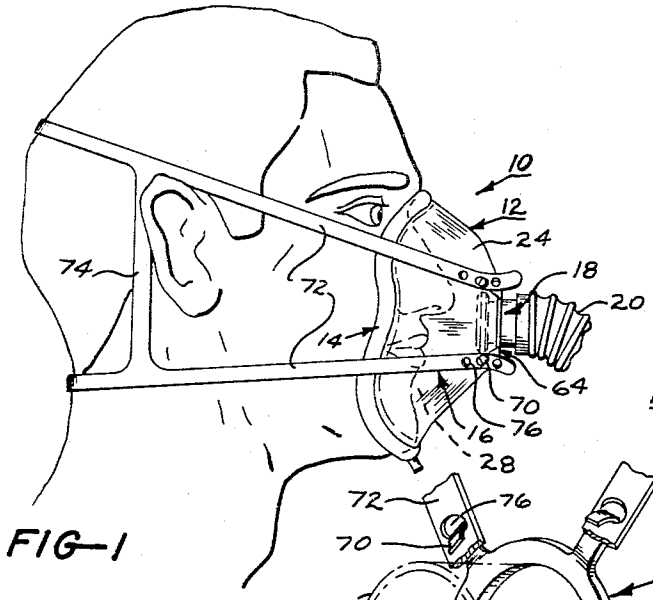
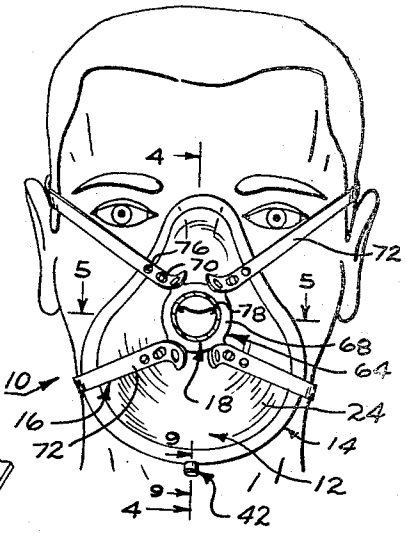
July 11, 1967 V. R. BENNETT 3,330,274

