

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(10) International Publication Number

WO 2013/144753 A1

(43) International Publication Date
3 October 2013 (03.10.2013)

(51) International Patent Classification:
A61M 16/06 (2006.01)

(21) International Application Number:
PCT/IB2013/051858

(22) International Filing Date:
8 March 2013 (08.03.2013)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/616,024 27 March 2012 (27.03.2012) US

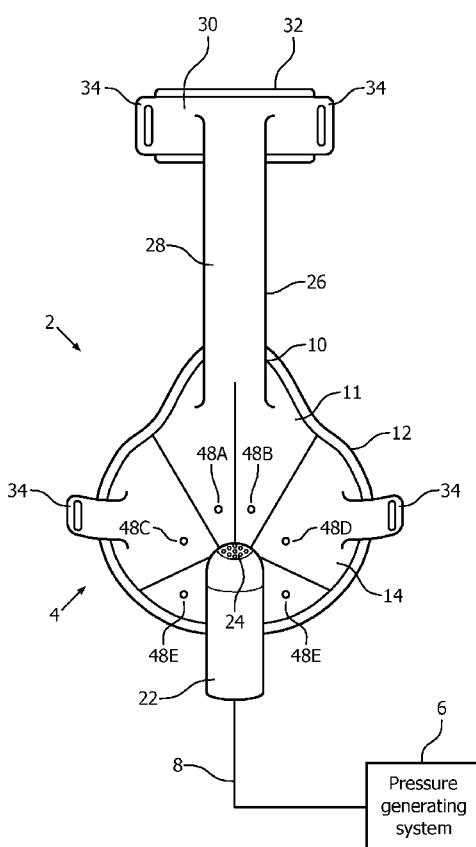
(71) Applicant: KONINKLIJKE PHILIPS N.V. [NL/NL];
High Tech Campus 5, NL-5656 AE Eindhoven (NL).

(72) Inventors: WILLARD, Nicolaas Petrus; c/o PHILIPS IP & S, High Tech Campus 44, NL-5656 AE Eindhoven (NL). HENDRIKS, Cornelis Petrus; c/o PHILIPS IP & S, High Tech Campus 44, NL-5656 AE Eindhoven (NL). POTZE, Willem; c/o PHILIPS IP & S, High Tech Campus 44, NL-5656 AE Eindhoven (NL). VONCKEN, Rudolf Maria Jozef; c/o PHILIPS IP & S, High Tech Campus 44, NL-5656 AE Eindhoven (NL). ASVADI, Sima; c/o PHILIPS IP & S, High Tech Campus 44, NL-5656 AE Eindhoven (NL). VAN ZANTEN, Joyce; c/o PHILIPS IP & S, High Tech Campus 44, NL-5656 AE Eindhoven (NL). KLEE, Mareike; c/o PHILIPS IP & S, High Tech Campus 44, NL-5656 AE Eindhoven (NL).

(74) Agents: STEFFEN, Thomas et al.; c/o PHILIPS IP & S, High Tech Campus 44, NL-5656 AE Eindhoven (NL).

[Continued on next page]

(54) Title: USER INTERFACE DEVICE PROVIDING FOR IMPROVED COOLING OF THE SKIN



(57) Abstract: A number of user interface device embodiments are disclosed that provide for increased cooling of the skin covered by the mask and/or increased flushing of gasses, including CO₂, from the mask.

FIG. 1



(81) **Designated States** (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) **Designated States** (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK,

EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

User interface device providing for improved cooling of the skin

FIELD OF THE INVENTION

The present invention relates to user interface devices for transporting a gas to and/or from an airway of a user, and in particular, to a user interface device including a mechanism for providing improved cooling of the skin covered by the user interface device.

5

DESCRIPTION OF THE RELATED ART

A variety of respiratory masks are known that have flexible seals and cover the nose, mouth, or both of a human user. The seals, which are also commonly referred to as cushions, are intended to create a seal against the user's face. Because of the sealing effect 10 that is created, gases can be provided at a positive pressure within the mask for delivery to the airway of the user. Such seals are typically coupled to a rigid or semi-rigid shell or frame member which provides support for the mask.

The uses for such masks range from high altitude breathing, i.e., aviation applications, to mining and fire fighting applications, to various medical diagnostic and 15 therapeutic applications. For example, such masks are used in the delivery of continuous positive airway pressure (CPAP) or variable airway pressure, such as a bi-level pressure that varies with the user's respiratory cycle or an auto-titrating pressure that varies with the monitored condition of the user. Typical pressure support therapies are provided to treat a medical disorder, such as sleep apnea syndrome, in particular, obstructive sleep apnea (OSA), 20 or congestive heart failure. During use, such respiratory masks, also often referred to as patient interface devices, are strapped on the head of the patient in order to interface the pressure generating device (e.g., a CPAP machine) with the patient.

A requisite of such respiratory masks is that they provide an effective seal against the user's face to prevent leakage of the gas being supplied, while also providing a 25 comfortable user/seal interface. This problem is significant because such masks are typically worn for an extended period of time. For example, in the case of respiratory masks used to provide pressure support therapies to treat medical disorders as described above, the mask is worn for several hours in bed. Such extended use can create several discomfort problems for the user, such as the formation of red marks on the user's face, skin irritation, and/or heat and

moisture discomfort. These discomfort problems can lead to reduced therapy compliance by patients as they may wish to avoid wearing an uncomfortable mask.

SUMMARY OF THE INVENTION

5 Accordingly, it is an object of the present invention to provide a user interface device that overcomes the shortcomings of conventional user interface device. This object is achieved according by providing a number of user interface device embodiments that provide for increased cooling of the skin covered by the mask and/or increased flushing of gasses, including CO₂, from the mask.

10 In one embodiment, a user interface element is provided that includes a first orifice for receiving a first flow of gas, and one or more second orifices for letting a second flow of gas out of the user interface element, wherein the first orifice and the one or more second orifices are positioned relative to each other such that during use of the user interface element the second flow of gas: (i) flows over and cools a skin surface of the user and out of 15 the user interface element through the one or more second orifices, and/or (ii) flushes at least 85% of any CO₂ present in an interior of the user interface element (from the last patient exhalation) from the user interface element through the one or more second orifices.

20 In one particular exemplary embodiment, a user interface device is provided that includes a cushion having a first end portion structured to sealingly engage a user's face and a second end portion opposite the first end portion, wherein the cushion defines a chamber. The user interface device also includes a shell member including a plurality of flow segments, each of the flow segments including a chamber having an inlet located at a first end of the shell member and one or more open orifices located opposite the inlet, wherein the second end portion of the cushion is coupled to the first end of the shell member 25 such that the chamber is in fluid communication with each of the flow segments, and wherein in response to a flow of breathing gas being delivered to the user interface device through the shell member, the user interface device is structured to cause a continuous flow of gas to flow through the chamber of the cushion and through each of the flow segments from the inlet of the flow segment to the open orifice of the flow segment.

30 In another particular exemplary embodiment, a user interface device is provided that includes a cushion member having a contacting portion structured to engage a portion of a user's face when the user interface device is donned by the user, wherein the cushion member defines a chamber. The contacting portion includes a textured surface having a plurality of surface features defining plurality of gaps each having a height, wherein

each of the heights is greater than 100 microns, and wherein in response to a flow of breathing gas being delivered to the user interface device, the user interface device is structured to cause a continuous flow of gas to flow through the chamber of the cushion member and between the cushion member and the portion of the user's face through the gaps

5 In yet another particular exemplary embodiment, a user interface device is provided that includes a cushion having a first end portion and a second end portion opposite the first end portion, wherein the cushion defines a chamber. The user interface device also includes a spacer/liner member located adjacent to the first end portion, wherein the spacer/liner member is structured to engage a portion of a user's face when the user interface 10 device is donned by the user, wherein the spacer/liner member is made of a porous material, wherein in response to a flow of breathing gas being delivered to the user interface device, the user interface device is structured to cause a continuous flow of gas to flow through the chamber of the cushion and between the cushion and the portion of the user's face through the spacer/liner member.

15 In still another particular exemplary embodiment, a method of making a user interface device for a user is provided, wherein the user interface device has a cushion member having a contacting portion structured to engage a portion of the user's face when the user interface device is donned by the user, the cushion member defining a chamber, the contacting portion including a textured surface having a plurality of surface features defining 20 a plurality of gaps each having a height. The method includes evaluating a surface roughness of the user's skin, and choosing the actual height of each of the gaps based on the evaluated surface roughness such that the effective height of each of the gaps responsive to the user interface device being donned by the user is greater than 100 microns.

25 These and other objects, features, and characteristics of the present invention, as well as the methods of operation and functions of the related elements of structure and the combination of parts and economies of manufacture, will become more apparent upon consideration of the following description and the appended claims with reference to the accompanying drawings, all of which form a part of this specification, wherein like reference numerals designate corresponding parts in the various figures. It is to be expressly 30 understood, however, that the drawings are for the purpose of illustration and description only and are not intended as a definition of the limits of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1 and 2 are front and side elevational views, respectively, of a system adapted to provide a regimen of respiratory therapy to a patient according to one exemplary embodiment;

5 FIG. 3 is an exploded view of the respiratory mask of the system of FIGS. 1 and 2;

FIG. 4 is a schematic diagram of the system of FIGS. 1 and 2 showing a partial cross-sectional view of the respiratory mask thereof;

10 FIG. 5 is a front elevational view of a system adapted to provide a regimen of respiratory therapy to a patient according to an alternative exemplary embodiment;

FIG. 6 is a schematic diagram in partial cross-section of a system adapted to provide a regimen of respiratory therapy to a patient according to another alternative exemplary embodiment;

15 FIGS. 7A-7D are schematic representations alternative exemplary cushions that may be employed in the respiratory masks described herein;

FIG. 8 is a schematic diagram in partial cross-section of a system adapted to provide a regimen of respiratory therapy to a patient according to still a further alternative exemplary embodiment;

20 FIGS. 9A-9D are schematic representations of contacting portion of a cushion according to a number of alternative exemplary embodiments;

FIG. 10 is a schematic diagram in partial cross-section of a system adapted to provide a regimen of respiratory therapy to a patient according to yet a further alternative exemplary embodiment;

25 FIG. 11 is a schematic diagram in partial cross-section of a system adapted to provide a regimen of respiratory therapy to a patient according to another further alternative exemplary embodiment; and

FIG. 12 is a front elevational view of spacer/liner that may be employed in the system of FIG. 11 according to one non-limiting embodiment.

30 DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

As used herein, the singular form of “a”, “an”, and “the” include plural references unless the context clearly dictates otherwise. As used herein, the statement that two or more parts or components are “coupled” shall mean that the parts are joined or operate together either directly or indirectly, i.e., through one or more intermediate parts or

components, so long as a link occurs. As used herein, “directly coupled” means that two elements are directly in contact with each other. As used herein, “fixedly coupled” or “fixed” means that two components are coupled so as to move as one while maintaining a constant orientation relative to each other.

5 As used herein, the word “unitary” means a component is created as a single piece or unit. That is, a component that includes pieces that are created separately and then coupled together as a unit is not a “unitary” component or body. As employed herein, the statement that two or more parts or components “engage” one another shall mean that the parts exert a force against one another either directly or through one or more intermediate 10 parts or components. As employed herein, the term “number” shall mean one or an integer greater than one (i.e., a plurality).

As used herein, the term “user interface element” shall mean a user (e.g., patient) interface device that, alone or in combination with one or more associated components, is structured to enable the delivery of a flow of breathing gas to the airways of 15 an individual wearing the user interface element, and may include, for example and without limitation, a device that includes a cushion attached to a shell or frame member, a shell or frame member that may be coupled to a cushion, a device that includes a cushion without an associated shell or frame member, and a device that includes a cushion (with or without an associated shell or frame member) and a liner coupled to the cushion for contacting the face 20 of the user.

Directional phrases used herein, such as, for example and without limitation, top, bottom, left, right, upper, lower, front, back, and derivatives thereof, relate to the orientation of the elements shown in the drawings and are not limiting upon the claims unless expressly recited therein.

25 Respiratory masks used to provide pressure support therapy (e.g., CPAP therapy) as described elsewhere herein have a volume of space (i.e., a chamber) that is located between the patient’s face and the shell or frame member of the mask. In the prior art, for most of the time during which such a respiratory mask is used, that spatial volume is filled with the patient’s exhalation gasses, which are warm and humid. It is only during 30 inhalation that this spatial volume is flushed with air from the pressure generating device (e.g., CPAP machine) that provides the therapy breathing gas.

Thus, in the prior art, the temperature, humidity and CO₂ concentration inside the mask (inside the spatial volume described above) tends to be much higher than the normal values in the surrounding environment (e.g., the patient’s bedroom). As a result, the

skin that is covered by the mask (i.e., both the skin that is actually under and directly engaged by the mask cushion and the skin that is inside the mask but not directly covered/engaged by the mask cushion) becomes warmer and starts to sweat. However, sweating will typically not lead to any cooling as the humidity inside the mask is already very high. The increased skin 5 temperature and humidity is uncomfortable for patients and increases the moisture level of the skin, the latter often leading to other skin problems like red marks, skin irritation, skin damage and skin wounds (e.g., pressure ulcers), particularly for the skin portions that are engaged and therefore pressed by the cushion. In addition, the higher CO₂ concentration is not beneficial as it will be inhaled at the next breath and increase the CO₂ concentration in 10 the patient's lungs. Described herein are a number of patient interface device embodiments that provide for increased cooling of the skin covered by the mask and/or increased flushing of gasses, including CO₂, from the mask.

FIGS. 1 and 2 are front and side elevational views, respectively, of a system 2 adapted to provide a regimen of respiratory therapy to a patient according to one exemplary 15 embodiment. As seen in FIGS. 1 and 2, system 2 includes a respiratory mask 4, also referred to as a patient interface device, according to one exemplary embodiment that is shown schematically attached to a pressure generating system 6 via a user circuit 8, as is conventionally known in the art. Pressure generating system 6 is any device capable of generating a flow of breathing gas or providing gas at an elevated pressure. Examples of 20 such pressure generating systems include ventilators, constant pressure support devices (such as a continuous positive airway pressure device, or CPAP device) in which the pressure provided to the user is constant over the user's respiratory cycle, and variable pressure devices (e.g., BiPAP®, Bi-Flex®, or C-Flex™ devices manufactured and distributed by Philips Respironics of Murrysville, Pennsylvania) in which the pressure provided to the user 25 varies with the user's respiratory cycle, and auto-titration pressure support devices.

