the interior of said mask body and communicating with the exterior of said mask for permitting measurement of exhaled gas from within said mask body.
6. A mask according to claim 1 wherein said wall is generally cup-shaped comprising a free edge contoured so as to conform, when the mask is in position on a patient, generally to the shape of a patient's nose and mouth area but spaced apart therefrom when in use.

7. A mask as defined in claim 1 wherein said wall has a maximum top to bottom distance when said mask is vertical of 40 mm above and below said nozzle and a maximum side to side distance of 20 mm on either side of said nozzle, when said mask is positioned in an upright position.
8. A mask as defined in claim 1, wherein said diffuser is positioned so as to maintain a spacing of between 12 and 40 mm between said diffuser and said user's face as measured from the skin surface between nose and mouth.
9. The mask of claim 1 wherein said openings comprise between 30 and 80 per cent of the total surface area of said body, said surface area comprising open and covered areas.
10. The mask of claim 9 wherein said openings comprise between 50 and 75 per cent of the total surface area of said body.
11. A mask as defined in claim 1, wherein said diffuser is positioned so as to be centered over a point about halfway between the user's nose and upper lip.
12. A mask as defined in claim 1, wherein at least one of said openings provides access from the mask exterior to the user's nostrils.
13. The mask of claim 1 further comprising a sensor for monitoring exhaled gases within the interior of said mask.
14. The mask of claim 1 wherein said wall protrudes inwardly from said central portion by between about 13 mm and 20 mm.
15. The mask of claim 1 wherein said web comprises an array of bridges between said central portion and said rim radiating from said central portion, said web further comprising at least one stiffening rib protruding inwardly from at least one of said bridges, joining with said diffuser.

17. A face mask as defined in claim 1 further comprising an elbow-shaped connector engaged to said nozzle for providing a passageway for delivery of said gas into the interior of said mask body.

18. A face mask as defined in claim 1 configured to deliver an FIO₂ concentration to a patient within a range of 21% to 90%, by controlling the flow of O₂ to said diffuser within a range of 1.5 LPM and 15 LPM.

19. A face mask as defined in claim 1 configured to deliver an FIO₂ concentration to patient within a range of about 21% to about 92%, by controlling the flow of O₂ to said diffuser within a range of 1.5 LPM and 40 LPM.

20. A face mask as defined in claim 1 configured to deliver an FIO₂ concentration to patient within a range of about 21% to about 92%, by controlling the flow of O₂ to said diffuser within a range of 1.5 LPM and 30 LPM.

