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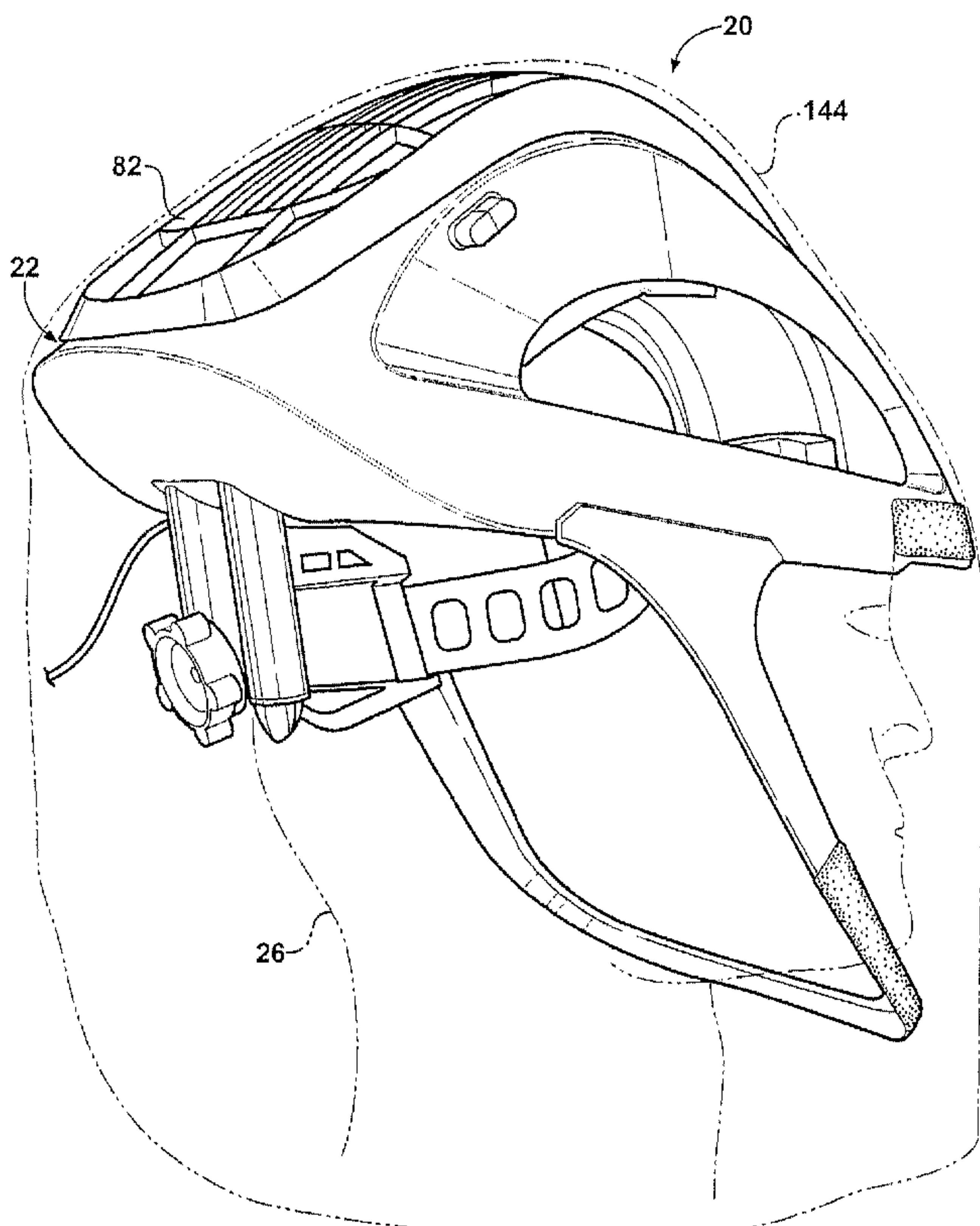
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(54) Title: METHOD OF MANUFACTURING A HOOD FOR USE WITH A PERSONAL PROTECTION SYSTEM



(57) Abrégé/Abstract:

A method of manufacturing a hood for use with a personal protection system. The hood includes a shell formed from at least partially out of a filter medium. At least one transparent layer is initially attached to a transparent face shield. The transparent layer-face shield assembly is sterilized with gamma radiation and attached to the shell to form the hood. The hood is then sterilized with ethylene oxide.

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ABSTRACT

A method of manufacturing a hood for use with a personal protection system. The hood includes a shell formed from at least partially out of a filter medium. At least one transparent layer is initially attached to a transparent face shield. The transparent layer-face shield assembly is sterilized with gamma radiation and attached to the shell to form the hood. The hood is then sterilized with ethylene oxide.

METHOD OF MANUFACTURING A HOOD FOR USE WITH A PERSONAL PROTECTION SYSTEM

CROSS-REFERENCE TO RELATED APPLICATION

[0001] The present application is a divisional application of Canadian Patent No. 2,602,821, filed on March 24, 2006.

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0002] The subject invention generally relates to a personal protection system mountable to a user for distributing air to the user. The personal protection system is utilized in the medical profession during surgical procedures. The subject invention more specifically relates to a helmet assembly and gown for use in the personal protection system.

2. Description of the Prior Art

[0003] Personal protection systems and helmet assemblies utilized in personal protection systems are known in the art. As indicated above, personal protection systems and helmet assemblies are worn by users throughout the medical profession, such as surgeons, during surgical procedures.

[0004] Conventional personal protection systems and helmet assemblies are deficient for one reason or another. For example, U.S. Pat. No. 6,990,691 to Klotz et al. (the '691 patent) discloses a helmet assembly that draws air in with a fan assembly and distributes the air to front and rear air exits. However, when the helmet assembly is worn by the user, the air exit is disposed such that the air is vented near the middle of the back of the head of the user. Thus, the air cannot be directed toward the neck of the user, where most surgeons desire the air's cooling presence.

[0005] Other deficiencies of prior art personal protection systems are with the fan assembly. For instance, the shape of the blades of the fan, which rotate to draw in air, do not provide for the most efficient and quietest flow of air possible. This causes excessive power consumption, which leads to premature drain of battery packs, and excessive noise, which can be distracting for a surgeon performing delicate operations.

[0006] Furthermore, the prior art helmet assemblies tend to transfer vibrations caused by the rotation of the fan to the user, as well as being noisy in general. The vibrations, as well as the noise, can be distracting to the surgeon, who obviously needs to focus his efforts at the complex task at hand.

5 [0007] Yet another deficiency of the '691 patent concerns the multiple removable layers disposed on the face shield. The '691 patent is silent as to sterility of the multiple removable layers. However, sterilization concerns are of an utmost importance for any product involved in the surgical process.

10 [0008] For the above mentioned reasons, it is desirous to provide a personal protection system which provides more control over air flow to the neck of the user and which provides more efficient and quieter means for moving the flow of air. Furthermore, it is desirous to provide a personal protection system which noise and vibrations, which can be distracting to the surgeon, are kept to a minimum. Moreover, it is desirous to provide a face shield with removable layers that is 15 sterilized in an efficient manner.

SUMMARY OF THE INVENTION AND ADVANTAGES

20 [0009] In a first aspect of the invention, a personal protection unit is disclosed. The personal protection unit includes a support structure for suspending a hood over the head of an individual. A fan module is attached to the support structure, with the fan module receiving air and discharging air. A duct is connected to the support structure and has an opening positioned to receive the air discharged from the fan module. The duct is shaped to have a rear air exit. The duct is arranged relative to the fan module so that only a fraction of the air discharged from the fan 25 module enters the duct. The duct extends from the support structure and the rear air exit is positioned so that air is discharged from the rear air exit directly onto the neck of the individual. By the duct extending from the support structure and discharging air directly on to the neck, the comfort of the individual (e.g., a surgeon) is increased, allowing the individual to focus on the task he or she is performing (e.g., surgery).

30 [0010] In a second aspect of the invention, the personal protection unit includes the support structure for suspending the hood over the head of the individual. The personal protection unit includes a fan for circulating air. A motor is attached to the support structure and is connected to the fan for actuating the fan. An elastomeric,

vibration dampening member holds the motor to the support structure. The vibration dampening member helps to reduce transmission of noise and/or vibrations generated by the fan and/or motor to the user. Reduction of noise and/or vibrations will decrease distractions to the individual.

5 [0011] A third aspect of the subject invention provides the personal protection system with the hood formed of flexible sterilizable material, a portion of which is filter material, and shaped to be worn over the head. A transparent face shield is attached to the hood. The personal protection system includes a support structure for suspending the hood over the head. A fan is attached to the support
10 structure for circulating air through the hood. A plurality of individually removable layers of sterile transparent material are disposed over the face shield.

15 [0012] A fourth aspect of the invention provides a method of assembling a sterilized hood assembly having a transparent face shield. The method includes the step of providing a hood formed from sterilizable flexible material, a portion of the material being filter material. A transparent face shield assembly is attached to the hood where the shield assembly includes a face shield. The method further includes the step of sterilizing the hood and face shield assembly using a sterilization process that does not adversely affect the filter material. The transparent shield assembly further includes a plurality of removable transparent layers disposed over the face shield. Sterilizing the face shield and removable layers together as a
20 whole provides for a more effective assembly process by negating the possibility of introducing contaminants during subsequent assembly operations.

BRIEF DESCRIPTION OF THE DRAWINGS

25 [0013] Other advantages of the present invention will be readily appreciated, as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

30 [0014] Figure 1 is a perspective view of a personal protection system embodied as a helmet assembly mounted on a head of a user;

[0015] Figure 2 is a cross-sectional view of the helmet assembly;

[0016] Figure 3 is an exploded perspective view of the helmet assembly;

[0017] Figure 4 is an exploded view of a preferred embodiment of a fan module of the present invention;

[0018] Figure 5 is a cross-sectional view of the preferred embodiment of the fan module;

5 [0019] Figure 6 is a cross-sectional view of an alternative embodiment of the fan module;

[0020] Figure 7 is a perspective view of a fan of the fan module showing fan blades having an airfoil shape.

10 [0021] Figure 8 is a top view of the fan showing the fan blades having air foil shapes;

[0022] Figure 9 is a elevational view of a nozzle assembly of the present invention;

[0023] Figure 10 is a perspective view of a nozzle tip of the nozzle assembly;

15 [0024] Figure 11 is a bottom view showing a port of a nozzle of the nozzle assembly;

[0025] Figure 12 is an exploded view of a first alternative nozzle of the present invention and a first adjustable air flow volume mechanism;

20 [0026] Figure 13 is an exploded view of a second alternative nozzle of the present invention and a second adjustable air flow volume mechanism;

[0027] Figure 14 is a perspective view a hood having an integrated face shield attached to the helmet assembly; and

[0028] Figure 15 is an elevational view of a removable face shield layer attached to the face shield.

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DETAILED DESCRIPTION OF THE INVENTION

[0029] Referring to the Figures, wherein like numerals indicate corresponding parts throughout the several views, a personal protection system or personal protection unit is generally shown at 20. The personal protection system 20 is mountable to a user (i.e., an individual) for distributing air to the user. The personal protection system 20 of the present invention is adapted from the personal protection systems disclosed in United States Patent Nos. 6,481,019 to Diaz et al. (the '019

patent) and 6,973,677 to Diaz et al. (the '677 patent).

[0030] In the preferred embodiment, as shown in Figure 1, the personal protection system **20** is implemented as a helmet **22** or helmet assembly **22**.
5 The personal protection system **20** filters air between a head **24** and body **26** of a user, e.g., a medical professional, and an environment external to the user. When in use, the preferred helmet assembly **22** of the personal protection system **20** is mounted to the head **24** of the user. The helmet assembly **22** distributes air about the head **24** of the user as will be described below. More specifically, in the preferred embodiment,
10 the helmet assembly **22** distributes air toward both a front of the head **24**, i.e., a face of the user, and a back of the head **24**, i.e., a neck of the user.

