(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 2 201 921 A2

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
30.06.2010 Bulletin 2010/26

(51) Int Cl.:
A61G 13/12 *(2006.01)*

(21) Application number: **09179406.5**

(22) Date of filing: **16.12.2009**

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO SE SI SK SM TR

(30) Priority: **16.12.2008 US 138040 P**

(71) Applicant: **Davis, Edmund Scott**
Ft. Lauderdale 33301 (US)

(72) Inventor: **Davis, Edmund Scott**
Ft. Lauderdale 33301 (US)

(74) Representative: **Heine, Christian Klaus**
KNH Patentanwälte
Kahlhöfer Neumann Rößler Heine
Postfach 10 33 63
40024 Düsseldorf (DE)

(54) Methods for using head positioning pillows to optimize respiratory titration

(57) Presented herein are various methods for using head positioning pillows to optimize respiratory titration. More specifically, the method includes a first step of determining an optimal relative angle between the patient's mouth and throat at which the patient's airway is optimally opened. The method also includes a second step of adjusting a head positioning pillow relative to the patient's head and neck to modify and transform the configuration of the pillow to achieve a pillow position that achieves the optimal relative angle.

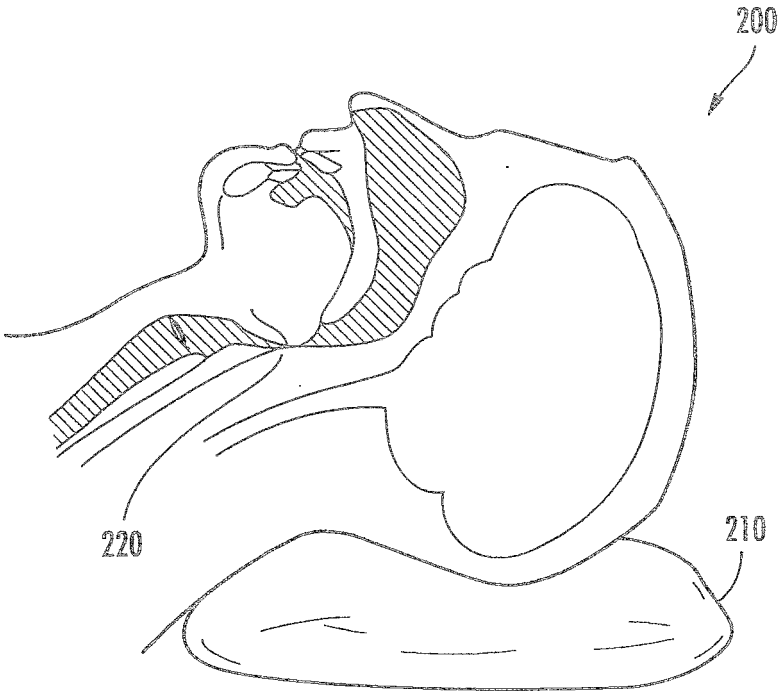


FIG. 2

EP 2 201 921 A2

Description

FIELD OF THE INVENTION

[0001] The present invention relates generally to methods for using head positioning pillows to optimize respiratory titration.

BACKGROUND OF THE INVENTION

[0002] Respiratory titration is the process of adjusting the output of a respiratory assistive device, such as a respiratory mask attached to a positive airway pressure device to match the patient's needs. Users of respiratory masks often have difficulty resting or sleeping because pressure on the mask exerted by a pillow while side sleeping can impede the performance and comfort of the mask, cause the mask seal to separate from the face and result in air leakage (which can cause irritation from the eyes drying out), and/or cause the mask to press uncomfortably against the user's face. Users of respiratory masks often try to compensate for leaks and positional problems by tightening the mask against the face more than otherwise required, causing further discomfort. The ultimate effect of these problems is sleep interruption or non-compliance by the user (i.e., the user stops using the mask).

[0003] In addition, it has also been discovered that titration processes performed in a clinic setting are not effective in the home, which reduces the effectiveness of the respiratory device. The largest variable is the pillow used by the patient. Pillows supporting the head and neck can have a direct impact on the alignment of the patient's airway. Most pillows come in many different constructions and sizes, each of which will change the positioning of the head and neck relative to the upper body and can adversely impact the alignment of the airways and subsequent efficiency of air flow through the trachea, mouth, and throat.

[0004] Further, a variety of positioning variables found in the home make it difficult for users of respiratory masks to maintain the salutary effects of a respiratory titration in the clinic setting. Accordingly, there remains a need for a device and method to be used in a clinic setting that may then be used at home.

SUMMARY OF THE DISCLOSURE

[0005] Presented herein are various methods for using head positioning pillows to optimize respiratory titration. More specifically, the method comprises a first step of determining an optimal relative angle between the patient's mouth and throat at which the patient's airway is optimally opened. The method also comprises a second step of adjusting a head positioning pillow relative to the patient's head and neck to modify, transform and optimize the configuration of the pillow to thereby achieve a pillow position that achieves the optimal relative angle.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

[0006] Reference will now be made to the accompanying drawings, which are not necessarily drawn to scale, and wherein:

FIG. 1 is a side view of a patient's open airway where the patient's head and neck are positioned in a generally upright position;

FIG. 2 is a side view of a patient's closed airway where the patient's head and neck are lying in a generally horizontal position;

FIG. 3 is a general process flow, according to one embodiment of the present invention;

FIG. 4 is top plan view of four embodiments of a head positioning pillow;

FIG. 5 is a perspective view of a pillow, according to one embodiment of the invention;

FIG. 6 is a top plan view illustrating the pillow of FIG. 5;

FIG. 7 is a front elevational view illustrating the pillow of FIG. 5;

FIG. 8 is a right side view illustrating the pillow of FIG. 5;

FIG. 9 is a left side view illustrating the pillow of FIG. 5;

FIG. 10 is a rear elevational view illustrating the pillow of FIG. 5;

FIG. 11 is a bottom plan view illustrating the pillow of FIG. 5;

FIG. 12 is a rear view illustrating the cover for the pillow of FIG. 5;

FIG. 13 is a bottom plan view illustrating the cover of FIG. 12;

FIG. 14 is a perspective view illustrating the cover of FIG. 12;

FIG. 15 is a top plan view illustrating the cover of FIG. 12;

FIG. 16 shows a user wearing a respiratory mask and in a back-lying position with his/her head supported on the pillow of FIG. 5; and

FIG. 17 shows a user wearing a respiratory mask and in a side-lying position with his/her head supported on the pillow of FIG. 5.

DETAILED DESCRIPTION OF THE DRAWINGS

[0007] Embodiments of the present invention now will be described more fully hereinafter with reference to the accompanying drawings, in which some, but not all, embodiments of the invention are shown. Indeed, the invention may be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will satisfy applicable legal requirements. Where possible, any terms expressed in the singular form herein are meant to also include the plural form, and vice versa. Also, as used herein, the term "a" shall mean "one or more," even though the phrase "one or more" is also used herein. Like numbers refer to like elements throughout.

[0008] In general terms, described herein are various methods for using head positioning pillows to modify and transform the pillow's configuration to optimize respiratory titration. These head positioning pillows are for use with assisted breathing or respiratory masks, such as continuous positive airway pressure ("CPAP") masks, auto adjusting positive airway pressure ("APAP") masks, dual positive airway pressure ("BiPAP") masks, and demand positive airway pressure ("DPAP") masks, and other mask types for oxygen, etc., to facilitate resting and sleep. Respiratory titration, as described herein, is the process of adjusting the output of these and other respiratory assistive devices, such as a head positioning pillow, in order to address individual patient's needs.

[0009] Figure 1 provides an exemplary diagram **100** of a patient's airway and some of its features, including the patient's mouth, nostrils, hard palate, soft palate, and a portion of the patient's throat, which includes a nasopharnyx, oropharnyx, hypophamyx, epiglottis, vocal cords, larynx, and trachea. Diagram **100** illustrates how these features are positioned relative to each other when the patient's head and neck are positioned in a generally upright position. More specifically, diagram **100** shows that the patient' airway is generally opened, as indicated by the continuous flow of gray shade extending from the nostrils and mouth down through the throat to the trachea.

[0010] Figure 2 provides an exemplary diagram **200** of a patient's closed airway where the patient's head and neck are lying in a generally horizontal position on a regular pillow **210.** As shown, the patient's airway is generally closed at position **220,** which restricts the patient's ability to breathe. The methods and pillows described herein help patients overcome this problem.