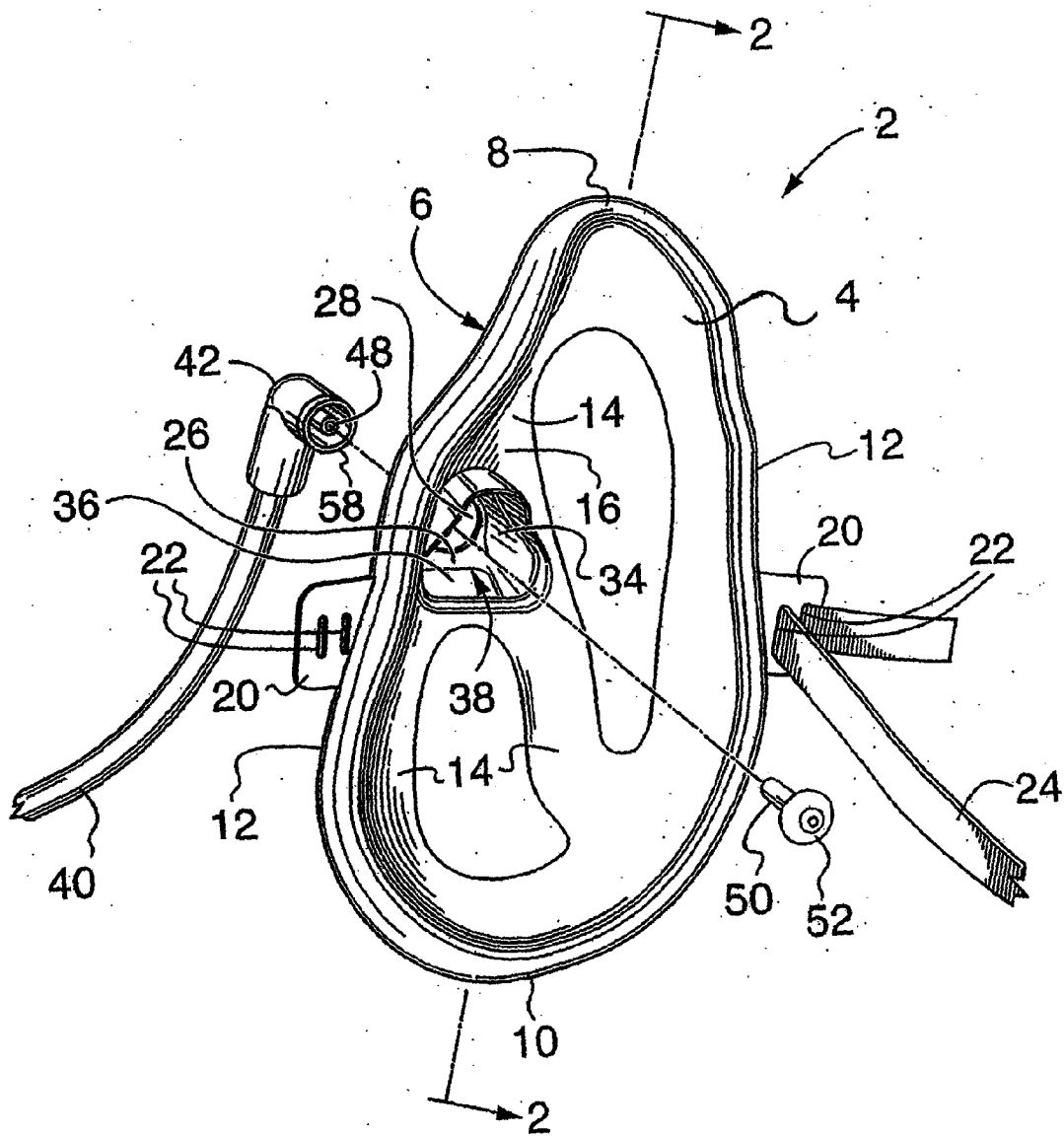


FIG. 1

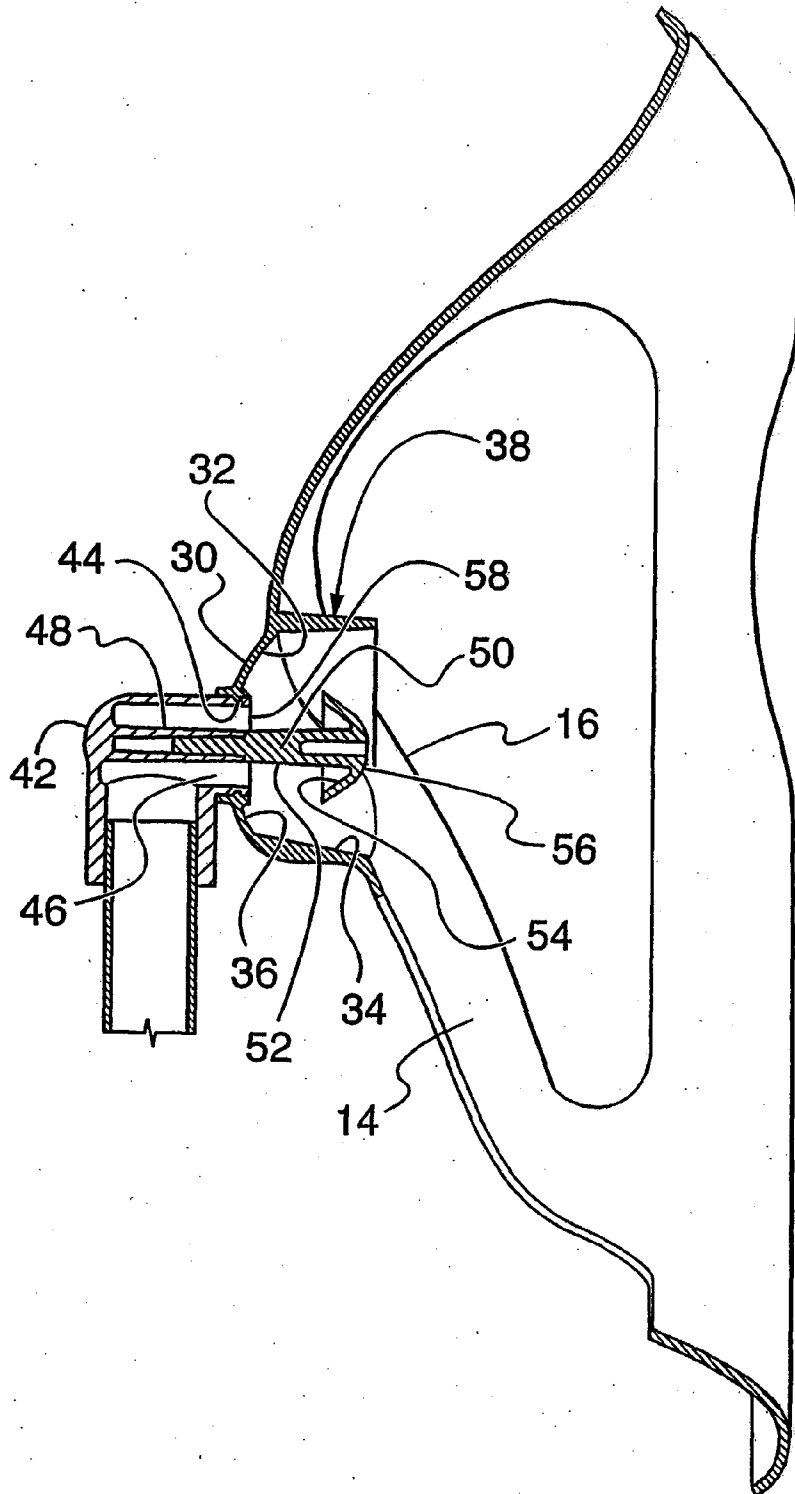


FIG. 2

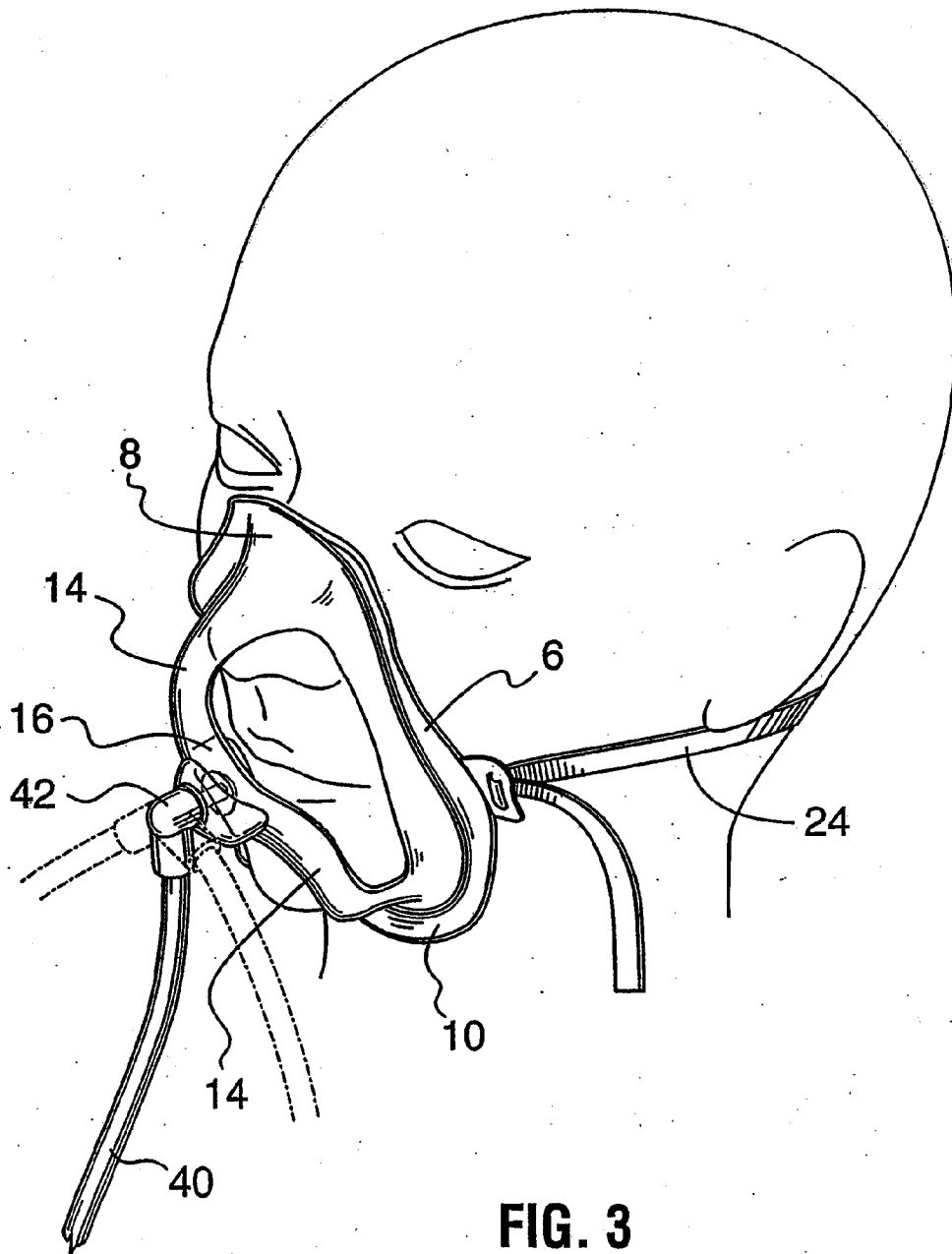


FIG. 3

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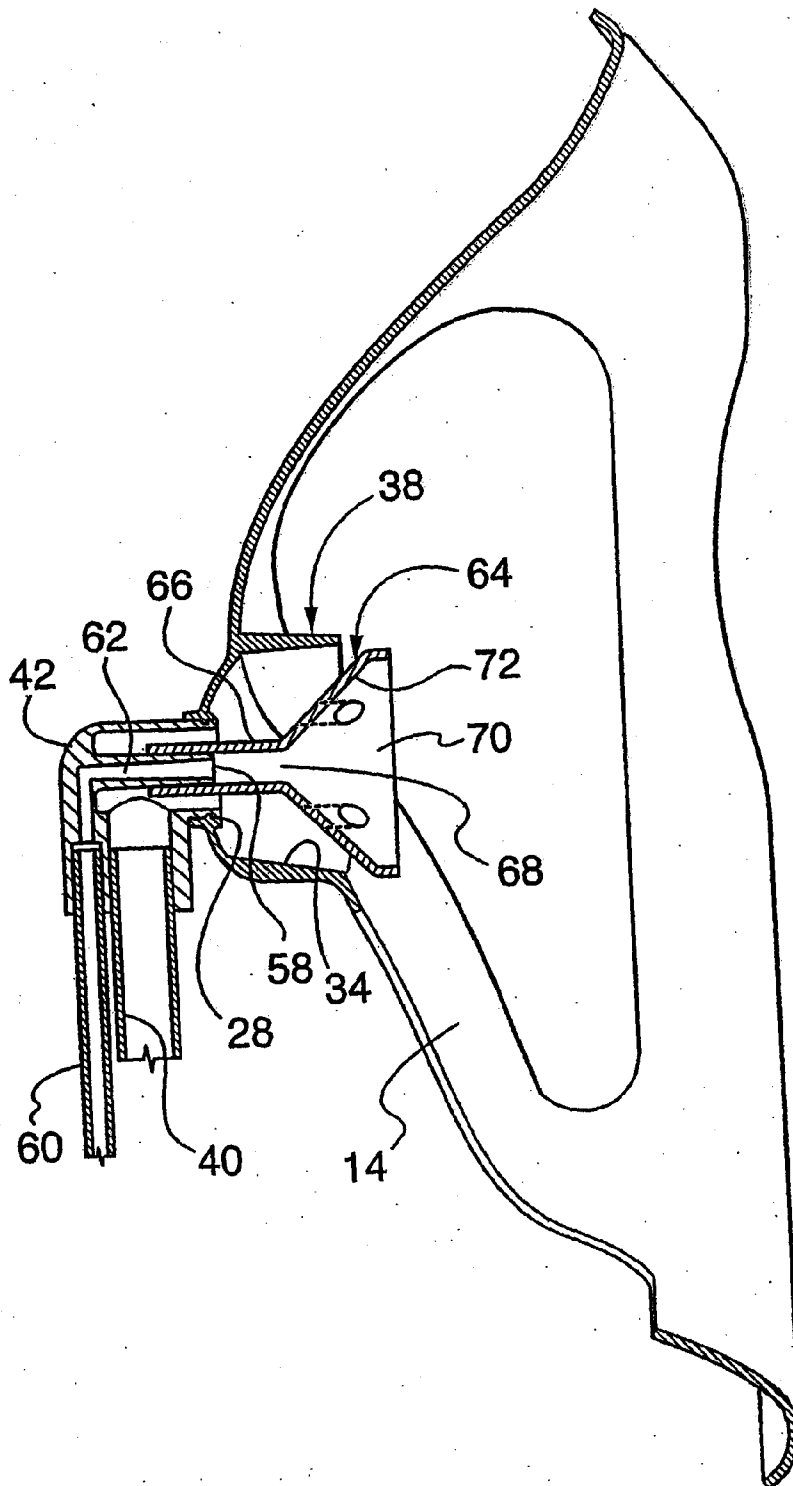