ORO-NASAL FACE MASK WITH IMPROVED PNEUMATIC SEALING CUFF

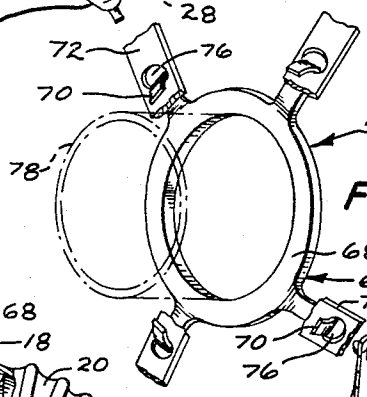
Filed Oct. 15, 1964



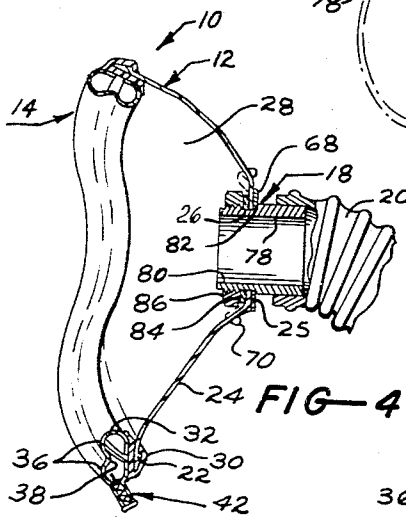
FIG—1



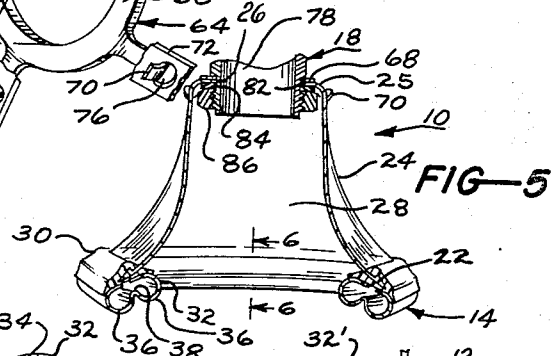
FIG—2



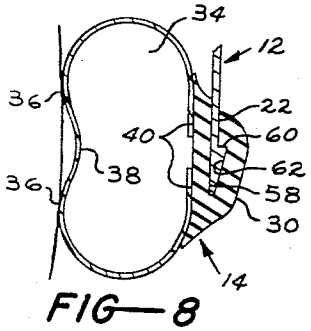
FIG—3



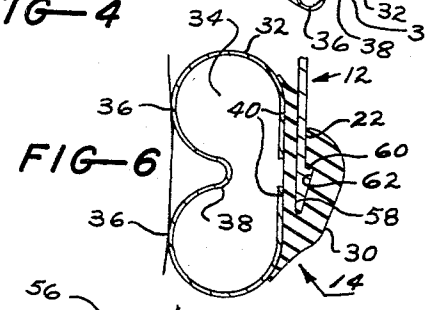
FIG—4



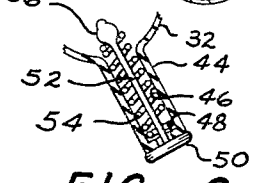
FIG—5



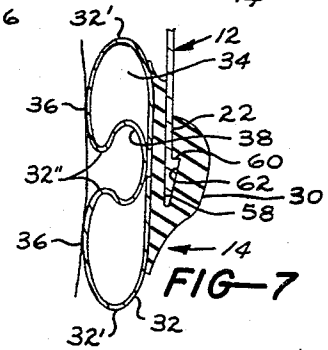
FIG—8



FIG—6



FIG—9



FIG—7

INVENTOR.
V. RAY BENNETT

BY
Fulwider, Patton, Rieber, Lee & Utecht
ATTORNEYS

United States Patent Office 3,330,274 Patented July 11, 1967

3,330,274

ORO-NASAL FACE MASK WITH IMPROVED PNEUMATIC SEALING CUFF

V. Ray Bennett, Yucca Valley, Calif., assignor to Puritan Compressed Gas Corporation, Kansas City, Mo., a corporation of Missouri

Filed Oct. 15, 1964, Ser. No. 404,122
7 Claims. (Cl. 128—146.7)

This invention relates to an improved oro-nasal face mask for respiratory use, and more particularly to such a mask embodying an improved pneumatic or unflated sealing cuff for effecting a seal between the perimeter of the mask and the face and for cushioning the force exerted by the mask against the face.

The sealing cuff of the invention finds particularly useful application with an oro-nasal mask, and, for this reason, it is described in conjunction with an improved mask of this type. It is to be noted at the outset, however, that the cuff may be used to advantage with other devices adapted to be positioned in sealing engagement with portions of the body, such as respiratory mouth pieces, bathing caps and ear-covering devices. Thus, the illustration and description of the cuff in conjunction with this one type of device is not intended to be limitative.

Oro-nasal masks have widespread application in the medical field. Breathing gas, which often has an anesthetic or medicament added, is administered to a patient. In many cases, it is essential to accurately meter the volume of gas being supplied to the patient. In these cases any leakage, of course, adversely affects the accuracy of the measurement.

A specific use for oro-nasal masks in the medical field is in administering intermittent, positive pressure-breathing therapy, commonly known as IPPB, to patients having a wide variety of respiratory disorders. In IPPB therapy, the lungs are inflated under a control pressure during the inspiration phase of the breathing cycle. This in turn results in distention of the lung-thorax system somewhat more than in normal inspiration, and hence in more uniform and thorough alveolar aeration. Here again, it will be readily appreciated that effective sealing is essential. Any leakage will prevent the desired control pressure from being applied to the lungs so that full ventilation is not achieved.

In addition to the necessity of good sealing, comfort to to the wearer is an extremely important factor, both from psychological and physiological standpoints. Frequently, an oro-nasal mask is necessarily worn for prolonged periods, as when receiving IPPB therapy. Thus, cushioning of the force exerted by the mask against the face is an important function of the cuff. In the event excessive force is applied against the limited facial areas in order to achieve over-all sealing, damage to the facial tissue is likely to occur. Furthermore, severe apprehension frequently stems from the physical discomfort.

Masks heretofore available have not been entirely successful in meeting these requirements of sealing and comfort. It has been found that with a substantial percentage of users, the facial contours differ so greatly from the design standard that in some cases sealing cannot be achieved. In other cases, the mask is pressed so tightly against facial areas in order to seal in relatively depressed areas as to cause damage to the tissue and bring about severe discomfort and apprehension. In either case the result is undesirable. Moreover, pneumatic cuffs, while possessing certain inherent advantages over other types, have been particularly efficient where substantial facial irregularities are present.