[0011] Referring now to a method for using a positioning pillow to optimize respiratory titration, Figure 3 provides an exemplary flow diagram illustrating a general process flow **300.** As represented by block **310,** the first step is to determine an optimal relative angle between the patient's mouth and throat at which the patient's airway is optimally opened. The next step is to adjust a head positioning pillow to modify and transform the configuration of the pillow relative to the patient's head and neck to achieves a pillow position and configuration that achieves the optimal relative angle, as illustrated by block **320**.

[0012] The order of the steps described in blocks **310** and **320,** in Figure 3 may vary. For example, in one embodiment, the step described in block **320** may occur before, after, or substantially simultaneous with the step described in block **310.**

[0013] In other embodiments of the present invention, general process flow **300** may include other steps. One embodiment may divide the represented by block **320** into two or more separate steps, i.e., a step of adjusting the pillow relative to the patient's neck to modify and transform the configuration of the pillow may be separate from a step of adjusting the pillow relative to the patient's head. Another embodiment may include the steps of measuring the flow of air through the patient's airway and comparing that flow to a target flow rate, A further embodiment may provide for one or more iterative steps, i.e., the step of repeating one or more of the other process steps to, for example, determine via trial and error a relative angle between the patient's mouth and throat at which air flow through the patient's airway is maximized.

[0014] In many of the embodiments of general process flow **300,** the head positioning pillow is adjustable. Adjustable head positioning pillows directly impact the alignment of the patient's airway and affect the flow of air through the patient's trachea, throat, and mouth. Accordingly, they are particularly helpful in "tuning" the patient's airway alignment and efficiency during any kind of respiratory titration process, including methods involving CPAP, BiPAP, DPAP, and APAP titration. These are also helpful when used in connection with surgical procedures where the patient users assisted respiration.

[0015] In one embodiment, the pillow is height adjustable, such that a rear side, a front side, a first lateral side, and/or a second lateral side of the pillow can adjust in height to better align the patient's head and neck. In other embodiments, other features of the pillow, including a central indentation and/or a raised section, are adjustable to help raise or lower the patient's head and neck.

[0016] In another embodiment of the present invention, the pillow is adjustable by increasing or reducing the support of the patient's neck. For example, a section of the pillow that contacts the patient's neck and/or head can include a bladder in which air or fluid can be added or released to adjust the elevation and amount of support provided. In other embodiments, an indentation and/or a raised of the pillow may adjust in other ways to properly align and support the patient's neck.

[0017] In still another embodiment of the present invention, the pillow may be adjustable by changing the rotation of the patients head and/or neck position. Other embodiments may include a pillow that adjusts to change

the incline angle of the patient's head and/or neck position.

[0018] The adjustable pillows described herein are important only if used correctly. More specifically, it is important that patients are able to utilize the optimized respirator titration process and reconfigured pillow that is initially performed in a clinic setting or in the home setting, when they are away from that setting. By increasing the user's compliance, fewer inconsistencies are introduced into the patient's daily respiratory process, which creates less of a need to "overcorrect" certain settings on the respiratory device to deliver the proper air flow. For example, many patients will correct for mask leaks by increasing the pressure setting on the respiratory device. By providing a configured pillow optimized for the patient, a patient does not need to readjust the respiratory device, and this helps to reduce unintended side effects.

[0019] Referring now to Figure 4, four embodiments of a head positioning pillow are illustrated. Pillow **410** includes raised back section **412,** raised front section **414,** central recess section **416,** and a plurality on raised contact points **418.** Pillow **420** includes front receding edge **422,** side receding edges **424** and **426,** and central raised section **428.** Pillow **430** includes side wings **432** and **434,** and central raised section **436.** Pillow **440** includes front receding edge **442,** side receding edges **444** and **446,** central raised section **448,** and side wings **441** and **443.**

[0020] Other embodiments of a head positioning pillow **10** are described in Figures 5-17. Pillow **10** includes a pliable and resilient body **12,** which can be formed of any suitable material, non-exhaustive examples of which include polymer foam, gel, fiber fill inside a casing, and fluid inside a bladder. The configuration of the pillow **10** may vary. In the embodiment illustrated in FIG. 5, the pillow **10** is generally rectangular in and includes a rear side **14**, a front side **16,** a first lateral side **18,** and a second lateral side **20.** Preferably but not necessarily, the pillow **10** has an axis of symmetry 22 extending between the rear side **14** and front side **16.** The pillow **10** has a width. W extending between the first lateral side **18** and the second lateral side **20** and a length L extending between the rear side **14** and the front side **16** (shown in FIG. 6). The pillow **10** includes a head-supporting upper surface **30** and an opposite bottom surface **32.** As illustrated in FIG. 11, the bottom surface is relatively plantar. In another embodiment (not shown), the bottom surface **32** may optionally include a plurality of ridges.

[0021] The body **12** includes a first portion **40** and a second portion **42** that are preferably formed together as a unitary member. The first portion **40** and second portion **42** of the body **12** are preferably fabricated from the same material, such as foam, fiber fill, gel, etc., that provides good support and resiliency and, optionally, memory properties. The body **12** could also be a form-shaped bladder (not shown) inflated with air or liquid. The invention is not limited to any particular material making up the body **12.**

[0022] According to the embodiment illustrated in FIGS. 5-11, the first portion **40** and second portion **42** of the body **12** are generally rectangular in shape. The upper surface of the second body portion **42** includes a recess **34** adjacent to each of the first lateral side **18** and second lateral side **20** of the body **12** and a raised section **36** therebetween. Advantageously, as illustrated in FIG. 17, the recesses **34** provide pressure relief on the mask when the user of the pillow **10** is resting or sleeping on his/her side, so that the pillow will not exert any substantial degree of pressure on the mask and tubing for the mask. As illustrated in FIG. 6, one or both of the recesses **34** may extend into the first portion of the body **12.** The recesses **34** are adjacent to pillow surfaces that comfortably support the user's head in the side-lying position, as further described below.

[0023] In one embodiment, as illustrated in FIG. 6, the second portion **42** of the body **12** can include an indentation **38** in the front side **16.** This indentation **38** provides a curved area for the user's shoulder to rest for proper position and neck support when in the side-lying position.

[0024] The raised section **36** of the second portion **42** of the body **12** provides neck support for both back and side sleeping and resting. In one embodiment (not shown), the raised section **36** can include a bladder in which air or fluid can be added or released to adjust the elevation and amount of support provided. As illustrated in FIG. 5, the upper surface **30** of the raised section **36** may include an indentation **44** with raised areas **46** on each side of the indentation. Advantageously, the indentation **44** receives the user' neck and the raised areas 46 function to retain the user's neck within the indentation while the user is resting or sleeping.

[0025] In addition to recesses **34,** as illustrated in FIGS. 5 and 6, the upper surface **30** of the body **12** may include a central indentation **50.** The edge of the central indentation **50** in the first portion **40** of the body is curved and gently sloping to thereby provide a head support area for the user. As with the indentation **44** and raised areas **46** of the raised section **36,** the central indentation **50** receives the user's head and the sloped walls about the periphery of the central indentation function to retain the user's head within the central indentation while the user is resting or sleeping.

[0026] Referring to FIG. 10, the first portion **40** of the body **12** may include raised areas **54** adjacent to each of the first lateral side **18** and second lateral side **20.** As illustrated in FIG. 17, the raised **54** provide support to the user's forehead when resting or sleeping in the side position to keep the user's head from rotating downward.

[0027] Referring to FIGS. 5 and 6, on either side of and adjacent to the indentation **44** and the central indentation **50,** secondary recessed area **56** may be provided. These secondary recessed areas **56** are for receiving either of the user's ears when in either of the left and right side-lying positions, to help relieve excess pressure on the ears and thereby improve overall comfort of the user.

[0028] In other embodiments (not shown), the pillow

10 can include other structure to accommodate or secure a hose for a respiratory mask. In one embodiment, the structure may include a routing channel or aperture formed into the pillow to reduce interference with the hose.