FIG. 4

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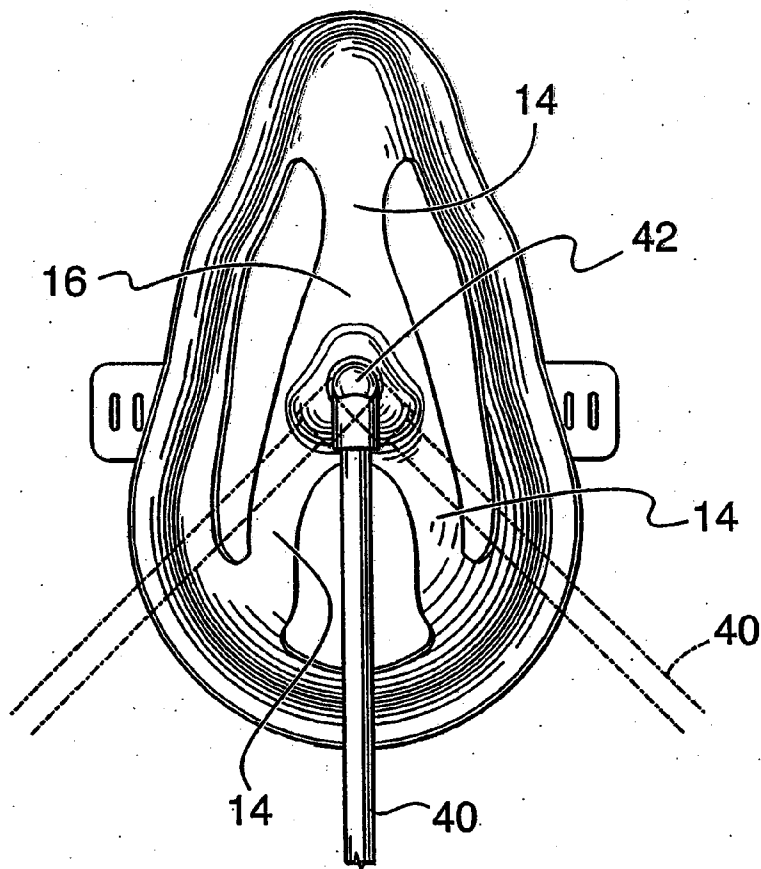


FIG. 5

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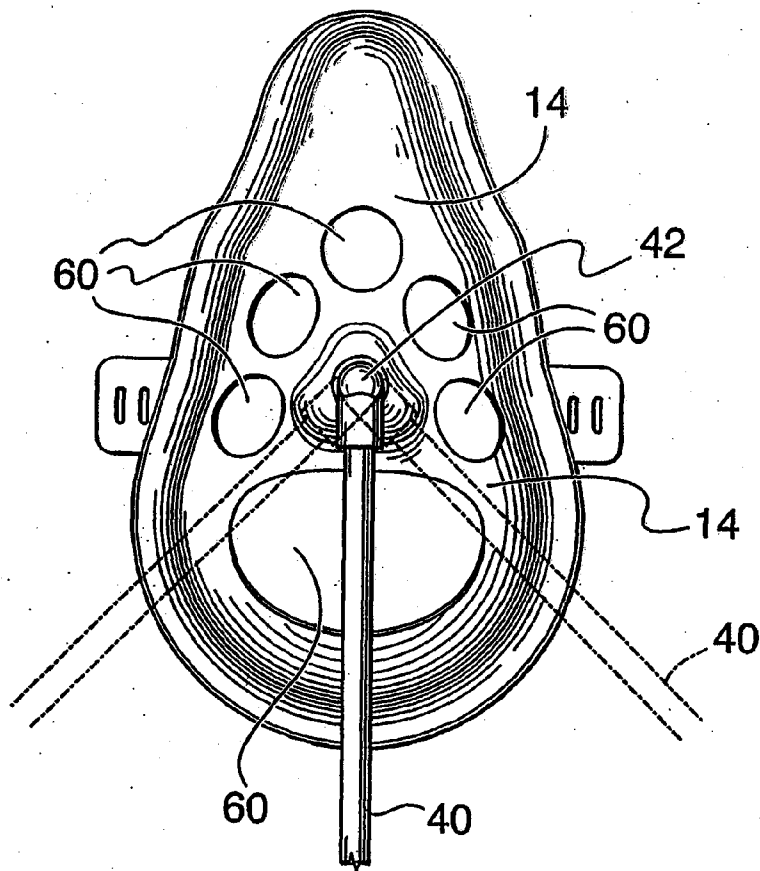


FIG. 6A

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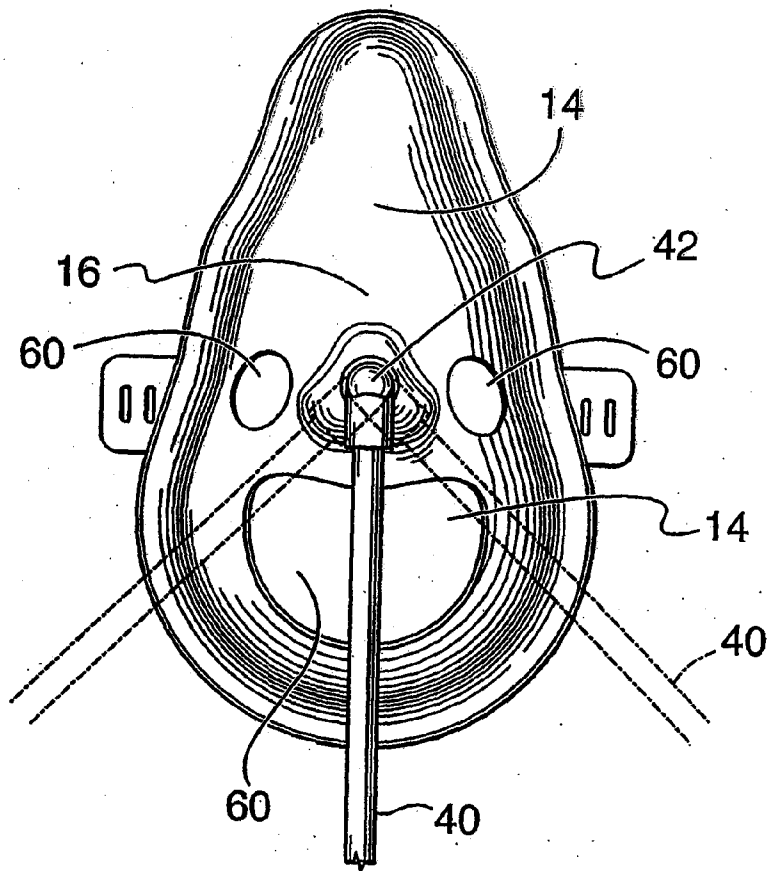