[0031] The personal protection system **20** of the subject invention may be described hereafter in terms of the helmet assembly **22** of the preferred embodiment. However, this should not be construed as limiting the personal
15 protection system **20** to the helmet assembly embodiment.

[0032] Referring to Figure 2, the helmet assembly **22** includes a shell **28** providing structural support (i.e., a support structure **28**). The shell **28** preferably includes an inner shell portion **30** facing the user and an outer shell portion **32** facing away from the user. In the preferred embodiment, the outer shell portion **32** is spaced
20 apart from the inner shell portion **30** to define at least one air flow channel **34** between the inner and outer shell portions **30, 32**. It is to be understood that the present invention may include more than one discrete air flow channel **34**. However, the preferred embodiment includes a single unitary air flow channel **34** and the present invention will be described below in terms of this air flow channel **34**. The shell **28** is
25 preferably formed of acrylonitrile butadiene styrene (ABS), but may be formed, in alternative embodiments, of glass-filled polypropylene or other suitable materials.

[0033] The air flow channel **34** channels air about the head **24** of the user. The inner and outer shell portions **30, 32** may form the air flow channel **34** from a two-sheet thermoforming process which improves the structural strength of the shell
30 **28**. More specifically, each of the inner and outer shell portions **30, 32** include an outer periphery, and in the two-sheet thermoforming process, the inner and outer shell portions **30, 32** are pinched together at their outer peripheries. The air flow channel **34** is subsequently thermoformed between the pinched outer peripheries.

[0034] The helmet assembly 22 also includes a facial section 36 extending from the shell 28 to define a facial opening 38. The facial section 36 of the helmet assembly 22 is a chin bar 40. Preferably, the chin bar 40 is flexible and is formed of plastic. The chin bar 40 may also be formed of a polypropylene component. 5 The flexibility of the chin bar 40 protects the user's face and also absorbs impact when the user contacts an external object with the helmet assembly 22.

[0035] Referring now to Figure 3, the helmet assembly 22 includes a fan module 42 supported by the shell 28. More specifically, the fan module 42 is mounted in a cavity 44 formed by the shell 28. The fan module 42 operates to 10 generate a flow of air which is fluidly communicated into the air flow channel 34. As shown in Figure 4, the fan module 42 includes a fan 46 and a motor 48 mounted to a scroll housing 50. The motor 48 includes a drive shaft 52 operatively connected to the fan 46 to drive the fan 46 at a plurality of rotational speeds correlating to an amount, or a volume, of air flowing into the air flow channel 34. As appreciated by 15 those skilled in the art, the rotational speeds of the fan 46 can be measured in revolutions per minute (RPMs).

[0036] Referring again to Figure 3, a cover plate 54 is fixed to the shell 28 and the fan module 42 to hold in the fan module 42 in the cavity 44. A fan module cushion 56 is disposed between the cover plate 54 and a base of the fan module 42. The 20 fan module cushion 56 reduces the transmission of noise from the motor 48 to the user.

[0037] Referring to Figures 4 and 5, in the preferred embodiment, a motor cushion 58 is disposed between the motor 48 and a motor mount 60. A plurality of motor mount cushions 62, embodied as grommets, is placed between the motor mount 60 and the scroll housing 50 (although shown below the scroll housing 25 50 for clarity, the arrangement is best shown in Figure 5). The motor cushion 58 and motor mount cushions 62 work together as a vibration dampening member to reduce shock loads and vibrations. More specifically, the motor mount cushions 62 are the primary component for shock reduction between the helmet structure, e.g., shell 28, and the motor 48, thereby extending the bearing life of the motor 48 and providing 30 low sound characteristics. The motor mount cushions 62 completely isolate the motor 48 from the rest of the helmet structure. By having two sets of cushioning, i.e., the motor cushion 58 between the motor 48 and motor mount 60 and the motor mount cushions 62 between the motor mount 60 and the scroll housing 50, the transmission

of energy between the helmet structure and the motor 48 can be fine tuned. The motor cushion 58 and the motor mount cushions 62 may be formed of foam and/or an elastomeric material.

[0038] Referring to Figure 6, in an alternative embodiment of the invention, the motor mount 60 for mounting the motor 48 to the scroll housing 50 is formed of elastomeric material. Preferably, the motor mount 60 is formed of silicone having a durometer of from 10 to 80 shore A. Much like the motor mount cushions 62 of the preferred embodiment, the elastomeric motor mount 60 reduces shock loads and vibrations. Moreover, the scroll housing 50 may be formed of glass-filled polypropylene to further reduce vibrations.

[0039] Referring now to Figure 7, the fan 46 includes a plurality of curved blades 64 and a hub portion 66. The curved blades 64 of the fan 46 encourage air into the scroll housing 50. The blades 64 are further defined as centrifugal fan blades having a foil cross-section, i.e., the blades 64 taper along their length. This configuration moves air more efficiently and more quietly than blades 64 with a constant thickness. The foil cross-section of each of the blades 64 preferably has an angle of attack of from 30 to 50 degrees. The fan 46 is preferably formed of glass-filled polypropylene, more preferably 30% glass-filled polypropylene.

[0040] Referring back to Figure 4, the scroll housing 50 includes a base portion 68 and an outer wall 70 circumferentially extending around the base portion 68. The outer wall 70 includes an upper edge 72. The scroll housing 50 further includes at least one air inlet 74 and at least one air outlet 76. In the preferred embodiment, the scroll housing 50 includes a plurality of air outlets 76, i.e., at least two air outlets 76. Other embodiments of the present invention (not shown) may also only include the fan module 42 without the scroll housing 50. In such embodiments, the at least one air inlet 74 and the at least one air outlet 76 can be described as components of the fan module 42.

[0041] The scroll housing 50 of the preferred embodiment may include an inclined surface 78 (or cutoff) along the outer wall 70 at one or more of the air outlets 76. The inclined surface 78 in the preferred embodiment is inclined relative to a rotational axis of the fan 46 and motor 48. The inclined surface 78 moves air more efficiently through the air outlet 76. In effect, a blade-pass frequency at each air outlet 76 employing the inclined surface 78 is altered such that at least two blades 64

5 pass the air outlet 76 simultaneously. The outer wall 70 is preferably wrapped outwardly away from the fan 46 at the outlet with the inclined surface 78 such that a flange portion 80 of the outer wall 70 defines the inclined surface 78. Preferably, the outer wall 70 is rounded at the flange portion 80 to provide a smooth transition to the air outlet 76. This reduces noise from the air flowing through the air outlet 76.

[0042] Referring again to Figure 2, the helmet assembly 22 further includes an intake grid 82 mounted to the outer shell portion 32. The intake grid 82 includes a top surface 84 spaced from the outer shell portion 32 of the helmet assembly 22. The intake grid 82 is contoured to the outer shell portion 32 between the front and rear of the shell 28. Air is drawn into the scroll housing 50 through the intake grid 82 by the fan 46. The blades 64 of the fan 46 are dimensioned such that a top of each of the blades 64 is from about 0.14 to 0.20 inches below the upper edge 72 of the outer wall 70 of the scroll housing 50. This provides clearance between the blades 64 and the outer shell portion 32 above, which results in low noise and high efficiency.

[0043] The air inlet 74 of the scroll housing 50 is in direct communication with a hole 86 formed within the outer shell portion 32 of the shell 28 for drawing air into the scroll housing 50. In alternative embodiments of the present invention, an external structure, not shown in the Figures, can be mounted external to the helmet assembly 22 to establish the air inlet 74 of the scroll housing 50 for drawing air into the scroll housing 50. The hole 86 formed in the outer shell portion 32 may be circular in shape. The diameter of the hole 86 may be sized in relation to a diameter of the fan 46 such that only a portion of the fan 46 diameter is exposed when viewed through the air inlet 74 in the outer shell portion 32. This ratio of air inlet 74 diameter to fan 46 diameter may be from 1:2 to 1:1, more preferably, from 1:1.5 to 1:1.1.

[0044] Referring to Figure 4, a support pedestal 88 protrudes from the motor mount 60. Preferably, the support pedestal 88 is integrally formed as a part of the motor mount 60, which is fixed to the base portion 68. Alternatively, it is also to be understood that the support pedestal 88 can be a separate part. That is, the support pedestal 88 can be a separate part that is mounted or connected to the base portion 68 of the scroll housing 50 via connecting screws, snap-fit, and the like. The hub portion 66 of the fan 46 is rotatably mounted in the scroll housing 50 about the support

pedestal 88. The motor 48 of the fan module 42 is mounted within an underside of the support pedestal 88 for space-saving purposes in the helmet assembly 22. As appreciated, the underside of the support pedestal 88 is essentially hollow. The motor 48 shaft protrudes through an opening in the support pedestal 88 to rotatably engage 5 the fan 46. The cover plate 54 operates as a motor 48 cover to close the fan module 42 at the inner shell portion 30. The motor 48 has a pair of bearings, as will be appreciated by those skilled in the art. The fan 46 is configured with a center of gravity that is centered between the motor 48 bearings. This reduces force moments about the motor 48 bearings thus reducing stress to the motor 48 bearings. In essence, 10 loads on the fan 46 are thus shared between the motor 48 bearings.

15 [0045] In operation, the motor 48 rotates the fan 46 to draw air into the air inlet 74 of the scroll housing 50 through the intake grid 82 and the air inlet 74 in the outer shell portion 32 and distributes air out of the scroll housing 50 through the air outlet 76 or outlets and into the air flow channel 34 where the air is distributed about the head 24 of the user. Cutoffs (in some embodiments, inclined cutoffs as 20 previously described) cut the air as the fan 46 moves the air within the scroll housing 50. More specifically, as shown in the Figures, the present invention incorporates several air flow cutoffs in the scroll housing 50 to cut the air. A power supply is incorporated in the present invention to power the motor 48 to rotate the fan 46 via the motor 48 shaft. Preferably, the power supply is a rechargeable DC battery. Also preferred, the power supply is disposed within, i.e., integrated into, the helmet assembly 22. In such a case, the power supply is referred to as an integral power supply. Alternatively, the power supply can be mounted to the body 26 of the user 25 (not shown). The power supply powers the motor 48 through pulse width modulation (PWM) which will be discussed further below. The design of the scroll housing 50 provides more efficient movement of air with less power being required from the power supply overall. Furthermore, in addition to such reduced power requirements, the scroll housing 50 provides that sufficient air flow can be maintained with overall less air velocity. This results in a quieter helmet assembly 22.

30 [0046] With respect to the at least two air outlets 76, the outer wall 70 of the scroll housing 50 is partitioned to define the air outlets 76. In the preferred embodiment of the present invention having the at least two air outlets 76, it is to be understood that the present invention is not limited to at least two air outlets 76. That

is, the present invention may include, for example, three or four air outlets 76. The air outlets 76 provide a complete balance of air as the air is distributed from the scroll housing 50 about the head 24 of the user. To accomplish this, the helmet assembly 22 includes at least two helmet air exits 90, 92 in fluid communication with the air flow channel 34. The air outlets 76 are in fluid communication with the at least two helmet air exits 90, 92 to distribute the air from the air outlets 76, which is in the air flow channel 34, toward the head 24 of the user. In the preferred embodiment of the present invention where the helmet assembly 22 includes the at least two helmet air exits 90, 92 it is not critical that the scroll housing 50 include at least two air outlets 76. To the contrary, the scroll housing 50, in these embodiments, may only have at least one air outlet 76. Furthermore, the helmet assembly 22 may also have only one air exit.

