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(54) FACE MASK WITH TRANSPARENT WINDOW AND METHOD OF PRODUCTION

(57) The invention relates to face masks which allow others to see the wearer's mouth and a method for their production. The face mask has a breathable section **20** of air-permeable material that filters air, a window **30** within the breathable section **20** and a film **10** of transparent material. The window **30** is defined by an inner contour **32** of the breathable section **20** and is covered by the film **10.** The film **10** and the breathable section **20** are connected along the inner contour **32** by a closed continuous weldline **44** for example by ultrasonic welding. With a mask of the invention, the wearer's mouth is always in a position that allows visual contact and communication while allowing breathability on the other. The respiration is achieved by the breathable section **20,** which is not covered by the film **10** of transparent material. By applying continuous welding in the connection of the breathable section **20** and the transparent film **10,** the overlap of the breathable section **20** and the transparent film **10** is minimized. Such a mask is certified as medical according to international standards.

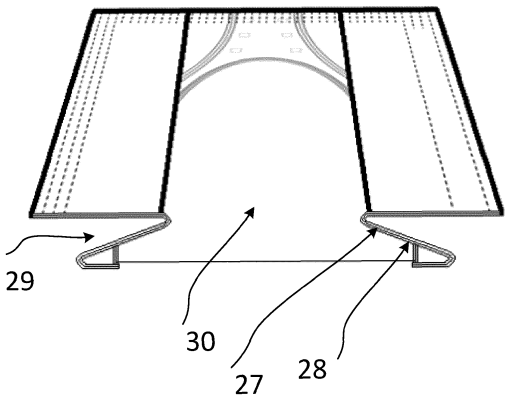

Figure 3

EP 4 088 603 A1

Description

[0001] The invention relates to face masks. The invention particularly relates to face masks, which allow others to see the wearer's mouth. The invention also relates to medical and surgical face masks. The invention further relates to method of production of face masks and a machine for this purpose.

[0002] Known masks that allow the wearer's mouth to be seen usually have a window in the mouth area (see for example WO2008/109438, WO2019/046434). This configuration makes it difficult to seal the mask and to certify it as a medical or surgical mask, i.e. a mask that is intended for use by health care professionals in an operating room or in other medical settings with similar requirements, according to generally accepted standards.

[0003] An object of the invention is a mask with a window which prevents suspended particles from penetrating between the mask and the user's face, while ensuring breathability. It is also an object of the invention to produce such a mask. Another object of the invention is a mask with a window that can be certified as a medical or surgical mask. Another object of the invention is a window mask that can be certified as a medical or surgical mask according to EN 14683: 2019 + AC: 2019 "Medical face masks - Requirements and test methods". Another object of the invention is a machine to produce effectively face masks.

[0004] The invention is defined in the independent claims. Dependent claims define additional features which offer further advantages to the invention.

[0005] A face mask according to the invention has a breathable section of air-permeable material that filters air, a window within the breathable section and a film of transparent material. The window is defined by an inner contour of the breathable section and is covered by the film. The film and the breathable section are connected along the inner contour by a closed continuous weldline.

[0006] With a mask of the invention, the wearer's mouth is always in a position that allows visual contact and communication without the need to constantly reposition it on one hand, while allowing breathability on the other. The respiration is achieved by the breathable section, which is not covered by the film of transparent material. By applying continuous welding in the connection of the breathable area and the transparent film, the overlap of the breathable section and the transparent film is minimized.

[0007] Continuous weldline may be effected by ultrasonic welding.

[0008] The inner contour may be a curve with no corners, preferably a curve with elliptical shape. A contour with no corners is less vulnerable to tearing, in particular tearing during welding.

[0009] The breathable section has an outer contour with one or more welding lines running parallel to the outer contour. Small portions of the outer contour may coincide with corresponding portions of the contour of the film. The welding lines connect the breathable section and the film along these portions.

[0010] The breathable section may have two or more layers. In some embodiments it has two layers of spunbond material and one layer of meltblown fabric therebetween. Other breathable materials may be also used for the breathable section.

[0011] The film may be made of polyolefin, for example polypropylene, polyethylene, polyester.

[0012] The mask may have at least one of the following characteristics: a) bacterial filtration efficiency $\geq$ 98%, b) differential pressure < 60Pa/cm^2, splash resistance $\geq$ 16.0kPa, bioburden $\leq$ 30 cfu/gr. Optionally the mask is certified as medical mask type I or II or IIR, preferably as type II or IIR, according to international standards, such as EN 14683:2019+AC:2019.

[0013] A method of producing masks according to the invention includes the following steps: a) supplying a continuous sheet of breathable material, b) making a plurality of openings to the sheet, each one of which is defined by an inner contour of the sheet, c) supplying a waterproof and airproof continuous film of transparent, material, which covers at least partially the sheet, d) sealing the sheet and the film along a closed, continuous weldline around each one of the plurality of openings to obtain a continuous multilayer, which includes the sheet and the film on a face of the sheet.

[0014] To obtain the individual masks, the multilayer may be cut along lines that are normal with respect to the direction of production.

[0015] Sealing may be performed by ultrasonic welding.

[0016] The method may include welding along one or more weldlines that run parallel to the outer contour of each mask under production and at a distance from each opening of said mask. Joining of the sheet and the film may be also effected by welding at individual spots that are between the continuous weldlines and the weldlines that run parallel to the outer contour, so as to fit effectively the film on one side of the sheet.

[0017] Shaping of the film by cutting its edges along the production line may be performed before sealing. Optionally, the film is heated in the cutting station, so as to obtain smooth cutting lines.

[0018] Openings to the sheet may be performed by passing the sheet through a generator of ultrasonic and a first cylindrical anvil with a surface and a lip projecting therefrom, which corresponds to the contour of an opening.

[0019] Sealing of the sheet and the film may be performed by passing the sheet and the film through a generator of ultrasonic and a second cylindrical anvil with a surface and a wall projecting therefrom. The wall has a shape of a continuous ring that follows the contour, which corresponds to an opening of the plurality of openings.

[0020] According to the invention, a machine for the production of masks includes: a) an entry station to re-

ceive a continuous sheet of breathable material, b) an entry station to receive a waterproof and airproof continuous film of transparent material, c) means to cut a plurality of openings to the sheet, each one of which being defined by an inner contour of the sheet, which means includes a generator of ultrasonic and a first cylindrical anvil with a surface and a lip projecting from its surface, which lip defines the inner contour of the sheet, which corresponds to an opening of the plurality of openings, means to seal the sheet and the film along weldlines, which means includes a generator of ultrasonic and a second cylindrical anvil with a surface and a wall projecting from its surface, which wall has a shape of a continuous ring that follows the inner contour of the sheet, which corresponds to an opening of the plurality of openings.