FIG. 6B

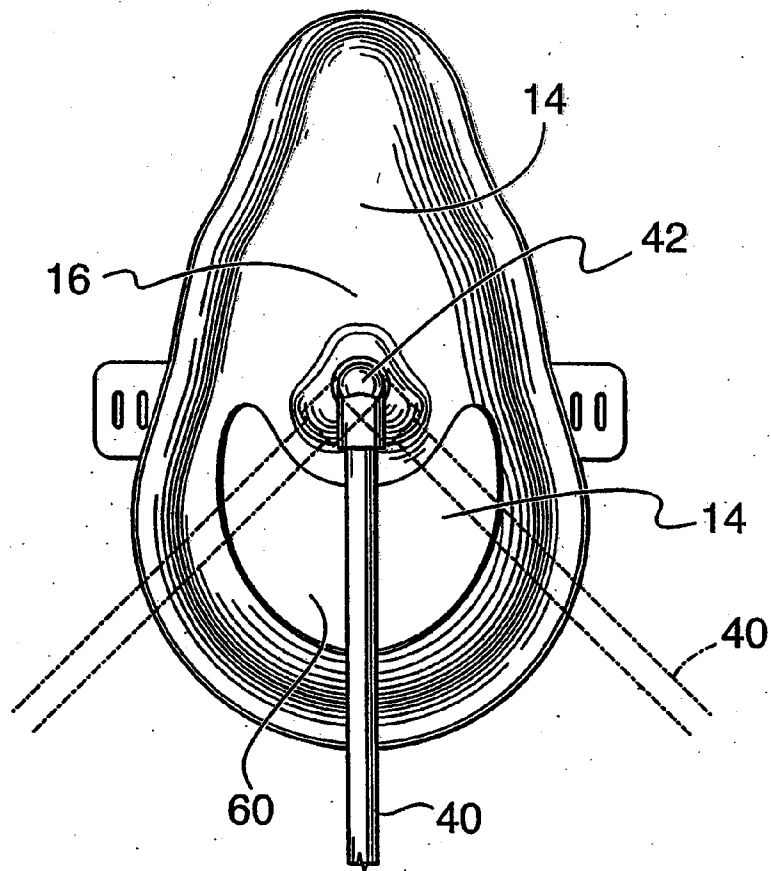


FIG. 6C

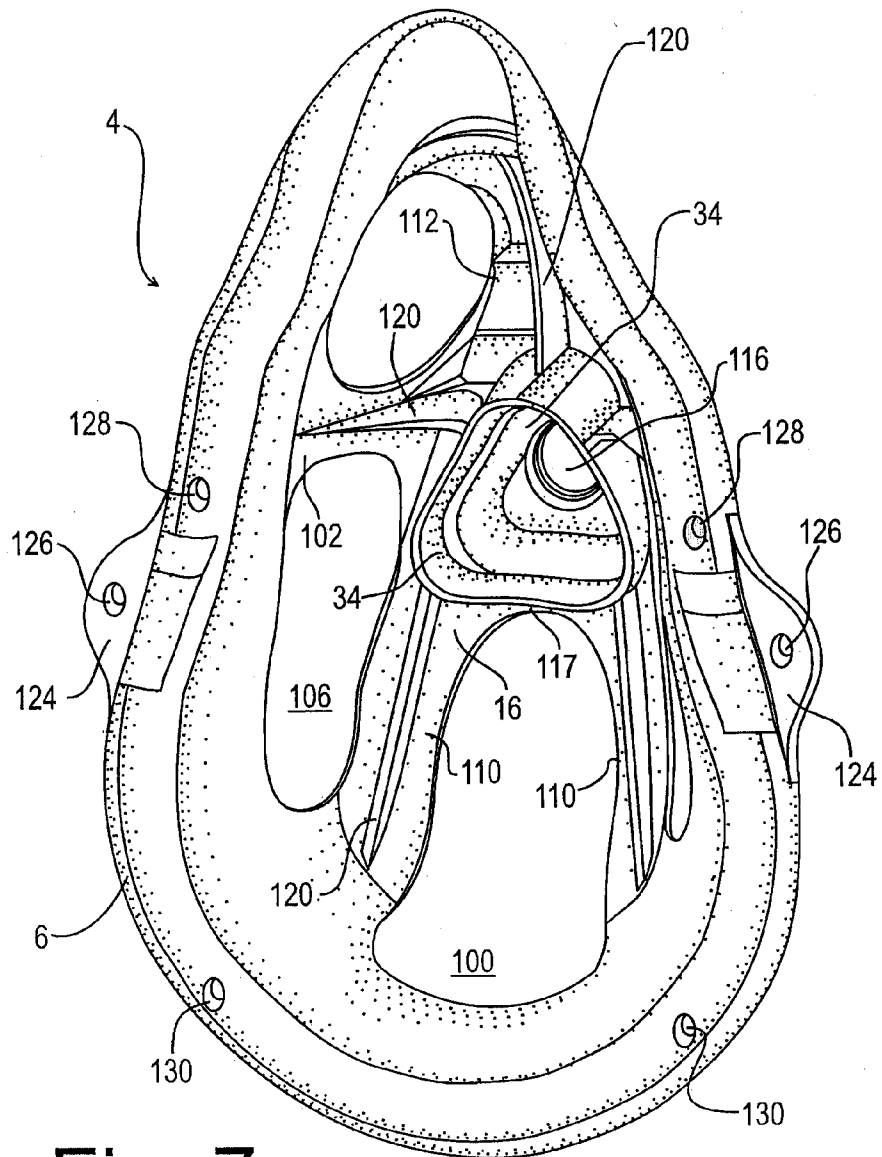


Fig. 7

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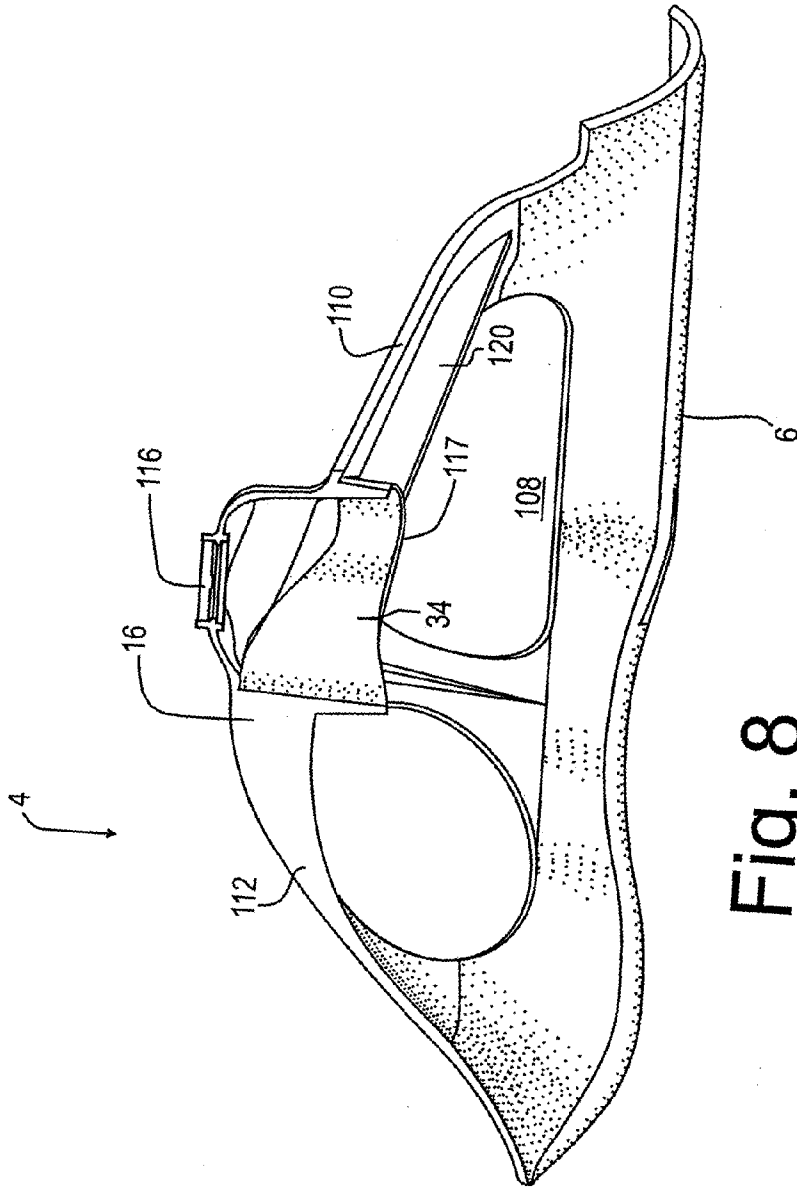
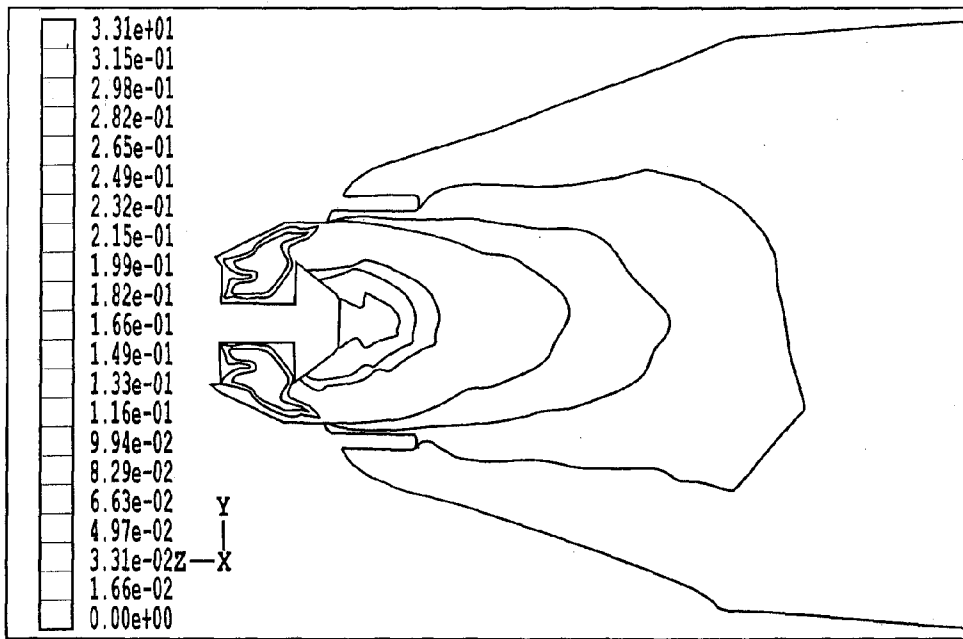