[0047] In an alternative embodiment, at least one air bleed valve (not shown) may be incorporated in the scroll housing 50 to influence the amount, or the volume, of air flowing into the air flow channel 34 from each of the air outlets 76. This is shown in the '019 patent to Diaz et al.

[0048] In the preferred embodiment, as best shown in Figure 2, the air exits 90, 92 are a front air exit 90 and a rear air exit 92 in that they are disposed at a front section 94 and a rear section 96 of the helmet assembly 22, respectively, to effectively distribute air toward both the face and neck of the user. However, in alternative embodiments, the air exits 90, 92 can be disposed in alternate locations to distribute air toward any portion of the user's head 24. For instance, the air exits 90, 92 can be side air exits 90, 92 such that air is distributed toward the side of the user's head 24. For descriptive purposes only, the present invention will be described below only in terms of front and rear air exits 90, 92 and will be numbered accordingly. More specifically, the front air exits 90 are disposed at the front section 94 for distributing air from the air flow channel 34 toward the front of the head 24 of the user, and the rear air exits 92 are disposed at the rear section 96 for distributing air from the air flow channel 34 toward the back of the head 24 of the user.

[0049] Still referring to Figure 2, the air flow channel 34 defined between the inner and outer shell portions 30, 32 terminates at the front section 94 with the front air exits 90. More specifically, the inner and outer shell portions 30, 32 converge toward the front section 94 to define the front air exits 90. The front air

5 exits **90** may have an air deflector (not shown) defined between the outer shell portion **32** and the inner shell portion **30** wherein the outer shell portion **32** angles toward the inner shell portion **30** at the front air exits **90** for proper deflection of air toward the front of the head **24** of the user. Such an air deflector is best shown in the '019 patent to Diaz et al. The air flow channel **34** diverges upon approaching the front air exits **90**. The convergence and divergence of the air flow channel **34** maintains a balanced flow of air about the user's head **24**. Ultimately, this also has the effect of minimizing or even completely eliminating noise within the helmet assembly **22** due to the air flow.

10 [0050] The rear air exits **92** are incorporated in a nozzle assembly **98** (also referred to as a duct **98** or a duct assembly **98**). Referring to Figure 9, the nozzle assembly **98** includes a nozzle **100** with rotatably adjustable nozzle tips **102**. The nozzle **100** is mounted to the scroll housing **50** such that a wall **104** of the nozzle **100** is disposed in the air flow channel **34** and diverts air from at least one of the air outlets **76** into at least one port **106**, preferably two. The ports **106** may be referred to herein 15 as conduit-defining discharge members **106**, or simply discharge members **106**. The ports **106** feed air to the rotatably adjustable nozzle tips **102** and the rear air exits **92** are defined in the nozzle tips **102**. As shown in Figure 2, the nozzle tips **102** and rear air exits **92** extend below the front air exits **90** and direct air against the neck of the user, when the personal protection system is mounted to the user. As described below, the 20 rear air exits **92** also extend below a head support assembly **108** of the helmet assembly **22**.

25 [0051] Referring to Figure 10, each of the nozzle tips **102** includes a nozzle head **110** defining the rear air exits **92** of the nozzle tip **102**. Each of the nozzle tips **102** also includes a pair of snap-locking fingers **112** for rotatably locking the nozzle tip **102** to the nozzle **100**. Referring to Figure 11 along with Figure 10, the nozzle **100** includes a inner flange **114** disposed in each of the ports **106** and the snap-locking fingers **112** are axially retained by the inner flange **114** once snap-locked to the nozzle **100**. The nozzle tip **102** includes an outer flange **116** that abuts a distal end of the nozzle **100** to further axially retain the nozzle tip **102**, while a cylindrical 30 shoulder **118** of the outer flange **116** fits inside the port **106** to rotatably support the nozzle tip **102** therein. The snap-locking fingers **112** extend from the shoulder. In addition, a plurality of detent fingers **120** extend from shoulder to ride along a

plurality of corrugations 122 defined in an inwardly protruding surface of the inner flange 114. This allows the nozzle tips 102 to rotate in the nozzle 100 in a stepped and controlled manner to prevent incidental rotation of the nozzle tips 102. The nozzle tips 102 can be adjusted to change the direction of airflow toward or away 5 from the neck of the user, based on the user's preference. In alternative embodiments, an adjustable deflector (not shown) could be incorporated in the nozzle tips 102 to further vary the location on the user's neck at which the air is directed from the rear air exits 92.

[0052] The nozzle 100 is preferably formed of ABS, while the nozzle 10 tips 102 are preferably formed of LEXAN® polycarbonate. Of course, the nozzle 100 and nozzle tips 102 may be formed of other suitable materials known to those skilled 10 in the art.

[0053] Referring to Figures 12 and 13, alternative nozzles 100 and 15 adjustable air flow volume mechanisms for use therewith are shown. Referring first to Figure 12, a first alternative nozzle 100 is shown as including an aperture 124. The aperture 124 is adapted to slidably receive an arm 126 of an airflow closer 128 disposed in the air flow channel 34. A user of the helmet assembly 22 may adjust the air flow volume out through the ports 106, and subsequently through the rear air exits 92 by varying the position of the airflow closer 128. By sliding the arm 126 in the 20 aperture 124, the user can adjust a position of a baffle 130 of the air flow closer. As the baffle 130 is adjusted toward the air outlet 76 of the scroll housing 50, the air flow through the air outlet 76 to the nozzle 100 is reduced, and vice versa. The airflow closer 128 may be positioned at a fully open position, a fully closed position, or at any 25 number of intermediate positions therebetween.

[0054] Referring to Figure 13, the nozzle 100 includes a nozzle vent 132 and the adjustable air flow volume mechanism is in the form of a slider 134. The slider 134 is movable between a plurality of positions. In a wide open position, a slider vent 136 in the slider 134 is lined-up with the nozzle vent 132 in the nozzle 100. As a result, a large air flow volume from the air outlet 76 of the scroll housing 50 is 30 released from the nozzle 100 before reaching the ports 106. This significantly reduces the air flow volume through the rear air exits 92. In a fully closed position, the nozzle vent 132 is closed by a panel 138 of the slider 134 and the full air flow volume from the air outlet 76 in the scroll housing 50 is directed to the rear air exits 92. A knob

140 is attached to the slider **134** through a slot in the nozzle **100** and is used by the user to vary the position of the slider **134** and control the air flow volume.

5 [0055] A method of maintaining a constant volume of air flowing into the helmet assembly **22** during or throughout the entire use of the personal protection system **20** by the user is provided by the present invention. The method includes the step of selectively activating and deactivating the power supply as detailed in the '677 patent.

10 [0056] Referring again to Figure 3, an adjustable head support assembly **108** assists in minimizing the strain on the head **24** and the neck of the user. Strain and torque on the head **24** and neck of the user is minimized by maintaining the weight of the fan module **42** over the neck of the user even upon adjustment of the helmet assembly **22** to fit various sized heads **24**. The head support assembly **108** includes a rear support **142** that rigidly extends from the shell **28** and is connected to the rear section **96**. It is to be understood that the rear support **142** can be a separate 15 part that is connected to the helmet assembly **22** or can be an integral part of the helmet assembly **22**. In the preferred embodiment, the rear support **142** is connected to and extends from the rear section **96** of the inner shell portion **30**. However, it is to be understood that the rear support **142** can connect to and extend from any portion of the shell **28**.

20 [0057] Viscoelastic foam pads (not shown) may be applied to the helmet assembly **22** at various locations to provide a comfortable barrier between the user and the helmet assembly **22**. In the preferred embodiment, the materials used to form the helmet assembly **22**, particularly the materials used to form the shell **28**, scroll housing **50**, and the fan **46**, were selected based on their sound-dampening 25 characteristics. The stiffness of these materials was selected to reduce vibration and change the frequency of transmitted sound to more appeasing frequencies.

30 [0058] Referring back to Figure 1, the personal protection system **20** includes a hood **144** for covering the helmet assembly **22**, which houses the head **24** of the user. The hood **144** operates as a filter medium to filter air between the user and the external environment as described in the '019 patent.

[0059] Referring now to Figure 14, the present invention also includes a face shield **146** that permits the user to view through the hood **144** and the facial

opening 38 of the helmet assembly 22. The face shield 146 may include anti-reflective and/or anti-refractive coatings to enhance vision through the face shield 146. The face shield 146 is mounted to the hood 144 such that the face shield 146 covers the facial section 36 and the facial opening 38 of the helmet assembly 22 once 5 the user dresses into the personal protection system 20. More specifically, the face shield 146 is attached to the hood 144 to maintain a complete barrier between the user and the external environment. The facial opening 38 of the helmet assembly 22 essentially receives the face shield 146. Preferably, the facial section 36 of the helmet assembly 22 includes a hook-and-loop fastener to further facilitate attachment of the 10 face shield 146 to the facial section 36 for covering the facial opening 38.

[0060] Referring to Figure 15, the face shield 146 incorporated into the hood 144 or gown preferably includes at least one removable or peelable layer 150 that provides an easier and effective manner of removing debris accumulated on the face shield 146 during use. This will eliminate the need to wipe the face shield 146 of 15 the accumulated debris during use. In the most preferred embodiment, multiple removable layers 150 are used. These removable layers 150 would be delivered to the user in a sterile fashion with the face shield 146 being sterilized between the removable layers 150 so that no contaminates are present or exposed after removing the removable layers 150 away from the face shield 146. The removable layers 150 20 are transparent and preferably flexible. In one embodiment, the removable layers 150 are thin, flexible, and conform to the shape of the face shield 146. Furthermore, air gaps between the removable layers 150 are minimized to reduce multiple reflected/refracted images. Preferably, the removable layers 150 are sterilized using gamma radiation. In the preferred embodiment, the face shield 146 and removable layers 150 are 25 assembled. The face shield 146 and removable layers 150 are then sterilized with gamma radiation. The sterilized face shields 146 with removable layers 150 are then attached to the hood 144 in a clean room environment. The hood 144 or gown with the attached face shields 146 are then individually packaged and sterilized with ethylene oxide.

30 [0061] However, in an alternative embodiment, the removable layers 150 may be sterilized with Ethylene Oxide (EtO) gas. In this embodiment, the removable layers 150 must be breathable for effective EtO gas sterilization.

[0062] In one embodiment, the removable layers **150** are attached directly to the face shield **146** using a self-adhering method of attachment such as static forces, transparent adhesive, and the like. As shown, the removable layers **150** may include peel tabs **152** that the user or an assistant can grab to peel-away the removable layers **150** from the face shield **146**. The tabs **152** can be positioned at any portion of the removable layers **150** such as at the top for “peel down” removal, at the bottom for “peel up” removal, or at the side for “peel across” removal. Furthermore, each of the removable layers **150** may have multiple tabs **152**. The removable layers **150** preferably include anti-reflective and/or anti-refractive coatings to improve vision by reducing multiple images. In one embodiment, the removable layers **150** are formed from a 1 to 5 mil clear urethane film. In further embodiments, the removable layers **150** are formed of polyester, e.g., Mylar[®], or other gamma radiation stable materials to reduce or eliminate air layers **150** between adjacent removable layers **150**.

[0063] In an alternative embodiment, the removable layers **150** are thin and semi-rigid or rigid and conform to the shape of the face shield **146**, while still minimizing the air gap between adjacent removable layers **150**. The removable layers **150** may be formed as a semi-rigid or rigid film. In this embodiment, the removable layers **150** may be attached at a periphery of the face shield **146** in a non-continuous manner such as by adhesive, tape, spot-welding, static cling attachment, or other conventional methods of attachment. This allows EtO gas to penetrate the periphery for terminal sterilization between the removable layers **150**. In this embodiment, the removable layers **150** may be manufactured in a flat configuration and then wrapped to conform to the curvature of the face shield **146**, which minimizes the air gaps between the removable layers **150** to reduce unwanted images when looking through the face shield **146** and the removable layers **150**. The removable layers **150** in this embodiment may also include anti-reflective and/or anti-refractive coatings to improve vision and may also include tabs **152** to remove the removable layers **150**.