FIG. 3 is an exploded view of respiratory mask 4. As seen in FIGS. 1-3, respiratory mask 4 includes a shell or frame assembly 10 and a cushion 12 attached to frame assembly 10 (frame assembly 10 and a cushion 12 may be collectively referred to as a flow delivery assembly/element). Frame assembly 10 includes a faceplate portion 11 having a 30 segmented outer shell member 14 that receives and holds an inner shell member 16, each of which is described in greater detail elsewhere herein. User circuit 8 is coupled to ports 18 and 20 defined in outer shell member 14 and inner shell member 16, respectively, and, in the illustrated embodiment, includes an elbow connector 22 for that purpose. In the exemplary embodiment, user circuit 8 is connected to frame assembly 10 so as to pivot or rotate relative

to the frame assembly 10 and may or may not be detachable therefrom. In short, any suitable coupling technique for joining user circuit 8 to frame assembly 10 is contemplated by the present invention.

In the illustrated exemplary embodiment, an exhaust vent 24 is provided in 5 elbow connector 22 for exhausting a flow of gas from mask 4 to ambient atmosphere. Such exhaust vents are conventionally used in pressure support systems that use a single-limb, i.e., a single conduit, to communicate a flow of gas to an airway of a user. Thus, the present invention contemplates that exhaust vent 24 can be any suitable exhaust vent, and can be located not only on elbow connector 22, but alternatively on another part of respiratory mask 10 4, such as on frame assembly 10.

Respiratory mask 4 can have any one of a number of different configurations, shapes, and sizes. In the illustrated, exemplary embodiment, respiratory mask 4 is a nasal/oral mask structured to cover the nose and mouth of the patient. However, other types 15 of respiratory masks, such as, without limitation, a nasal mask, a nasal cushion or a full face mask, which facilitate the delivery of the flow of breathing gas to the airway of a patient, may be substituted for respiratory mask 4 while remaining within the scope of the present invention.

Frame assembly 10, in the exemplary embodiment, is formed from a rigid or semi-rigid material, such as a polycarbonate or an injection molded thermoplastic. In 20 addition, as seen in FIGS. 1 and 2, frame assembly 10 includes a forehead support 26. The forehead support is generally T-shaped and includes a support arm 28 which is coupled to a forehead support bracket 30. Forehead support bracket 30 includes a forehead pad 32 disposed on the user contacting side to engage the forehead of the user. It is to be understood that the present invention contemplates that forehead support 26, and its individual 25 components, can have any one of a variety of alternative configurations. The present invention also contemplates that forehead support 26 can be eliminated entirely.

In the illustrated, exemplary embodiment, a headgear (not shown) attaches to respiratory mask 4 via headgear clips 34. Headgear clips 34 attach to straps (not shown) of the headgear, for example by inserting the straps into slots provided in headgear clips 34. In 30 the illustrated embodiment, headgear clips 34 are attached to each side of forehead support bracket 30 and to each side of the lower portion of frame assembly 10.

Cushion 12, also referred to as a seal or sealing member, is, in the exemplary embodiment, a unitary structure made of a soft, flexible, cushiony, elastomeric material, such as, without limitation, silicone, an appropriately soft thermoplastic elastomer, a closed cell

foam, or any combination of such materials. As seen in FIG. 3, cushion 12 includes a first end portion 36 (defining an orifice) structured to sealingly engage the patient's face, a second end portion 38 (defining an orifice) opposite first end portion 36 that couples to the rear of frame assembly 10, and a sidewall 40 extending between first end portion 36 and second end portion 38 such that cushion 12 defines an inner chamber 41. In the illustrated embodiment, faceplate portion 11 and cushion 12 are generally triangular-shaped and thus each include an apex region, a bottom region opposite the apex region, and first and second opposite side regions. It is to be understood that the present invention contemplates using any suitable technique for attaching second end portion 38 of cushion 12 to frame assembly 10. Such techniques may include permanently bonding cushion 12 to frame assembly 10, for example using adhesives or molding cushion 12 onto frame assembly 10, or attaching cushion 12 to frame assembly 10 using mechanical fasteners in a manner wherein cushion 12 is selectively detachable from frame assembly 10. When coupled to frame assembly 10, chamber 41 of cushion 12 receives the nose and mouth of the user when respiratory mask 4 is donned by the user so that the user's airway is in fluid communication with chamber 41.

As noted elsewhere herein, frame assembly 10 includes two parts, namely segmented outer shell member 14 and inner shell member 16. As seen in FIG. 3, outer shell member 14 includes a central chamber 42 surrounded by a plurality of flow segments 44 each comprising a chamber having an inlet 46 at a first end thereof and one or more smaller orifices 48 at a second, opposite end thereof. In the illustrated, non-limiting embodiment, outer shell member 14 includes five flow segments 44, labeled 44A-44E in the FIGS. As described in greater detail herein, flow segments 44A and 44B control flow over the left and right sides of the patient's nose, respectively, flow segments 44C and 44D control flow over the left and right cheeks of the patient, respectively, and flow segment 44E controls flow over the chin of the patient.

In addition, as seen in FIG. 3, inner shell member 16 defines a chamber 50 that extends from a first end 52 thereof to orifice 20. When respiratory mask 4 is assembled, inner shell member 16 is received and held within central chamber 42 of outer shell member 14 to form frame assembly 10. Inner shell member 16 may be held in place by any suitable means, such as an adhesive or a mechanical means such as a snap fit or friction fit. Cushion 12 is then attached to the back end of frame assembly 10. In particular, as seen in FIG. 4, which is a schematic diagram of system 2 showing a partial cross-sectional view of respiratory mask 4, cushion 12 is attached to frame assembly 10 in a manner such that that outer edge of second end portion 38 of cushion 12 is aligned with the outer edge of outer

shell member 14 and only partially covers the inlet 46 of each flow segment 44. As a result, and as described in greater detail below, gasses are able to flow from inner chamber 41 of cushion 12 into and through flow segments 44.

The operation of respiratory mask 4 will now be described in connection with

5 FIG. 4. As described elsewhere herein, during use, a flow of breathing gas, represented by arrow 54, is generated by pressure generating system 6 and delivered to elbow connector 22 (in the exemplary embodiment the flow of breathing gas is generated from air in the environment surrounding pressure generating system 6). A portion of the gas flow, represented by arrow 56, will exit respiratory mask 4 through exhaust vent 24 as an
10 intentional leak of system 2. In addition, the remainder (non-leaked portion) of the gas flow will be delivered to inner chambers 50 and 41. That remaining flow will, as a result of the structure of respiratory mask 4 as described herein, provide two gas flow portions. A first gas flow portion, represented by arrow 58, will be the breathing gas that is delivered to the airway of the patient during the inspiratory phase of the patient (that flow is also present
15 during the expiratory phase but the majority thereof is not delivered to the patient's airway and instead is opposed by the exhalation flow of the patient into chamber 50 and 41). A second gas flow portion, represented by arrows 60, will, according to an aspect of the exemplary embodiment of the present invention, be caused to flow within respiratory mask 4. That flow will be a continuous flow of gas (on the order of several ml/min as compared to
20 several l/min for the flow represented by arrow 58) that will flow from chamber 50 to chamber 41 and to the skin that is inside respiratory mask 4 but not directly covered/engaged by cushion 12. Thereafter, the continuous flow of gas will flow to flow segments 44 (and through the chambers 46) and out of frame assembly 10 through orifices 48 of flow segments 44.

25 The flow represented by arrows 60 as just described will continuously flush the inner chambers 50 and 41 of respiratory mask 4 and as a result will minimize the CO₂, heat and moisture effects of exhaled breaths inside respiratory mask 4 that are described elsewhere herein. Instead, the flow represented by arrows 60 will cause the inside of respiratory mask 4 to be filled with cooler, drier air from pressure generating system 6 (as noted elsewhere herein, that air is, in the exemplary embodiment, taken from the environment surrounding pressure generating system 6 and will thus generally have the same temperature and humidity as such air). As a result, the skin that is inside respiratory mask 4 but not directly covered/engaged by cushion 12 will receive the flow of gas represented by arrows 60 and be cooled. In the exemplary embodiment, the flow of gas represented by arrows 60 is

more than a negligible flow and is a predetermined percentage of an intentional (designed in) leak flow of respiratory mask 4 when the patient is not inhaling during use of respiratory mask 4, wherein the predetermined percentage is not more than a certain maximum percentage value. In one particular embodiment, the flow of gas represented by arrows 60 5 when the patient is not inhaling, while more than a negligible flow, is at most 10% of the intentional (designed in) leak flow (i.e., the certain maximum percentage value is 10%). In one exemplary implementation, the flow represented by arrows 60 when the patient is not inhaling is greater than or equal to 0.1% of the intentional (designed in) leak flow and less than or equal to 10% of the intentional (designed in) leak flow, while in another exemplary 10 implementation the flow represented by arrows 60 when the patient is not inhaling is greater than or equal to 1% of the intentional (designed in) leak flow and less than or equal to 10% of the intentional (designed in) leak flow. In addition, the flow of gas represented by arrows 60 flows over at least one part of a user's face, the at least one part being chosen from the group of parts comprising: the nose bridge, the upper lip, the lower lip, the chin and/or the 15 cheeks. In one particular embodiment, the parts include the nose bridge, the upper lip and the cheeks. In another particular embodiment, the parts include the nose bridge, the upper lip, the lower lip, and the cheeks. In still another particular embodiment, the parts include all of the nose bridge, the upper lip, the lower lip, the chin and the cheeks.

In addition, the higher CO₂ concentration gas, from the exhaled breath of the 20 patient, will be flushed out of the mask by the flow of gas represented by arrows 60. In the exemplary embodiment, at least 85% of any CO₂ present in the interior of the mask (from the last exhalation) will be flushed out of the mask by the flow of gas represented by arrows 60. This value is based on a calculation that assumes exhaled breath contains 4 % carbon dioxide, 500 ml of fresh air is inhaled for each breath, the dead volume of the mask is 100 ml and 25 1000 ppm CO₂ or less is not harmful for people. If the mask is flushed and at least 85% of all CO₂ in the mask from the last exhalation is removed, a safe level will be achieved. The corresponding flow depends on the breathing rate, the volume of inhaled air, the time between inhalation and exhalation and the actual dead volume of the mask filled with the patient nose and exhaled breath. Furthermore, as will be appreciated, the flow of gas 30 represented by arrows 60 creates a gas flow away from the patient and minimizes the risk of direct and potentially uncomfortable gas flow directed toward the face of the patient.

As noted elsewhere herein, in the exemplary embodiment, respiratory mask 4 is a nasal/oral mask structured to cover the nose and mouth of the patient. Furthermore, in the exemplary embodiment, the length of a first flow path within respiratory mask 4 along

which the flow of gas represented by arrows 60 flows in order to the reach the user's face will be at least a certain first minimum value, wherein that first flow path is defined as the shortest pathway measured from the axis of the inflow port of shell member 16 to which elbow connector 22 is attached and alongside shell member 16 and cushion 12 to the face of the user. Also, the length of a second flow path within respiratory mask 4 along which the flow of gas represented by arrows 60 flows from the user's face to an orifice 48 will be at least a certain second minimum value, wherein that flow path is defined as the shortest pathway measured from the face of the user alongside cushion 12 and shell member 16 to an orifice 48. In the exemplary embodiment, the length of the first flow path will be at least 4 cm (4-6 cm in one embodiment) and the length of the second flow path will be at least 4 cm (4-6 cm in one embodiment) such that the total of the first and second flow paths will be at least 8 cm (8-12 cm in one embodiment). The value for the first and second flow paths just described would also apply to a full/total face mask type patient interface device.

In addition, if respiratory mask 4 was adapted to be a nasal mask structured to cover the nose of the patient, the length of the first flow path in the exemplary embodiment will be 1.5-3 cm (2 cm in one particular embodiment) and the length of the second flow path in the exemplary embodiment will be 1.5-3 cm (2 cm in one particular embodiment) such that the total of the first and second flow paths in the exemplary embodiment will be 3-6 cm (4 cm in one particular embodiment).

FIG. 5 is a front elevational view of a system 2' adapted to provide a regimen of respiratory therapy to a patient according to an alternative exemplary embodiment. System 2' includes many of the same components as system 2 described above, and like components are labeled with like reference numerals. As seen in FIG. 5, system 2' includes alternative respiratory mask 4' having a plurality of cover members 62 that may be selectively and sealingly attached to faceplate portion 11 over orifices 48. Cover members 62 may be attached to faceplate portion 11 using, for example, and without limitation, an adhesive (e.g., an adhesive rim provided around the cover member 62), or Velcro. In another exemplary embodiment, wherein cover members 62 are made of foam (see below) or another compressible material, cover members 62 may be attached to faceplate portion 11 by compressing the cover member 62 and inserting the cover member 62 into a small pocket formed in faceplate portion 11. Once inserted, the foam cover member 62 will expand and fill the pocket creating a stable configuration. In the illustrated, exemplary embodiment, at least six cover members 62A-62E are provided for selectively covering orifices 48A-48E. Cover members 62 enable a patient to selectively control the nature/degree of the flow of gas

through segmented outer shell member 14 by selectively controlling the rate of flow through each of the flow segments 44 by controlling the resistance to flow at orifices 48. In particular, cover members 62 may be made of a porous material, such as a fabric, foam, sponge, perforated foils, hairy materials like fur, high pile carpet or moleskin, or silicone 5 rubber having a number of holes provided therein, which enables a certain degree of restricted gas flow through the associated orifice 48. Alternatively, cover members 62 may be made of a non-porous material, such as silicone rubber (or another silicone material), natural rubber, man-made rubber, cork, or an elastomer material, to prevent gas flow through the associated orifice 48 and thus completely restrict flow through the associated flow 10 segment 44. In one particular, exemplary embodiment, one or more porous cover members 62 (e.g., having different degrees of porosity) and a non-porous cover member 62 are provided for each orifice such that the patient may, for each orifice 48, choose to leave it open/uncovered, choose to cover it with a porous cover member 62 so as to restrict flow to a certain degree (depending on the porosity of the material used to make the cover member 62), 15 or choose to cover it with a non-porous cover member 62 so as to completely restrict flow. In this manner, the patient is able to selectively design the flow through respiratory mask 4' to suit his or her particular likes and needs. Depending on the pressure that needs to be provided to the patient by pressure generating device, the patient will be able to find a configuration that provides a comfortable skin temperature while still delivering the needed 20 pressure. Other methods for controlling the nature/degree of the flow of gas through segmented outer shell member 14 include controlling the dimensions and/or number of the orifices 48.