A further problem inherent in the masks of the prior art is in maintaining the desired conditions of sanitation.

Particularly in medical usage, it is often the case that masks are used by many different patients. Thus, it will be readily understood that it is important that they be thoroughly cleaned after each use. Certain designs heretofore available have made it extremely difficult, at best, to achieve proper cleaning.

In view of the foregoing, it is a primary object of the invention to provide an improved oro-nasal face mask which obviates the problems of the prior art.

A more specific object is to provide an oro-nasal mask for general use with an improved pneumatic sealing cuff capable of functioning in its intended manner to provide an effective perimeter seal and to cushion the force exerted by the mask against the face notwithstanding substantial irregularities in facial contour.

Another object is to provide a mask of the type described, further characterized in that it may be worn comfortably by persons with a wide variety of facial contours.

A further object is to provide a mask of the type described embodying a pneumatic cuff having an expansible-contractable chamber with a movable wall portion adapted to make sealing engagement with the face, the cuff being configurated so that pressing the mask firmly against the face causes the chamber to expand and contract in different regions to urge the wall portion into such sealing engagement with corresponding relatively depressed and raised facial areas.

Another object is to provide a mask of the type described which is readily adapted to be thoroughly cleaned following use.

A still further object is to provide a mask of the type described embodying a sealing cuff with simple, yet highly efficient means for detachably connecting the cuff to the face piece.

A further object of the invention is to provide an improved oro-nasal face mask with an improved adjustable harness assembly for maintaining the mask positioned for use.

It is another object of the invention to provide an improved oro-nasal mask, having a face piece of narrow width and profile, so as to afford a relatively small breathing chamber and thereby minimize re-breathing of expired gas.

It is a still further object to provide an improved mask of the type described capable of accomplishing all of the foregoing objects, yet which is relatively simple in construction and capable of being economically mass produced.

Still another object is to provide an improved pneumatic sealing cuff for effecting good sealing between a cover member and a portion of the body engageable by such member, even where substantial irregularities are encountered in the surface of the body portion.

These and other objects, features and advantages of the invention will be better understood by referring to the following detailed description, taken in conjunction with the accompanying drawings, in which:

FIGURE 1 is a side elevational view of the mask of the invention positioned for use;

FIGURE 2 is a front elevational view of the mask illustrated in FIGURE 1;

FIGURE 3 is a perspective view of a portion of the improved harness assembly of the invention, including a spider on the forward portion of the mask and portions of the head harness;

FIGURE 4 is a vertical sectional view taken along the line 4—4 of FIGURE 2;

FIGURE 5 is a horizontal sectional view taken along the line 5—5 of FIGURE 2;

FIGURE 6 is a fragmentary sectional view on an enlarged scale taken along the line 6—6 of FIGURE 5, illustrating the improved sealing cuff of the invention in a normal or undeformed condition;

FIGURE 7 is a fragmentary sectional view, similar to FIGURE 6, illustrating the cuff in a contracted condition, as where overlying relatively raised facial areas;

FIGURE 8 is a fragmentary sectional view on an enlarged scale similar to FIGURE 6, illustrating the cuff in an expanded condition, as where overlying relatively depressed facial areas; and

FIGURE 9 is a fragmentary sectional view on an enlarged scale taken along the line 9—9 of FIGURE 2, illustrating valve means on the pneumatic cuff of the invention.

Referring to the drawing and in particular to FIGURES 1 and 2, the mask of the invention, designated by the reference numeral **10**, includes generally a face piece **12**, a sealing cuff **14**, an attachment harness **16**, and a connector assembly **18**. The latter member is adapted for connection to a combined inlet-outlet conduit **20** of suitable respiration apparatus.

The face piece **12** is shaped to cover the frontal portion of the face, including the nose and mouth. It is sized to extend from the bridge of the nose down to a location just under the chin. The width increases from a minimum adjacent the nose to a maximum adjacent the mouth, and then progressively decreases toward its lower end.

The marginal edge **22** of the face piece **12** around its entire perimeter is shaped to conform generally to the surface contour of the face of an average person. The mask is intended for general use and, therefore, the shape is determined by the characteristics of an average person. When the face piece is positioned over the nose and mouth, the rearward side of the marginal edge **22** is in close proximity to the adjacent surface of the face. Actual contact is, of course, prevented by the resilient, deformable sealing cuff **14** which, in addition, provides for perimeter sealing notwithstanding the known differences in facial contour from person to person.