[0029] Typical materials of which the body **12** can be made (such as polymer foam, gel, fluid-filled bladders, etc.) may not be very comfortable if the skin is in direct contact with them, because they may not "breathe" very well. Accordingly, in preferred embodiments of the invention, a cover is provided for the pillow in order to enhance the comfort of the pillow. Referring to FIGS. 12-15, a fitted cover **60** for the pillow **10** is illustrated. It is important for the cover to substantially conform to the contours of the pillow, and in particular to the mask-receiving recesses **34,** in order for the recesses to function properly to relieve pressure on the mask.

[0030] As shown in FIG. 13, the fitted cover preferably includes an opening **61** on the bottom side of the cover corresponding to the bottom surface of the pillow, so that the pillow may be into and removed from the cover to enable cleaning of the cover. As shown, a zipper is provided for closing the opening **61.** As illustrated in FIGS. 12-15 and as discussed above, the cover is preferably fitted so that the cover substantially follows the contours and configurations of the pillow, and particularly those depressions, recesses, cavities, apertures, and/or raised portions that are structured to accommodate the mask or tubing for the mask. The cover **60** may also include structure to accommodate or secure a hose for the mask. In one embodiment (not shown), the structure of the cover may include one or more tethers to keep the hose from sliding or being positioned unfavorably. The cover can be sewn to fit the pillow. The cover may be made of a material that can be formed to fit the contours of the pillow by pressure, heat, or other means. Alternatively, instead of a separately made cover that is removable, the cover may comprise a material permanently applied to the surface of the pillow by any of various techniques, such as painting, dipping, or spraying. For example, flocking may be sprayed onto the pillow and adhered thereto by a suitable adhesive material.

[0031] In a preferred embodiment as shown in FIGS. 12-15, the cover **60** is a fitted cover made from pieces of fabric sewn together. More particularly, a first fabric piece **62** is sized and shaped to cover the majority of the upper surface of the pillow except for the recesses that receive the mask. The first fabric piece also drapes down over the opposite lateral sides of the pillow (except in the regions of the recesses). A second fabric piece **64** is sized and shaped to cover the front side and is sewn to the first fabric piece along a seam **66.** Third, fourth, and fifth fabric pieces **68a, 68b, 68c** are sized and shaped to cover the steeply sloped walls of the left-hand recess of the pillow, and a sixth fabric piece **70** is sized and shaped to cover the bottom wall of that recess. The fabric pieces **68a-c** are sewn to the first fabric piece **62** along seams **72.** The sixth fabric piece **70** is sewn to the fabric pieces **68a-c** along seams **74.**

[0032] Seventh, eighth, and ninth fabric pieces **76a, 76b, 76c** are sized and shaped to cover the steeply sloped walls of the raght-hand recess of the pillow, and a tenth fabric piece **78** is sized and shaped to cover the bottom wall of that recess. The fabric pieces **76a-c** are sewn to the first fabric piece **62** along seams **80.** The fabric pieces **76a-c** are sewn to the tenth fabric piece **78** along seams **82**. An eleventh fabric piece **84** (FIG. 12) is sized and shaped to cover the rear side of the pillow and is sewn to the first fabric piece **62** along a seem **86.** Finally, twelfth and thirteenth fabric pieces 88, 89 (FIG. 13) are sized and shaped to cover the bottom surface of the pillow and are sewn to the eleventh fabric piece **84** along a seam **90,** to the second fabric piece **64** along a seam **92,** to the opposite edges of the first fabric piece **62** along seams **94,** and to the sixth and tenth fabric pieces **70, 78** along seams **96,**

[0033] Various types of fabric (woven, knitted, non-woven, etc.) made from various fiber types (natural, synthetic, natural/synthetic blends, etc.) can be used to make the sewn cover **60.** In one embodiment, quilted woven fabric is employed for part of the cover and knitted fabric is employed for the rest. More particularly, in one embodiment, fabric pieces **62, 84, 88,** and **89** are knitted fabric, with velour being particularly preferred. Fabric pieces **64, 68a-c, 70, 76a-c,** and **78** are quilted woven fabric.

[0034] Referring to FIGS. 16 and 17, the pillow **10** is shown in use in the back-and side-lying positions. The pillow of the present invention may also be used in the stomach sleeping and resting positions. Advantageously, the cover of the pillow substantially follows the contours of the pillow and provides the user with contact-free use of a respiratory mask and the ability to easily sanitize the pillow after use. According to one embodiment, the pillow is used by positioning a cover on the pillow such that the cover substantially follows the contours and configurations of the pillow. A respiratory mask is positioned on the user's head. The user is positioned so that the user's shoulder is received in the lateral indentation **38** formed in the front side **16** of the second portion **42** of the pillow. The user's neck is positioned within the indentation **44** formed in the raised section **36** of the second portion **42** of the pillow. The user's head is positioned within the central indentation **50** formed in the first portion **40** of the pillow. In one embodiment, the positioning of the user's head comprises positioning the user's head so that it is facing away from the pillow. In another embodiment, the positioning of the user's head comprises positioning the user's head so that the side of the user's head is in contact with the cover of the pillow. In one embodiment, the method includes positioning the mask or hose for the mask in one of the recesses **34** formed in the second portion **42** of the pillow so that the pillow does not exert substantial pressure on the mask or hose.

[0035] In sum, the various embodiments of the head positioning pillow of the present invention may have de-

pressions, recesses, cavities, apertures, and/or raised portions to accommodate various respiratory masks, such as those used for nighttime respiratory therapy. The depressions, recesses, cavities, apertures, and/or raised portions relieve pressure against the mask and the hoses or tubing supplying the mask when side sleeping or stomach sleeping. Since pressure against the mask can impede the performance and comfort of the mask, cause the mask seal to separate from the face and result in air leakage (which can cause irritation from the eyes drying out), and/or cause the mask to press uncomfortably against the user's face, the embodiments of the pillows of the present invention and method of using the eliminate many of the impediments to the user resting or sleeping while using a respiratory mask. Advantageously, the pillow and cover of the present invention allow the user to move and sleep in multiple positions-left side, right side, back, and stomach-while minimizing the pressure that is exerted on the respiratory mask.

[0036] Many modifications and other embodiments of the inventions set forth herein will come to mind to one skilled in the art to which these inventions pertain having the benefit of the teachings presented in the foregoing descriptions and the associated drawings. Therefore, it is to be understood that the inventions are not to be limited to the specific embodiments disclosed and that modifications and other embodiments are intended to be included within the scope of the appended claims. Although specific terms are employed herein, they are used in a generic and descriptive sense only and not for purposes of limitation.

Claims

1. method for respiratory titration, the method comprising:

   determining an optimal relative angle between the patient's mouth and throat at which the patient's airway is optimally opened; and
   adjusting a head positioning pillow relative to the patient's head and neck to thereby modify and transform the configuration of the pillow to achieve a pillow position that achieves the optimal relative angle.

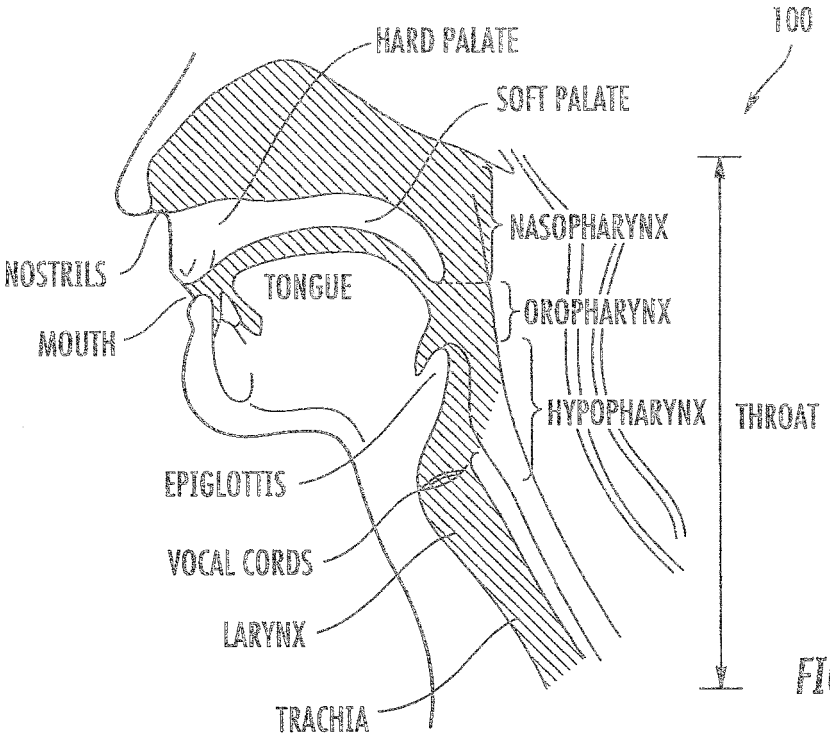

100
HARD PALATE
SOFT PALATE
NASOPHARYNX
NOSTRILS
TONGUE
OROPHARYNX
MOUTH
HYPOPHARYNX
THROAT
EPIGLOTTIS
VOCAL CORDS
LARYNX
TRACHIA