FIG. 6 is a schematic diagram in partial cross-section of a system 2" adapted to provide a regimen of respiratory therapy to a patient according to a further alternative 25 exemplary embodiment. System 2" includes many of the same components as systems 2 and 2' described above, and like components are labeled with like reference numerals. In system 2", an alternative respiratory mask 4" is provided. As seen in FIG. 6, respiratory mask 4" includes an inner shell member 16" having an extension member 64 extending from the first end 52 of inner shell member 16" into inner chamber 41 of cushion 12. In the exemplary 30 embodiment, extension member 64 follows the contours of respiratory mask 4", and in particular the outer contours of cushion 12. As seen in FIG. 6, and entry channel 66 is formed between the distal end of extension member 64 first end portion 36 of cushion 12. The configuration of this embodiment will produce a flow represented by arrows 60". As

seen in FIG. 6, that flow will contact more of the inner surface of cushion 12, and in particular, more of sidewall 40 of cushion 12, as compared to flow 60 shown in FIG. 4.

FIG. 7A is a schematic representation of a portion of a cushion 12A according to an alternative exemplary embodiment that may be employed in respiratory mask 4, respiratory mask 4', or respiratory mask 4" as described herein. As seen in Fig. 7A, cushion 12A is perforated with a number of small channels 68 that extend through the walls of cushion 12A. As the gas flow through cushion member 12A is provided in the manner described elsewhere herein, the gas will flow through cushion 12A and cool cushion 12A. In the exemplary embodiment, channels 68 are small enough to minimize the potential for discomfort to the patient that may result from gas flowing through channels 68 and directly onto the skin. In one particular embodiment, the diameter of channels 68 is between 0.1 mm and 5 mm, and in another particular embodiment, the diameter of channels 68 is between 0.1 mm and 1 mm. Also, in the exemplary embodiment, the size and number of channels 68 is controlled so as to avoid making cushion 12A too flexible (i.e., potentially unstable). The optimal size and number of channels 68 will be determined by each particular application, and can lead appropriately flexible/stable and cool mask.

FIG. 7B is a schematic representation of a portion of a cushion 12B according to a further alternative exemplary embodiment that may be employed in respiratory mask 4, respiratory mask 4', or respiratory mask 4" as described herein. As seen in Fig. 7B, cushion 12B includes a layer 70 of material having a high specific heat conductivity that is provided on the inner surface 72 of cushion 12B. In the exemplary embodiment, layer 70 is a relatively thin layer of material, having a thickness of 20 nm – 1 mm in one particular embodiment, or, alternatively, 20 nm – 100 nm in another particular embodiment. Layer 70 will provide a substantially uniform temperature along inner surface 72 (by helping to spread the heat flow) and improve the heat exchange between the flow of gas within inner chamber 41 and cushion 12. In the exemplary embodiment, the material of layer 70 has a thermal conductivity of 50 W /mK or more . In one embodiment, layer 70 is made of a thin film/foil of material (e.g., metal), such as, without limitation, aluminum, Au, Cu , Ag, W, amorphous diamond, graphite, aluminum nitride, boron nitride, or graphene.

FIG. 7C is a schematic representation of a portion of a cushion 12C according to yet a further alternative exemplary embodiment that may be employed in respiratory mask 4, respiratory mask 4', or respiratory mask 4" as described herein. As seen in Fig. 7C, cushion 12C includes a varying surface texture that is provided on the inner surface 72 of cushion 12C. In the exemplary embodiment, the varying surface texture is provided by a

plurality of dimples or indentations 74 that are provided in inner surface 72. In one particular implementation, dimples 74 are generally partially spherical in shape and have a diameter of between 0.1 and 5 mm. The varying surface texture of this embodiment will cause a turbulent gas flow over inner surface 72, which is a more efficient type of flow for 5 facilitating heat exchange.

FIG. 7D is a schematic representation of a portion of a cushion 12D according to still a further alternative exemplary embodiment that may be employed in respiratory mask 4, respiratory mask 4', or respiratory mask 4" as described herein. As seen in Fig. 7D, cushion 12D includes a plurality of heat conductive particles or fibers 76 which are provided 10 (e.g., randomly or uniformly) within the body of cushion 12D during the manufacturing thereof (e.g., a molding process) in order to increase the heat conductivity of cushion 12D so as to increase the heat flow from the patient's skin to the heat exchange area within inner chamber 41 of cushion 2. Heat conductive particles or fibers 76 may be, for example and without limitation, aluminum, tungsten, gold, copper, silver, aluminum nitride, aluminum 15 oxide, zinc oxide, boron nitride, or carbon black particles or fibers. The optimal type and number of particles or fibers 76 will be determined by each particular application, with care being taken to not unduly increase the stiffness of cushion 12. In the exemplary embodiment, each of the particles or fibers 76 is connected to and forms a bridge (i.e., is directly or indirectly connected to) to an outside edge of cushion 12D, such as being connected to one or 20 more other particles or fibers (i.e., the particles or fibers 76 do not all need to be connected to one another, rather at least some need to be connected and form pathways for the heat transport to an outside edge of cushion 12D; generally, the more the better, but the more that are used, the stiffer the cushion 12 will become, and care should be taken to not unduly increase the stiffness). In addition, in an alternative configuration, rather than a plurality of 25 heat conductive particles or fibers 76, a plurality of lines of such heat conductive materials may be provided within cushion 12 extending from inner surface 72 to the outside/outer surface of cushion 12.

FIG. 8 is a schematic diagram in partial cross-section of a system 80 adapted to provide a regimen of respiratory therapy to a patient according to still a further alternative exemplary embodiment. System 80 includes many of the same components as system 2 described elsewhere herein, and like components are labeled with like reference numerals. In system 80, an alternative respiratory mask 82 is provided. As seen in FIG. 8, respiratory mask 82 includes a shell member 16 as described elsewhere herein having an alternative cushion 84 attached thereto (in the exemplary embodiment, cushion 84 may be made from

any of the same materials as cushion 12 described elsewhere herein). Cushion 84 includes an end portion 86 (defining an orifice) structured to engage the skin 87 of the patient's face (in the exemplary, non-limiting embodiment, end portion 86 is structured to sealingly engage the skin 87), an end portion 88 (defining an orifice for receiving gas flow into the cushion) 5 opposite end portion 86 that couples to the rear of shell member 16, and a sidewall 90 extending between end portion 86 and end portion 88 such that cushion 12 defines an inner chamber 91. Shell member 16 and cushion 84, or cushion 84 alone, may be referred to as a flow delivery assembly/element.

10 End portion 86 includes a contacting portion 92 that comprises a textured surface structured to contact the skin of the user. In one embodiment, contacting portion 92 covers the entire exposed surface of end portion 86. In an alternative embodiment, contacting portion 92 covers only selected, well defined areas of end portion 86.

15 In one exemplary embodiment, the textured surface is a random surface having a plurality of surface features, such as, for example and without limitation, bumps, dimples, pillars, domes, valleys, ridges, undulations and serrations. In another exemplary embodiment, the textured surface is an engineered surface. As used herein, the term "engineered surface" shall mean a designed surface texture having a plurality of one or more types of surface features wherein for each type of surface feature the surface feature has a non-random, predefined/predesigned geometry and/or non-random, predefined/predesigned 20 dimensions and/or interrelationships among one another. The surface features that may form part of an engineered surface include, for example and without limitation, bumps, dimples, pillars, domes, valleys, ridges, undulations and serrations. These surface features minimize the real area of contact with the skin, thereby providing low friction (compared to a nominally flat surface). In one particular exemplary embodiment, the surface features that 25 may form part of an engineered surface are "non-connected surface features". As used herein, the term "non-connected surface feature" shall mean a surface feature that extends upwardly from a surface and that is not connected to any adjacent surface features at a point located above the surface from which the surface feature extends by, for example, a ridge or similar connecting structure. Examples of such "non-connected surface features" are the 30 pillars shown in FIGS. 9C and 9D and described below.

In the embodiment of FIG. 8, the textured surface of contacting portion 92 provides well defined gaps between cushion 84 and skin 87. By providing such gaps, a small continuous gas flow as indicated by arrows 94 will be created within and through cushion 84. As seen in FIG. 8, that gas flow will flow over skin 87 and out of respiratory mask 82

through the gaps. The gas flow just described will be in direct contact with skin 87 and as a result will effectively cool skin 87, remove moisture from skin 87, and flush CO₂ from inner chamber 91. In the exemplary embodiment, the flow of gas represented by arrows 94 is more than a negligible flow and is a predetermined percentage of an intentional (designed in) leak flow of respiratory mask 82 when the patient is not inhaling during use of respiratory mask 82, wherein the predetermined percentage is not more than a certain maximum percentage value. In one particular embodiment, the flow of gas represented by arrows 94 when the patient is not inhaling, while more than a negligible flow, is at most 10% of the intentional (designed in) leak flow (i.e., the certain maximum percentage value is 10%). In one exemplary implementation, the flow represented by arrows 94 when the patient is not inhaling is greater than or equal to 0.1% of the intentional (designed in) leak flow and less than or equal to 10% of the intentional (designed in) leak flow, while in another exemplary implementation the flow represented by arrows 94 when the patient is not inhaling is greater than or equal to 1% of the intentional (designed in) leak flow and less than or equal to 10% of the intentional (designed in) leak flow. Also, in the exemplary embodiment, at least 85% of any CO₂ present in the interior of the mask 82 (from the last exhalation) will be flushed out of the mask by the flow of gas). Respiratory mask 82 will leak, but the leakage is small and the required patient pressure will still be achieved.

In addition, the flow of gas represented by arrows 94 flows over at least one part of a user's face, the at least one part being chosen from the group of parts comprising: the nose bridge, the upper lip, the lower lip, the chin and/or the cheeks. In one particular embodiment, the parts include the nose bridge, the upper lip and the cheeks. In another particular embodiment, the parts include the nose bridge, the upper lip, the lower lip, and the cheeks. In still another particular embodiment, the parts include all of the nose bridge, the upper lip, the lower lip, the chin and the cheeks.

As noted elsewhere herein, in the exemplary embodiment, respiratory mask 82 is a nasal/oral mask structured to cover the nose and mouth of the patient. Furthermore, in the exemplary embodiment, the length of the flow path within respiratory mask 82 along which the flow of gas represented by arrows 94 flows in order to the reach the user's face will be at least a certain minimum value, wherein that flow path is defined as the shortest pathway measured from the axis of the inflow port of shell member 16 to which elbow connector 22 is attached and alongside shell member 16 and cushion 90 to the face of the user (which engages the inner edge of contacting portion 92). In the exemplary embodiment, the length of the flow path will be at least 4 cm 4-6 cm in one particular embodiment). The

value for the flow path just described would also apply to a full/total face mask type patient interface device. In addition, if respiratory mask 82 was adapted to be a nasal mask structured to cover the nose of the patient, the length of the flow path in the exemplary embodiment will be 1.5-3 cm (2 cm in one particular embodiment).

5 FIG. 9A is a schematic representation of contacting portion 92A according to one exemplary embodiment. As seen in FIG. 9A, contacting portion 92A comprises an engineered surface having a plurality of dome/pillar (smooth) shaped surface features, each labeled with reference numeral 95, which provide a plurality of gaps, each labeled with reference numeral 96. Each gap 96 is defined by a height H and width W. As used herein, 10 the term "height" shall mean the vertical distance between the highest point of the tallest surface feature 95 immediately adjacent the gap 96 and the lowest surface of contacting portion 92 on which the surface features 95 sits, and the term "width" (also commonly called "pitch") shall mean the largest of the distances between highest points of adjacent surface features 95 which define the gap. As seen in FIG. 9A, the gaps 96 have equal heights H and 15 widths W (as used herein, when comparing height and width values of gaps within a textured surface, "equal" shall mean the values are all within a 10% or less manufacturing tolerance of one another). FIGS 9B-9D are schematic representations of contacting portions 92B-92D according to alternative exemplary embodiments. As seen in FIG. 9B-9D, contacting portion 92B comprises an engineered surface where the surface features 95 have a rectangular cross-section, and contacting portions 92C and 92D comprise engineered surfaces with different, 20 alternative dome/pillar shaped surface features 95.

25 The capacity of gas flow 94 to cool skin 87 depends on the flow rate, the heat exchange efficiency, and the temperature and humidity of the gas (which, as described elsewhere herein, is in the exemplary embodiment generated from the air in the environment surrounding system 80). The flow rate in the gaps (e.g., gaps 96 in FIGS. 9A-9D) between skin 87 and cushion 84 is governed by the system pressure (e.g., CPAP pressure) and the flow resistance. The system pressure is set by the physician and cannot be changed. Thus, the only factor that may be easily controlled is the flow resistance. In the embodiment of FIG. 8, the flow resistance can be controlled by controlling the effective gap height H and/or 30 the effective gap width W (i.e., pitch within the gap). It should be noted that the effective height of the gaps is a combination of the surface roughness of skin 87 and the roughness or texture of cushion 84. If the effective gap is too small, not enough gas (e.g., air) will flow through the gap and skin 87 will not be cooled enough. If the gaps are too large, too much gas will flow, skin 87 will become too cold and the flow will make noise that can be a

nuisance for the patient. Furthermore, the heat exchange efficiency will be lower with larger gaps as only a small part of the flow will interact with skin 87.

Through testing and modeling, the present inventors have determined that, in one embodiment, effective cooling can be provided by providing a textured surface on contacting portion 92 wherein the height of the gaps formed therein are 100 microns to 1000 microns, and, in another alternative embodiment, 100 microns to 200 microns, and wherein the width/pitch of the gaps are, in one embodiment, 10 microns to 1000 microns, and in another embodiment 100 microns to 1000 microns. The present inventors have also determined that, in one particular embodiment, optimal cooling efficiency can be provided by providing a textured surface on contacting portion 92 wherein the height of the gaps formed therein are 100 microns to 150 microns. In one specific implementation, the embodiments just described may be implemented in an engineered surface wherein the heights H of the gaps are equal and are greater than 100 microns and less than or equal to 1000 microns, greater than 100 microns and less than or equal to 200 microns, or greater than 100 microns and less than or equal to 150 microns. In another specific implementation, the embodiments just described may also be implemented in a random textured surface wherein the heights H of the gaps, while not equal, are greater than 100 microns and less than or equal to 1000 microns, greater 100 microns and less than or equal to 200 microns, or greater than 100 microns and less than or equal to 150 microns.

In one particular embodiment, the gaps described herein are provided such that a controlled flow of air is created in the order of 3 g/s per cm or more in the direction of the seal that cools the skin.