From its marginal edge **22** the face piece **12** projects forwardly and converges centrally to afford a cover-like central portion **24**. The forwardmost end **25** of the face piece **12** is flattened and provided with an inlet-outlet passage **26**. When the mask is positioned for use, as in FIGURES 1 and 2, the face piece **12** and the underlying frontal portion of the face cooperate to define the boundaries of a breathing chamber **28**. Preferably, this chamber is relatively small in volume in order to minimize the re-breathing of expired gas. Provision of a small breathing chamber **28** is achieved by making the face piece **12** of relatively narrow profile and width.

The face piece **12** is preferably formed with a relatively stiff plastic material. Plastic is preferred from the standpoint that it is strong and durable, impermeable to gas, easily cleaned and may be easily molded into the desired shape. However, other materials, such as metals, may be used.

In order to achieve sealing between the marginal edge **22** of the face piece **12** and the face and for cushioning engagement for comfort of the wearer, the sealing cuff **14** is provided. The cuff is secured to the face piece and extends entirely around its perimeter on the rearward side of the marginal edge **22**. Referring to FIGURES 4 to 6, it may be seen that the cuff **14** is substantially uniform in cross section about the entire perimeter of the face piece **12**.

The cuff **14** comprises an attachment flange **30** and a support member **32** secured to the flange to make a unitary structure. Preferably, both the flange and support member are formed of a resilient, highly flexible material. Certain plastics and rubber have been found to be particularly well suited. They have the desired physical properties and, in addition, may be easily molded into the desired shapes. The support member **32** is configurated and secured to the attachment flange **30** in such a manner as to define a sealed expansible-contractable chamber **34**. The material of the support member forming the chamber **34** is relatively thin, so that it may readily flex to permit chamber expansion and contraction, as well as to give a soft and pliable feel to the wearer.

In cross section, the support member **32** is generally rectangular in shape with semi-circular ends and is elongated in a direction parallel to the adjacent surface of the marginal edge **22**. The rearward wall portion of the chamber formed by the support member **32** is depressed or ribbed centrally. The effect is to provide a pair of rearwardly facing contact ridges **36** and a forwardly facing support rib **38** defining a rearwardly opening depression **39** separating the two ridges. In the substantially undeformed condition of the cuff **14**, illustrated in FIGURE 6, the rib **38** terminates short of the opposite wall of the chamber **34** (here comprising a section of the attachment flange **30**). In the illustrative showing, it extends inwardly slightly more than half the distance across the chamber **34** along a direction line perpendicular to the marginal edge **22**.

For convenience of manufacture, the support member **32** is formed as a configurated band, rather than being continuous or tubular in cross-section. As may be seen in FIGURES 6 to 8, its opposite ends are adjacent one another and bonded to the rearward surface of the attachment flange at **40**. Bonding may be achieved in any way capable of providing an airtight connection, as by a suitable adhesive.

Compressible gas, normally comprising ambient air, is supplied to the expansible-contractable chamber **34** of the cuff **14** through valve means **42**, illustrated in FIGURES 2 and 9. The valve means comprises of a tubular sleeve **44** formed integral with the support member **32** at the lower end of the cuff. A passage **46** is provided by the sleeve **44** from the chamber **34** to the exterior of the cuff, the diameter of the passage adjacent its lower end being necked down to afford an internal shoulder **48**. The passage **46** is normally closed by a valve element **50**, seated on the lower end of the sleeve **44**. To maintain the element seated, as in FIGURE 9, a valve stem **52** and a compression spring **54** are provided. The spring **54** is concentrically disposed on the stem in abutment with the shoulder **48** at one end and with a radial enlargement **56** on the stem **52** at the other end.

Air is permitted to enter the chamber **34** to inflate it up to ambient pressure by simply grasping the valve element **50** from the exterior and pulling it down relative to the sleeve **44** against the biasing force of the spring **54**. As previously noted, the natural resilience of the support member **32** forming the chamber **34** causes the cuff **14** to take the shape illustrated in FIGURE 6. Therefore, when the passage **46** is open to the exterior, the chamber pressure rapidly adjusts to ambient pressure, with the cuff taking the shape illustrated in the last mentioned figure. Releasing the element **50** enables it to move back to its seated position, wherein it blocks the passage **46** and prevents bleeding of the air trapped in the chamber **34** when it undergoes compression.