[0021] The machine may include means to synchronize the rotation of the first anvil and second anvil to achieve an automatic production.

[0022] Preferred embodiments of the invention are described with reference to Figures 1 to 8:

Figure 1 shows the inner face of an example of the invention, which contacts the face of the wearer

Figure 2 shows the outer face of an example of the invention, i.e. the face that is seen by someone looking at the wearer

Figure 3 shows a three-dimensional mask cut across the window

Figure 4 shows the production line of masks

Figures 5A and 5B show a flow chart of the production

Figure 6 shows a machine element used for shaping the transparent film

Figure 7 shows a machine element used for continuous welding

Figure 8 shows an alternative machine element used for continuous welding

[0023] **Figures 1 to 3** show an example of a face mask of the invention. The mask is flexible and has a breathable section **20,** which in the example is a multilayer with three layers **27, 28, 29.**

[0024] The two outer layers **27, 29** are of non-woven fabric, e.g. of spunbond usually obtained by thermobonding of thermoplastic elastomer fibers and the intermediate is a meltblown non-woven layer. Nonwoven layers can be made of polypropylene PP, polyethylene PE, polyester PET or a combination thereof. In some of these examples the meltblown layers are made of polypropylene. In other examples the breathable section **20** may have another number of layers, e.g. one, two, four, etc.

[0025] The breathable section **20** of an example of the invention is rectangular and has an outer contour **22, 24,** but other shapes are also anticipated. The outer contour **22, 24** of the breathable section **20** has four edges, which when the user wears the mask, the two **22** are parallel or almost parallel to his mouth and the two **24** are vertical or almost vertical. Inside, the mask has an opening - window **30,** which is defined by an inner contour **32** of the breathable section **20.** The inner contour **32** is curved, without corners and preferably has an elliptical shape with its large axis parallel to the mouth of the wearer of the mask. The breathable section **20** also has two pleats **50,** one to the right and one to the left of the window, or above and below the window, as shown in **Figures 1 and 2.** In the example of **Figures 1 and 2,** the window **30** in an unfolded mask, i.e. a mask with folded pleats, has a total area of 48 cm^2 covering approximately 24% of the area of the mask while in a folded mask, it covers approximately 17%. The invention allows the selection of different geometric features of the mask and breathable materials, in order to obtain a medical mask with particular characteristics, for example type IIR, on the one hand and a mask exposing the mouth of the wearer on the other.

[0026] Attached to one side of the breathable layer **20** is a waterproof and airtight transparent film **10,** preferably tested according to ISO 22610, which may be made of polypropylene or any suitable material. The transparent film **10** completely covers the window **30** of the mask and extends between the two parallel edges **24** of the breathable layer. The transparent film **10** has antifog technology so that it does not blur when using the mask.

[0027] The transparent film **10** has a contour **12** with two relatively small portions **14** coinciding with the outer contour **24** of the breathable section **20.** Between these two small portions **14,** the contour **12** of the transparent film **10** has no corners and is either straight or curved, preferably curved, with greater height in the window area and less height in the outer contour area **24** of the breathable section **20.**

[0028] The layers **27, 28, 29** of the breathable section **20** are joined together along the outer contour **22, 24.** In the example, the connection is performed preferably with ultrasonic welding, such as spot ultrasonic welding, or any other method. In the area, where the outer contour **22, 24** of the breathable section **20** coincides with the contour **14** of the transparent film **10,** the breathable section **20** is joined also with the film **10.** In other areas the connection holds the layers **27, 28, 29** of the breathable section **20** together. In the example, the connection along the outer contour **22, 24** of the breathable section **20** is effected along two or four weldlines **42.** Usually the weldlines **42** are at least two so as to obtain an effective sealing between the welding spots, if the welding is not continuous. In the example that is described, the weldlines **42** are within a distance of 15 mm from the outer contour **22, 24** of the breathable section **20.** This distance is given only as an example and other distances are anticipated.

[0029] The breathable section **20** is connected to the film 10 along the inner contour **32** of the breathable section **20** that defines the window **30.** The connection is achieved with a continuous weldline **44** obtained by ultrasonic welding and having no gaps. Thus, the connection of the breathable section **20** and the film is sealed effectively so that the mask meets the requirements for

a type 11R mask. The continuous weldline **44** is along the inner contour **32,** practically at a distance that allows welding, i.e. a couple of millimeters. The continuous welding may also be effected by other means, for example thermal welding, gluing. In some examples not shown in the Figures, there may be more than one continuous weldlines **44** that run along parallel paths.

[0030] Between the two connections, i.e. the weldlines **42** along the outer contour **22, 24** and the continuous welding 44 along the inner contour **32** of the breathable section **20,** the breathable section **20** and the transparent film 10 are attached at individual spots 46. Such an attachment facilitates the correct and effective alignment of the breathable section and the transparent film 10 during production of the masks, as it will be described below, and/or the fitting of the one on the other. In the example shown there are 12 such spots on each mask.

[0031] The mask described was tested according to EN 14683: 2019 + AC: 2019 and found to have the following characteristics: Bacterial filtration efficiency ≥ 98%, differential pressure < 60 Pa/cm^2, resistance against penetration ≥ 16.0 kPa, population of microorganisms bioburden test ≤ 30 cfu/gr. The relevant measurements were made according to the standard EN 14683:2019 + AC:2019, which describes the relevant procedures or refers to the relevant standards. For the resistance against penetration, ISO 22609:2004 - Test Method for resistance against penetration was applied and for the control of biological load (bioburden test) the EN ISO 11737-1:2018 - Determination of population of microorganisms on products was applied accordingly.

[0032] A method of production of masks follows below:

[0033] The raw materials are a continuous sheet **120** of breathable material and a waterproof and airtight continuous film **310** of transparent material. The sheet **120** and the film **310** are preferably provided as rolls. The production line of the masks is shown schematically in **Figure 4** and a flowchart in **Figures 5A and 5B.**

[0034] A continuous sheet **120** of breathable material is fed, preferably by roll unwinding, at station **100.** The transparent film **310** is fed at station **300,** by rolling or unwinding if it is provided as a roll.

[0035] Openings **30** at the breathable sheet **120** are made at station **200.** Each one of the openings **30** corresponds to an opening **30** of a mask under production. The openings **30** are made with ultrasonic cutting. To this end, the sheet **120** passes through an ultrasonic generator, a sonotrode or probe, and a rotating cylindrical shaft, i.e. an anvil, with a cutting lip, which has the shape of the openings **30.** The cutting lip may be formed for example by a series of bosses on the cylindrical shaft, i.e. an embossing roller, or by a continuous lip.