Moreover, as noted above, the “effective height” of the gaps is a combination of the surface roughness of skin 87 and the roughness or texture of cushion 84. Thus, in one particular embodiment, a cushion may be custom designed for a patient wherein the surface roughness of skin 87 of the patient is taken into account. More specifically, an engineered surface may be designed for a cushion 84 wherein the heights H of the gaps are chosen such that the “effective gap height” of each gap when worn by the patient will be greater than 100 microns and less than or equal to 200 microns or, alternatively, greater than 100 microns and less than or equal to 150 microns.

In addition, as is known, with many pressure generating systems 6, the patient is able to control the humidity of the flow of gas that is generated thereby. It should be noted that the higher the humidity of the generated gas flow, the less effective the cooling will be.

FIG. 10 is a schematic diagram in partial cross-section of a system 100 adapted to provide a regimen of respiratory therapy to a patient according to another alternative exemplary embodiment. System 100 includes many of the same components as systems 2 and 80 described elsewhere herein, and like components are labeled with like reference numerals. In system 100, alternative respiratory mask 102 includes a liner 104 (made of the same or a similar materials as cushion 12) that is attached (e.g., by any suitable method such as using an adhesive or molding) to end portion 36 of cushion 12. As seen in FIG. 10, liner 104 includes a contacting portion 92 having a textured surface as described elsewhere herein in connection with FIGS. 8-9D. As a result, alternative respiratory mask 102 is able to provide the same or similar continuous flow and the same or similar cooling effect as described in connection with respiratory mask 82 (see arrows 94). Shell member 16, cushion 12 and liner 104, or cushion 12 and liner 104 alone, may be referred to as a flow delivery assembly/element.

FIG. 11 is a schematic diagram in partial cross-section of a system 110 adapted to provide a regimen of respiratory therapy to a patient according to still another alternative exemplary embodiment. System 110 includes many of the same components as systems 2, 80 and 100 described elsewhere herein, and like components are labeled with like reference numerals. In system 110, alternative respiratory mask 112 includes a spacer/liner 114 that is attached (e.g., by any suitable method such as using an adhesive or molding) to first end portion 36 of cushion 12. Alternatively, spacer/liner 114 may simply rest between cushion 12 and skin 87 without being attached to cushion 12, in which case it will be held in place by the strapping forces of respiratory mask 112. In this embodiment, spacer/liner 114 is made of a porous material that allows a certain degree of fluid flow therethrough, as indicated by arrows 116 in FIG. 11. Liner 114 may be made of, for example and without limitation, a textile material, foam, a sponge material, fur, moleskin, high pile carpet materials. As used herein, the term "textile" shall mean a material consisting of a network of interlaced natural or artificial fibers made by, for example and without limitation, weaving, knitting, spreading, crocheting, or bonding the fibers to form the network. As a result, alternative respiratory mask 112 is able to provide a continuous gas flow and a cooling effect that is similar to that described in connection with respiratory masks 82 and 102 elsewhere herein (see arrows 116 in FIG. 11). In effect, spacer/liner 114 provides a gap for allowing fluid flow in between cushion 12 and skin 87. In one particular embodiment, the gap spacer/liner 114 is structured such that a controlled flow of air is created in the order of 3 g/s per cm or more in the direction of the seal that cools the skin. Shell member 16, cushion 12

and liner 114, or cushion 12 and liner 114 alone, may be referred to as a flow delivery assembly/element.

As noted elsewhere herein, the capacity of a gas flow through cushion 12 to cool skin 87 depends on the flow rate, the heat exchange efficiency, and the temperature and 5 humidity of the gas (which, as described elsewhere herein, is in the exemplary embodiment generated from the air in the environment surrounding system 110). The flow rate through spacer/liner 114 is governed by the system pressure (e.g., CPAP pressure) and the flow resistance. The system pressure is set by the physician and cannot be changed. Thus, the only factor that may be easily controlled is the flow resistance. In the embodiment of FIG. 10 11, according to one exemplary implementation, the flow resistance can be controlled/determined by the porosity of the material used to construct spacer/liner 114. As is well known in the art, porosity is a measure of the void (i.e., "empty") spaces in a material, and is a fraction/ratio of the volume of voids ("void volume") in the material over the total/bulk volume of the material, between 0–1, or as a percentage between 0–100%. In an 15 exemplary embodiment, weight per cubic meter is calculated by dividing weight per square meter by thickness. The specific weight of a material fabric gives the occupied volume of the solid fabric and this is recalculated to the ratio of void volume (without fabrics) to the total bulk volume. In one particular exemplary, non-limiting embodiment, the present inventors have found that effective cooling can be provided by constructing spacer/liner 114 of a 20 material having a porosity of 80% - 94%. In another particular exemplary embodiment, the porosity is 80% - 90%, with one particular implementation being 88%.

However, it should be noted that care should be taken when specifying/choosing a material based on porosity. Fabrics with the same porosity can have different flow resistance. For example, one thousand thin threads can weigh as much as two 25 big threads, but the flow resistance in the one thousand channels between the thin threads is much higher than the only channel between the two threads. Furthermore, hollow fibers have a very high porosity but can have a much smaller flow restriction. Thus, as described below, according to various other exemplary embodiments, the material for constructing spacer/liner 114 may be specified/chosen based on characteristics of the material relating to flow through 30 the material.

As is known in the art, respiratory masks have a certain level of designed in intentional leak. In one particular exemplary embodiment, the present inventors have found that effective cooling can be provided by constructing spacer/liner 114 of a material having a certain leakage flow through the fabric expressed as a % of the intentional leak flow of the

associated mask. In one exemplary implementation, the leakage flow through the fabric is 0-50 % of the intentional leak flow, in another exemplary implementation, the leakage flow through the fabric is 0-10% of the intentional leak flow, and in another exemplary implementation, the leakage flow through the fabric 0-5 % of the intentional leak flow. Thus, 5 for an exemplary embodiment at 10 cmH₂O having an intentional leak rate of 28 SLPM (standard liter per minute), the fabric may have a leakage flow of 1.4 SLPM (5%).

In another particular exemplary embodiment, the fabric of the spacer/liner 114 may be specified based simply on a value for the flow through the fabric at a certain pressure. In one embodiment, that flow at 10 cmH₂O is 0-50 SLPM (or 5-50 SLPM), and in another 10 embodiment, that flow at 10 cmH₂O is 0-5 SLPM.

In still another particular exemplary embodiment, the fabric of the spacer/liner 114 may be specified based on the permeability of the fabric to air (with pressures ranging from 500 Pa to 2000 Pa). In one exemplary embodiment, permeability is 0-15000 l/(m² s), in another exemplary embodiment, permeability is 0-1500 l/(m² s), and in still another 15 exemplary embodiment, permeability is 0-750 l/(m² s). Thus, in one exemplary implementation, a mask configuration having an air permeability of 750 will yield a flow of around 4.5 liters/min through the fabric. In one particular, non-limiting embodiment, spacer/liner 114 is made from polyester fabric and contains small flexible fibers, like pillars, which will bend under any shear stress of respiratory mask 112. Skin 87 will have minimal 20 shear stress which will lead to reduce red marks, skin irritation and even pressure ulcers for the patient.

In addition, in the exemplary embodiment, the thickness of spacer/liner 114 will be optimized to provide the most effective cooling. If spacer/liner 114 is too thick, e.g. 25 10 mm or more, and open, it will leak too much and even the required system (e.g., CPAP) pressure cannot be obtained. A thicker material will also have the disadvantage that a large part of the gas flow will not interact with skin 87. The heat exchange is also not efficient in this case. If spacer/liner 114 is too thin, not enough gas will flow and skin 87 will be not cooled. Furthermore, the stiffness of spacer/liner 114 is important since respiratory mask 112 is pressed onto the patient's face. If spacer/liner 114 is too soft, it will be pressed together 30 and the effective gap becomes too small. The present inventors have found that a certain pressure applied to the skin by a mask will give red marks on the skin. In particular, the present inventors have found that the majority of people will get red marks from a mask with a pressure of 90 g. per square cm (9 kPa) or more. Thus, in one embodiment, to avoid red mark formation, the stiffness of spacer/liner 114 is selected so that it will result in a gap of at

least 0.1 mm and a porosity in the range of 80-90 % when a pressure is applied with a value of 10 kPa or lower.

In addition, through testing, the present inventors have determined that, in one exemplary embodiment, effective cooling will be provided by a spacer/liner 114 having a 5 thickness between 0.1 mm and 8 mm, and in another, more particular embodiment, between 0.5 mm and 3 mm.

Furthermore, it is important to note that, in the embodiment of FIG. 11, the roughness of skin 87 has little influence on the degree of flow, and thus does not affect 10 cooling greatly. As a result, the embodiment of FIG. 11 may be employed to provide effective cooling with a wide variety of patients with varying degrees of skin roughness.

As noted elsewhere herein, in the exemplary embodiment, respiratory mask 112 is a nasal/oral mask structured to cover the nose and mouth of the patient. Furthermore, in the exemplary embodiment, the length of the flow path within respiratory mask 112 along 15 which the flow of gas represented by arrows 94 flows in order to the reach the user's face will be at least a certain minimum value, wherein that flow path is defined as the shortest pathway measured from the axis of the inflow port of shell member 16 to which elbow connector 22 is attached and alongside shell member 16 and cushion 12 to the face of the user (which engages the inner edge of spacer/liner 114). In the exemplary embodiment, the length of the flow path will be at least 4 cm (4-6 cm in one particular embodiment). The 20 value for the flow path just described would also apply to a full/total face mask type patient interface device. In addition, if respiratory mask 82 was adapted to be a nasal mask structured to cover the nose of the patient, the length of the flow path in the exemplary embodiment will be 1.5-3 cm (2 cm in one particular embodiment).

In one variation of the embodiments of FIGS. 8-11, shell member 16 may be 25 omitted, and elbow connector 22 may instead be attached directly to the orifice defined at the end portion 38, 88 of the cushion for receiving gas flow into the cushion.

FIG. 12 is a front elevational view of spacer/liner 114 according to one non-limiting embodiment. Eyes are very sensitive to any air flow and people will tend to wake up if they feel a small air flow in their eyes. Therefore, in the exemplary embodiment of FIG. 30 12, air flow is controlled to make sure that only the most sensitive areas of the patient are cooled and that there is minimal to no flow into the eyes of the patient. Spacer/liner 114 in this embodiment includes a porous portion 116 (made of a porous material as described elsewhere herein) and a non-porous sealing portion 118. Sealing portion 118 is made of a material such as, without limitation, silicone, liquid silicone rubber, other skin compatible

resins, low porous foam, or densely woven fabrics. As seen in FIG. 12, sealing portion 118 extends from the middle of the first side 120 of spacer/liner 114, over the apex 122 of spacer/liner 114 and to the second side 124 of spacer/liner 114. Sealing portion 118 also extends over the full depth of spacer/liner 114. As a result, the sides of spacer/liner 114 near 5 the eyes of the patient are sealed by sealing portion 118, which sealing will minimize gas flow out in the direction of the eyes of the patient. Instead, spacer/liner 114 has a flow pattern structured to guide the flow alongside to nose to the bottom side of respiratory mask 112 such that the main part of the flow through spacer/liner 114 will exit spacer/liner 114 at 10 the chin or mouth side of respiratory mask 112, depending on whether respiratory mask 112 is a nasal mask or a nasal/oral mask.

Alternatively, the part of spacer/liner 114 that is shown as being covered by sealing portion 118 (in the neighborhood of the eyes and on the nose bridge) may instead be closed by another mechanism. For example, that area of spacer/liner 114 may be filled up with a resin, rubber, or low porosity foam, or may be made of a highly densely woven fabric. 15 The air flow in the enclosed area will be smaller than in the non enclosed area as it has to flow a longer way than in other non enclosed area of the patch. The textile can be woven that there is a lower flow resistance in the enclosed area than in the non enclosed area. The fabric will have a lower density in the enclosed area than in the non enclosed area or it will have a higher gap height. Therefore, the amount of air flow in the enclosed area is the same as in the 20 non enclosed area.

In addition, in the exemplary embodiment, the flow rate is different in different parts of spacer/liner 114 to optimize the comfort. This is accomplished by controlled the density or openness of the material of spacer/liner 114. In particular, flow rate is smaller near the bottom side of respiratory mask 112, as indicated by the thicker and 25 thinner arrows. The difference in flow rate will generate areas with a different temperature, such that spacer/liner 114 will have a decreasing temperature gradient extending from top to bottom.

The effects described above in connection with FIG. 12 may also be accomplished in the embodiments that employ the textured surface for contacting the skin 30 (FIGS. 8-10). In these embodiments, flow rate is controlled by controlling the height and/or pitch of the surface feature as described herein. For example, smaller pitch (more features per square mm) and/or smaller height may be used at the top of the surface (over the nose), and larger pitch (less features per square mm) and/or smaller height, or a random roughness with a higher Ra value (higher roughness) may be used at the bottom, of the surface (near the

mouth). As a result, a textured surface may be designed so as to have a decreasing temperature gradient extending from top to bottom.

In the claims, any reference signs placed between parentheses shall not be construed as limiting the claim. The word “comprising” or “including” does not exclude the presence of elements or steps other than those listed in a claim. In a device claim enumerating several means, several of these means may be embodied by one and the same item of hardware. The word “a” or “an” preceding an element does not exclude the presence of a plurality of such elements. In any device claim enumerating several means, several of these means may be embodied by one and the same item of hardware. The mere fact that certain elements are recited in mutually different dependent claims does not indicate that these elements cannot be used in combination.

Although the invention has been described in detail for the purpose of illustration based on what is currently considered to be the most practical and preferred embodiments, it is to be understood that such detail is solely for that purpose and that the invention is not limited to the disclosed embodiments, but, on the contrary, is intended to cover modifications and equivalent arrangements that are within the spirit and scope of the appended claims. For example, it is to be understood that the present invention contemplates that, to the extent possible, one or more features of any embodiment can be combined with one or more features of any other embodiment.

CLAIMS:

1. A user interface element (10, 12, 16, 84, 104, 114) for delivering breathing gas to a user, comprising:

- a first orifice for receiving a first flow of gas, and one or more second orifices for letting a second flow of gas out of the user interface element, wherein the first orifice and the one or more second orifices are positioned relative to each other such that during use of the user interface element the second flow of gas: (i) flows over and cools a skin surface of the user and out of the user interface element through the one or more second orifices, and/or (ii) flushes at least 85% of any CO₂ present in an interior of the user interface element from the user interface element through the one or more second orifices.