FIG. 1

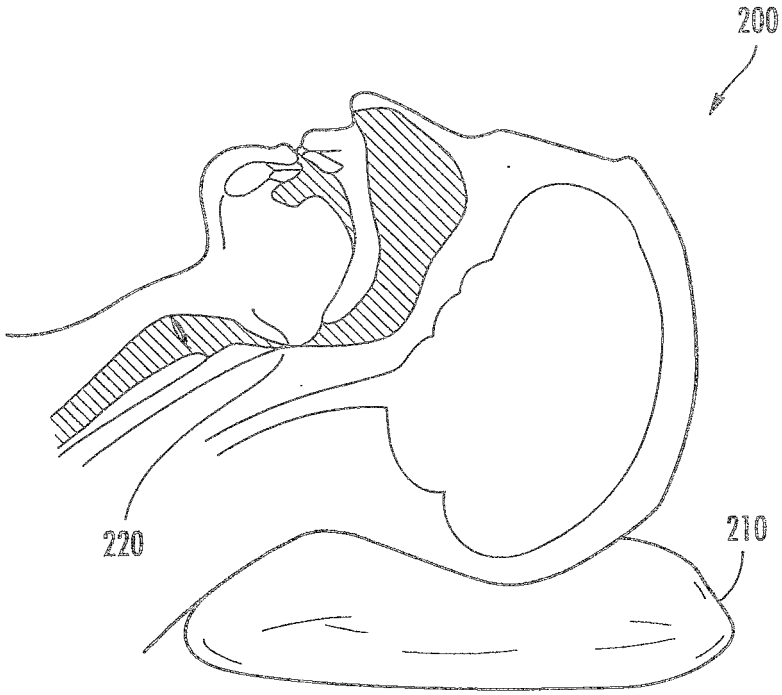

200
220
210

FIG. 2

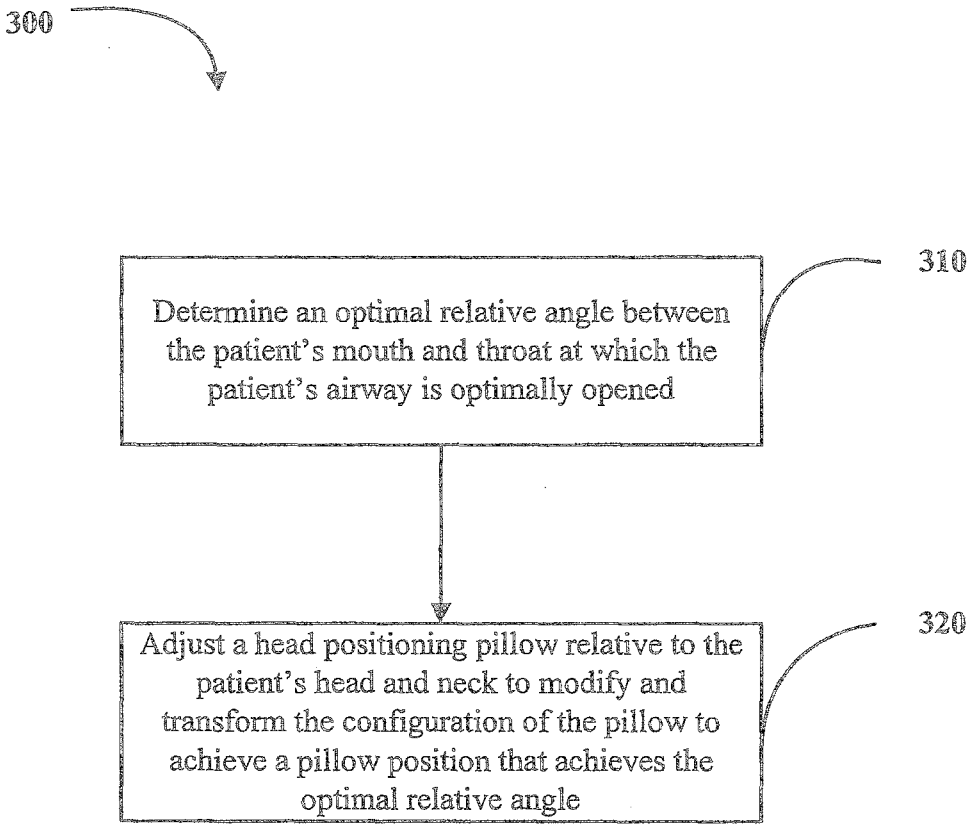

300
Determine an optimal relative angle between the patient's mouth and throat at which the patient's airway is optimally opened
310
Adjust a head positioning pillow relative to the patient's head and neck to modify and transform the configuration of the pillow to achieve a pillow position that achieves the optimal relative angle
320