[0036] The transparent film **310** is shaped at station **400.** At this station the two edges of the film **310,** which are parallel to the direction of production, are cut and obtain the shape of a wave with troughs and peaks with no corners. The forming of the edges of the film **310** may be done by cutting with ultrasonic and if this is the case the film **310** passes through an ultrasonic generator, sonotrode or probe, and a cylindrical anvil **76** having a lip **77** on its surface, which has the shape of the wave (see **Figure 6).**

[0037] It has been observed that the quality of the edges of the film **310** is improved, when the edges of the film **310** are at elevated temperature, for example at 60 °C to 90 °C. To this end the transparent film **310,** is heated for example during shaping, i.e. cutting, at station **400** by supplying thermal energy via the anvil at this station.

[0038] Alignment of the sheet **120** and the film **310** is performed at station **500,** so that the film **310** covers the openings **30** of the sheet **120.** During alignment a line between the opposite peaks of the edges of the film **310** is aligned with the vertical axis of symmetry of an opening **30.** The vertical direction is normal to the direction of production the sheet **120** and the film **310** (direction of production is designated with the dotted arrow in **Figure 4).**

[0039] The film **310** is applied on the sheet **120** at station **600.** The connection of these two elements of the mask follows at station **700,** where the film **310** and the sheet **120** pass through an ultrasonic generator, sonotrode or probe, and a cylindrical anvil **71** with a projection wall **72** on its surface, which has the shape of a continuous closed ring, as shown in **Figure 7.** The wall **72** of the anvil **71** and the lip of the anvil that is used for cutting the openings **30** have similar shape, in the example presented elliptical, so as the continuous weldline **44** coincides with the inner contour **32** of each opening **30.** In practice the inner contour **32** and the continuous weldline **44** are a couple of millimeters apart, a tolerance that is defined for an effective welding. By such a procedure the weldline guarantees that the connection of the sheet **120** and the film **310** does not allow any particles or droplets to intrude the space between the mask and the face of the wearer. In an alternative example of anvil **71** that is shown in **Figure 8,** the anvil **71** further carries bosses **73** to effect the individual welding spots **46.** With this example, the welding at the individual spots **46** and the continuous weldline **44** are effected as the film **310** and the sheet **120** pass through the ultrasonic generator and anvil **71.** The welding of the individual welding spots **46** may be effected before or after the continuous weldline, for example at station position **1100,** where the sheet **120** and the film **310** are welded together as presented below.

[0040] In station **800** pleats **50** are created, usually one on each side of the opening **30.** A nose wire that holds the mask on the wearer's nose is inserted in station **900.** In station **1000** the free edges **22** of the continuous sheet **120** of breathable material are folded.

[0041] At the position **1100,** the sheet **120** and the film **310** are welded along the contour of each mask under production.

[0042] After the connection of the sheet **120** and the film **310,** the multilayer that is produced, i.e. the multilayer comprising the sheet **120** and the film **310,** is ready for cutting to obtain the individual masks. Cutting of the multilayer is effected in station **1200.** Earloops are attached

to each mask at station **1300,** for example with ultrasonic welding.

[0043] A machine for the production of masks includes a) a first entry station **100** to receive a continuous sheet **120** of breathable material, b) a second entry station **300** to receive a waterproof and airproof continuous film **310** of transparent material, c) means to cut a plurality of openings **30** to the continuous sheet **120,** each one of being defined by an inner contour **32** of the sheet **120,** which means includes an ultrasonic generator - sonotrode or probe - and a rotatable first cylindrical anvil with a surface and a lip projecting from its surface, which lip defines the inner contour **32** of the sheet **120,** which corresponds to an opening **30** of the plurality of openings **30,** d) means to seal the sheet **120** and the film **310** along weldlines **44,** which means includes an ultrasonic generator- sonotrode or probe - and a rotatable second cylindrical anvil **71** with a surface and a wall **72** projecting from its surface, which wall **72** has a shape of a continuous ring that follows the inner contour **32** of the sheet **120,** which corresponds to an opening **30** of the plurality of openings **30.** The machine may have means to synchronize the rotation of the first anvil with the lip and the second anvil **71** with the wall **72,** so as to achieve automation of the production process without human intervention, using a single layout.

[0044] The difference of the ultrasonic cutting layout and the ultrasonic welding layout is the distance between the anvil and the sonotrode, since by adjusting this gap the layout may be used either for cutting or welding. Usually cutting requires a smaller gap.

Claims

1. Mask having a breathable section **(20)** of an air-permeable material that filters air, a window **(30)** within the breathable section **(20),** which window **(30)** is defined by an inner contour **(32)** of the breathable section **(20),** and a film **(10)** of transparent material covering the window **(30) characterized in that** the film **(10)** and the breathable section **(20)** are connected along the inner contour **(32)** by a closed continuous weldline **(44).**

2. Mask **according to claim 1,** whereby the continuous weldline **(44)** is made by ultrasonic welding.

3. Mask **according to claim 1 or claim 2**, whereby the inner contour **(32)** is a curve with no corners, preferably a curve with elliptical shape.

4. Mask **according to any of claims 1 to 3,** whereby the breathable section **(20)** has an outer contour **(22, 24)** and the film **(10)** has a contour with small portions **(14),** which coincide with the outer contour **(24),** and larger portions with no corners, which do not coincide with the outer contour **(22, 24).**

5. Mask according to any of claims 1 to 4, whereby the breathable section **(20)** has an outer contour **(22, 24)** and the film **(10)** is connected with the breathable section **(20)** with one or more weldlines **(42)** that run along the outer contour **(22, 24)** as well as at individual spots **(46),** which are between the continuous weldlines **(44)** and the weldlines **(42)** that run along the outer contour **(22, 24).**

6. Mask **according to any of claims 1 to 5**, whereby the breathable section **(20)** includes two layers **(27, 29)** of spunbond material and one layer **(28)** of meltblown fabric between the two layers **(27, 29)** of spunbond material.

7. Mask **according to any of claims 1 to 6,** whereby the film **(10)** is made of polyolefin, for example polypropylene, polyethylene, polyester.

8. Mask **according to any of claims 1 to 7,** with at least one of the following characteristics:

bacterial filtration efficiency	≥ 98%
differential pressure	< 60Pa/cm2
splash resistance	≥ 16.0kPa
bioburden	≤ 30 cfu/gr

9. Mask **according to any of claims 1 to 8**, certified as medical mask type I or II or IIR, preferably as type II or IIR, according to standard EN 14683:2019+AC:2019.

10. Method of producing masks including the following steps:

    • supplying **(100)** a continuous sheet **(120)** of breathable material
    • making a plurality of openings **(30)** to the sheet **(120),** each one of which is defined by an inner contour **(32)** of the sheet **(120)**
    • supplying **(300)** a waterproof and airproof continuous film **(310)** of transparent, material, which covers at least partially the sheet **(120)**
    • sealing **(700)** the sheet **(120)** and the film **(310)** along a closed, continuous weldline **(44)** around each one of the plurality of openings **(30)** to obtain a continuous multilayer, which includes the sheet **(120)** and the film **(310)** on a face of the sheet **(120).**

11. Method **according to claim 10,** including obtaining the multilayer along one direction and cutting the multilayer along lines that are normal with respect said one direction for the production of the individual masks.