2. The user interface element according to claim 1, wherein the second flow of gas is greater than or equal to 0.1% of an intentional leak flow of the user interface element when a user is not inhaling during use of the user interface element and less than or equal to 10% of the intentional leak flow of the user interface element when the user is not inhaling during use of the user interface element.

3. The user interface element according to claim 1, wherein the user interface element includes a shell member (14) structured to receive a cushion, the first orifice and the one or more second orifices being provided in the shell member.

4. The user interface element according to claim 3, wherein the shell member includes one or more flow segments (44), each of the flow segments including a chamber having an inlet (46) located at a first end of the shell member and one or more open orifices (48) spaced from the inlet, each of the one or more open orifices being one of the second orifices, wherein the first end of the shell member is structured to be coupled to the cushion such that an inner chamber of the cushion is in fluid communication with each of the flow segments, and wherein in response to the first flow of gas being received through the first orifice, the user interface element is structured to cause at least a part of the second flow of

gas to flow through each of the flow segments from the inlet of the flow segment to the open orifice of the flow segment.

5. The user interface element according to claim 4, wherein the one or more flow segments (44) are a plurality of flow segments (44), wherein the plurality of flow segments includes first and second flow segments (44A, 44B) located in a first portion of the shell member and structured to control flow over the sides of the user's nose, third and fourth flow segments (44C, 44D) located on opposite sides of a second portion of the shell member and structured to control flow over the cheeks of the user, and a fifth flow segment (44E) located 10 in a third portion of the shell member and structured to control flow over the chin of the user.

6. The user interface element according to claim 4, wherein the one or more flow segments (44) are a plurality of flow segments (44), wherein the shell member includes a central chamber (42) surrounded by the plurality of flow segments, and wherein the user 15 interface element further comprises an inner shell member (16) received within the central chamber, the inner shell member defining a second inner chamber (50) structured to be in fluid communication with the inner chamber of the cushion when the shell member is coupled to the cushion, wherein the second inner chamber is structured to receive the flow of breathing gas and deliver the flow of breathing gas to the inner chamber of the cushion.

20 7. The user interface element according to claim 4, wherein the one or more flow segments (44) are a plurality of flow segments (44), further comprising a plurality of cover members, each of the cover members being structured to be selectively attached to the shell member over a selected one of the open orifices, wherein each of the cover members is made 25 of either a porous material that permits restricted gas flow therethrough or a non-porous material that prevents gas flow therethrough.

8. The user interface element according to claim 4, further comprising an extension member (64) extending from the first end of the shell into the inner chamber of the cushion, the extension member being arranged for defining an entry channel (66) in between 30 a distal end of the extension member and a first end portion of the cushion when the shell member is coupled to the cushion.

9. The user interface element according to claim 4, wherein the shell member is coupled to the cushion, wherein at least one of: (i) the cushion is perforated with a number channels (68) that extend through one or more walls of the cushion, (ii) a layer (70) of material having a thermal conductivity of 50 W /mK or more is provided on an inner surface (72) of the cushion, wherein the layer is structured to provide a substantially uniform temperature along the inner surface, wherein the layer is at least one of: (a) a thin film of material having a thickness of 20 nm – 100 nm, and (b) made from aluminum, Au, Cu, Ag, W, amorphous diamond, graphite, aluminum nitride, boron nitride, or graphene, (iii) a plurality of indentations (74) are provided on an inner surface (72) of the cushion to form a varying surface texture such that the varying surface texture is structured to cause a turbulent gas flow over the inner surface, and (iv) a plurality of heat conductive particles or fibers (76) are provided within a body of the cushion.

10. The user interface element according to claim 1, wherein the user interface element comprises a cushion member (12), and wherein the one or more second orifices are provided in the cushion member.

11. The user interface element according to claim 10, wherein: (i) the cushion member is a cushion (84) having a first cushion end portion structured to engage the user's face and a second cushion end portion opposite the first cushion end portion, wherein the contacting portion is provided as part of the first cushion end portion, or (ii) the cushion member includes a cushion (12) having a first cushion end portion and a second cushion end portion opposite the first cushion end portion and a liner member (104) coupled to the first cushion end portion, wherein the contacting portion is provided as part of the liner member.

25 12. The user interface element according to claim 10, wherein the cushion member comprises:
- a cushion (12) having a first cushion end portion; and
- a spacer/liner member (114) located adjacent to the first cushion end portion,
30 wherein the spacer/liner member is made of a porous material including the one or more second orifices.

13. The user interface element according to claim 12, further comprising a sealing portion (118) coupled to the spacer/liner member, the sealing portion extending from a

middle of a first side (120) of the spacer/liner member, over an apex (122) of the spacer/liner member and to a second side (124) of the spacer/liner member, the sealing portion extending over a full depth of the spacer/liner member, wherein when the user interface element is donned by the user, the sides of the spacer/liner member near the user's eyes are sealed by 5 the sealing portion to minimize gas flow out of the spacer/liner member in the direction of the eyes of the user.

14. The user interface element according to claim 1, wherein the user interface element is a cushion member, wherein the first orifice and the one or more second orifices 10 are provided in the cushion member, wherein the first flow of gas enters the cushion member at the first orifice and the second flow of gas exits the cushion member at the one or more second orifices.

15. The user interface element according to claim 10 or claim 14, wherein the 15 cushion member has a contacting portion arranged to contact the user's skin during use of the user interface element, the contacting portion including a textured surface having a plurality of surface features defining a plurality of gaps each having a height, at least one of the gaps being one of the second orifices, wherein each of the heights is greater than 100 microns.

20 16. The user interface element according to claim 14, wherein (i) the cushion member is a cushion, wherein the first orifice and the one or more second orifices are provided in the cushion, or (ii) the cushion member is a cushion and a spacer/liner member (104, 114) coupled to the cushion, wherein the first orifice is provided in the cushion and the one or more second orifices are provided in the spacer/liner member.

25

17. The user interface element according to claim 1, wherein the user interface element is a shell member (14) structured to be coupled to a cushion, the first orifice and the one or more second orifices being provided in the shell member, wherein the first flow of gas enters the shell member at the first orifice and the second flow of gas exits the shell member 30 at the one or more second orifices.

18. A user interface device (2, 2', 2'', 80, 100) employing a user interface element according to any of the preceding claims.

19. A method of making a user interface device (80, 100) for a user, the user interface device having a cushion member (12, 84, 104) having a contacting portion structured to engage a portion of the user's face when the user interface device is donned by the user, the cushion member defining a chamber (41, 91), the contacting portion including a 5 textured surface having a plurality of surface features defining plurality of gaps each having a height, the method comprising:

- evaluating a surface roughness of the user's skin; and
- choosing the actual height of each of the gaps based on the evaluated surface roughness such that the effective height of each of the gaps responsive to the user interface 10 device being donned by the user is greater than 100 microns.