FIG. 3

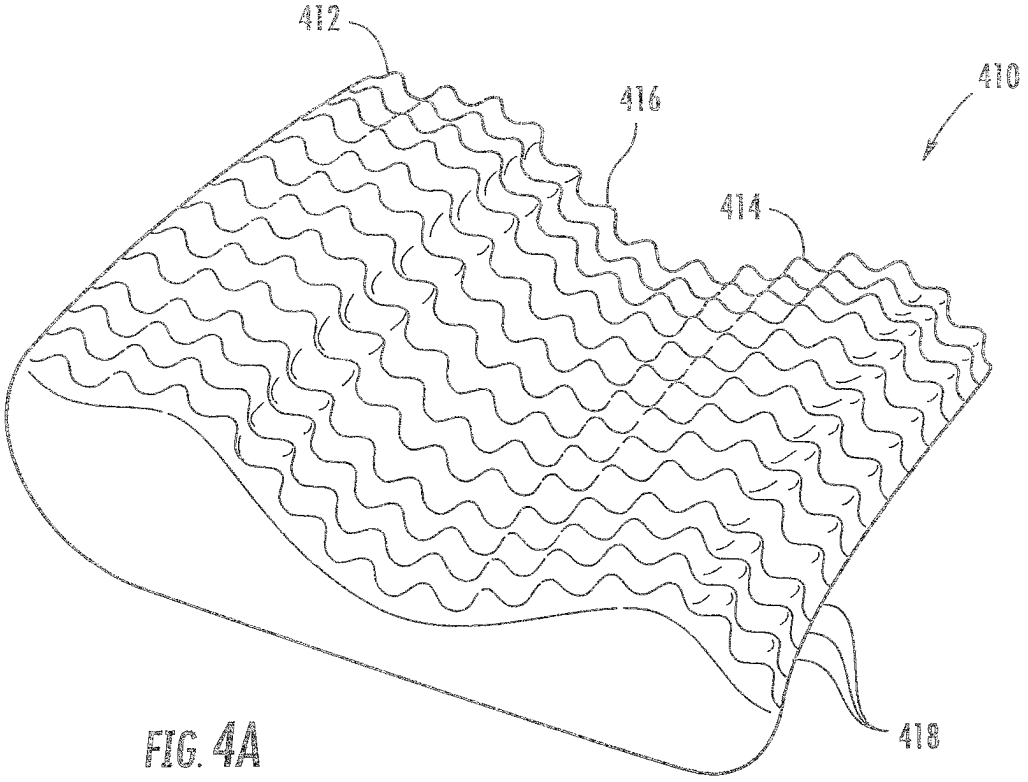


FIG. 4A

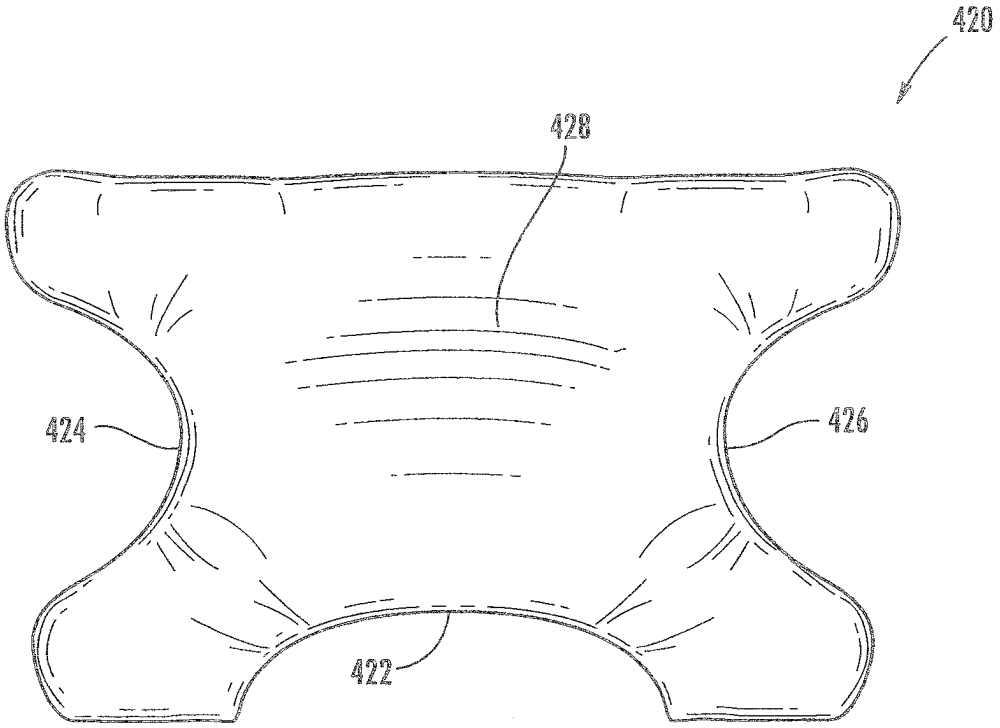


FIG. 4B

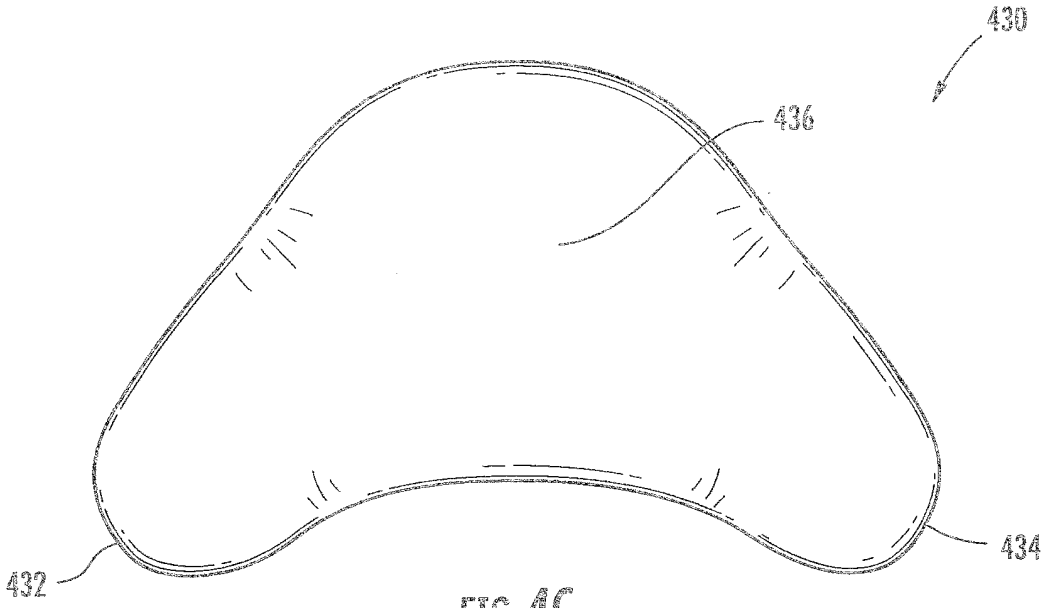


FIG. 4C

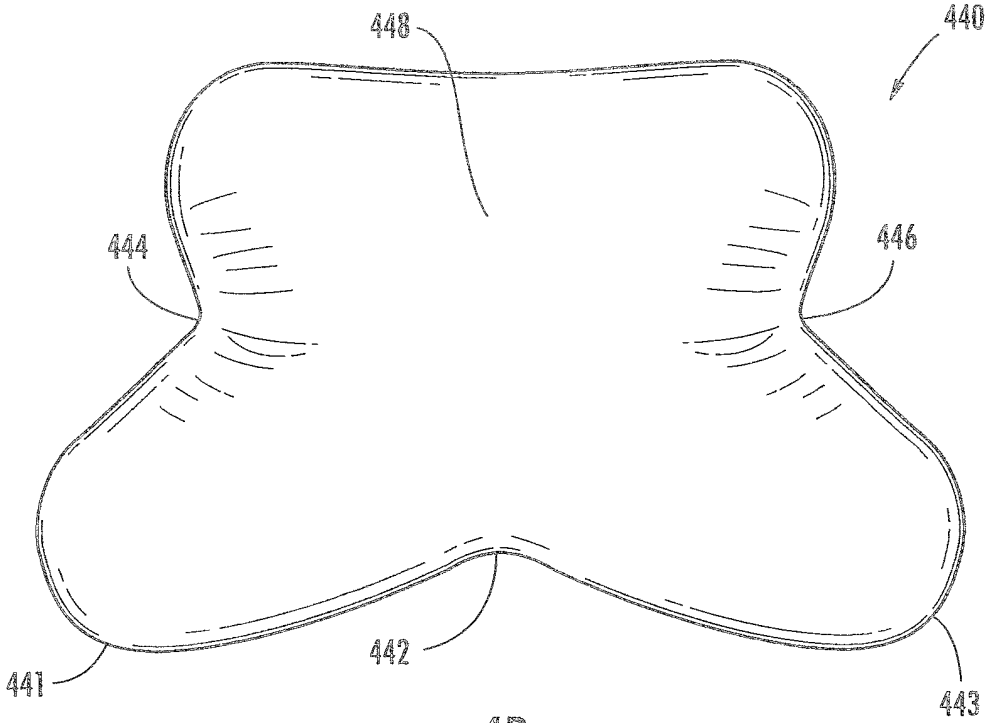