12. Method **according claim 10 or claim 11,** whereby sealing **(700)** is performed by ultrasonic welding.

13. Method **according to any of claims 10 to 12,** whereby each mask under production has an outer contour **(22, 24)** and the method includes welding along one or more weldlines **(42)** that run parallel to the outer contour **(22, 24)** and at a distance from each opening of each mask in production.

14. Method **according to claim 13,** whereby welding along one or more weldlines **(42)** that run parallel to the outer contour **(22, 24)** is performed exclusively in portions of the sheet **(120)** and in smaller portions of the sheet **(120)** and the film **(310).**

15. Method **according to claim 13 or claim 14,** including joining the sheet **(120)** and the film **(310)** at individual spots **(46)** that are between the continuous weldlines **(44)** and the weldlines **(42)** that run parallel to the outer contour **(22, 24).**

16. Method **according to any of claim 10 to 15,** whereby, for making openings **(30)** to the sheet **(120),** the sheet **(120)** passes through a generator of ultrasonicand a first cylindrical anvil with a surface and a lip projecting from its surface, which lip defines the inner contour **(32),** which corresponds to an opening **(30)** of the plurality of openings **(30).**

17. Method **according to any of claim 10 to 16,** whereby for the sealing **(700)** of the sheet **(120)** and the film **(310),** the sheet **(120)** and the film **(310)** passes through a generator of ultrasonic and a second cylindrical anvil **(71)** with a surface and a wall **(72)** projecting from its surface, which wall **(72)** has a shape of a continuous ring that follows the inner contour **(32),** which corresponds to an opening **(30)** of the plurality of openings **(30).**

18. Machine for the production of masks including :

- an entry station **(100)** to receive a continuous sheet **(120)** of breathable material
- an entry station **(300)** to receive a waterproof and airproof continuous film **(310)** of transparentmaterial
- means to cut a plurality of openings **(30)** to the sheet **(120),** each one of which being defined by an inner contour **(32)** of the sheet **(120),** which means includes a generator of ultrasonic and a first cylindrical anvil with a surface and a lip projecting from its surface, which lip defines the inner contour of the sheet **(120),** which corresponds to an opening **(30)** of the plurality of openings **(30)**
- means to seal **(700)** the sheet **(120)** and the film **(310)** along weldlines **(44),** which means includes a generator of ultrasonic and a second cylindrical anvil **(71)** with a surface and a wall projecting from its surface, which wall **(72)** has a shape of a continuous ring that follows the inner contour of the sheet **(120),** which corresponds to an opening **(30)** of the plurality of openings **(30).**

19. Machine **according to claim 19,** whereby the first anvil and the second anvil **(71)** are rotatable and the machine comprises means to synchronize the rotation of the first anvil and second anvil.

20. Machine **according to claim 18 or claim 19,** including means to shape **(400)** the film **(310)** by cutting, preferably comprising means to heat the film **(310).**