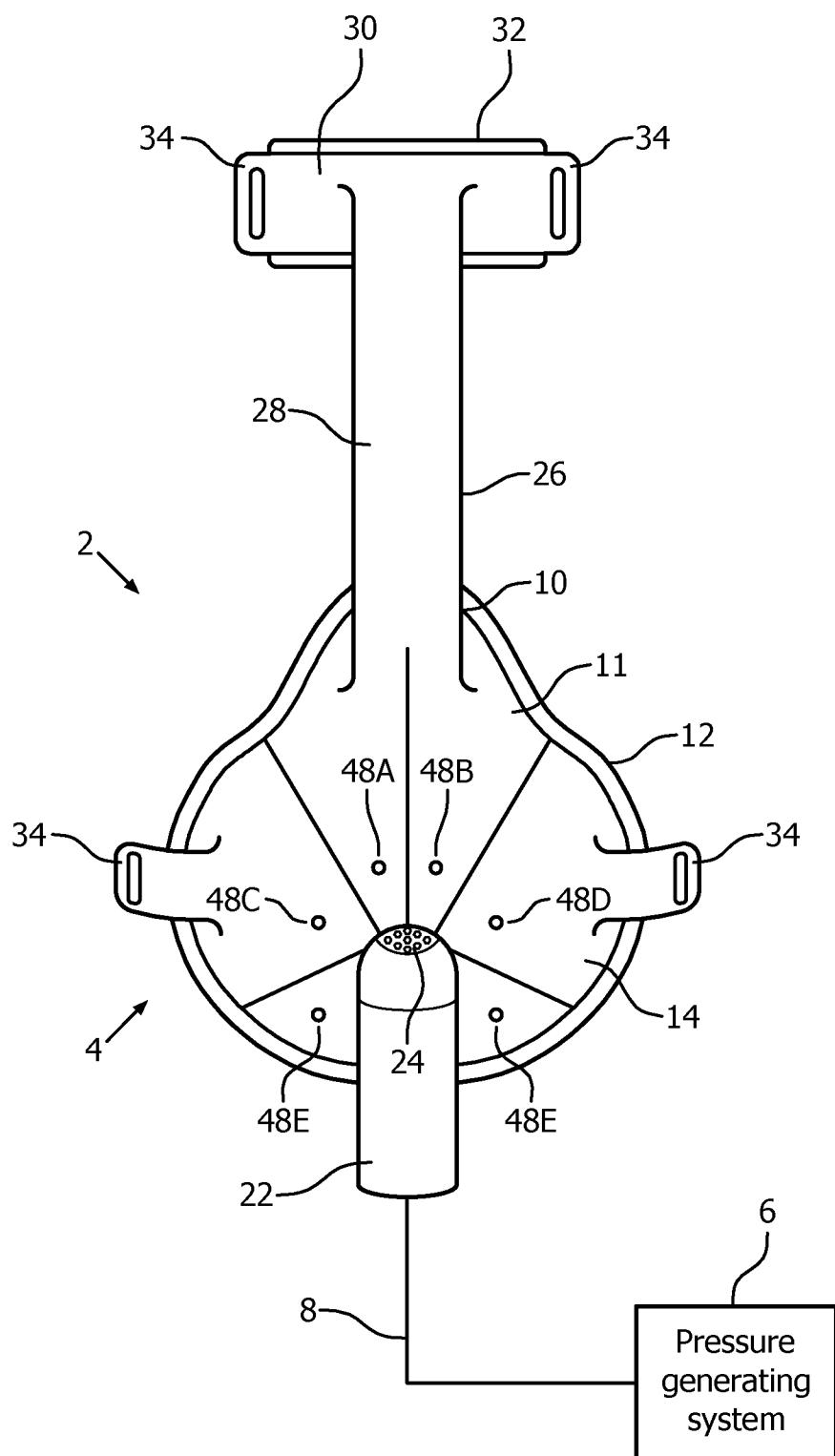


FIG. 1

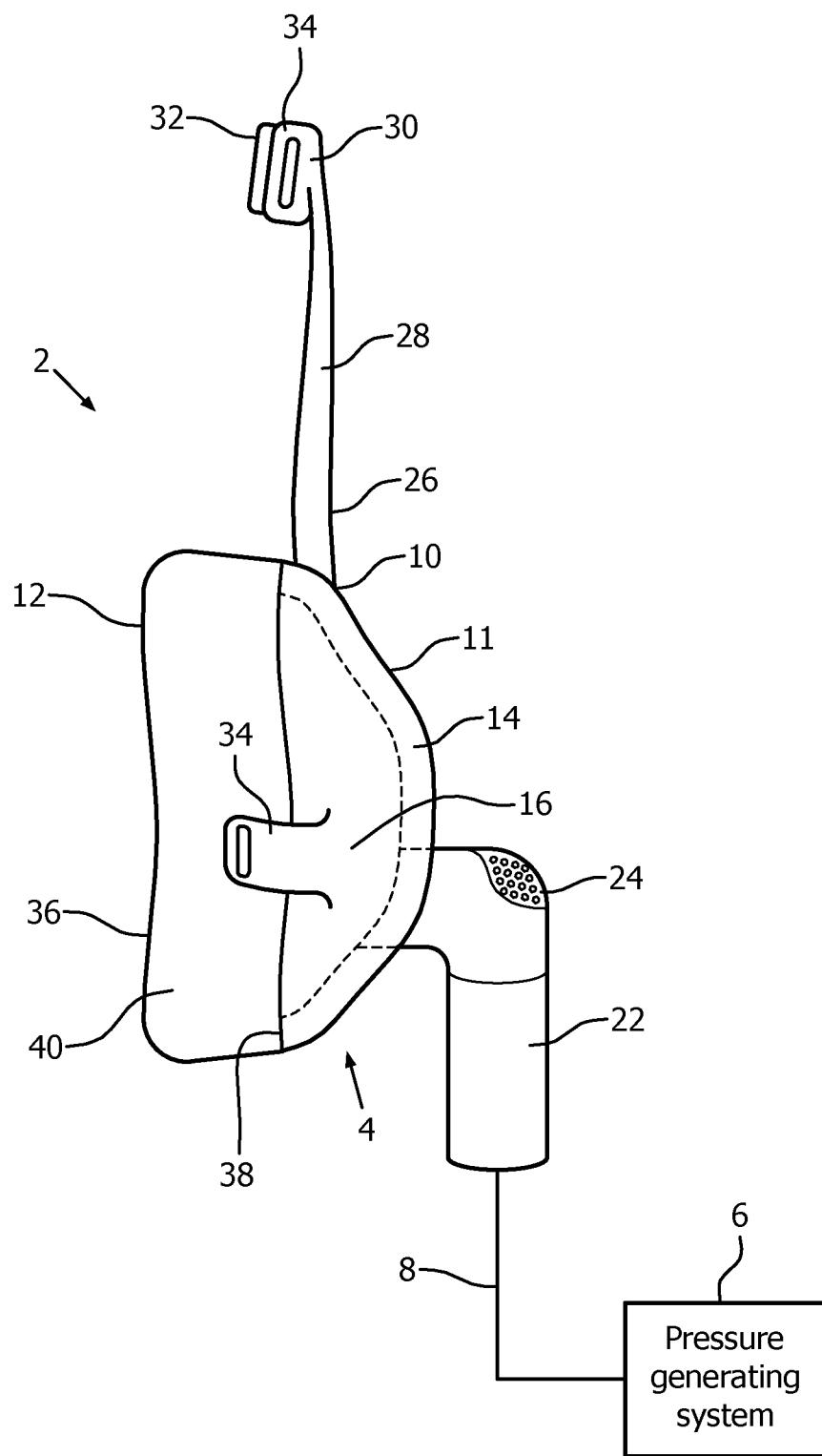


FIG. 2

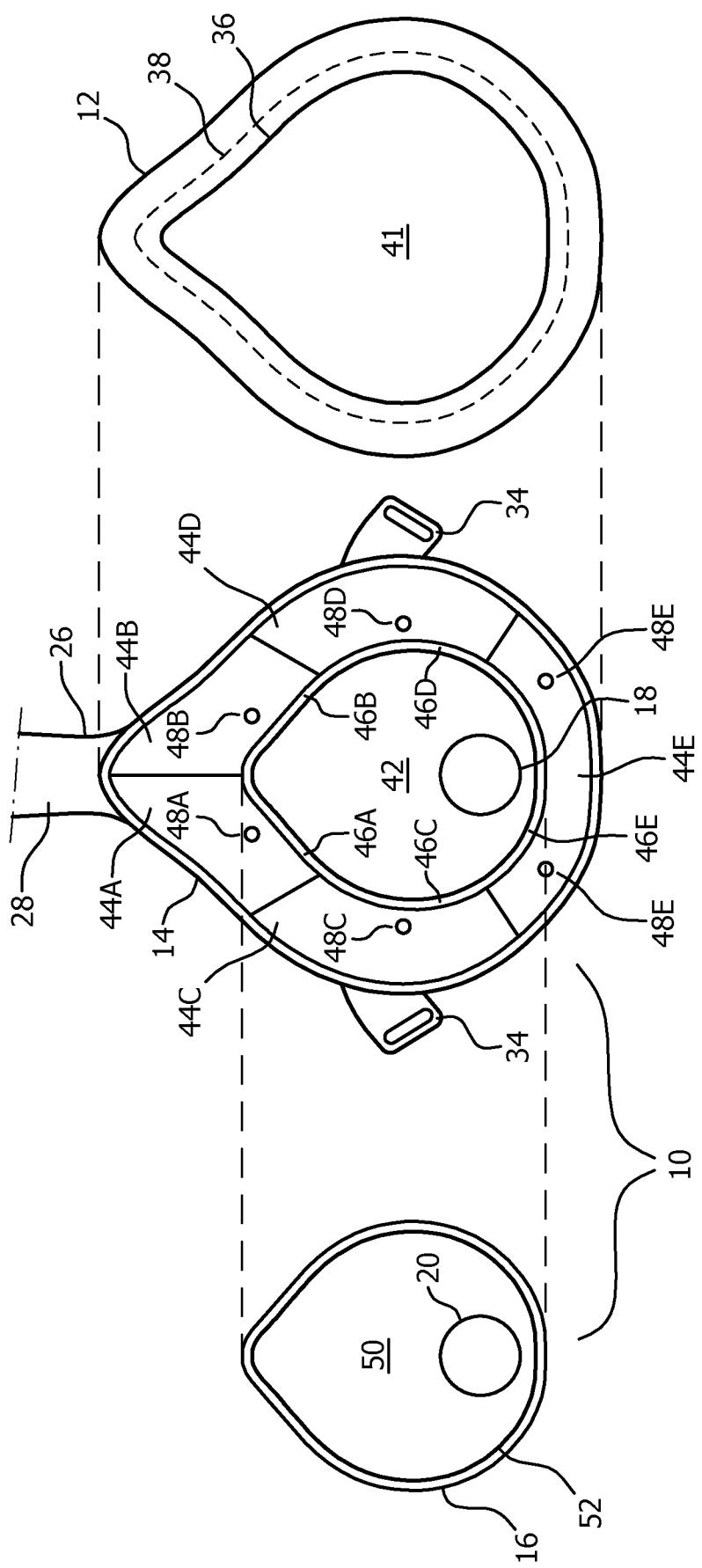


FIG. 3

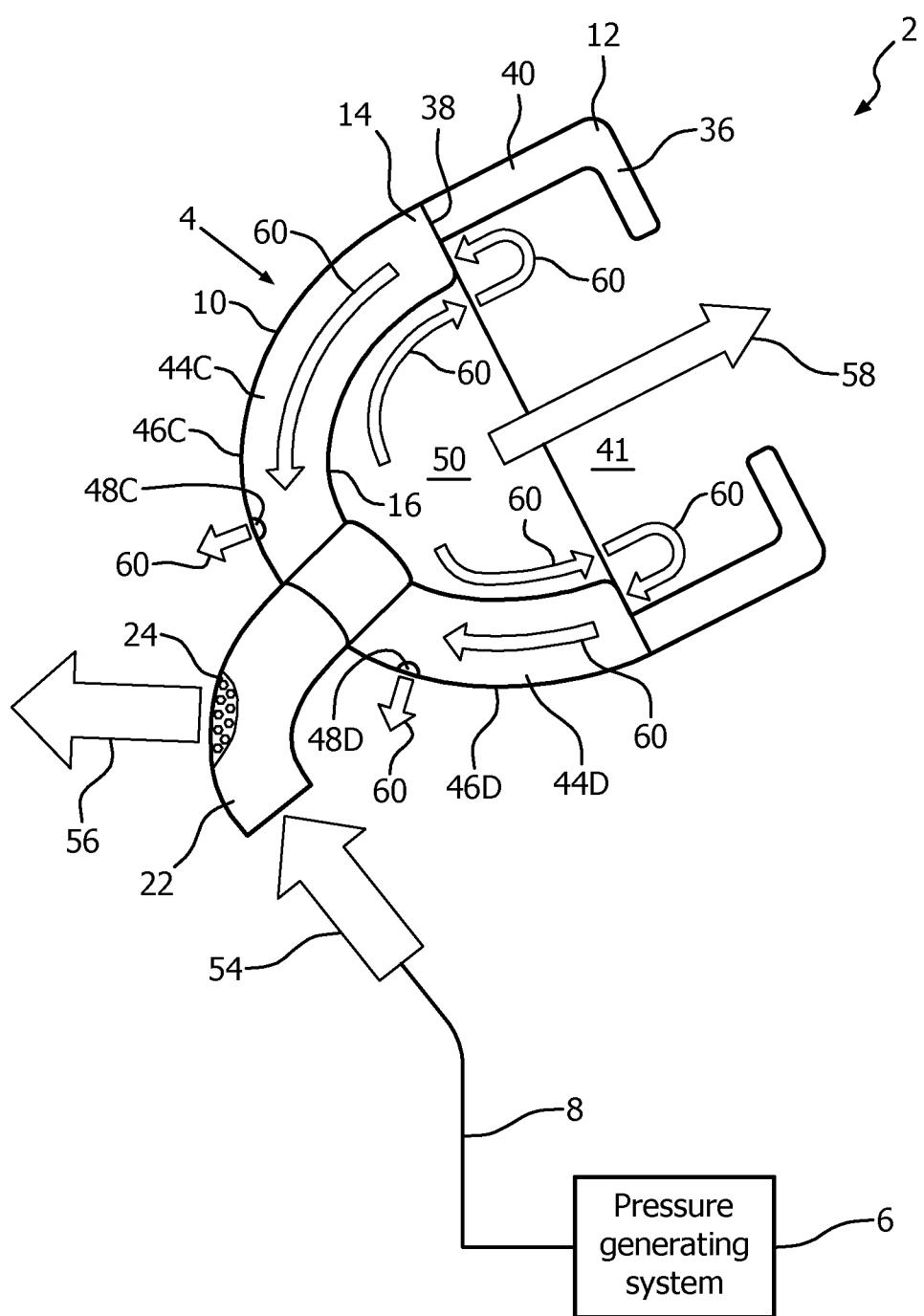


FIG. 4

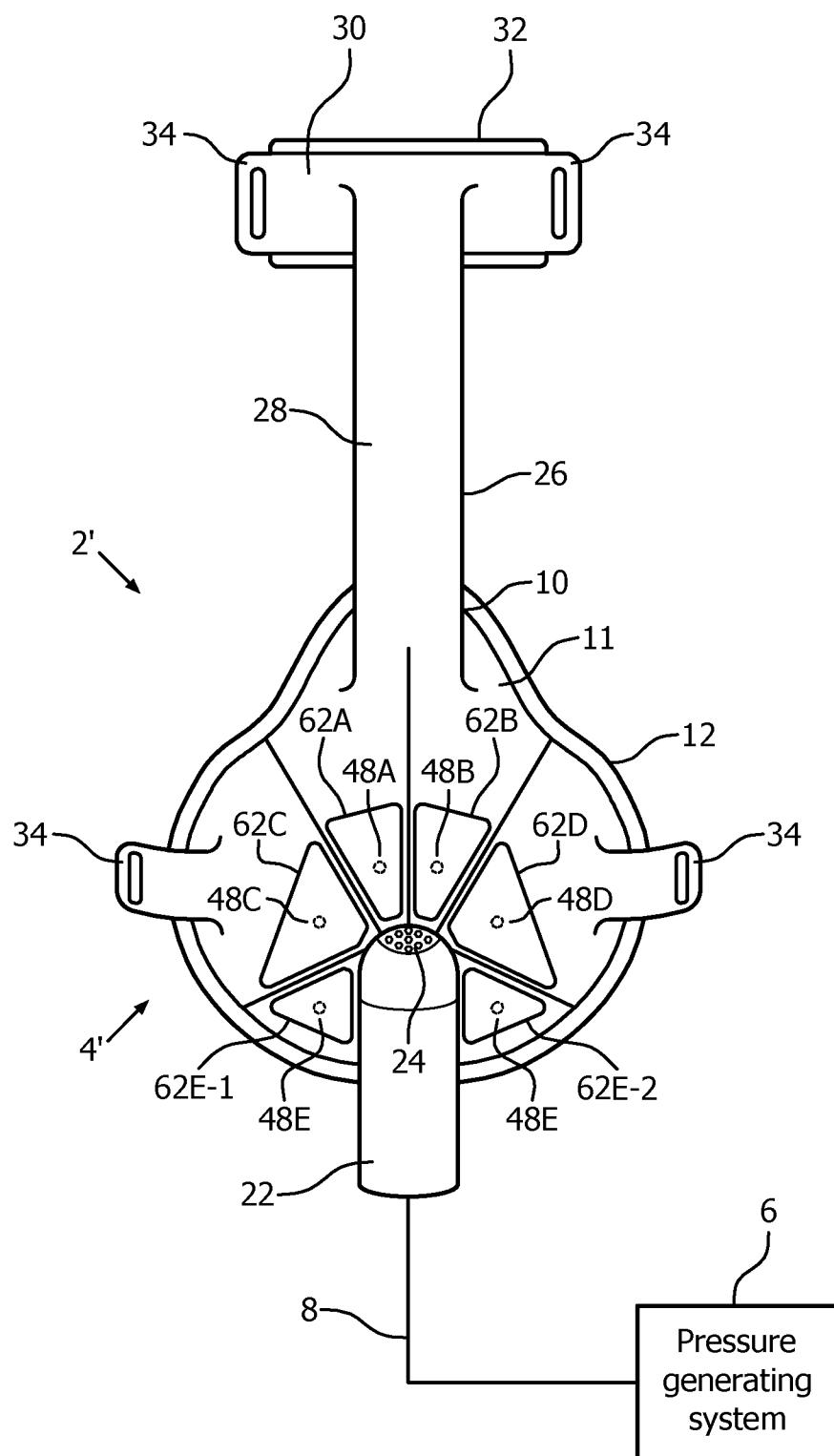


FIG. 5

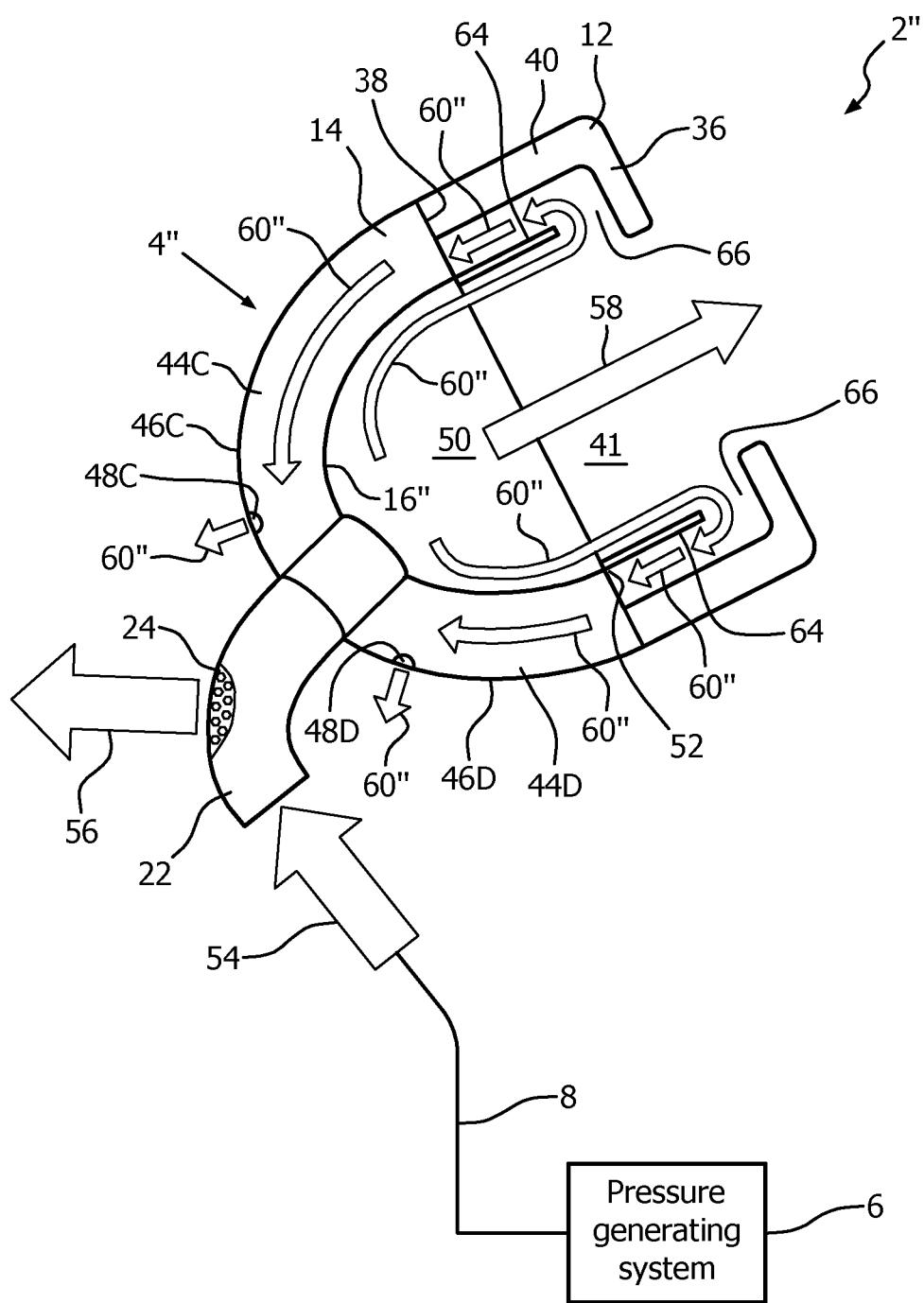


FIG. 6

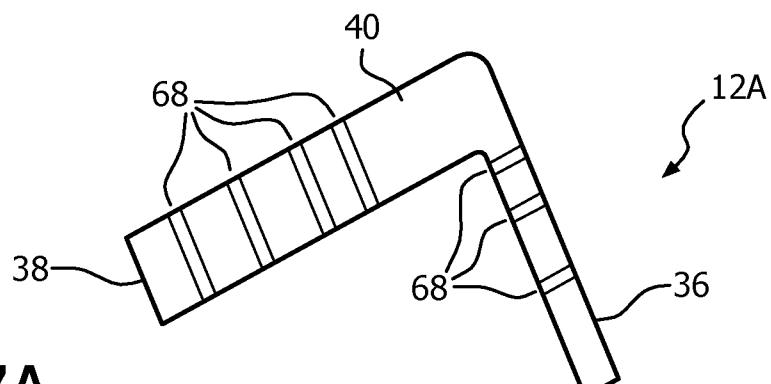


FIG. 7A

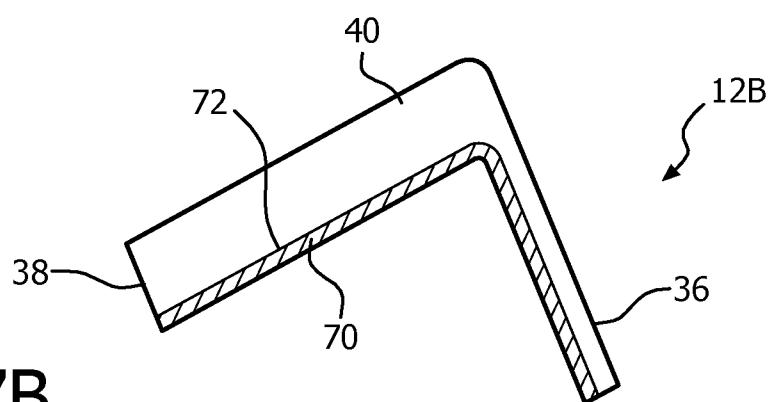


FIG. 7B

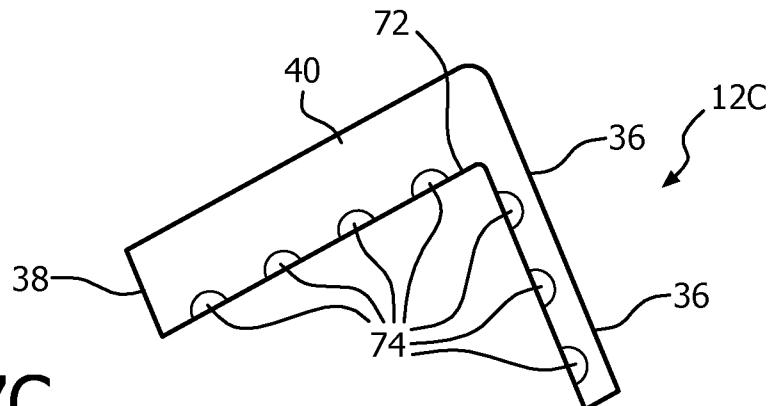


FIG. 7C

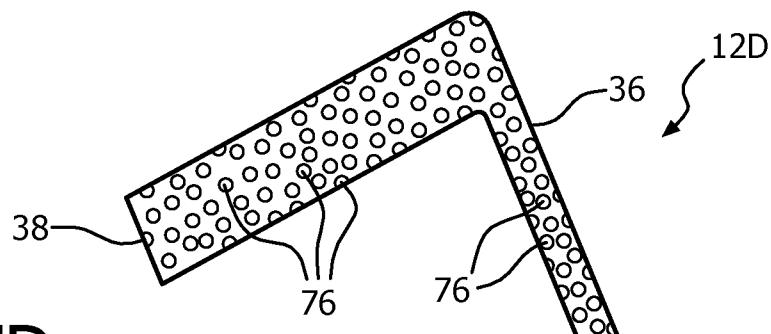


FIG. 7D

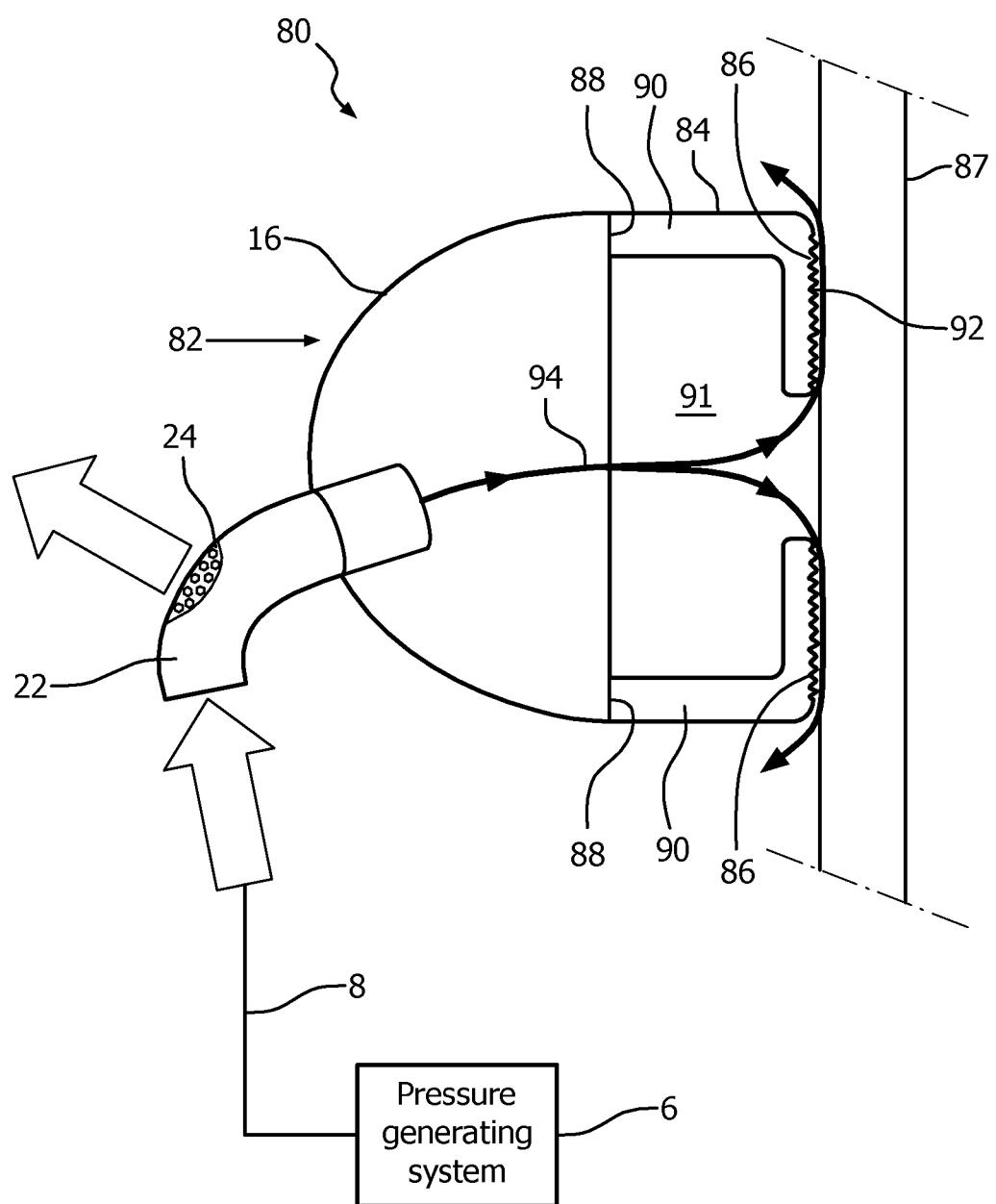


FIG. 8

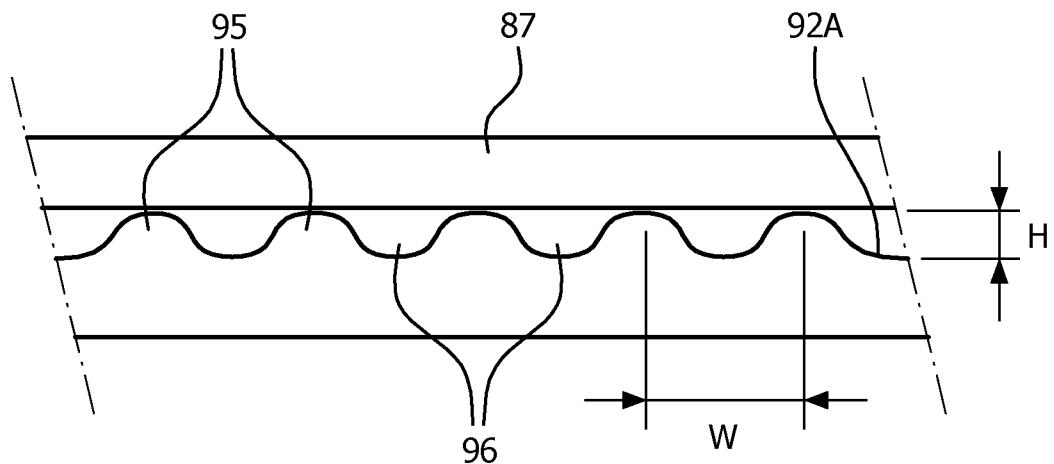


FIG. 9A

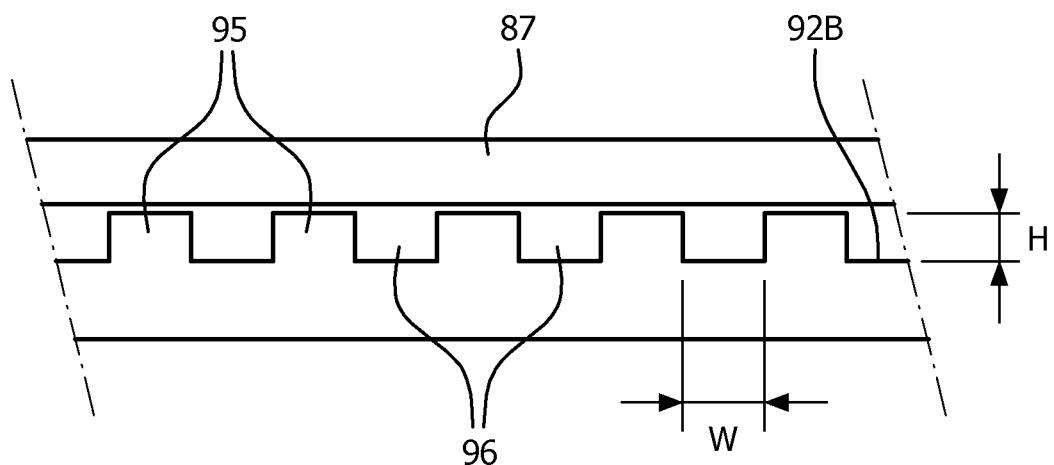


FIG. 9B

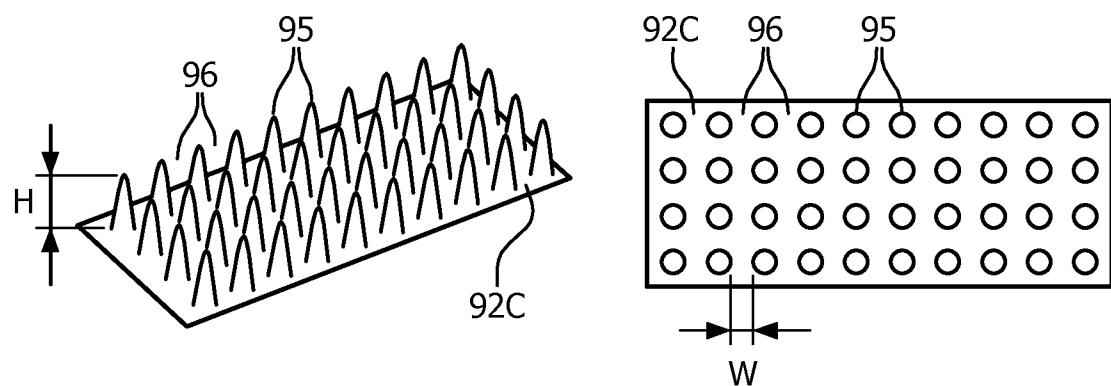


FIG. 9C

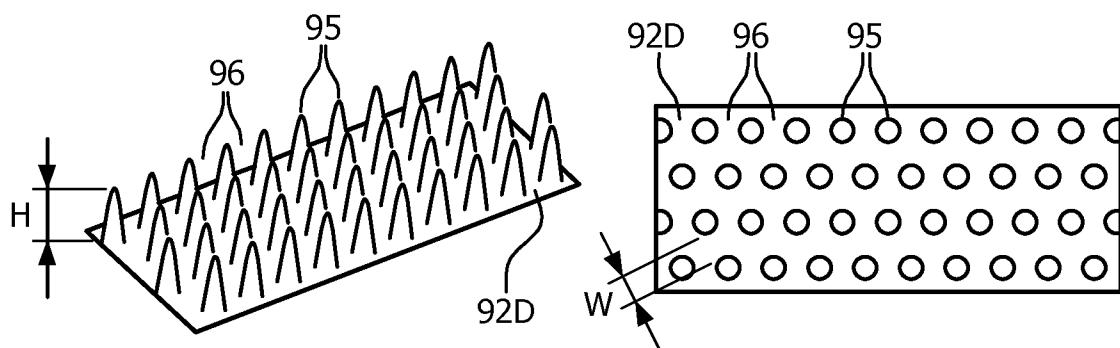


FIG. 9D

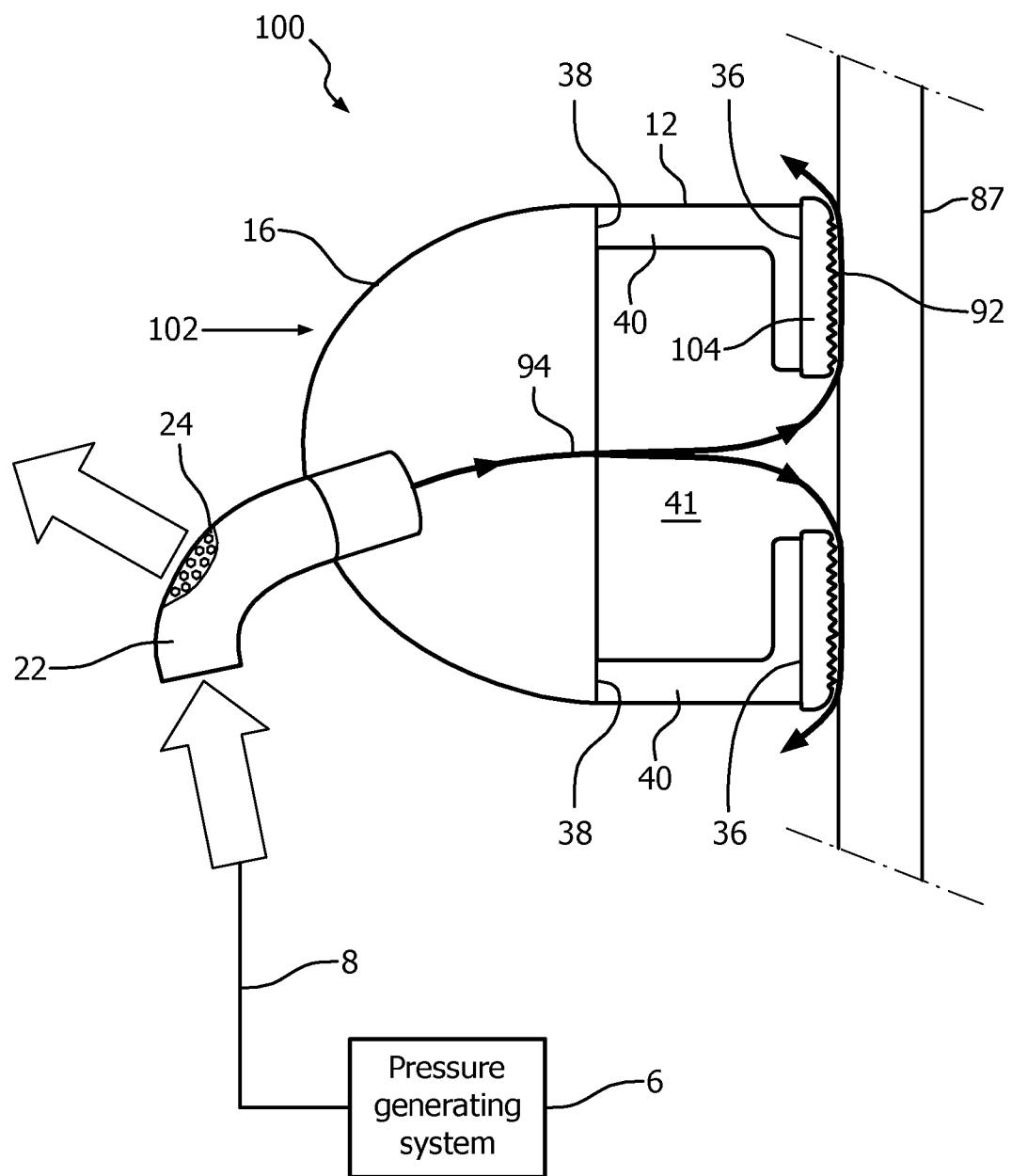


FIG. 10

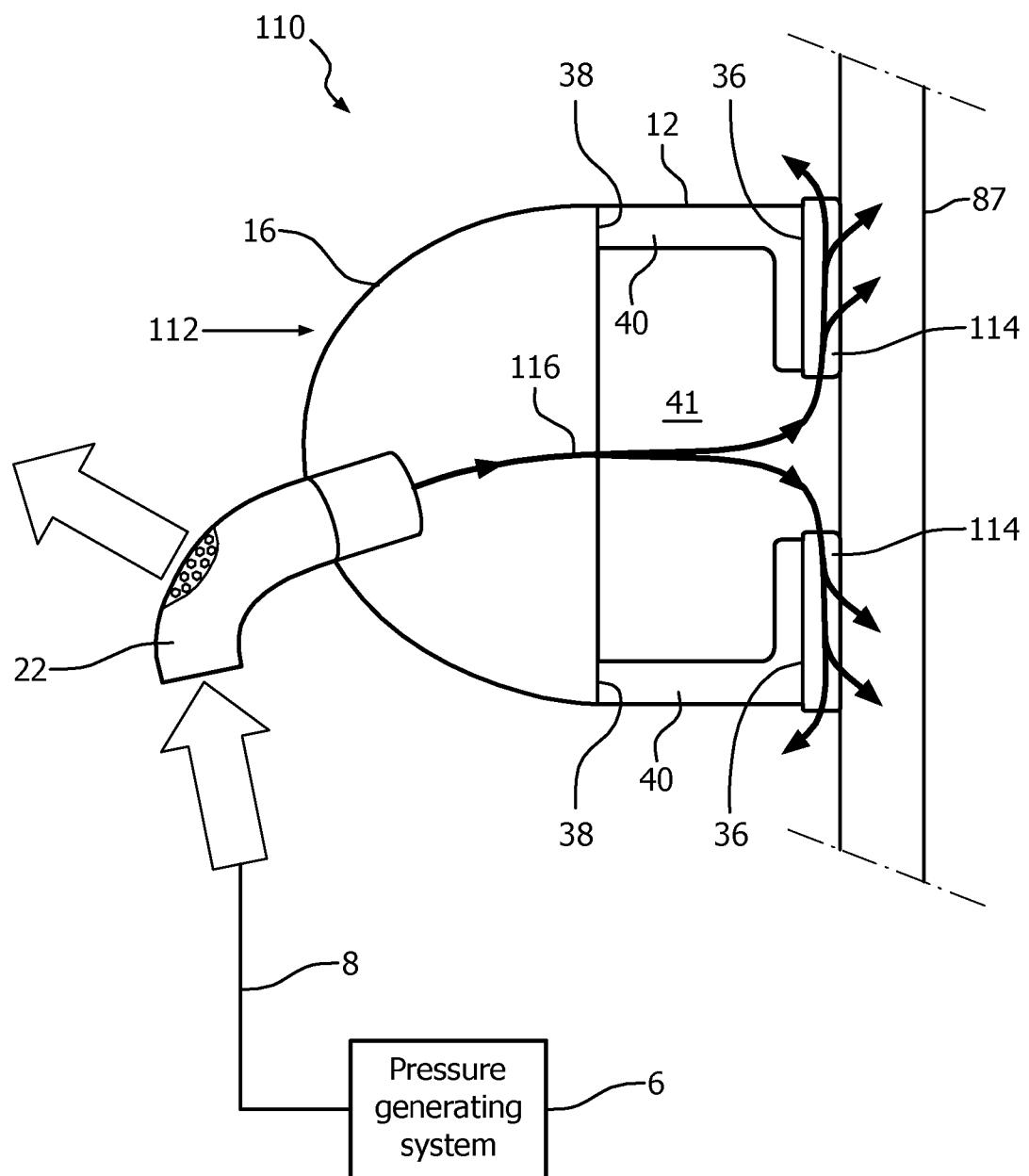


FIG. 11

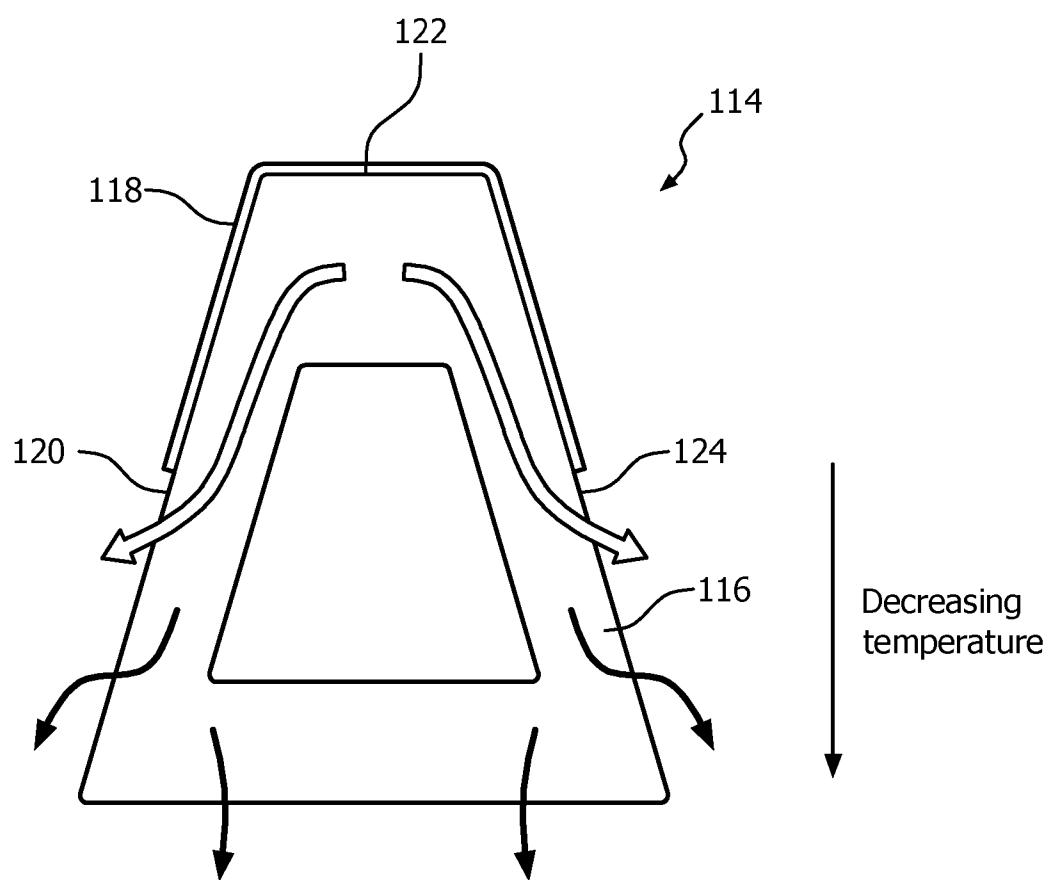


FIG. 12

INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2013/051858

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M16/06
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61M

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009/223519 A1 (EIFLER MARTIN [DE] ET AL) 10 September 2009 (2009-09-10) the whole document -----	1-3,17, 18
X	WO 2011/003130 A1 (COMPUMEDICS MEDICAL INNOVATION PTY LTD [AU]; ZIV HEDI [AU]; MCCOOEY CO) 13 January 2011 (2011-01-13) the whole document -----	1-9,17, 18
X	WO 2005/004963 A2 (MAP MEDIZIN TECHNOLOGIE GMBH [DE]; MADAUS STEFAN [DE]; STAUFFENBERG CA) 20 January 2005 (2005-01-20) the whole document ----- -/-	1-4,8, 17,18

Further documents are listed in the continuation of Box C.

See patent family annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

22 July 2013

31/07/2013

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Azaïzia, Mourad