Fig. 8

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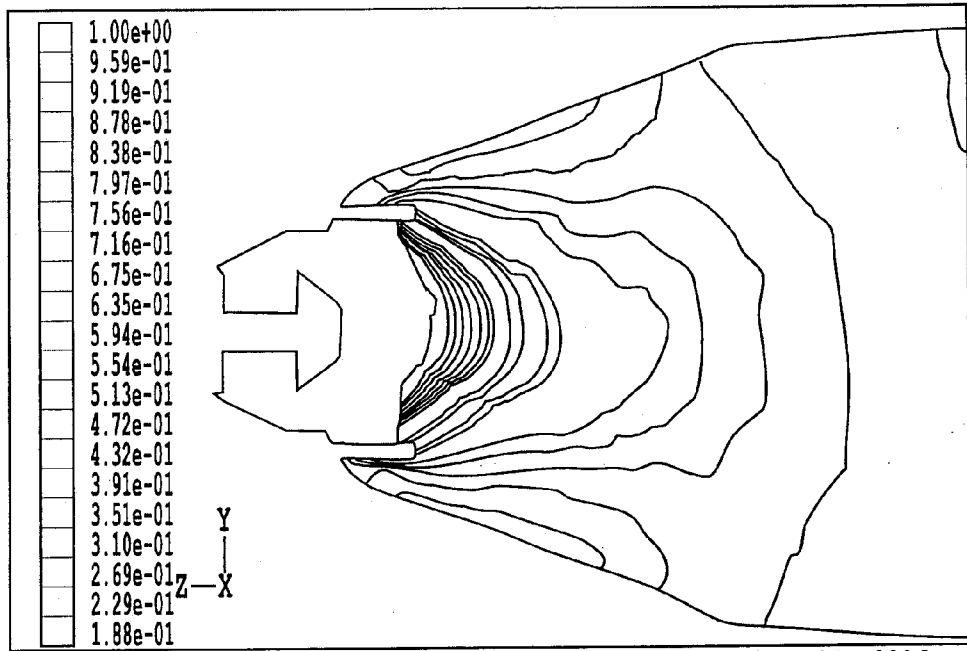
Mass flow rate = Q1 = 1.5 lpm



Contours of Velocity Magnitude (m/s)

Apr 04, 2006
FLUENT 6.2 (3d, segregated, spe, mgke)

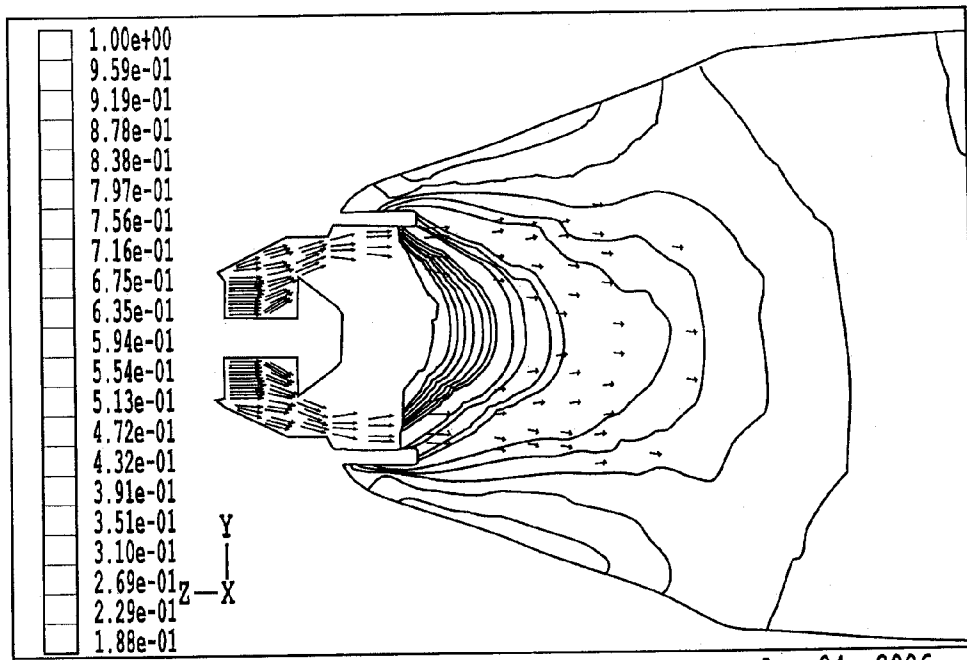
Fig. 9a



Contours of Mass fraction of o2

Apr 04, 2006
FLUENT 6.2 (3d, segregated, spe, mgke)

Fig. 9b

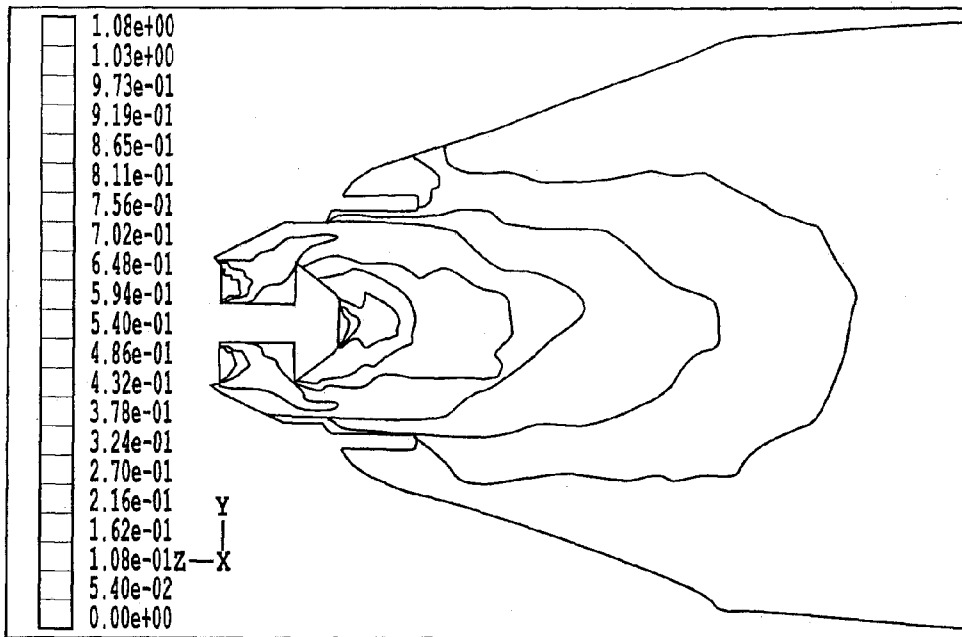


Contours of Mass fraction of o2

Apr 04, 2006
FLUENT 6.2 (3d, segregated, spe, mgke)

Fig. 9c

Mass flow rate = Q2 = 5.0 lpm



Contours of Velocity Magnitude (m/s)

Apr 04, 2006
FLUENT 6.2 (3d, segregated, spe, mgke)