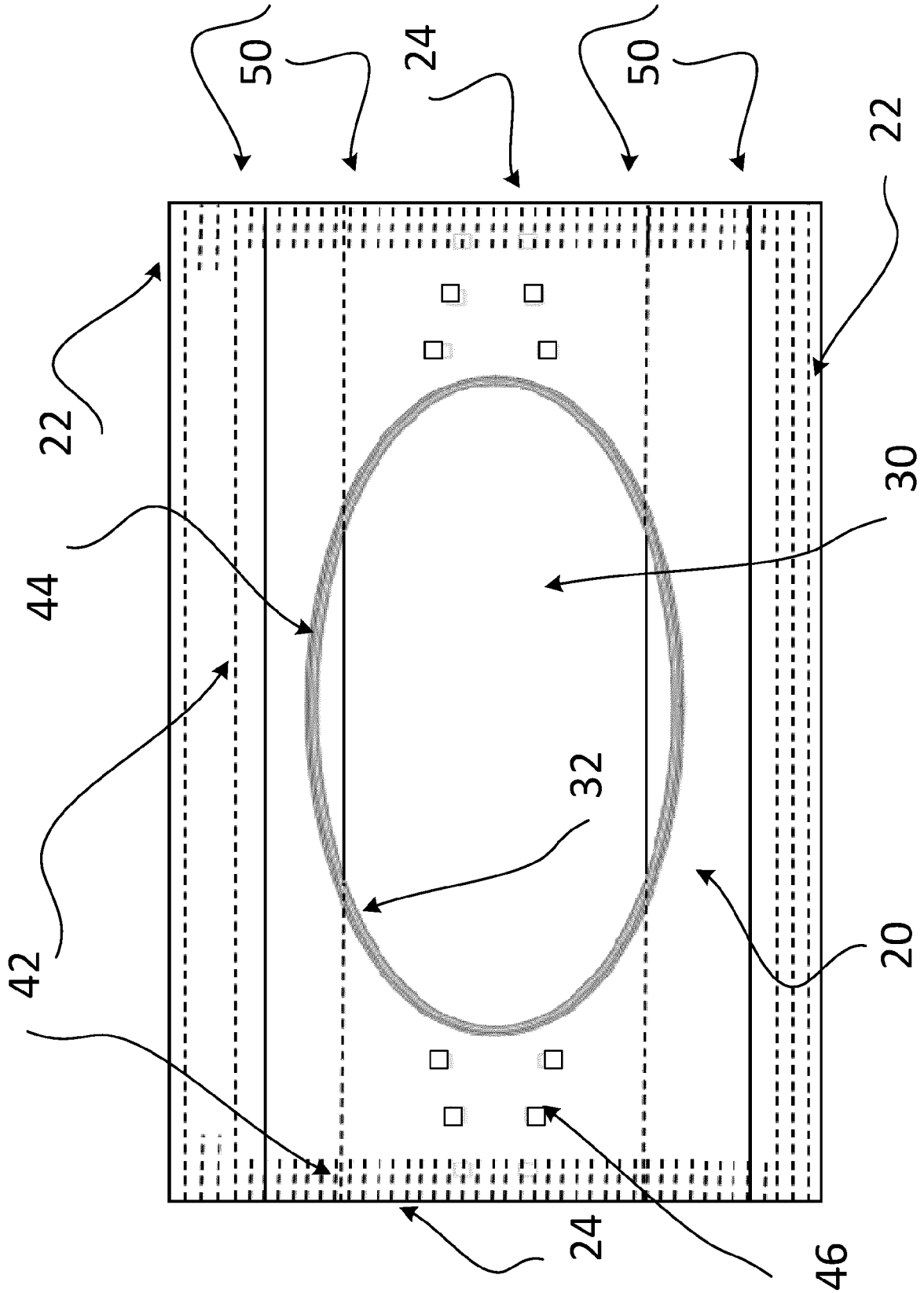

Figure 1

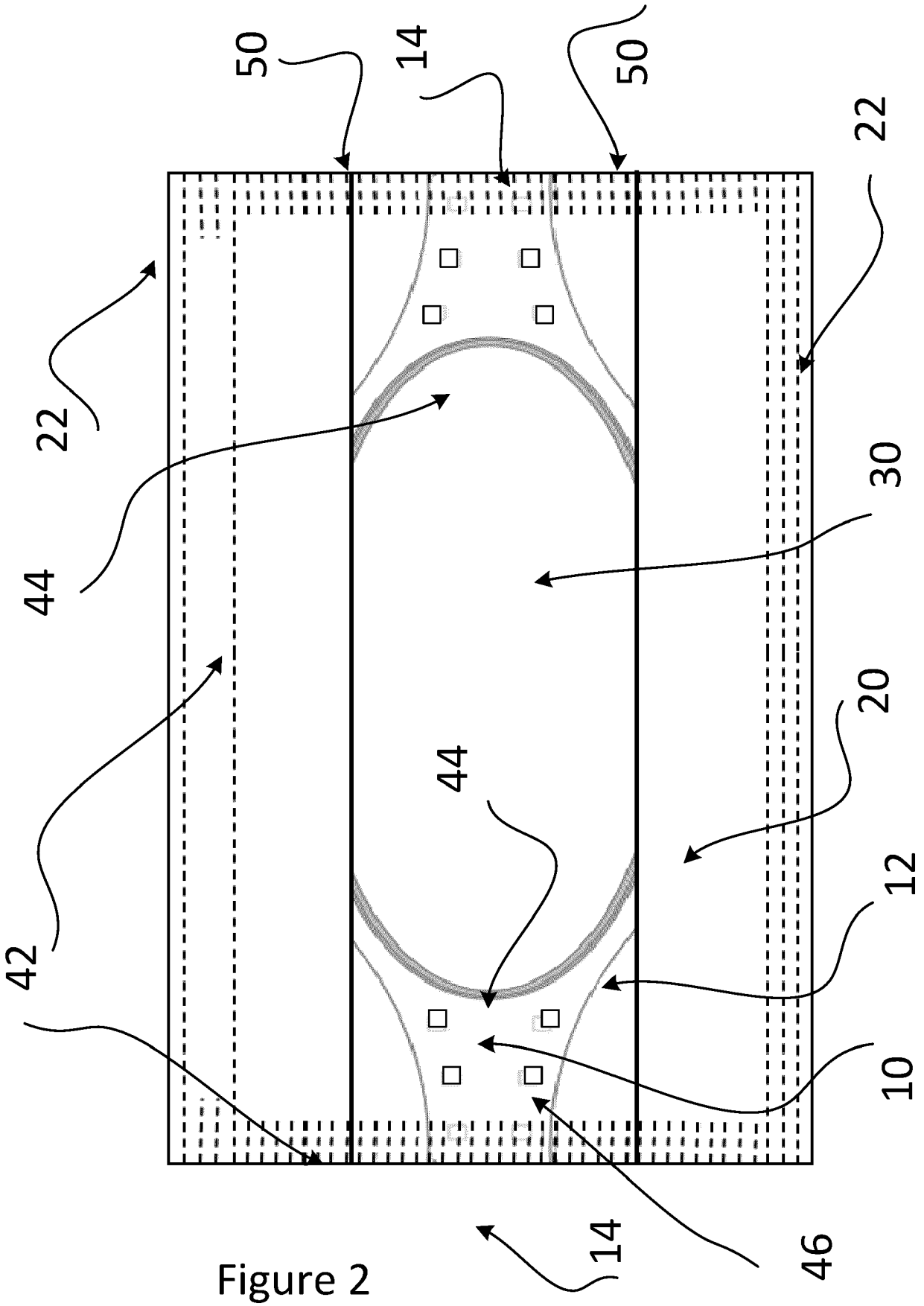

Figure 2

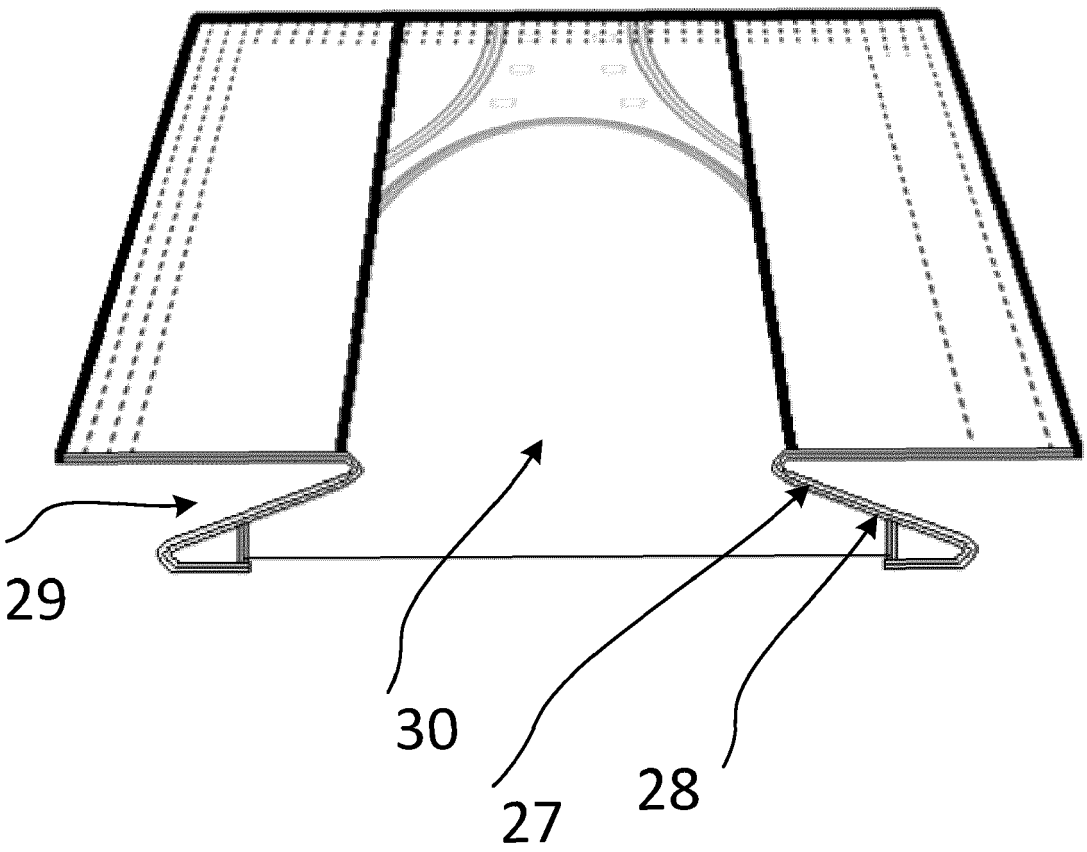

Figure 3

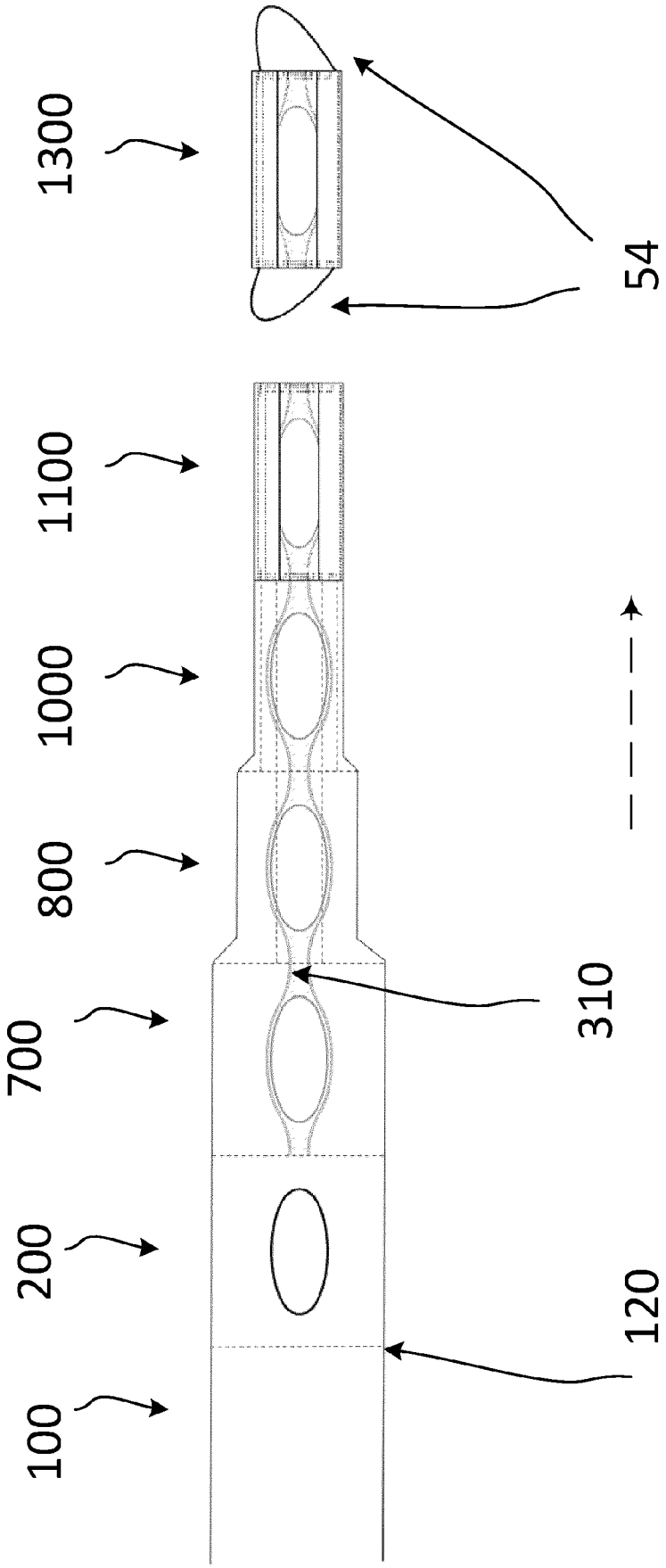

Figure 4

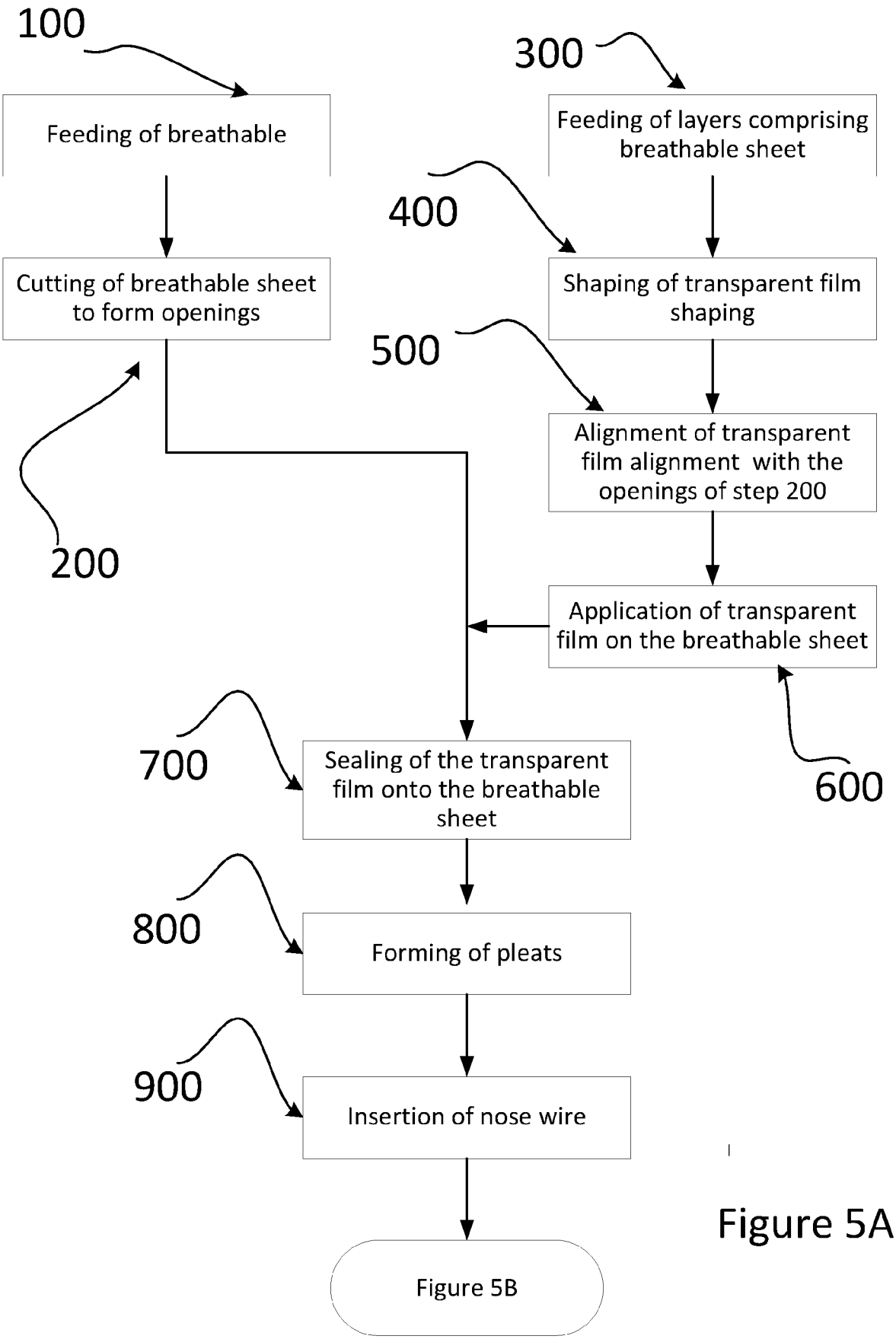
100
Feeding of breathable
300
Feeding of layers comprising breathable sheet
400
Cutting of breathable sheet to form openings
Shaping of transparent film shaping
500
Alignment of transparent film alignment with the openings of step 200
200
Application of transparent film on the breathable sheet
600
700
Sealing of the transparent film onto the breathable sheet
800
Forming of pleats
900
Insertion of nose wire
Figure 5B