FIG. 4D

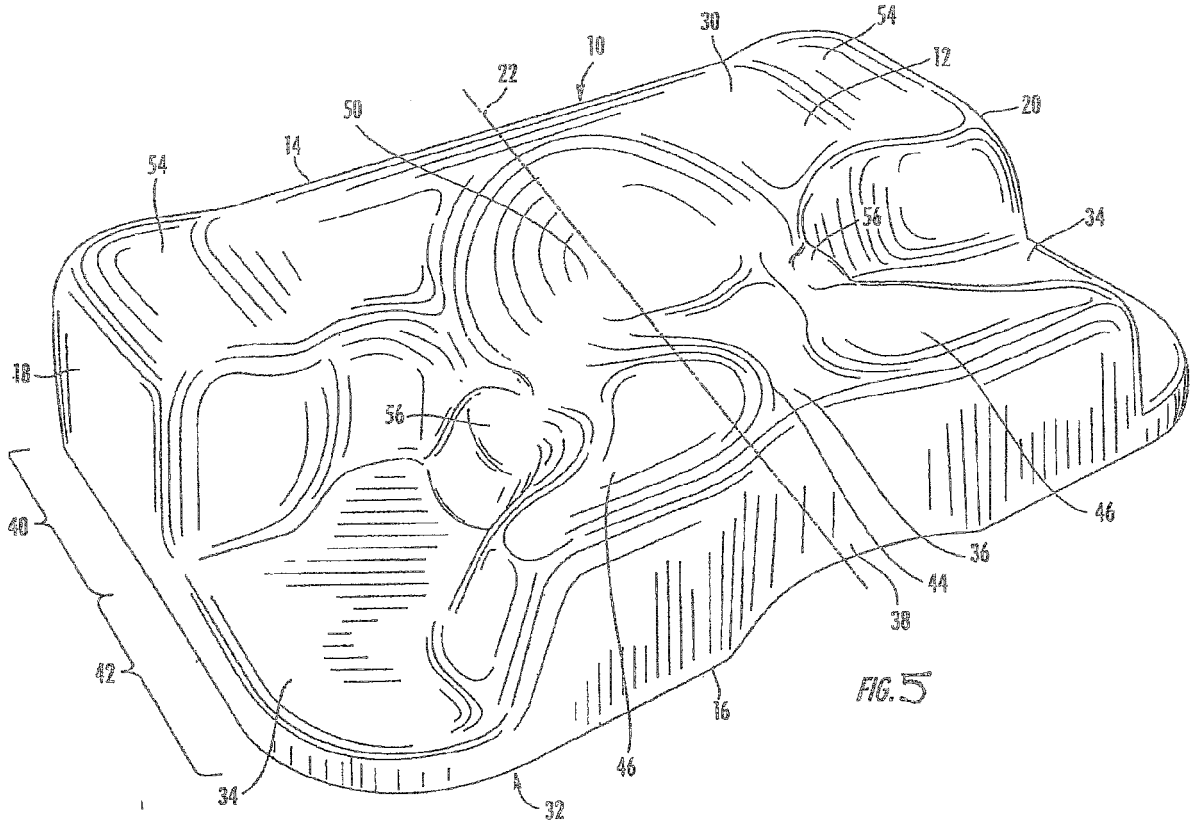


FIG. 5

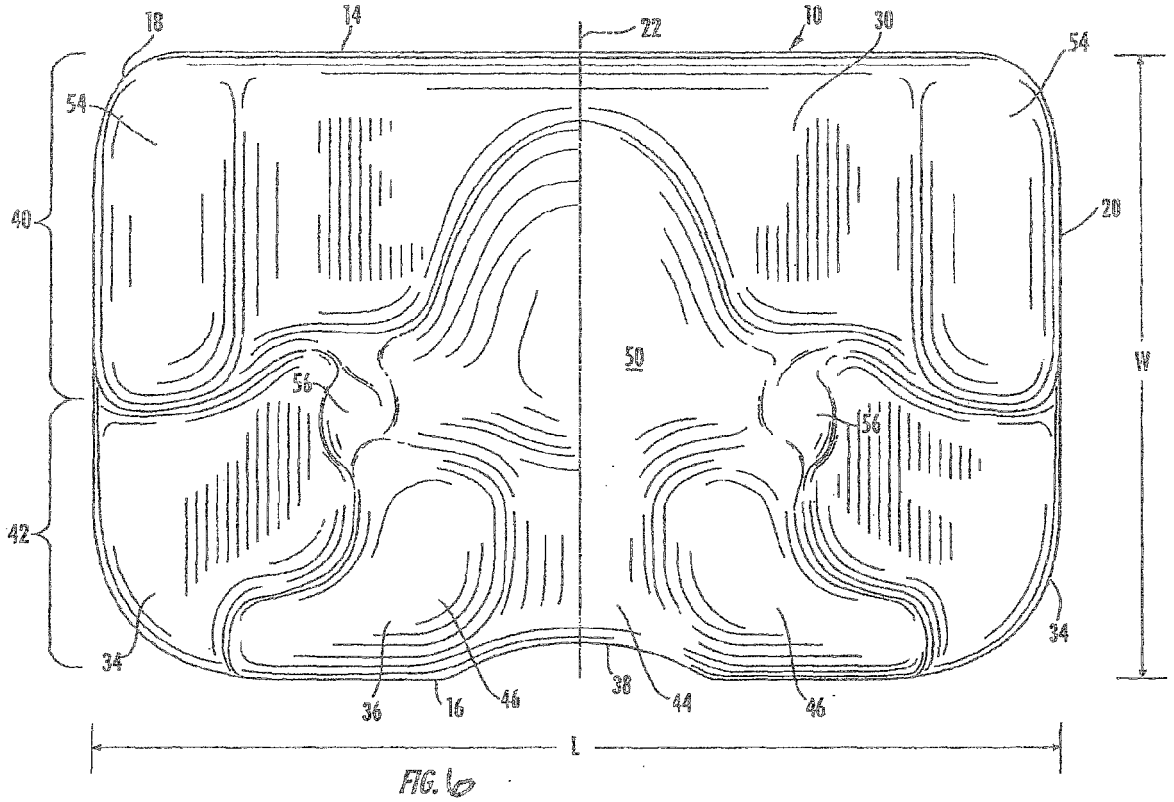


FIG. 6

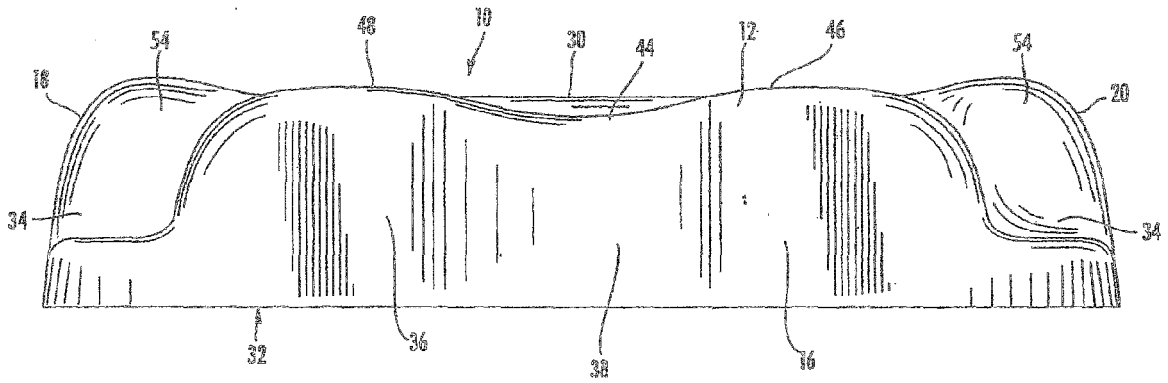


FIG. 7

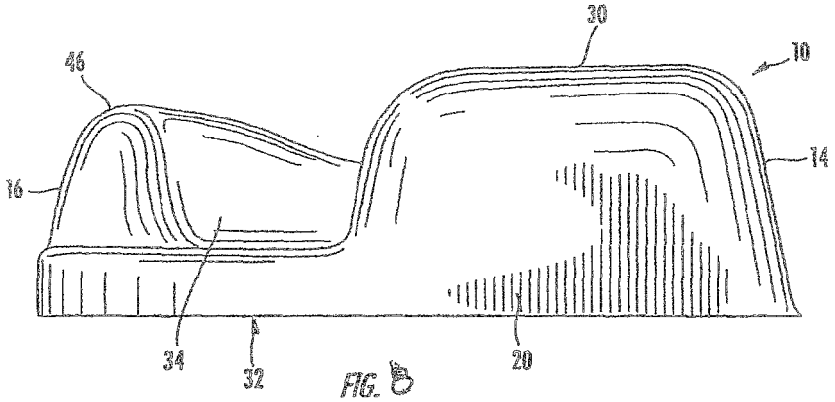


FIG. 8