[0064] In further embodiments, the removable layers **150**, whether thin and flexible or thin and semi-rigid or rigid, may be polarized using a polarized coating. The removable layers **150** may also include magnification coatings to improve the user’s view. Magnification may be carried out solely by the removable

layers **150**, or in alternative embodiments, magnification may be carried out by a combination of the removable layers **150** and the face shield **146**. In even further embodiments, magnification is carried out solely by the face shield **146**. In addition, the removable layers **150** may provide UV protection by using UV inhibiting films or adhesives.

5 [0065] The face shield **146** may be packaged with multiple removable layers **150** ready for removal from the face shield **146** during use. However, in some instances it may be beneficial to provide a user with greater flexibility in selecting the types of removable layers **150** to be used, e.g., thin and flexible or thin and semi-rigid or 10 rigid, or to provide the user the option of selecting whether the removable layers **150** will be used at all. To this end, each removable layer **150** (flexible, semi-rigid, or rigid) is packaged separately from the face shield **146** incorporated into the hood **144** or gown. As a result, the user can choose, which, and how many, of the removable layers **150** to 15 attach to the face shield **146** prior to use. Alternatively, a removable layer **150** (flexible, semi-rigid, or rigid) may be separately packaged and formed with anti-reflective, anti-refractive, and/or magnification coatings to improve image quality for the user. In this instance, the coatings may work with complementary coatings on the face shield **146** to improve the image quality for the user, or the removable layer **150** may be the sole source of these coatings.

20 [0066] In the event that the removable layers **150** are separately packaged, they will also be separately sterilized using either EtO gas sterilization, or preferably gamma radiation sterilization. When gamma radiation sterilization is used, the air layers **150** between adjacent removable layers **150** can be reduced or eliminated, which improves image quality through the removable layers **150**. The use of gamma 25 stable materials to form the removable layers **150** also improves optical clarity.

[0067] The present invention preferably includes a positioning and supporting system for assisting a single user in self-gowning as the user maintains sterility. This system is fully described in the '019 patent to Diaz et al. The present invention may also include a visual positioning system as disclosed in the '019 patent to 30 Diaz et al.

[0068] The scope of the claims should not be limited by particular embodiments set forth herein, but should be construed in a manner consistent with the specification as a whole.

CLAIMS:

1. A method of manufacturing a hood that is placed over a helmet of a personal protection system, said method of hood manufacture including the steps of:

5 providing a transparent face shield;

applying at least one transparent removable layer over the face shield using a method that allows the removable layer to be removed from the face shield during use of the hood, wherein said face shield and at least one transparent removable layer form a face shield-removable layer assembly;

10 sterilizing the face shield-removable layer assembly using gamma radiation;

after said sterilization of the face shield-removable layer assembly, attaching the sterilized face shield-removable layer assembly to a shell that includes at least a portion formed from a filter medium so as to construct the hood, wherein the at least one transparent removable layer is located on an outwardly facing surface of the face 15 shield;

packaging said hood, including both the shell and face shield-removable layer assembly, in a package; and

sterilizing the package and the shell with attached face-shield and removable layer therein with ethylene oxide.

20

2. The method of manufacturing a hood of claim 1, wherein the at least one transparent removable layer is formed from a polyester.

25

3. The method of manufacturing a hood of claim 1 or 2, wherein the package contains only one hood, said hood including the shell and face shield-removable layer assembly.

30

4. The method of manufacturing a hood of any one of claims 1 to 3, wherein the at least one transparent removable layer is formed from a gamma radiation stable material so that upon gamma radiation the at least one transparent removable layer maintains optical clarity.

5. The method of manufacturing a hood of any one of claims 1 to 4, wherein the face shield-removable layer assembly is sterilized in between the removable layers so that no contaminates are present or exposed after removing the removable layers away from the face shield.

5

6. The method of manufacturing a hood of any one of claims 1 to 5, wherein the at least one removable layer is thin, flexible, and conforms to a shape of the face shield.

7. The method of manufacturing a hood of any one of claims 1 to 6, wherein the
10 face shield is flexible.

8. The method of manufacturing a hood of any one of claims 1 to 7, wherein the at least one removable layer further includes at least one peel tab, wherein the at least one peel tab to peel-away the removable layers from the face shield.

15

9. The method of manufacturing a hood of claim 8, wherein the at least one peel tab is positioned at any top, bottom or side edge so that each removable layer may be peeled away in a downward, upward or sideward direction.

20 10. The method of manufacturing a hood of claim 1, wherein said hood is part of a gown.

11. The method of manufacturing a hood of claim 10, wherein said face shield is incorporated into said gown.

25

12. A packaged hood with transparent face shield that has at least one transparent removable layer attached to the face shield manufactured according to any one of claims 1 to 11.