Under most conditions of use, it has been found that an ambient pressure within the chamber **34** when the cuff is undeformed yields effective sealing and cushioning of the force of mask engagement. It is assumed for the purpose of relating the function of the cuff **14** that it is initially in the undeformed condition of FIGURE 6 with an ambient pressure existing within the chamber. As the mask is pressed against the face, both ridges **36** normally make sealing contact in the manner illustrated in that figure. Should an optimum condition exist wherein the marginal edge **22** of the face piece **12** were shaped to conform exactly to the facial contour, then the cuff would be deformed about its entire length uniformly to an extent between the conditions shown in FIGURES 6 and 7. Such deformation and resulting chamber contraction

would be resisted by the trapped air which undergoes slight compression and by the mechanical resistance imposed by the configurated support member **32** in changing shape.

Under actual conditions of use, such optimum sizing and shaping rarely, if ever, exist. Instead, relatively raised and depressed facial areas exist and the chamber **34** expands and contracts to accommodate the irregularities. In FIGURE 7, the chamber is contacted to accomplish sealing and cushioning in a relatively, raised facial area.

As the mask is pressed against the face, the ridges **36** first contact the face in the raised areas, and are flattened slightly from their normal convex shapes of FIGURE 6. Air in the coresponding portions of the chamber **34** is displaced to other portions of the cuff overlying relatively depressed facial areas. Besides the flattening of the ridges, movement of the rearward wall portion of the chamber toward the marginal edge **22** occurs. Such movement is rendered possible by bending of the support member **32** at its lateral extremities **32'** (FIGURE 7), the rib **38** being pivoted inwardly toward the opposite wall of the chamber **34**. There is some resistance to such flattening and bending in this initial stage because of the resilience of the support member **32**. However, since the material is relatively thin, the resistance is not appreciable.

Once the rib **38** contacts the opposite wall of the chamber **34**, as in FIGURE 7, the resistance to flattening increases. The chamber further contracts but additional resistance is imposed by virtue of bending also being required in the regions **32''** at the junctures of the individual ridges **36** with the rib **38**. As may be seen in FIGURE 7, this results in the depression **39** being widened out between the regions **32''** and its terminal or forward end. Such further contraction prevents excessive force from being exerted against the face in the raised facial areas, yet proper sealing is still assured.

Air displaced as a result of deformation of the cuff **14** toward the condition of FIGURE 7 cause chamber expansion to achieve sealing in other relatively depressed facial areas in the manner illustrated in FIGURE 8. The ridges **36** move rearwardly into facial contact as the rib **38** in effect unfolds or flexes out to reduce the extent of the depression **39**. It will be understood in this connection that such chamber expansion is the result of a change of shape and not of stretching of the material. Since the material forming the movable wall comprising the ridges **36** and rib **38**, is thin and highly flexible there is very little resistance to such chamber expansion. Accordingly, good sealing in the depressed facial areas obtains.

The ability to expand rearwardly and accomplish sealing in highly depressed facial areas is an important feature of the present invention. It will be appreciated that the rib **38** forming the depression **39** affords the chamber **34** a much greater perimeter and ability to expand rearwardly than would otherwise be the case. Moreover, the rib **38** has a mechanical stiffening effect on the rearward wall of the chamber. Thus, the support member may be formed of a thinner material than would otherwise be the case, yet it still normally takes and tends to remain in its configuration illustrated in FIGURE 6. By virtue of being thinner, the ridges, in turn, more readily conform to the surface of irregularities and afford the desired soft, pliable feel to the wearer.

Once the ridges **36** contact the face about the entire perimeter of the face piece **12**, some compression of the gas trapped within the chamber **34** occurs. This has a cushioning effect and, in addition, insures that the ridges are maintained in continuous, tight sealing engagement with the face.

It is noted that in both the conditions of FIGURES 7 and 8, it is the two ridges **36**, separated by the depression **39**, which contact the face, as opposed to continuous contact (in cross-section) across the entire rearward wall of the cuff. As a consequence, the unit pressure is greater, thereby enhancing the seal in this respect. Further, a double seal is provided, and if leakage should occur past the inner ridge, effective sealing may still be achieved by the outer one.