INTERNATIONAL SEARCH REPORT

International application No PCT/IB2013/051858

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 2 281 595 A1 (MAP MEDIZIN TECHNOLOGIE GMBH [DE] RESMED R & D GERMANY GMBH [DE]) 9 February 2011 (2011-02-09) the whole document -----	1,2,10, 11, 14-16,18
X	WO 2008/011682 A1 (RESMED LTD [AU]; KWOK PHILIP RODNEY [AU]; VELISS LEE JAMES [AU]; GUNNI) 31 January 2008 (2008-01-31) the whole document -----	1,2, 10-14, 16,18

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2013/051858

Patent document cited in search report	Publication date	Patent family member(s)			Publication date
US 2009223519	A1	10-09-2009	AT 341360 T		15-10-2006
			DE 10348532 A1		19-05-2005
			EP 1524003 A1		20-04-2005
			US 2005076912 A1		14-04-2005
			US 2006169286 A1		03-08-2006
			US 2009223519 A1		10-09-2009
<hr/>					
WO 2011003130	A1	13-01-2011	AU 2010269112 A1		09-02-2012
			CA 2770107 A1		13-01-2011
			CN 102470229 A		23-05-2012
			EP 2451518 A1		16-05-2012
			JP 2012531977 A		13-12-2012
			KR 20120111938 A		11-10-2012
			US 2011011397 A1		20-01-2011
			WO 2011003130 A1		13-01-2011
<hr/>					
WO 2005004963	A2	20-01-2005	EP 1646419 A2		19-04-2006
			EP 2295102 A1		16-03-2011
			US 2007131229 A1		14-06-2007
			WO 2005004963 A2		20-01-2005
<hr/>					
EP 2281595	A1	09-02-2011	EP 2281595 A1		09-02-2011
			US 2011023882 A1		03-02-2011
			US 2013174851 A1		11-07-2013
<hr/>					
WO 2008011682	A1	31-01-2008	AU 2007278766 A1		31-01-2008
			CN 102698349 A		03-10-2012
			EP 2046430 A1		15-04-2009
			EP 2051760 A1		29-04-2009
			EP 2425868 A1		07-03-2012
			EP 2428240 A1		14-03-2012
			EP 2428241 A1		14-03-2012
			JP 2009544371 A		17-12-2009
			JP 2009544372 A		17-12-2009
			NZ 567432 A		30-03-2012
			US 2008060649 A1		13-03-2008
			US 2009217929 A1		03-09-2009