Fig. 10a

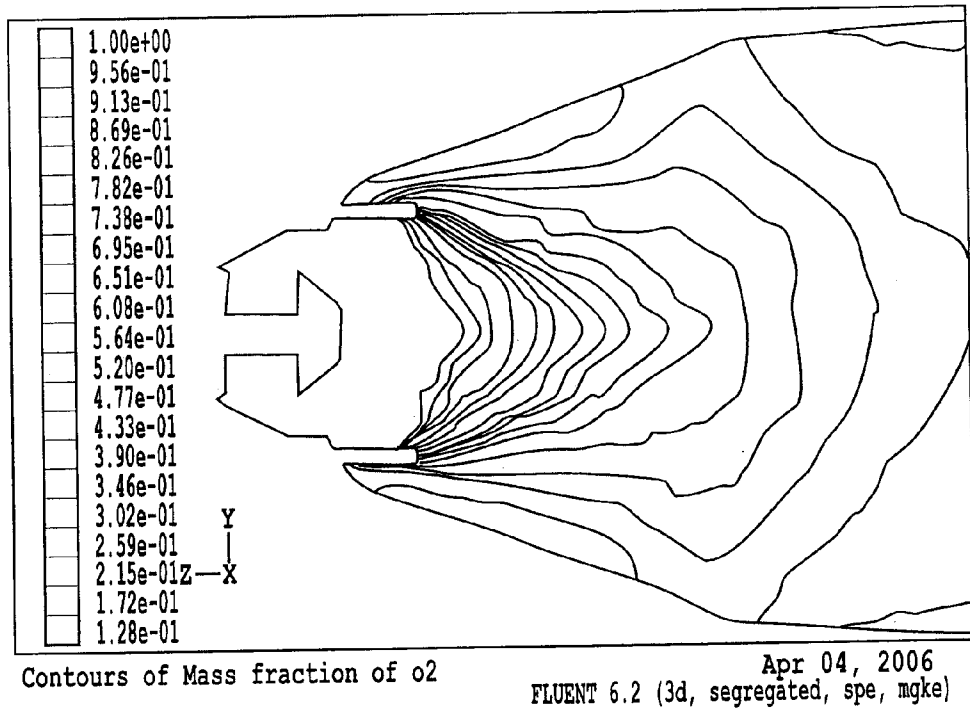
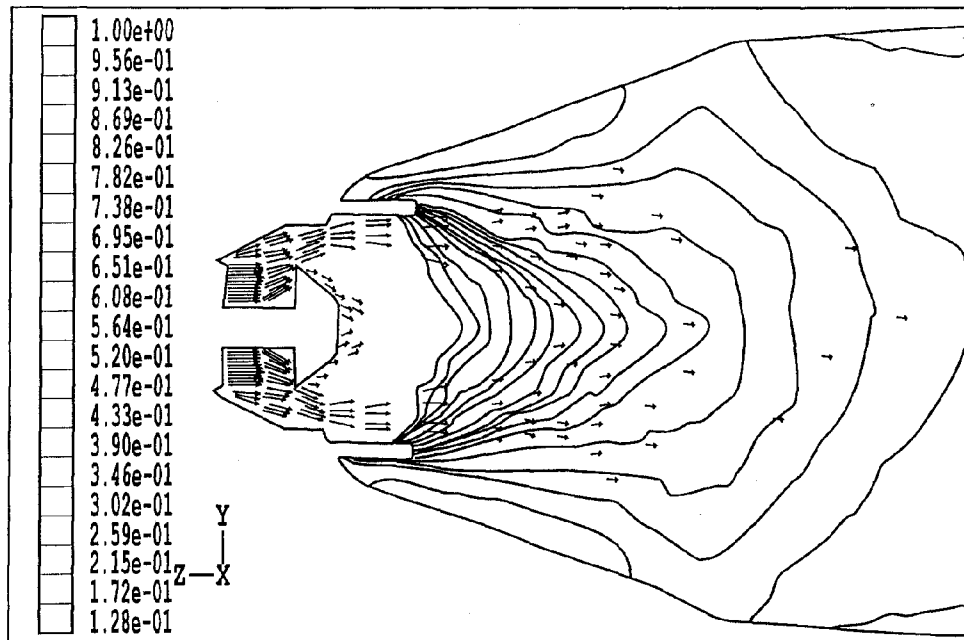


Fig. 10b

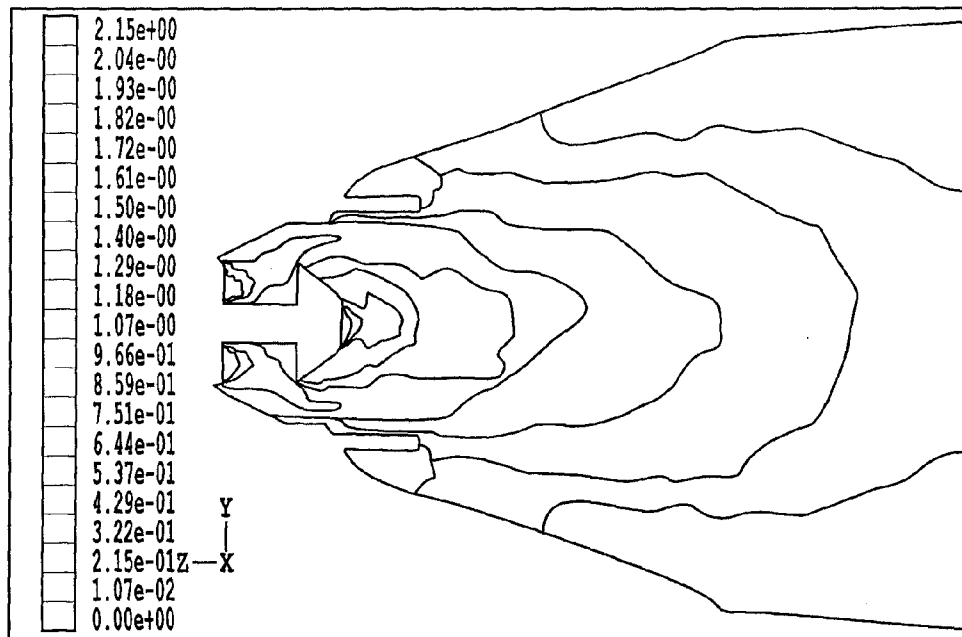


Contours of Mass fraction of o2

Apr 04, 2006
FLUENT 6.2 (3d, segregated, spe, mgke)

Fig. 10c

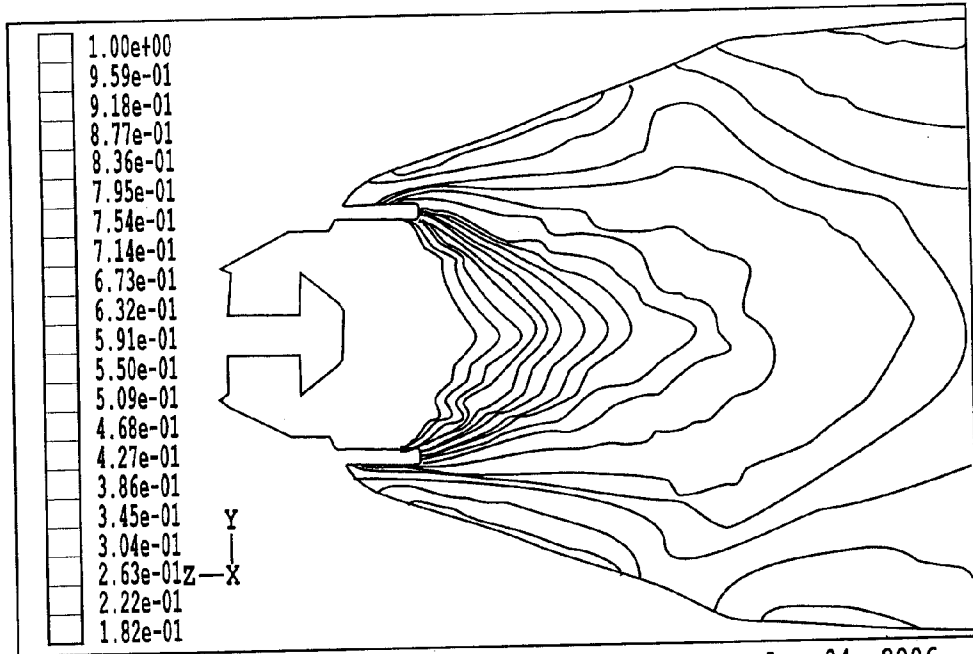
Mass flow rate = Q3 = 10.0 lpm



Contours of Velocity Magnitude (m/s)

Apr 04, 2006
FLUENT 6.2 (3d, segregated, spe, mgke)

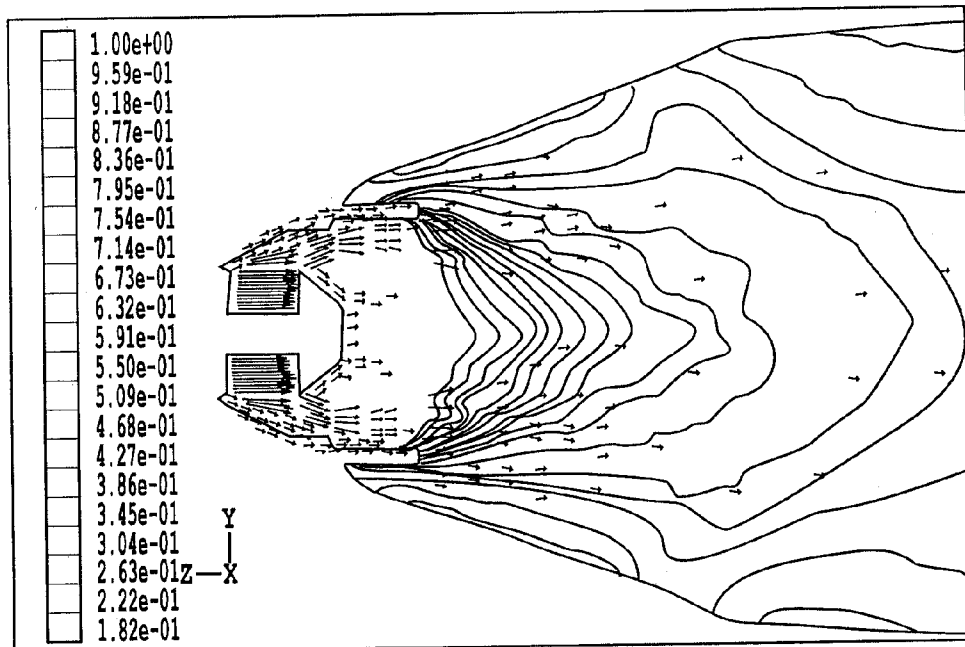
Fig. 11a



Contours of Mass fraction of o2

Apr 04, 2006
FLUENT 6.2 (3d, segregated, spe, mgke)