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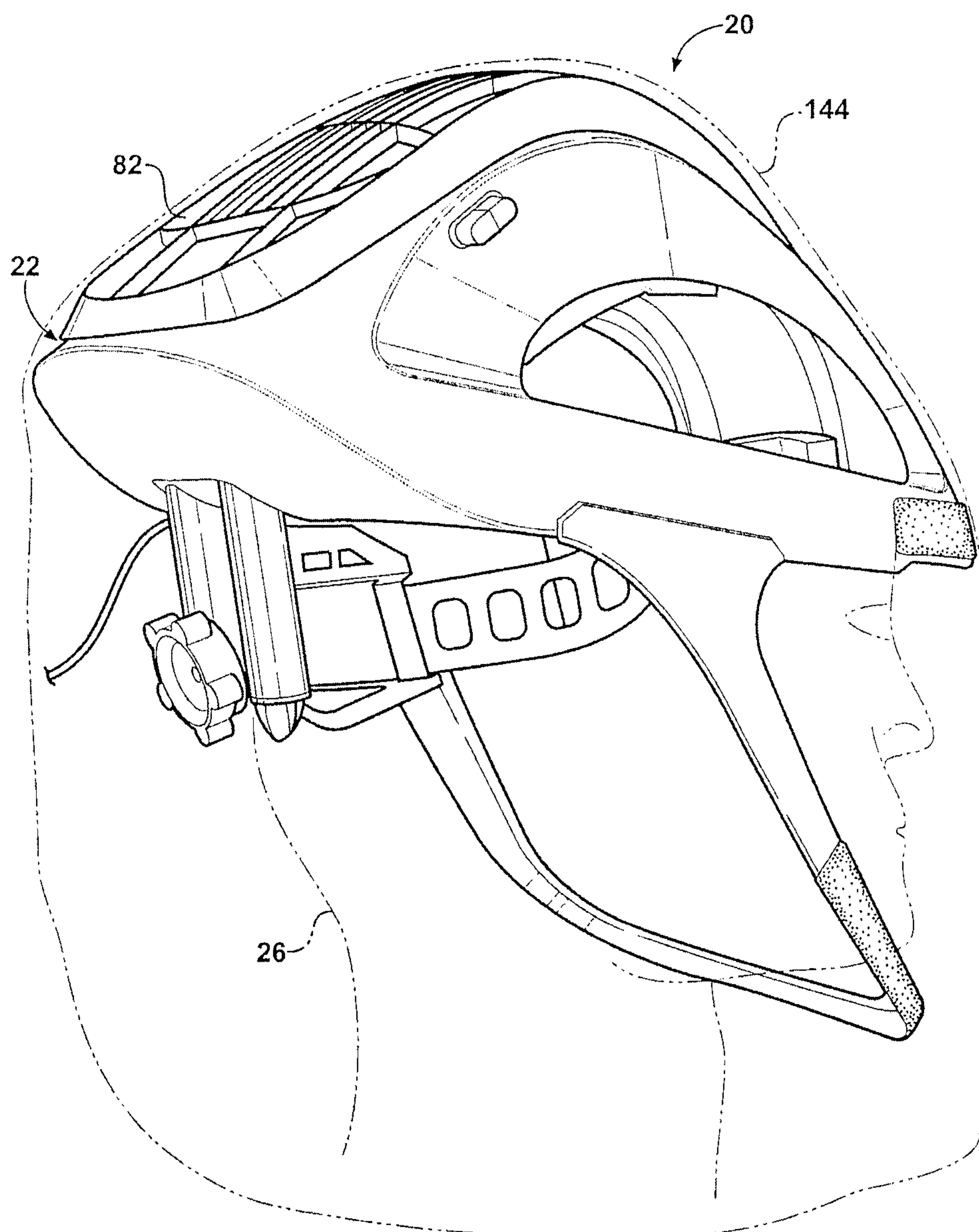
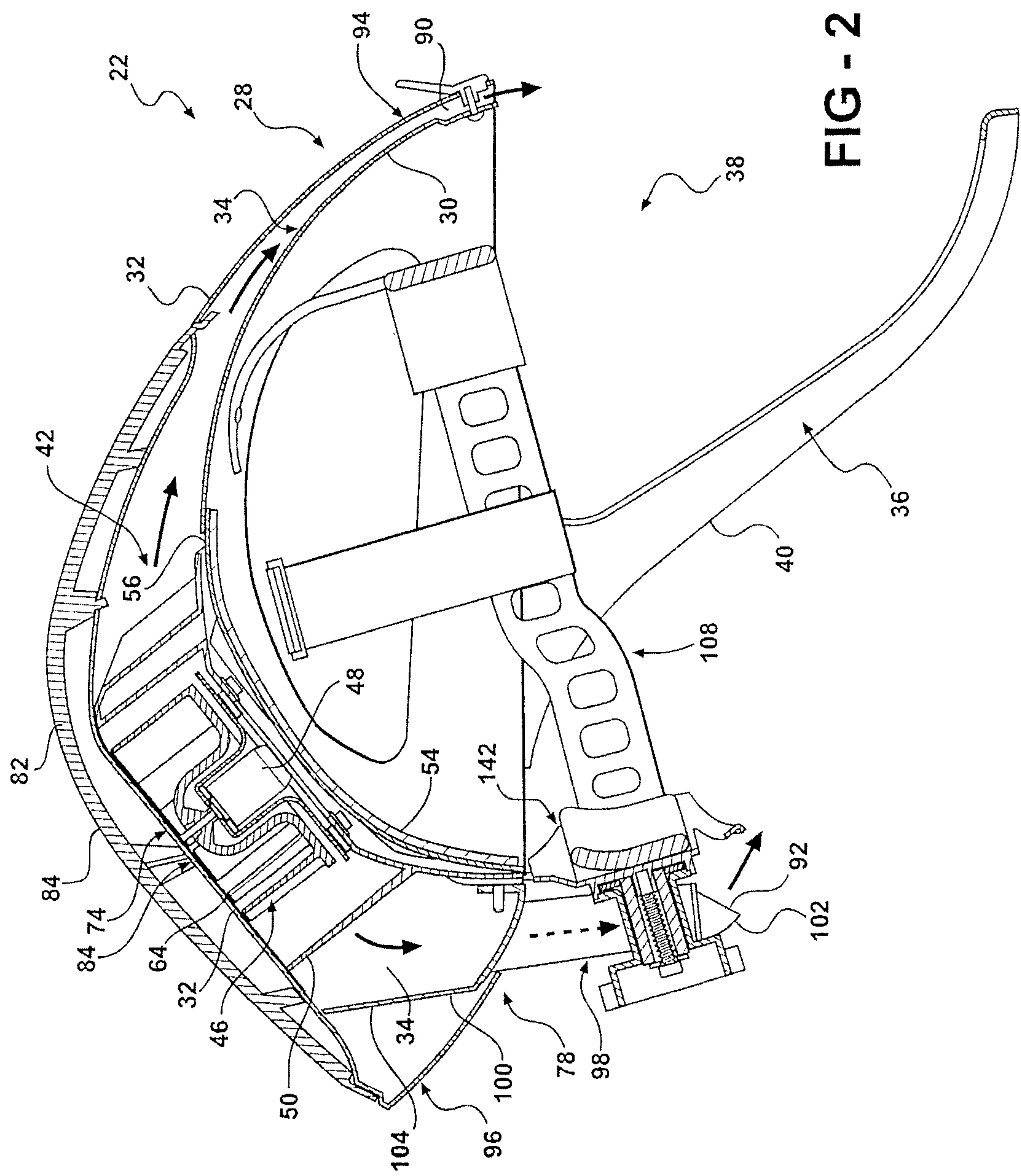
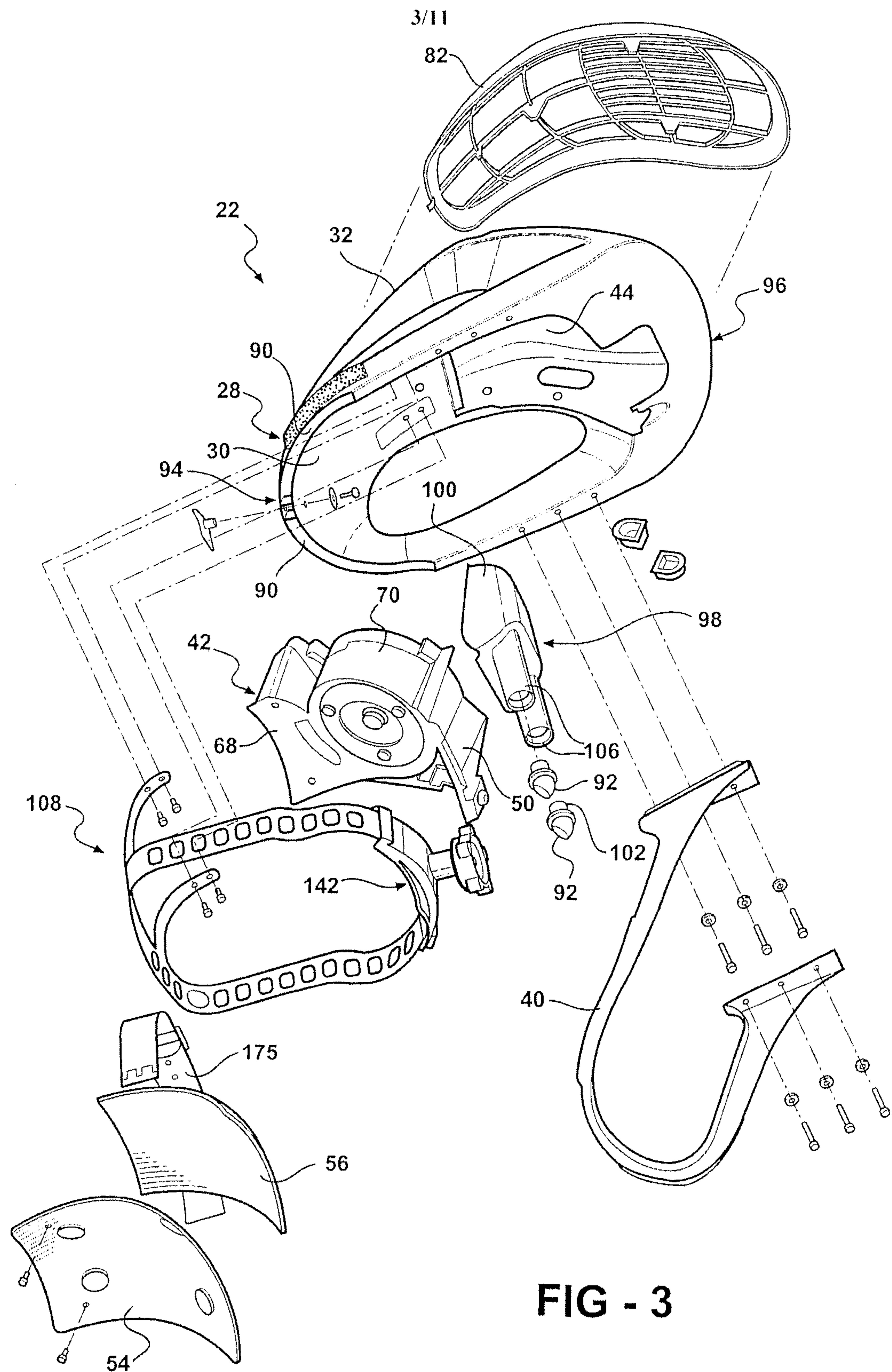
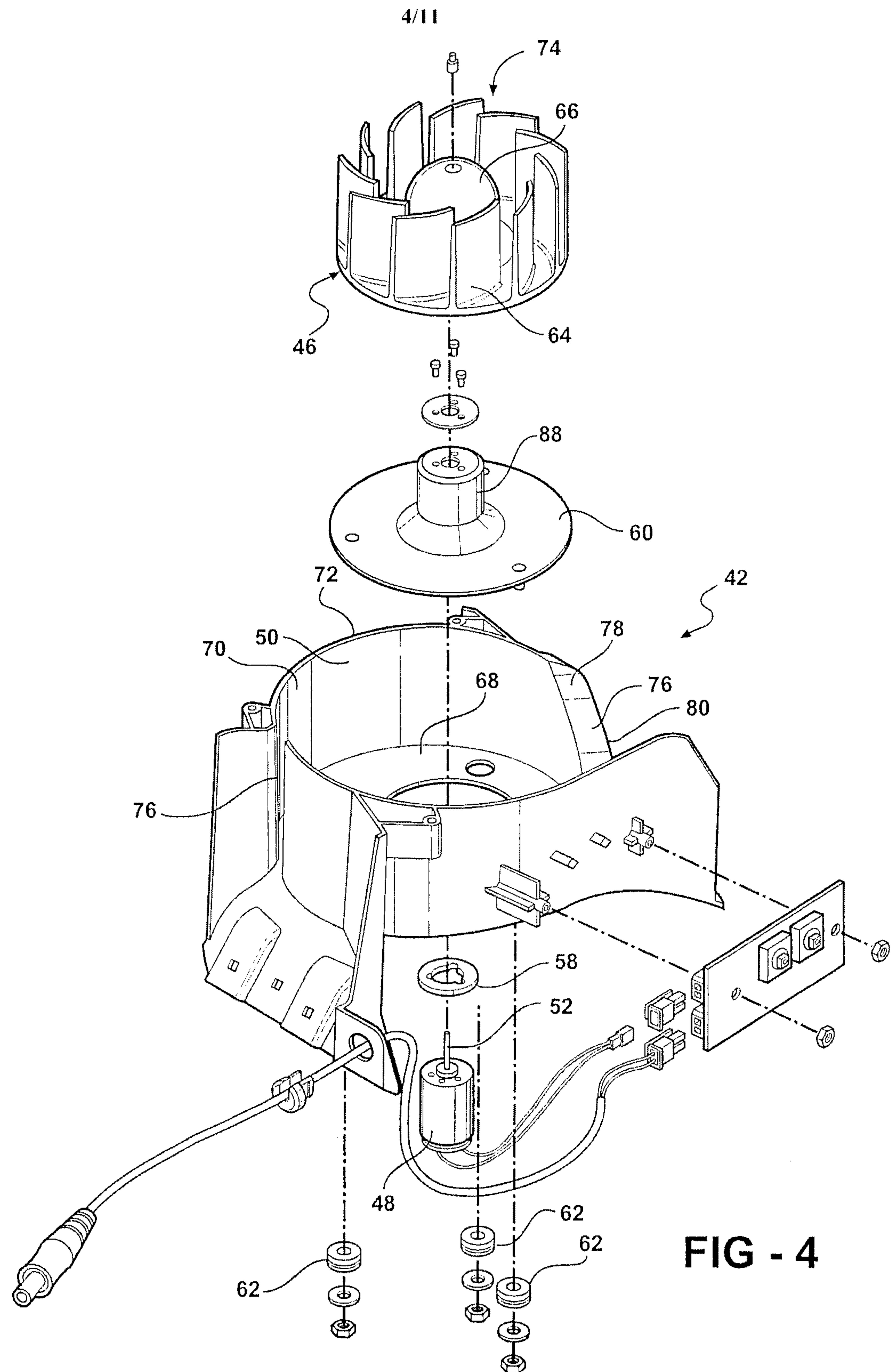