Figure 5A

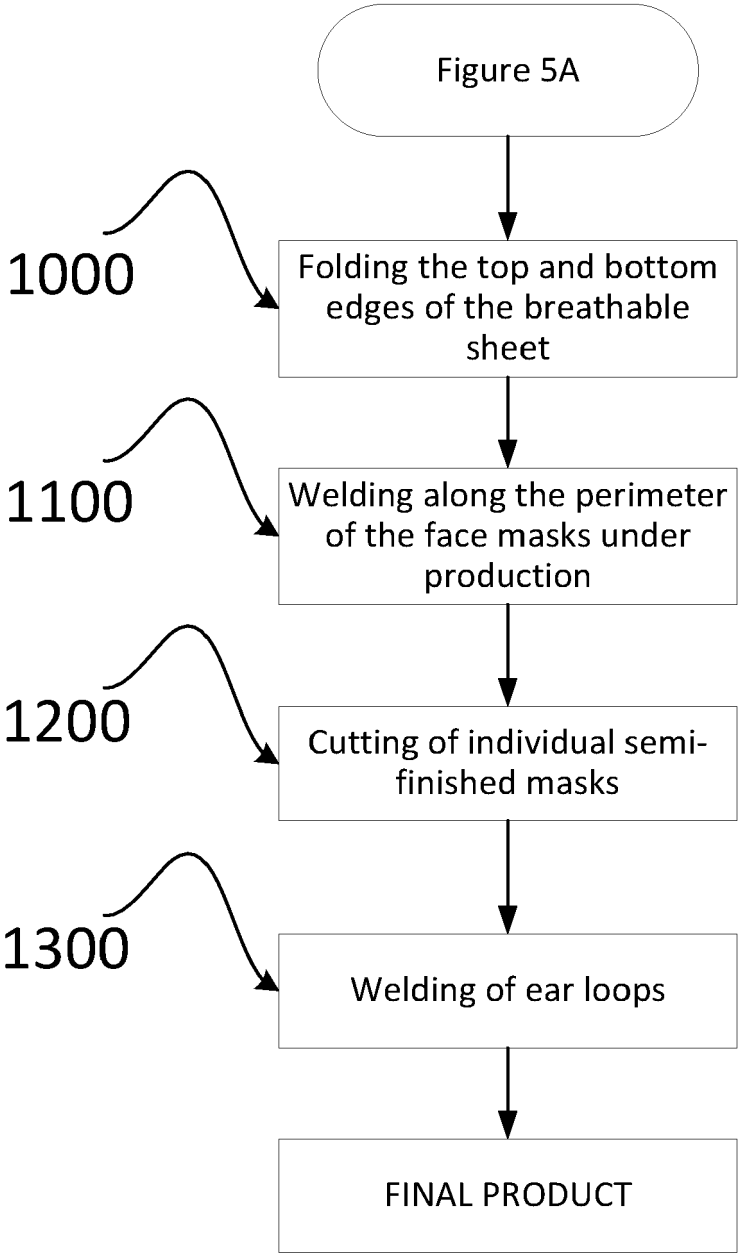
Figure 5A
1000
Folding the top and bottom edges of the breathable sheet
1100
Welding along the perimeter of the face masks under production
1200
Cutting of individual semi-finished masks
1300
Welding of ear loops
FINAL PRODUCT