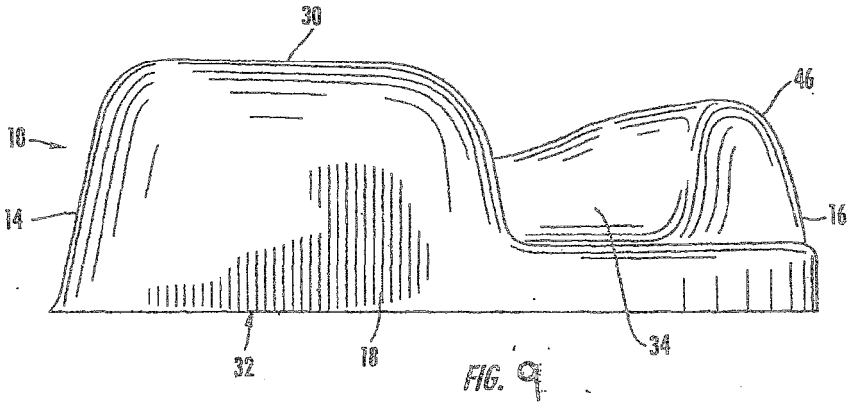


FIG. 9

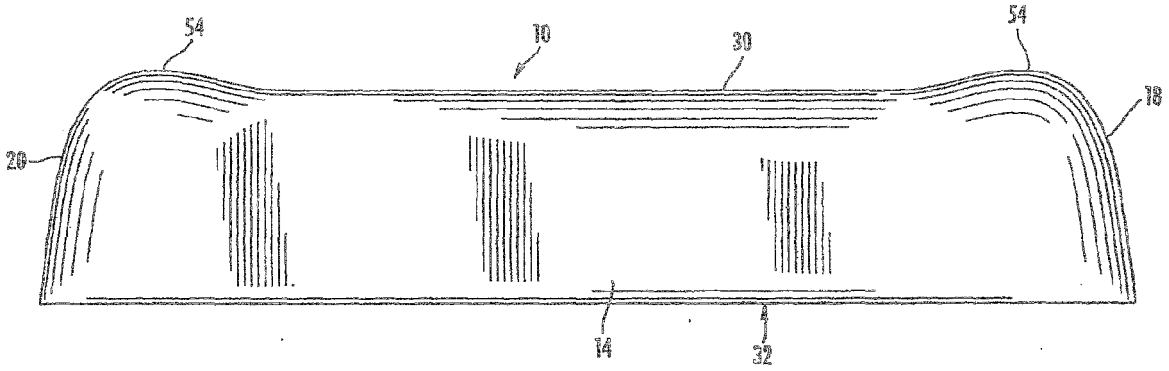


FIG. 10

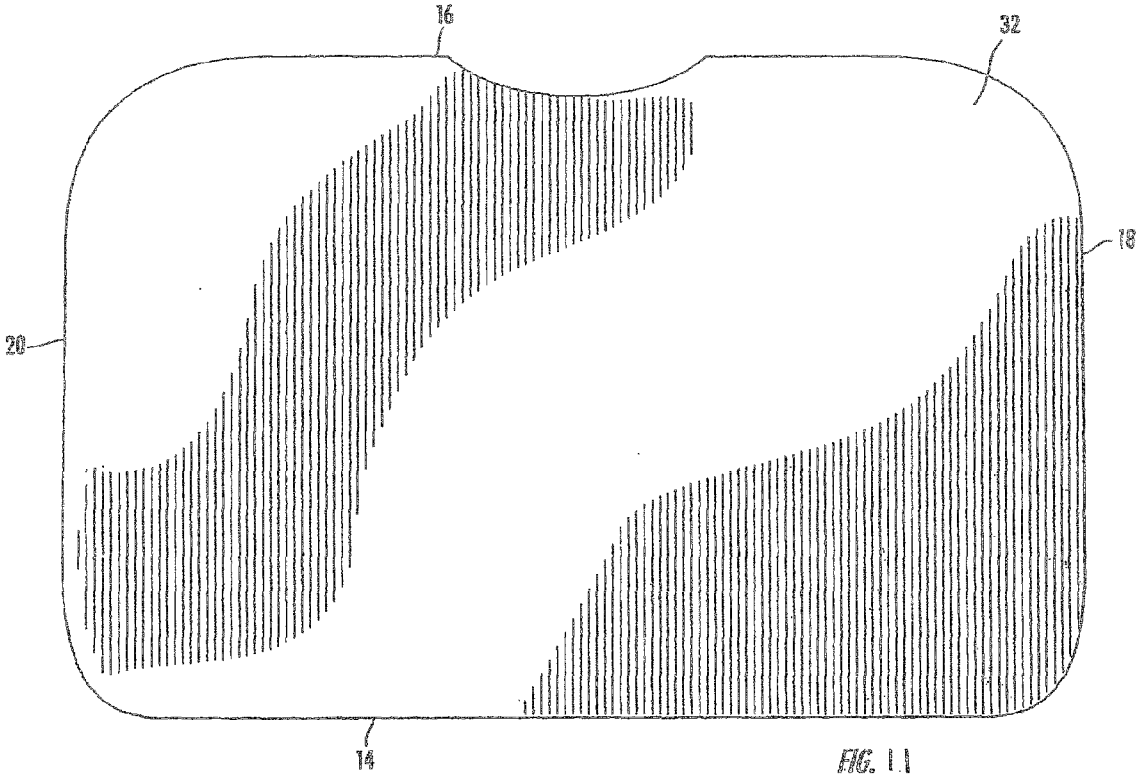


FIG. 1.1

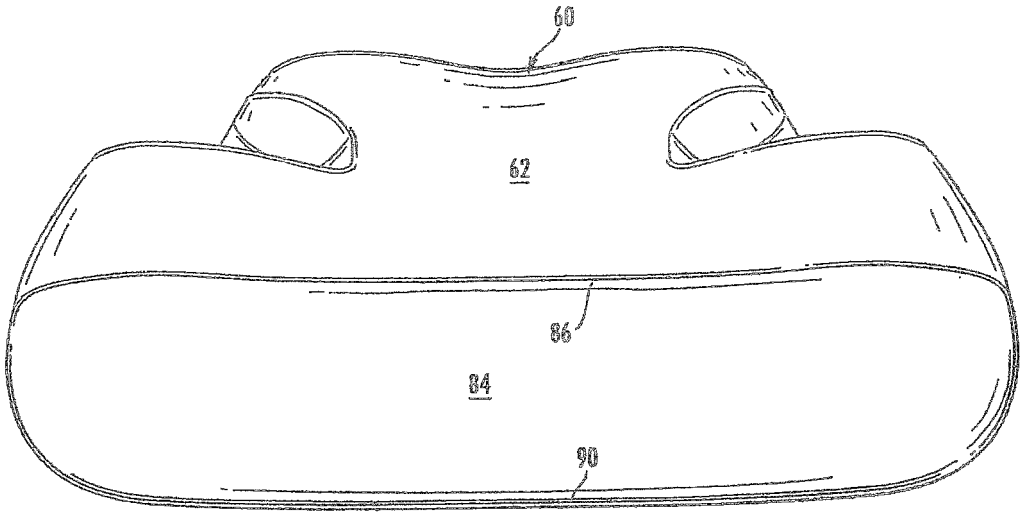


FIG. 12.