Preferably, the cuff **14** is detachably connected to the marginal edge **22** of the face piece **12**. Such a connection facilitates cleaning and provides for convenient manufacture and assembly. Detachable connection is accomplished by making the flange **30** with an inwardly facing slot **58** around its entire perimeter for receiving the perimeter of the face piece **12**. The perimeter of the flange portion forming the slot **58** is slightly smaller in overall dimension than the perimeter of the face piece. Accordingly, to carry out installation it is necessary to stretch the flange **30** slightly to enable the slot **58** to receive the edge. In the assembled condition of the parts, the flange portions forming the side walls of the slot resiliently grip the marginal edge **22** of the face piece and the bottom of the slot presses against the outer edge of the face piece.

In order to insure a secure gas tight connection, the wall thickness of the edge **22** on its forward side is tapered slightly to provide an inwardly facing stop shoulder **60**. This shoulder extends around the entire edge **22**, and the mating surface of the flange **30** is formed with a correspondingly shaped groove **62** for receiving the shoulder.

The mask **10** is held in place on the face of the wearer by the harness assembly **16**. It includes a spider **64** and a head harness. The spider **64** comprises an annular ring **68** having four radially projecting lugs **70** at angularly spaced locations. The ring **68** is positioned around the inlet-outlet passage **26** on the forward end **24** of the face piece, and is held in place by the connector assembly **18**.

The harness **66** may be of any suitable configuration for comfort, provided it is arranged to hold the mask firmly against the face. In the illustrative case, it includes a pair of straps **72**, one of which extends above and the other below the ears. The two straps are joined just behind the ears by a pair of webs **74**. At the ends of these straps, holds **76** are provided for receiving the lugs **70** on the spider in the manner illustrated in FIGURE 3. To enable adjustment for different head sizes, a plurality of holes **76** are provided in each strap.

For the purpose of supplying and exhausting gas from the breathing chamber **28** and for securing the spider **64** in position, the connector assembly **18** is provided. The assembly includes a tubular sleeve **78** of a diameter just slightly greater than that of the inlet-outlet passage **26**. The rearward end **80** of the sleeve is necked down so as to be receivable within the passage and to afford an annular rearwardly facing shoulder **82** at the juncture. Referring to FIGURES 4 and 5, it may be seen that the spider **64** is held in place by virtue of the ring **64** being interposed between the shoulder **82** and the forward end **25** of the face piece. To hold the assembly together and afford a sealed connection, a resilient, deformable washer **84** is disposed around the sleeve and against the face piece and a nut is threaded on the correspondingly threaded end of the sleeve. Connection of the mask to suitable respiration apparatus is achieved by simply slipping the end of the inlet-outlet conduit **20** over the forward portion of the sleeve **78**, as shown in FIGURE 4.

While one embodiment of the invention has been illustrated and described in considerable detail, it will be understood that is only by way of illustration, and that numerous changes in the details of the construction and arrangement of the various parts may be made without departing from the spirit and scope of the invention.

I claim:

1. An oral-nasal face mask, comprising: a face piece shaped to cover the nose and mouth, and having a forwardly projecting central portion with an inlet-outlet passage, and a marginal edge portion conforming generally to the surface contour of the face; and a sealing

cuff of unitary construction extending around the perimeter of the face piece along said marginal edge, said cuff including attachment means for securing said cuff to said face piece and a support member formed of a thin resilient, flexible and substantially non-stretchable material and shaped to provide, in cross section, a rearward movable wall portion with rearwardly facing ridge means normally spaced from the opposite wall of said cuff and movable toward and away from the same and adapted to make sealing contact with the face and forwardly facing rib means integral with said ridge means and defining a depression in said movable wall, said rib means being engageable with the opposite wall of the cuff for yieldably resisting such movement of said ridge means toward said opposite wall and flexing to permit said ridge means to move away from said opposite wall.

2. A sealing cuff for use with a member for covering a body portion to afford a perimeter seal and to cushion the force of engagement, comprising in cross section: attachment means adapted for securing said cuff to said cover member; and a support member formed of a thin, resilient, flexible material and secured to said attachment means, said support member being shaped to provide a movable wall spaced from the opposite wall of said cuff and including a pair of rearwardly facing contact ridges adapted to make continuous sealing contact with the body portion at spaced locations and a forwardly facing support rib separating said ridges, said ridges being movable toward and away from said opposite wall and said rib being engageable with said opposite wall to yieldably resist movement of said ridges toward the same.