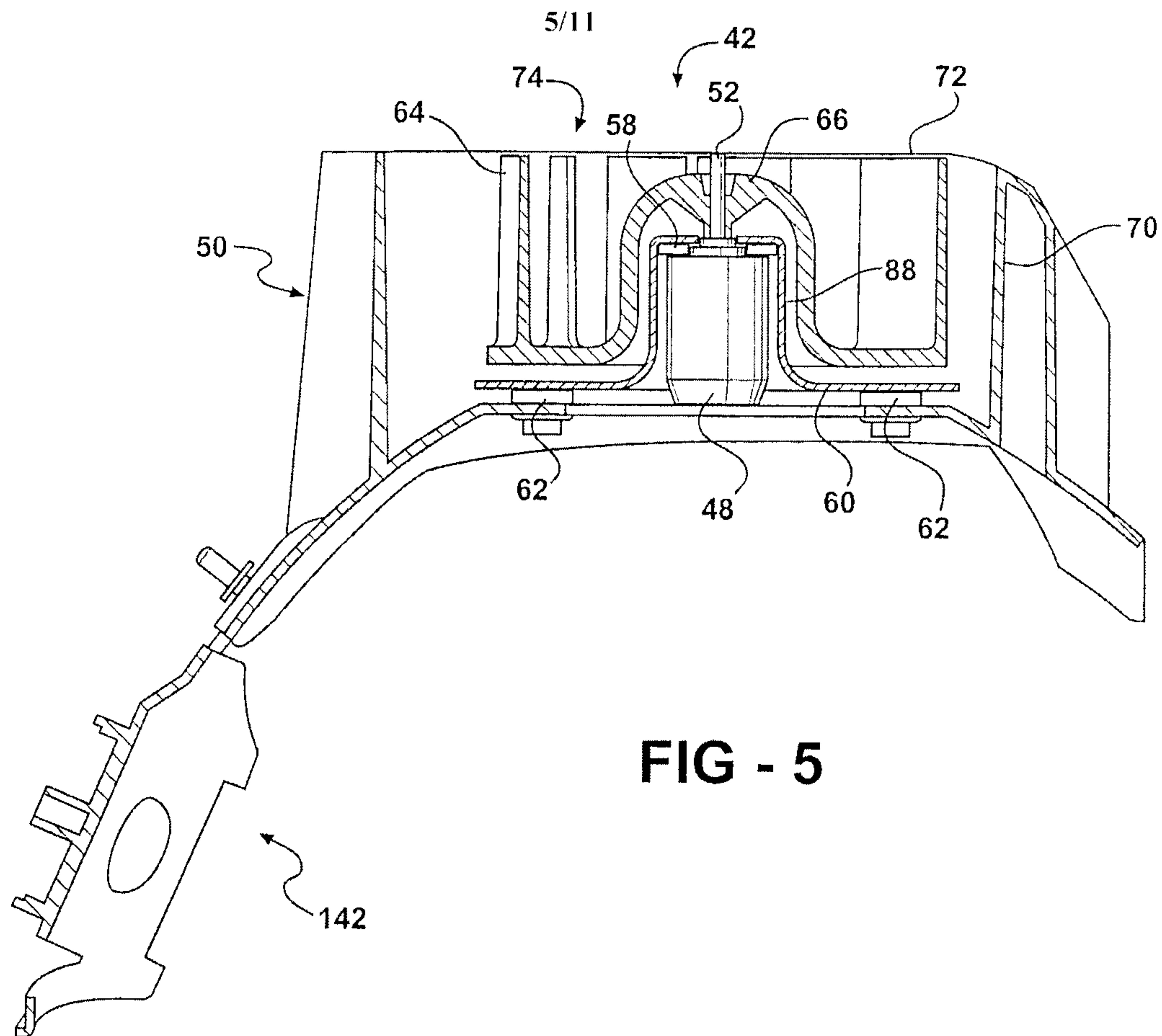
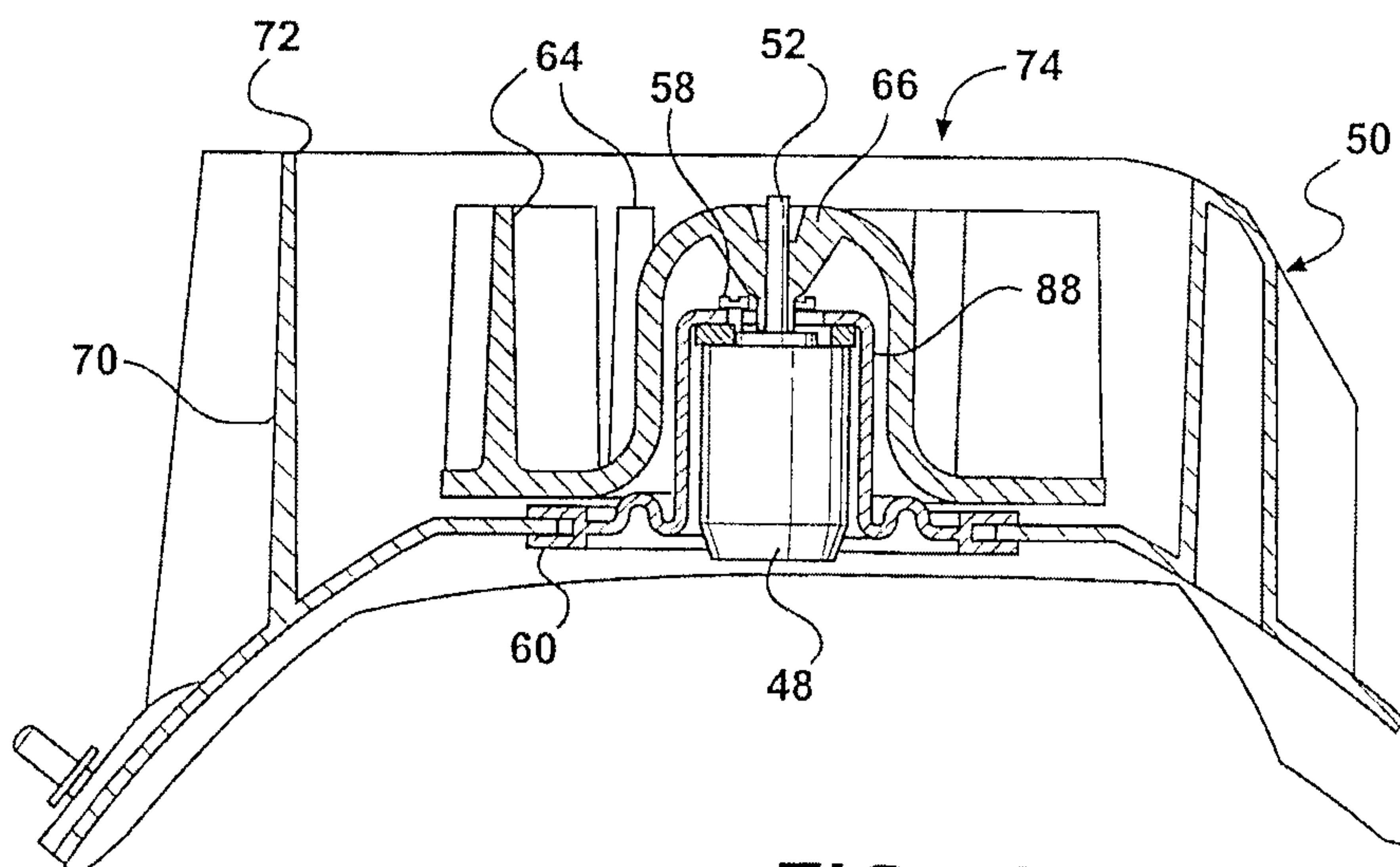
FIG - 1

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**FIG - 5****FIG - 6**

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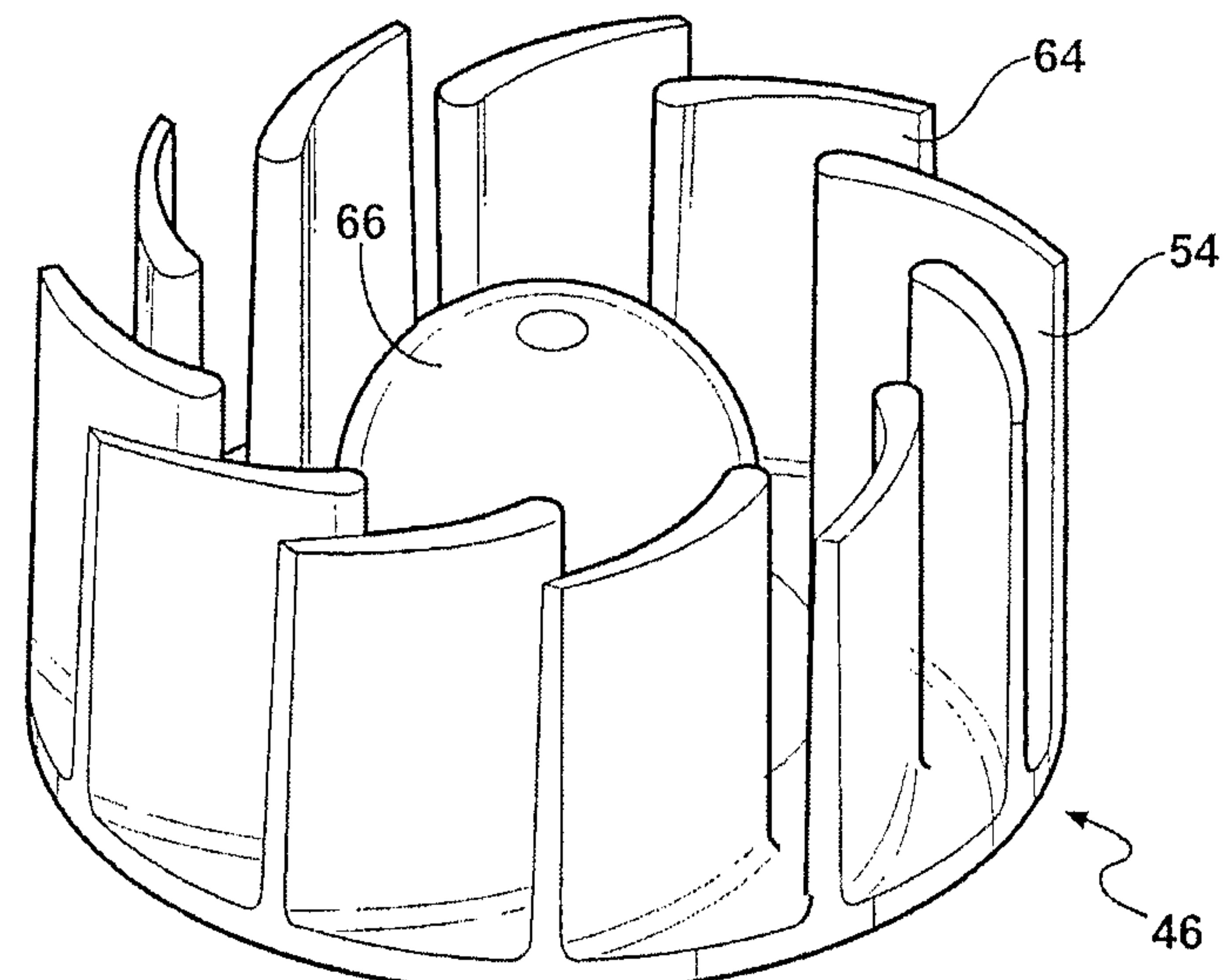