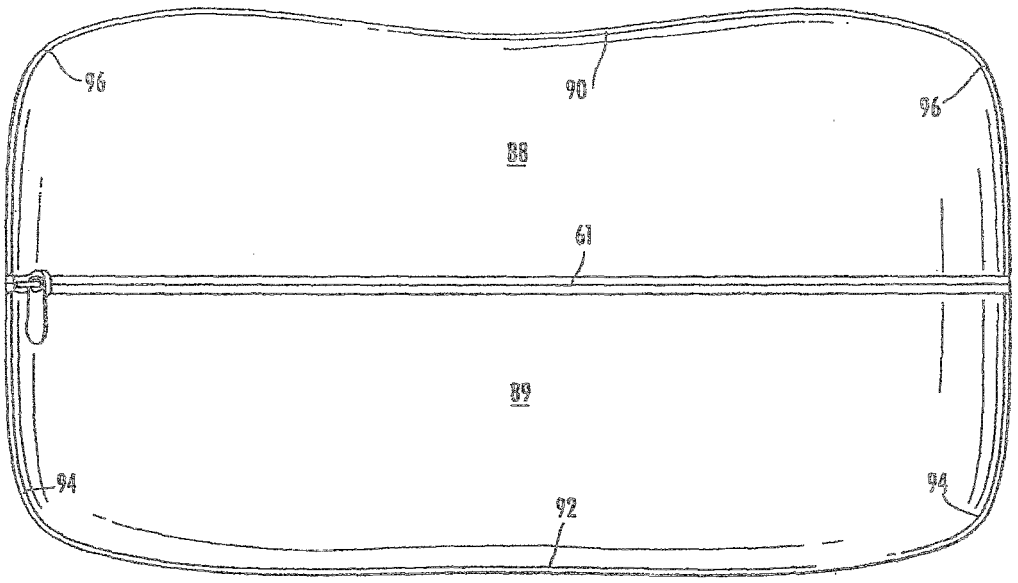


FIG. 13

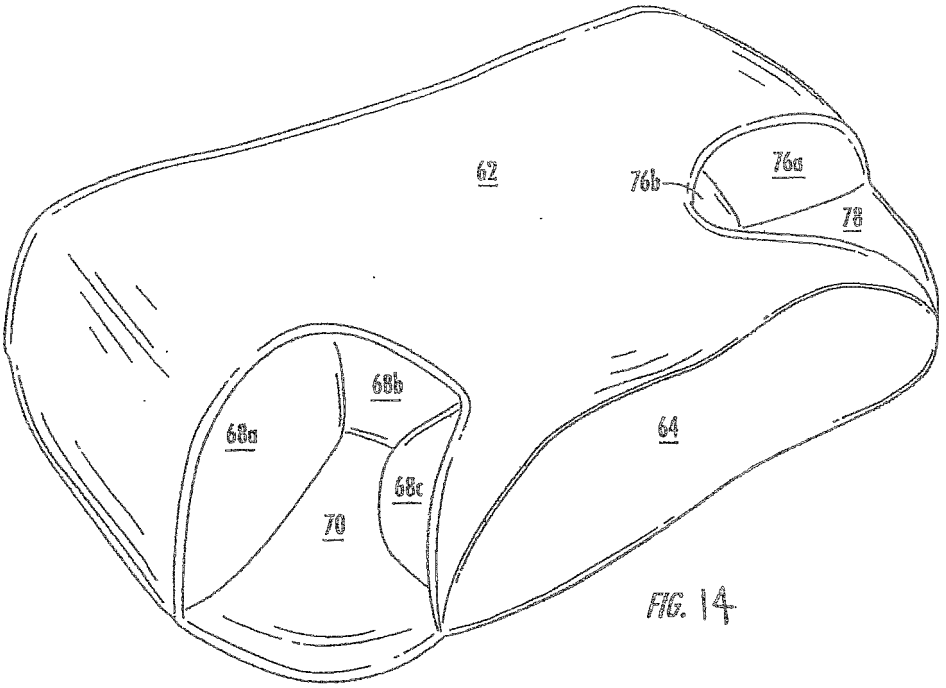


FIG. 14

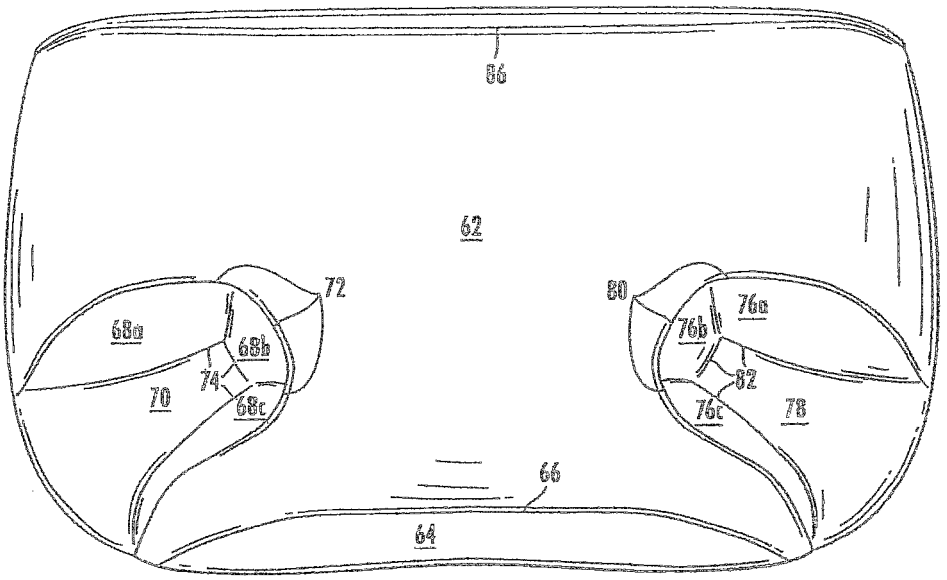


FIG. 15

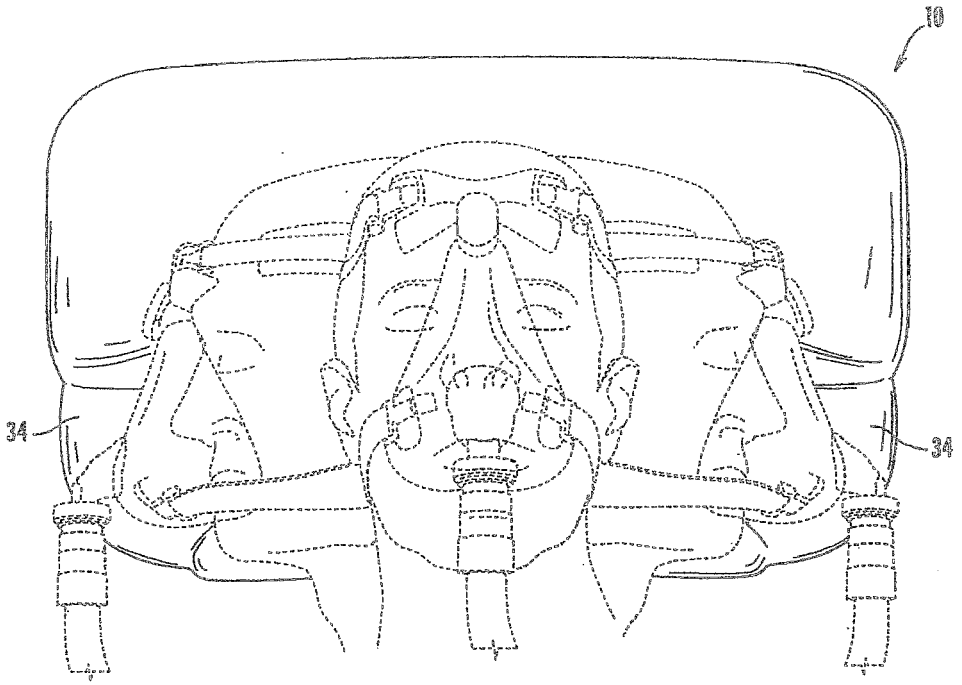


FIG. 10

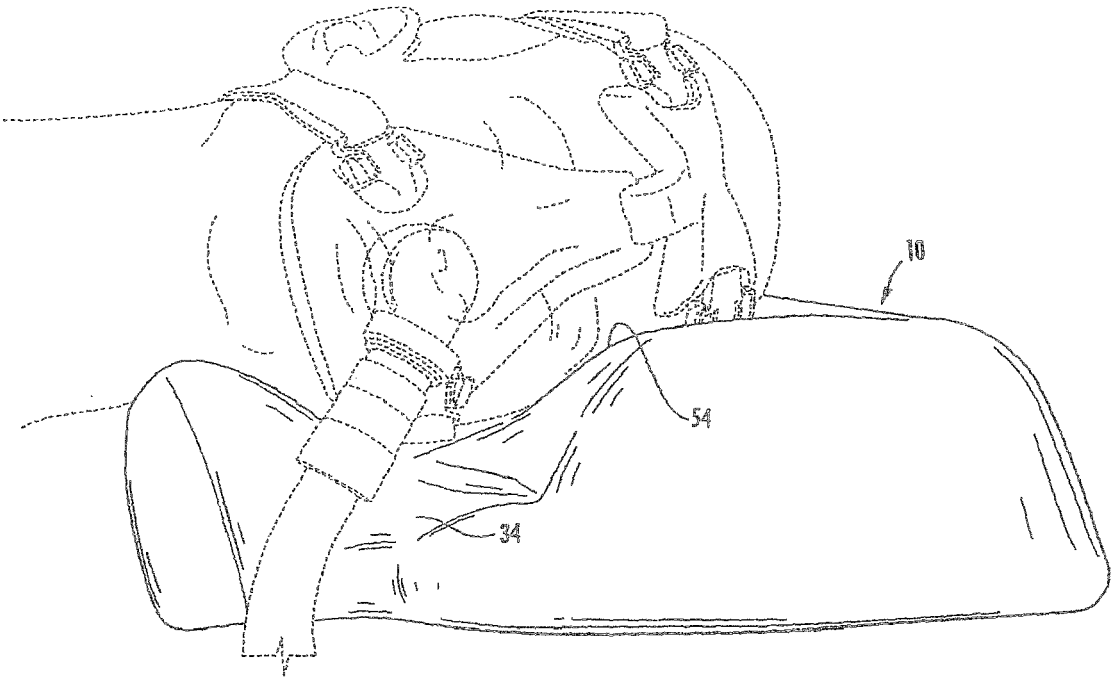


FIG. 17