3. The subject matter of claim 2 wherein said support member is shaped to provide a sealed expansible-contractable chamber, and a compressible gas in said chamber which is displaced upon contraction of said chamber in localized areas produced by movement of said ridges toward said opposite wall, so as to expand said chamber in other areas and move said ridges away from said opposite wall.

4. An oro-nasal face mask, comprising: a face piece shaped to cover the nose and mouth, and having a forwardly projecting central portion with an inlet-outlet passage, and a marginal edge portion conforming generally to the surface contour of the face; and a pneumatic sealing cuff formed of a resilient, flexible material and extending around the perimeter of said face piece on the rearward side of said marginal edge, said cuff including, in cross section, a pair of rearwardly facing contact ridges adapted to make continuous sealing contact with the face at spaced locations around the entire perimeter of said face piece and a forwardly facing support rib integral with said ridges and defining a depression separating said ridges, said ridges and rib cooperating to form a rearward wall portion of a sealed expansible-contractable chamber which, during such sealing contact, said chamber being contracted in areas overlying raised facial areas and expanded in areas overlying depressed facial areas, said ridges normally being spaced from the opposite wall of said chamber and movable toward and away from the same and said rib being engageable with the opposite wall of said chamber to yieldably resist movement of said ridges toward the same.

5. An oro-nasal face mask, comprising: a face piece shaped to cover the nose and mouth, and having a forwardly projecting central portion with an inlet-outlet passage, and a marginal edge portion conforming generally to the surface contour of the face; a pneumatic sealing cuff extending around the perimeter of said face piece and having a substantially uniform cross section,

said cuff including in cross section attachment means for detachably securing said cuff to said face piece and a support member formed entirely of a thin resilient, flexible material of substantially uniform thickness and shaped to provide a sealed expansible-contractable chamber on the rearward side of said marginal edge, the rearward wall portion of said chamber normally being spaced in its entirety from the opposite chamber wall, and having a pair of rearwardly facing contact ridges movable toward and away from said marginal edge and a forwardly facing support rib defining a depression separating said ridges and engageable with the opposite wall of said chamber to yieldably resist movement of said ridges toward said marginal edge and flexing to permit said ridges to move away from said marginal edge; and compressible gas within said chamber that is displaced upon chamber contraction in localized areas to expand said chamber in other areas, said ridges being moved forwardly upon contact with relative raised facial areas as said face piece is pressed firmly against the face to produce chamber contraction and being moved outwardly into contact with relatively depressed facial areas upon resulting chamber expansion.

6. The subject matter of claim 5 further characterized in that said attachment means for detachably securing said cuff to said face piece is formed of a resilient, flexible material and includes a slotted flange stretch-fit around the perimeter of said face piece, the marginal edge being tapered in thickness for a short distance from a minimum at the perimeter of said face piece to afford an inwardly facing shoulder and the adjacent wall of said slot being provided with a correspondingly shaped groove.

7. An oro-nasal face mask comprising: a face piece shaped to cover the nose and mouth, and having a forwardly projecting central portion with an inlet-outlet passage, and a marginal edge portion conforming generally to the surface contour of the face; and a sealing cuff extending around the perimeter of said face piece along said marginal edge, said cuff including in cross section attachment means for securing said cuff to said face piece and a support member on the rearward side of said marginal edge formed entirely of a thin resilient, flexible material and shaped to provide a rearward movable wall portion normally spaced in its entirety from the opposite wall of said cuff and including a pair of rearwardly facing ridges adapted to make sealing contact with the face and a forwardly facing rib integral with said ridges and defining a depression separating said ridges, said ridges making facial contact as the mask is pressed against the face and moving forwardly to pivot said ridges toward the opposite wall of said cuff against the resistance to bending of said support member at its lateral extremities, and, thereafter, upon said rib contacting the opposite wall of said cuff, further forward movement of said ridges being resisted by bending of said support member at said lateral extremities and at the junctures of said ridges and rib.

References Cited

UNITED STATES PATENTS

2,540,567	2/1951	Bennett	128—146
2,666,432	1/1954	Stanton	128—205
2,701,899	2/1955	Krupp	49—477

FOREIGN PATENTS

4,644	6/1905	France.

RICHARD A. GAUDET, *Primary Examiner.*

K. L. HOWELL, *Assistant Examiner.*