FIG - 7

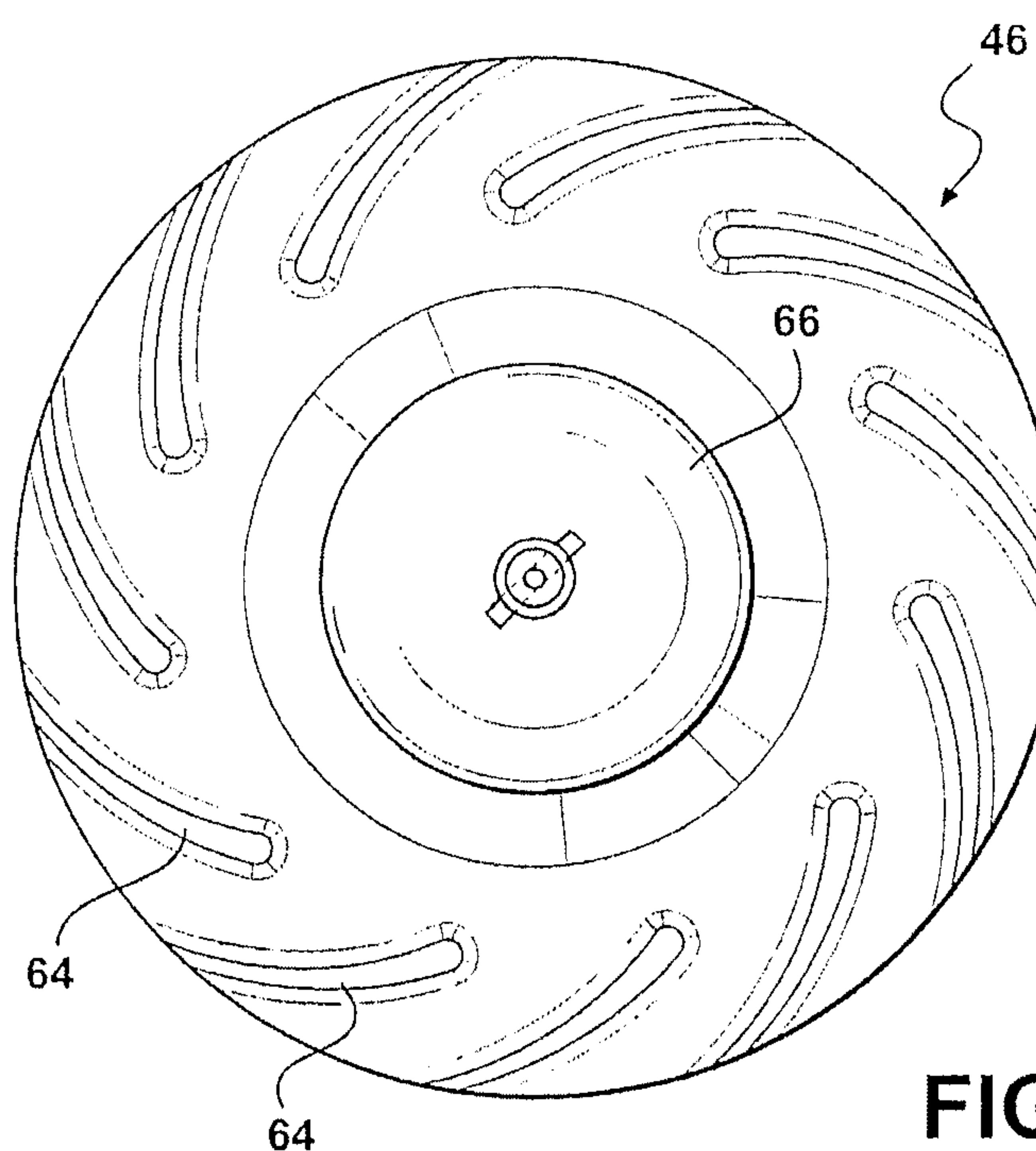
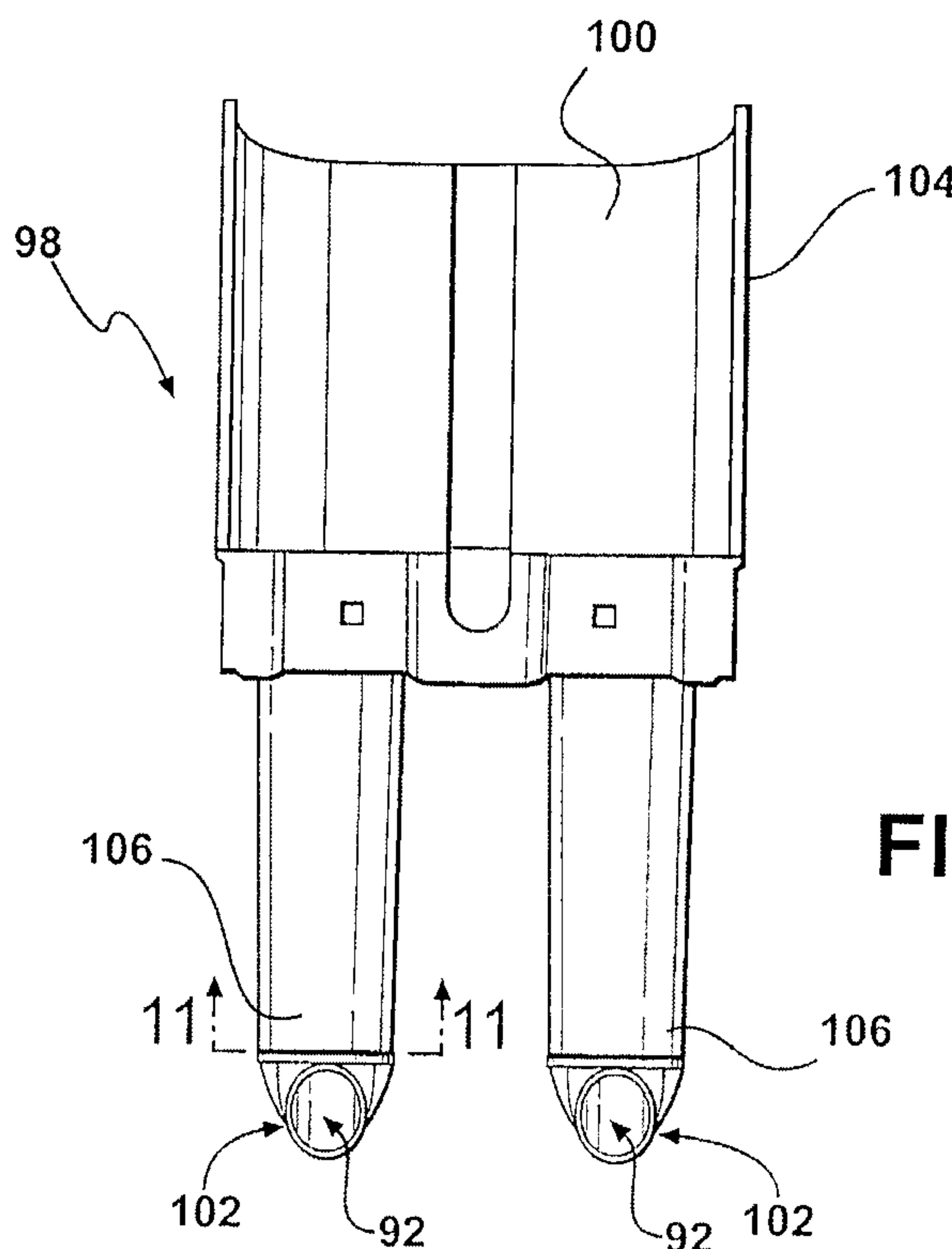
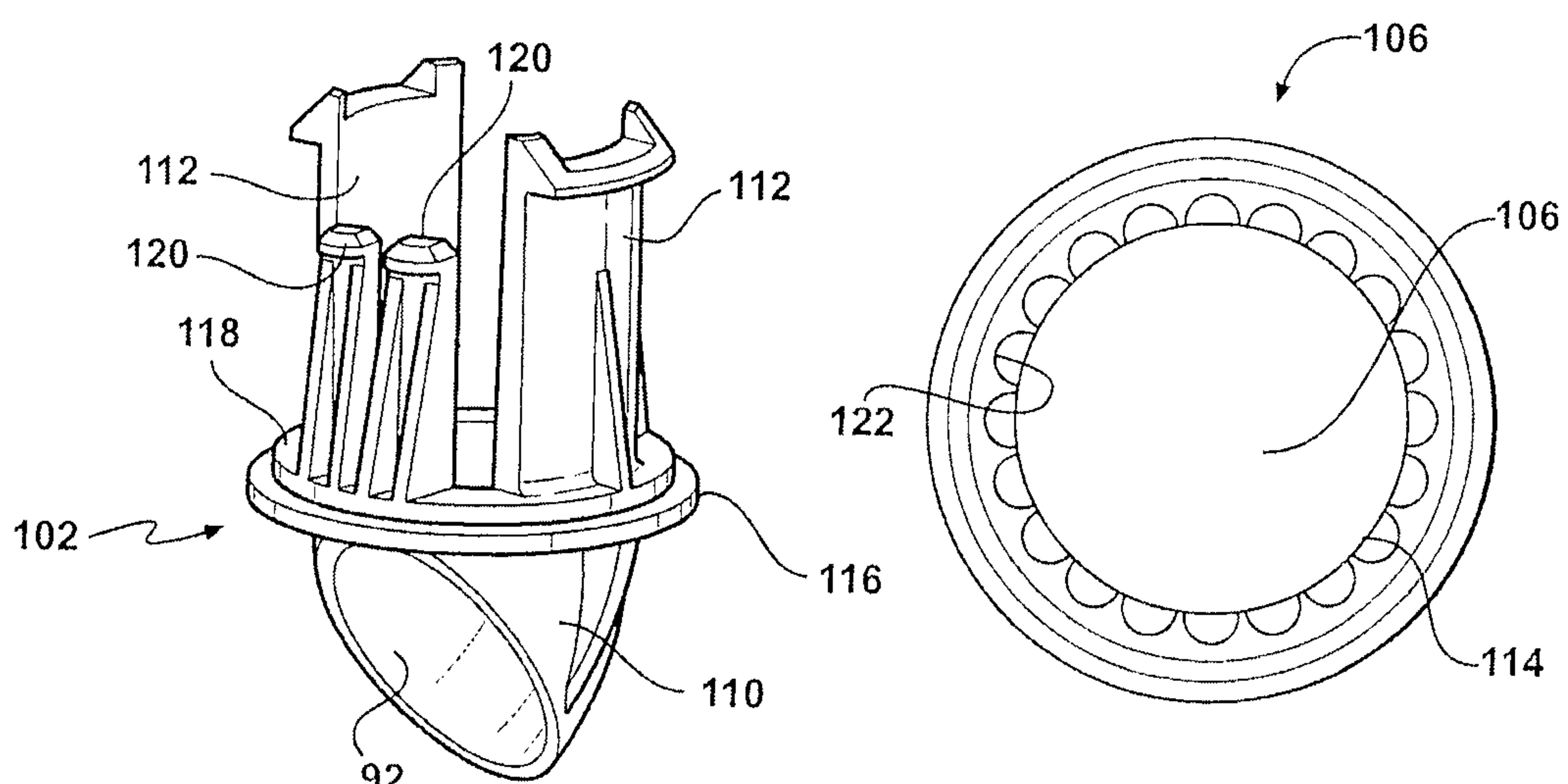
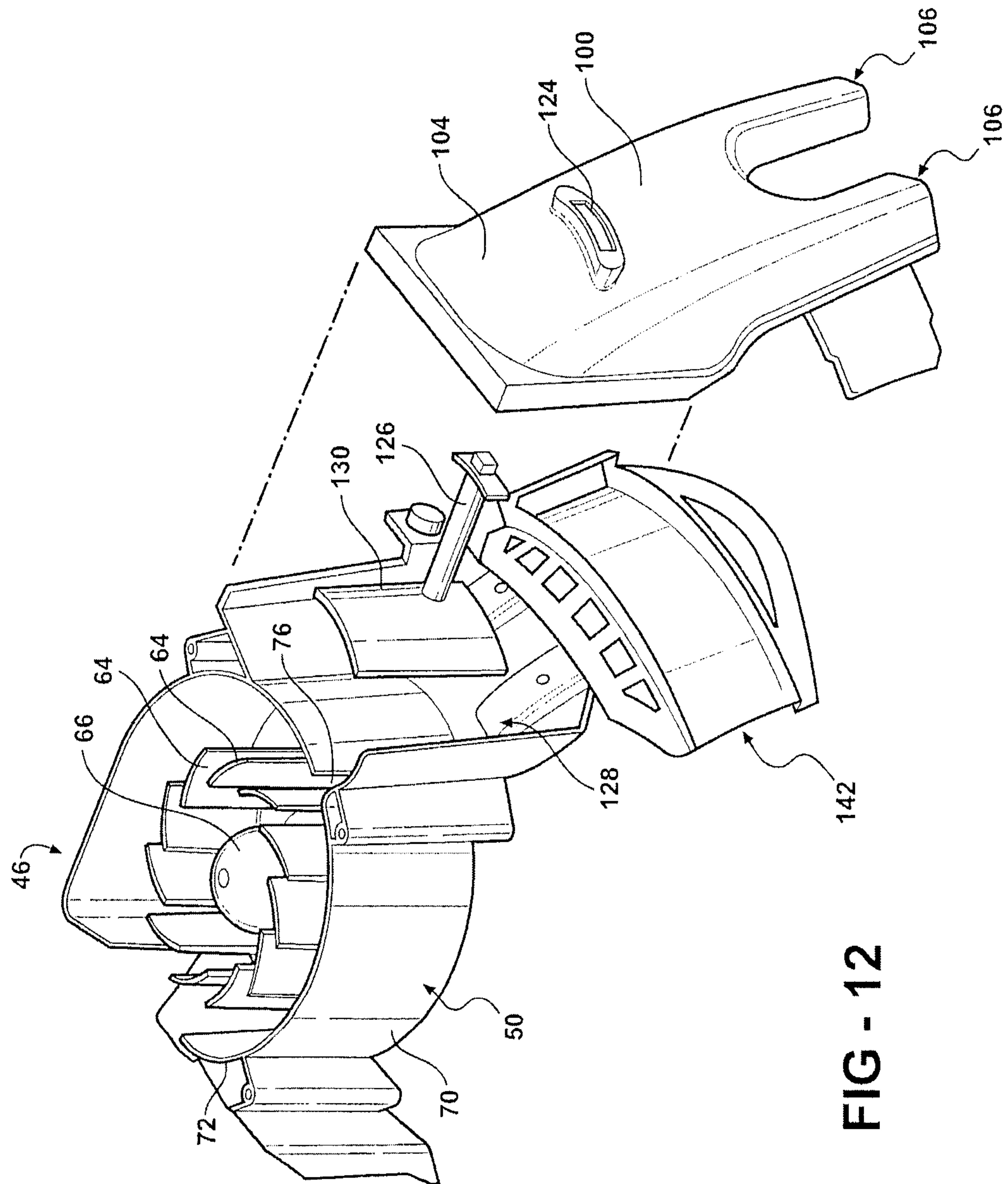