			US 2009223518 A1		10-09-2009
			WO 2008011682 A1		31-01-2008
			WO 2008011683 A1		31-01-2008
<hr/>					

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB2013/051858

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.: 19 because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.2

Claims Nos.: 19

Claim 19 is not in compliance with the clarity requirement of Article 6 PCT, as it is particularly burdensome for a skilled person to establish the subject-matter for which protection is sought.

The step of "choosing the actual height of each of the gaps based on the evaluated surface roughness (of the user's skin) such that the effective height of each of the gaps responsive to the user interface device being donned by the user is greater than 100 microns" merely represents a result to be achieved. However, the description does not contain a single embodiment explaining how the actual height of each of the gaps may effectively be chosen, based on the evaluated surface roughness of the user's skin, such that the effective height of each of the gaps responsive to the user interface device being donned by the user is greater than 100 microns.

To many undetermined parameters (like, for example, the material used to make the cushion, the force with which the user interface device is applied to the user's face, and the local roughness of the skin which varies considerably from place to place) put an undue burden to the skilled person to determine the scope of protection sought for.

The non-compliance with the substantive provisions is to such an extent that no meaningful search of claim 19 could be carried out at all (Article 17(2) PCT).

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guidelines C-IV, 7.2), should the problems which led to the Article 17(2) declaration be overcome.