Fig. 11b



Contours of Mass fraction of o2

Apr 04, 2006
FLUENT 6.2 (3d, segregated, spe, mgke)

Fig. 11c

Mass flow rate = Q4 = 20.0 lpm

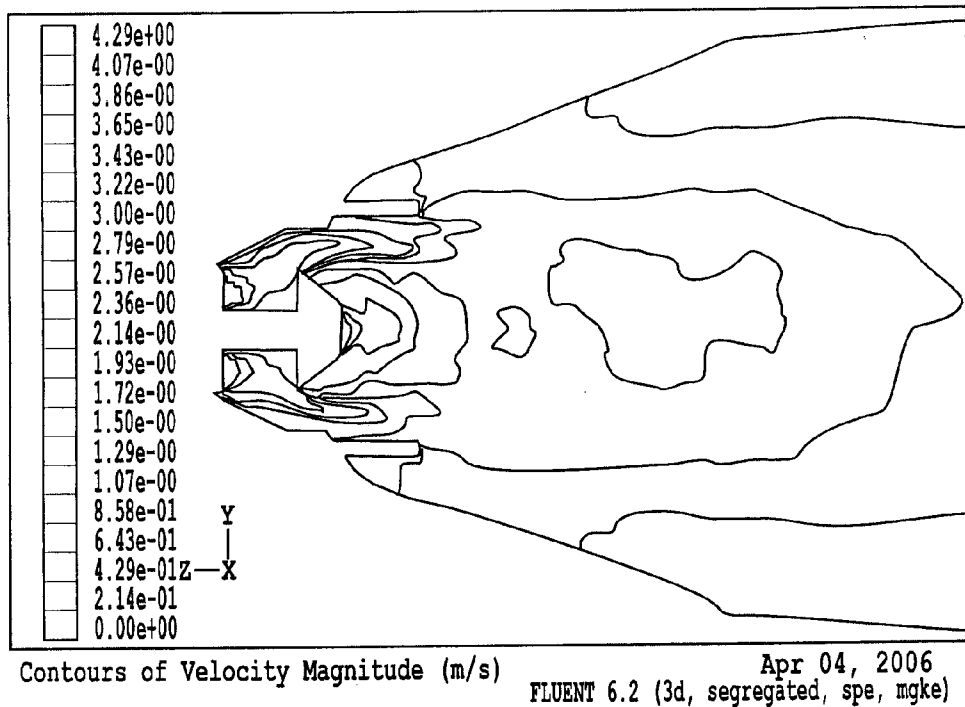
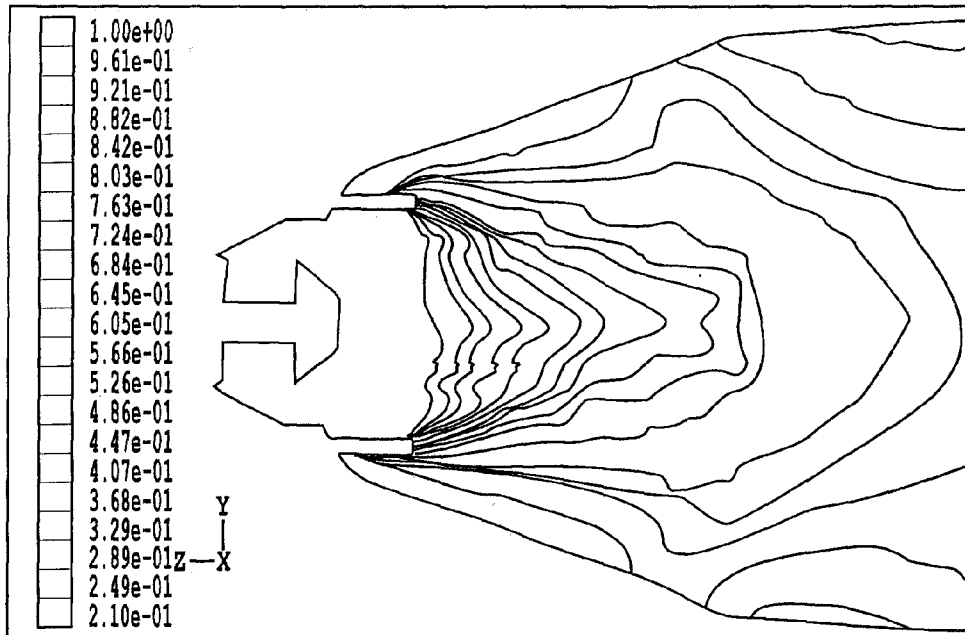


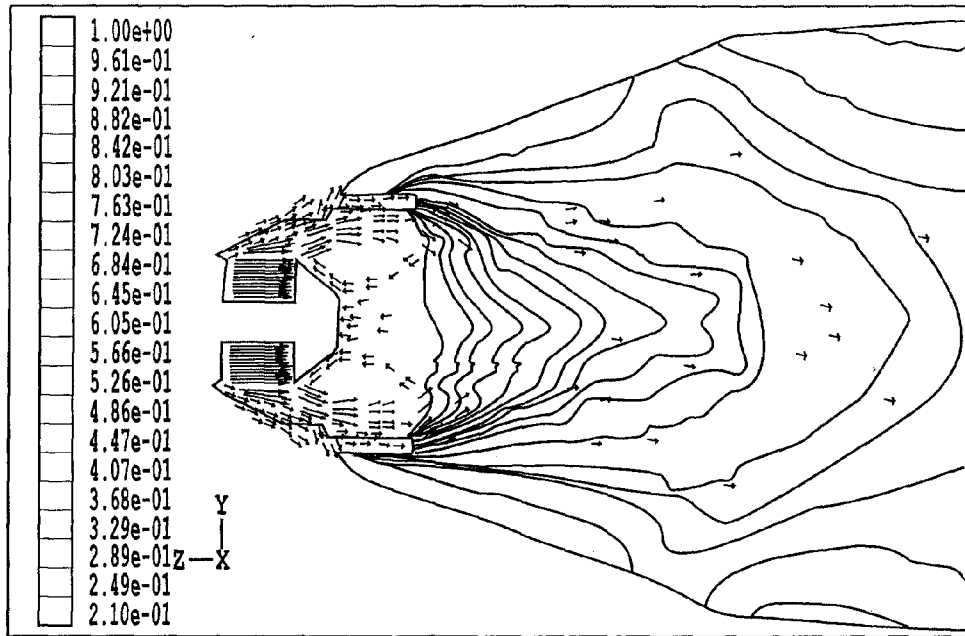
Fig. 12a



Contours of Mass fraction of o2

Apr 04, 2006
FLUENT 6.2 (3d, segregated, spe, mgke)

Fig. 12b

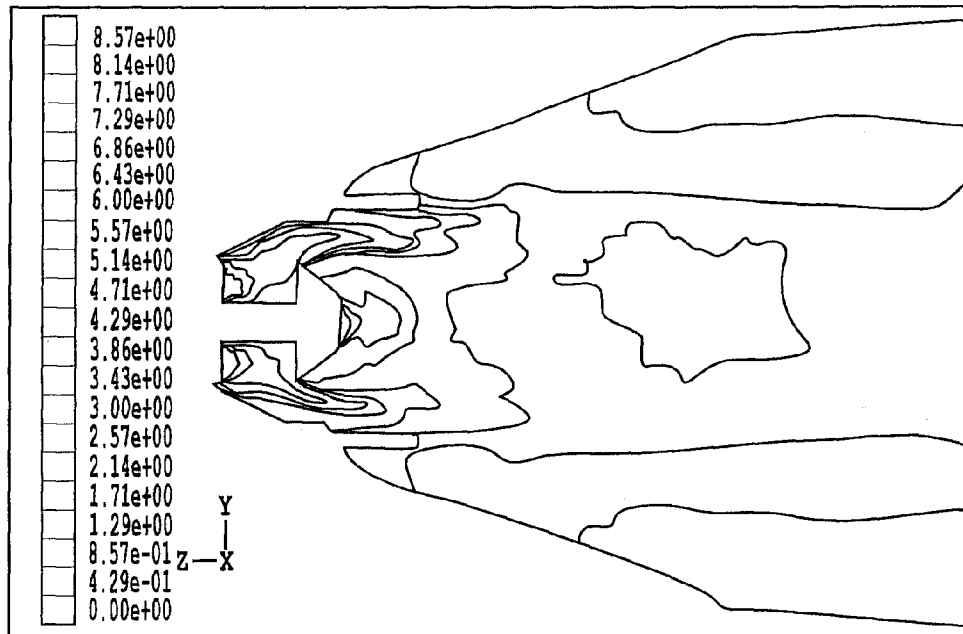


Contours of Mass fraction of o2

Apr 04, 2006
FLUENT 6.2 (3d, segregated, spe, mqke)