FIG - 8

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**FIG - 9****FIG - 10****FIG - 11**

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**FIG - 12**

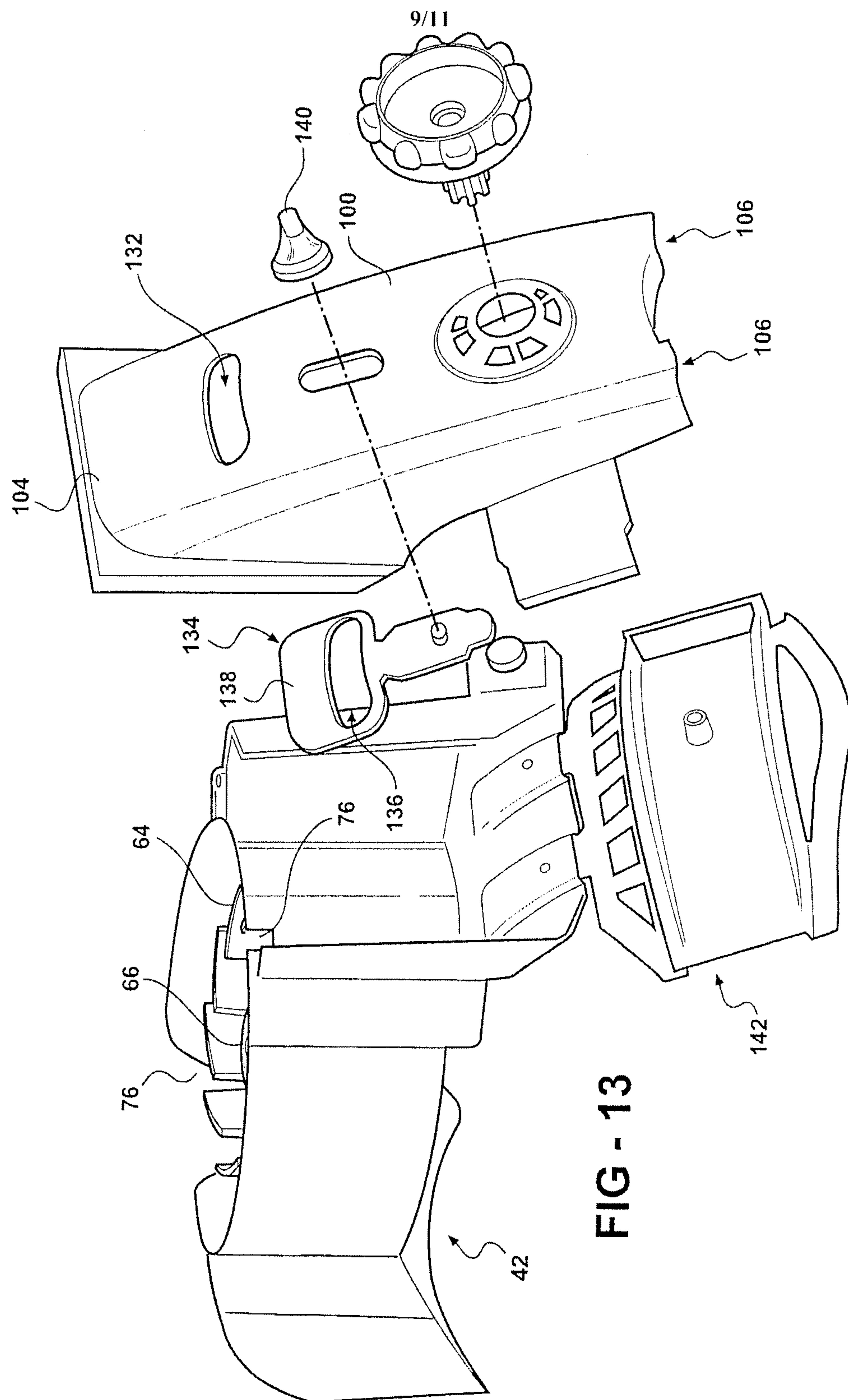
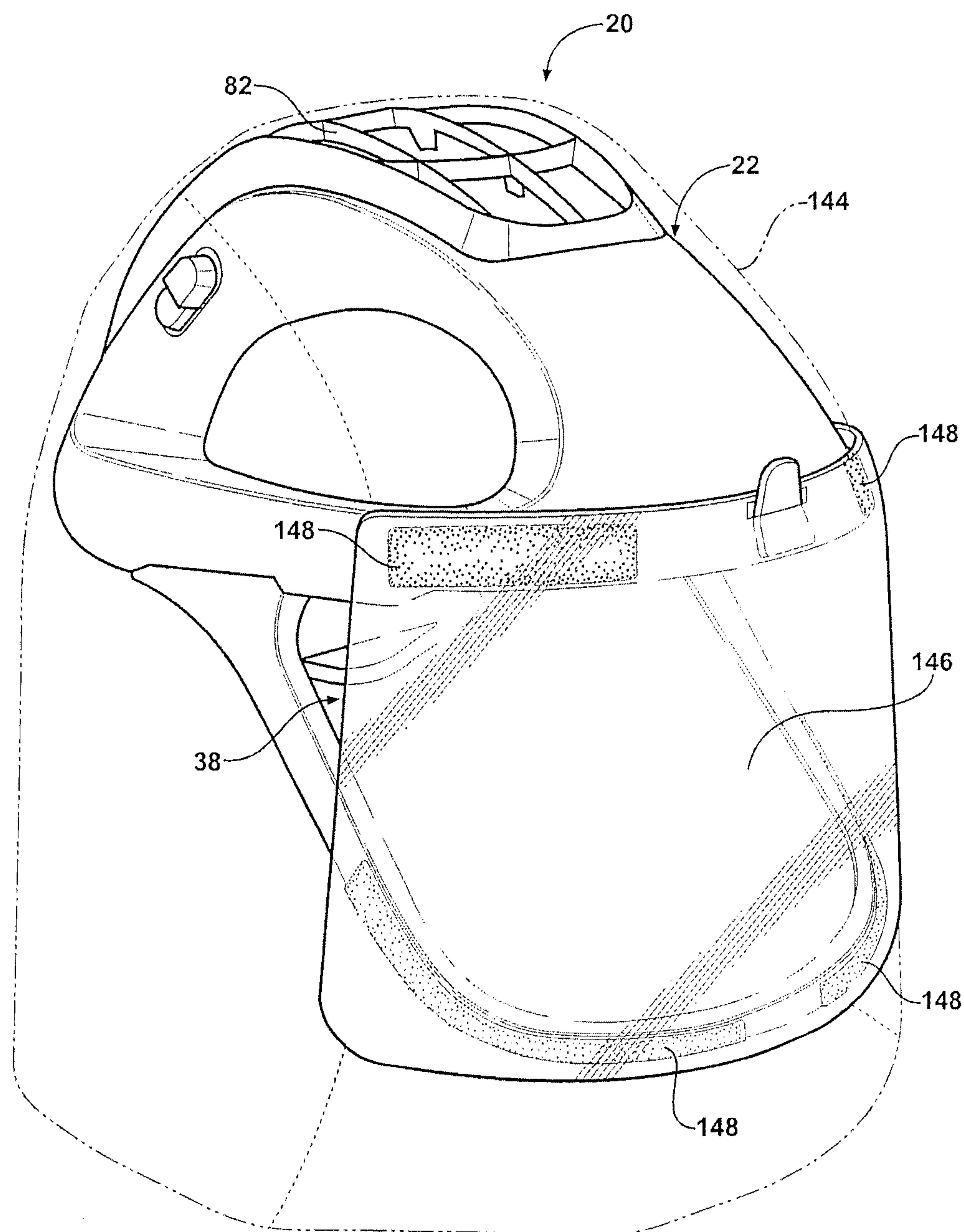


FIG - 13

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**FIG - 14**

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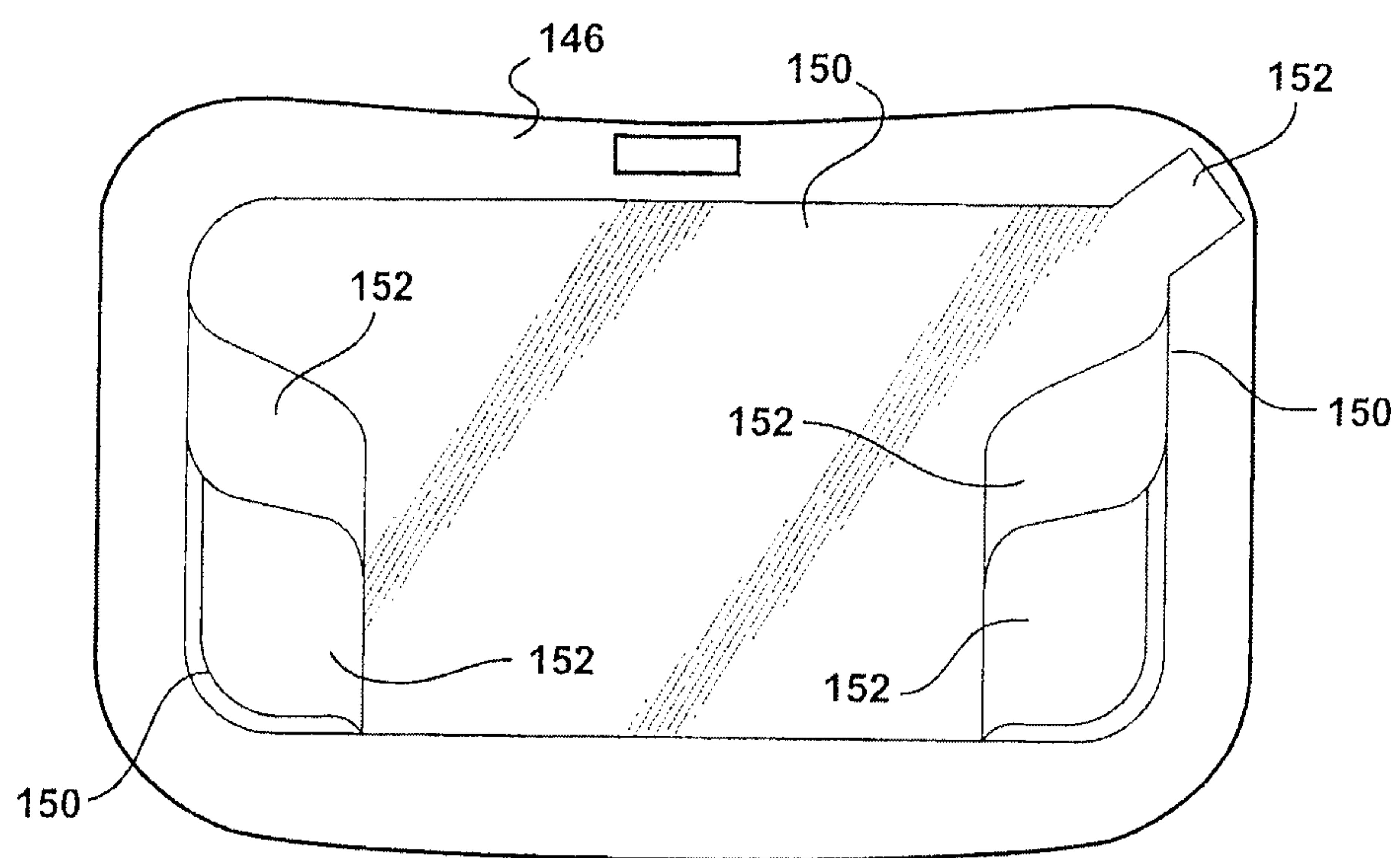


FIG - 15