Figure 5B

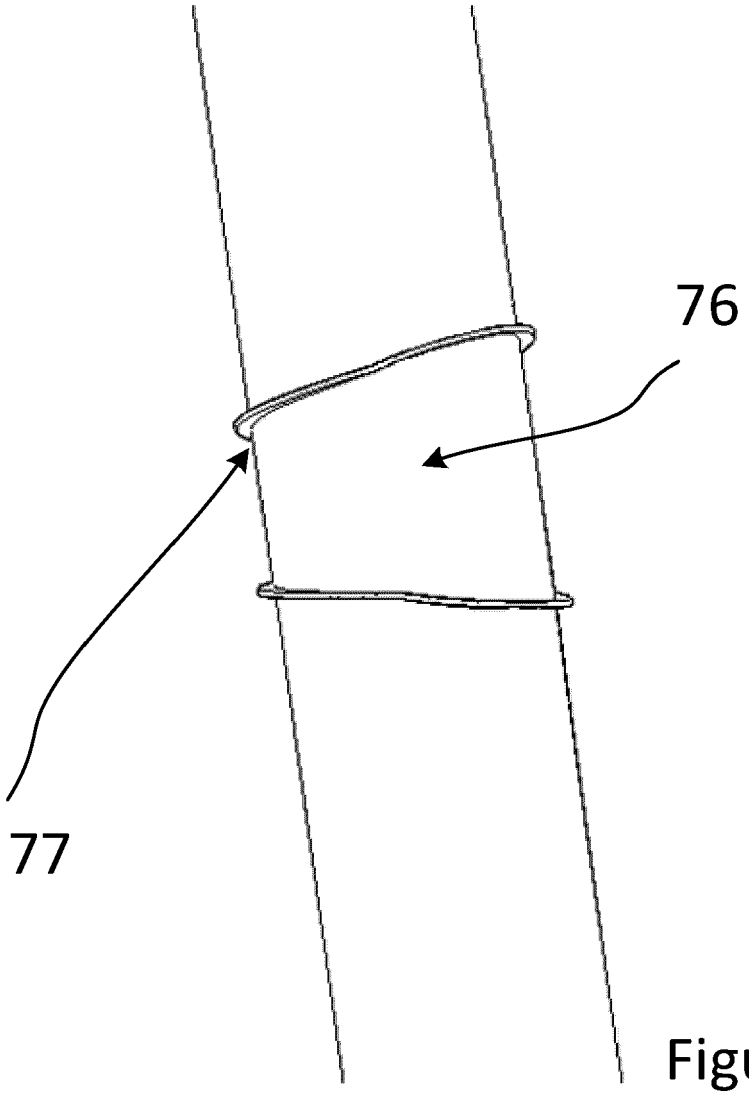

Figure 6

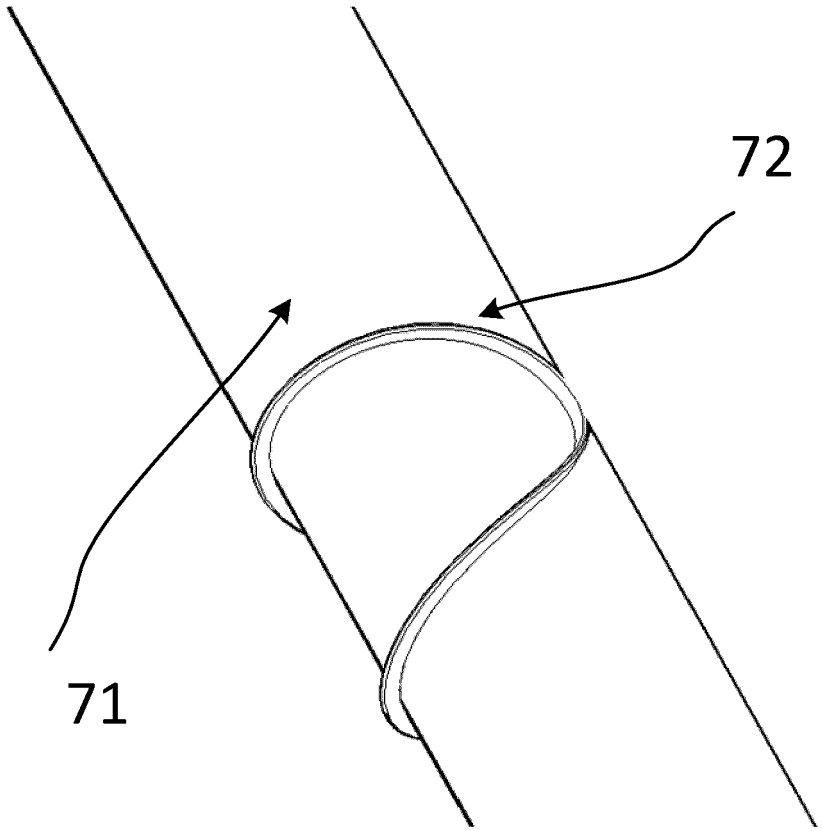

Figure 7

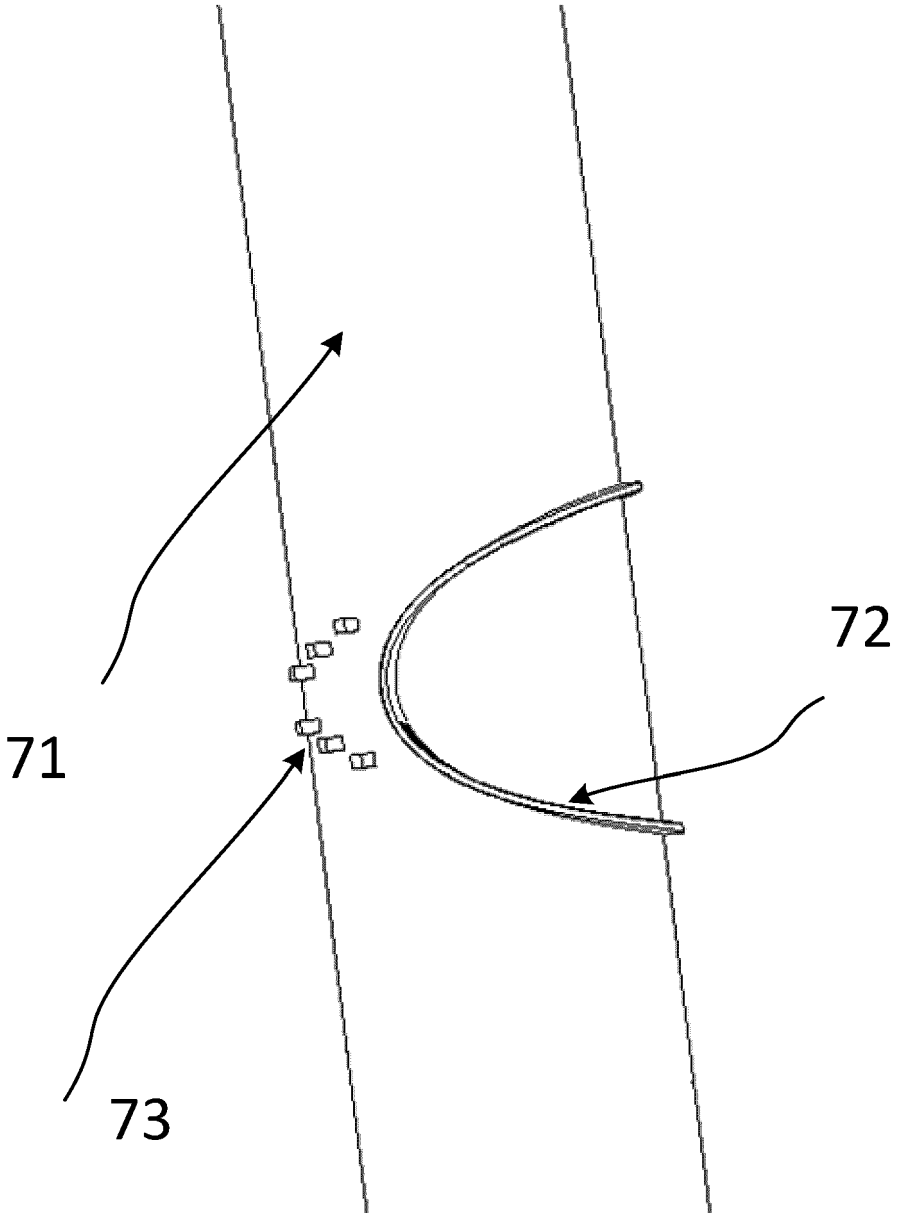

Figure 8

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EUROPEAN SEARCH REPORT

Application Number
EP 21 18 8981

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A		4-6,8,9	
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A41D
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1 The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Munich	14 January 2022	Arboreanu, Antoniu

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

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