Fig. 12c

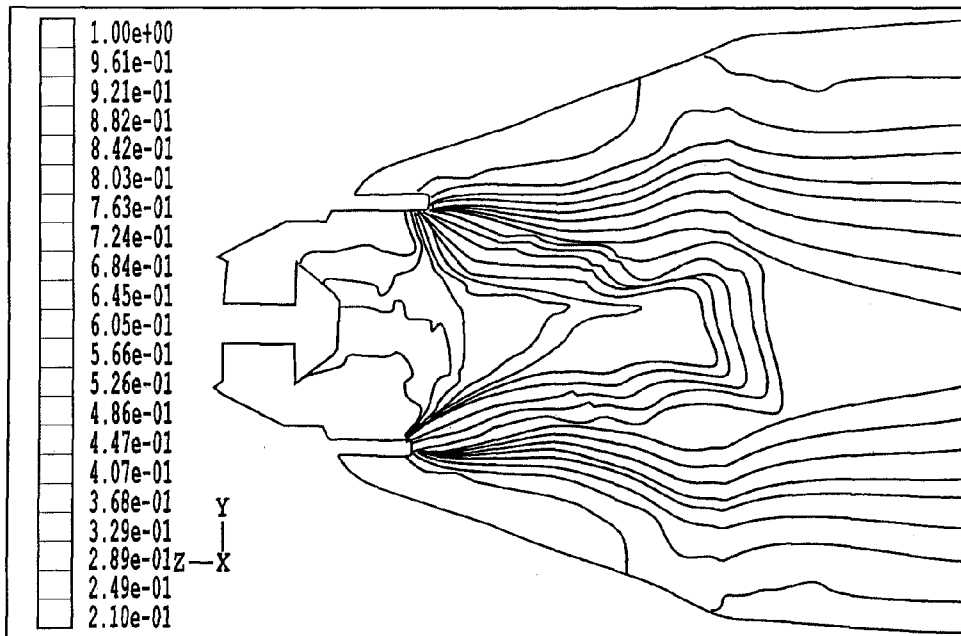
Mass flow rate = Q5 = 40.0 lpm



Contours of Velocity Magnitude (m/s)

Apr 04, 2006
FLUENT 6.2 (3d, segregated, spe, mgke)

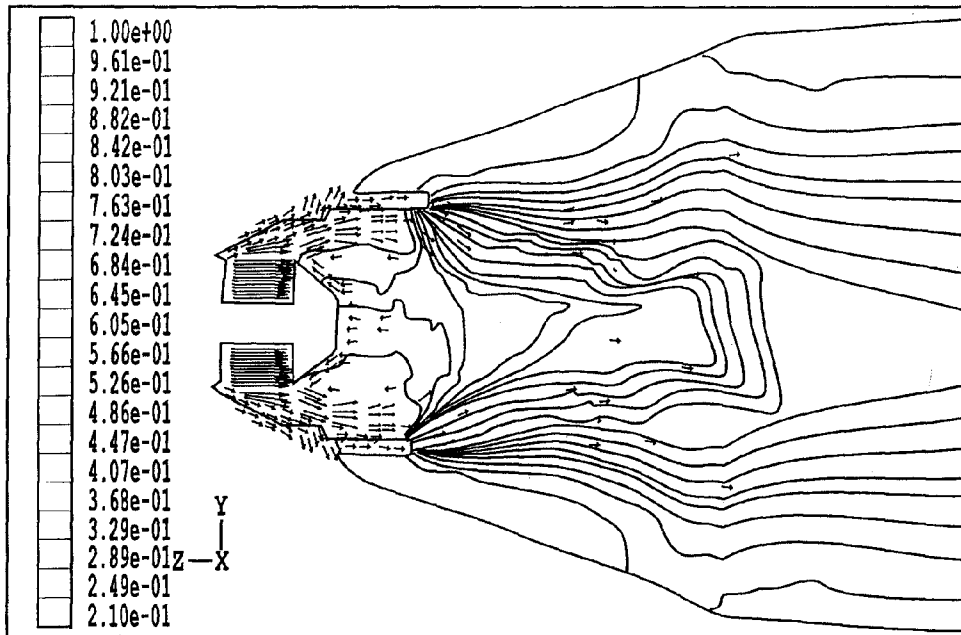
Fig. 13a



Contours of Mass fraction of o2

Apr 04, 2006
FLUENT 6.2 (3d, segregated, spe, mgke)

Fig. 13b



Contours of Mass fraction of o2

Apr 04, 2006
FLUENT 6.2 (3d, segregated, spe, mgke)

Fig. 13c

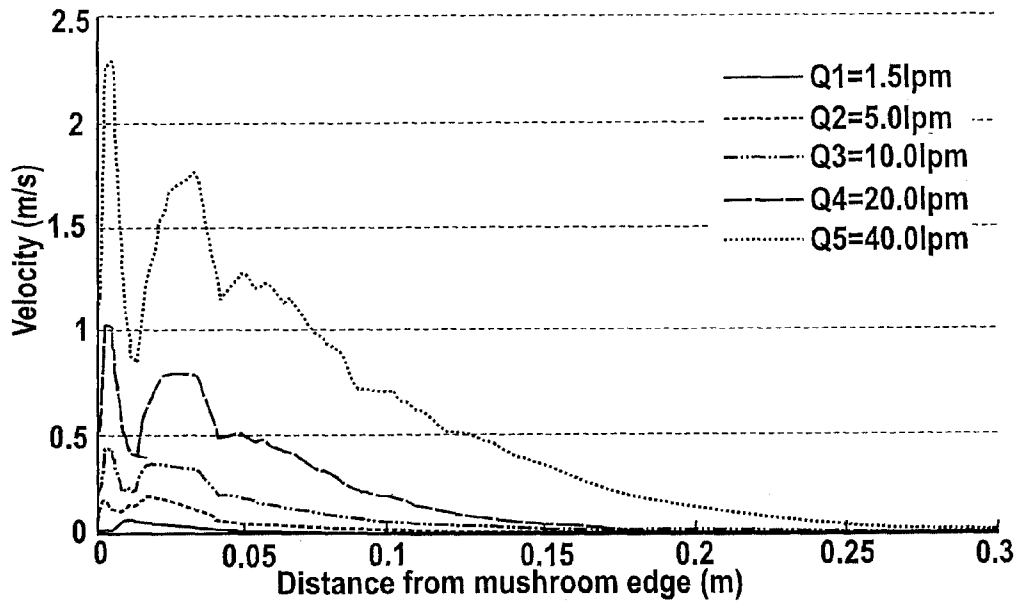


Fig. 14

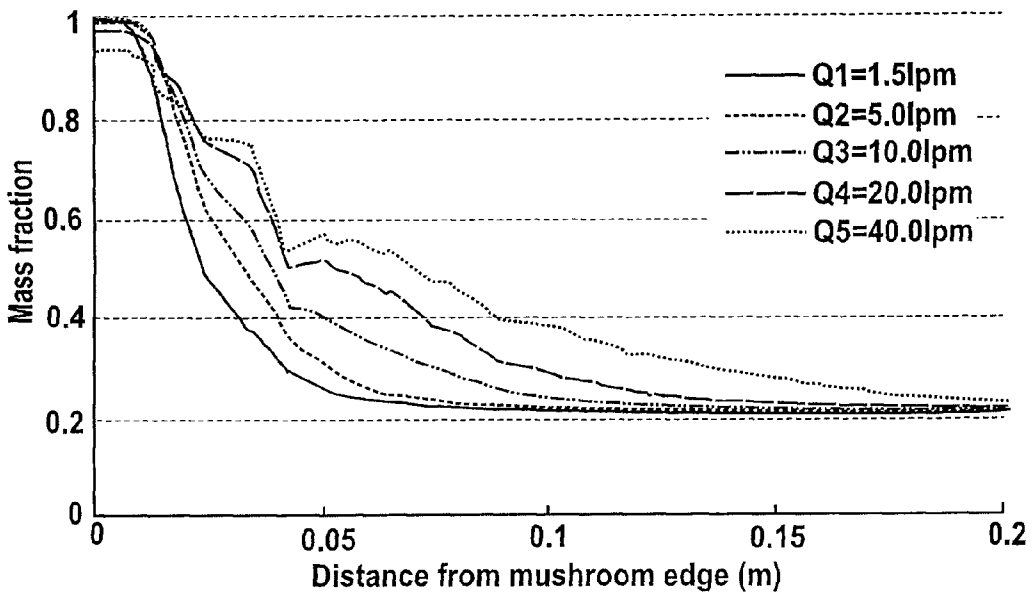


Fig. 15