

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
2 December 2004 (02.12.2004)

PCT

(10) International Publication Number
WO 2004/103478 A1

(51) International Patent Classification⁷: **A62C 13/62**

(21) International Application Number:
PCT/US2004/016181

(22) International Filing Date: 20 May 2004 (20.05.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/471,883 20 May 2003 (20.05.2003) US
60/485,305 3 July 2003 (03.07.2003) US

(71) Applicant and

(72) Inventor: **COLLINS, James, F.** [US/US]; 2-01 50th Avenue, Apartment 3R, Long Island City, NY 11101 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **CHINNOCK,**

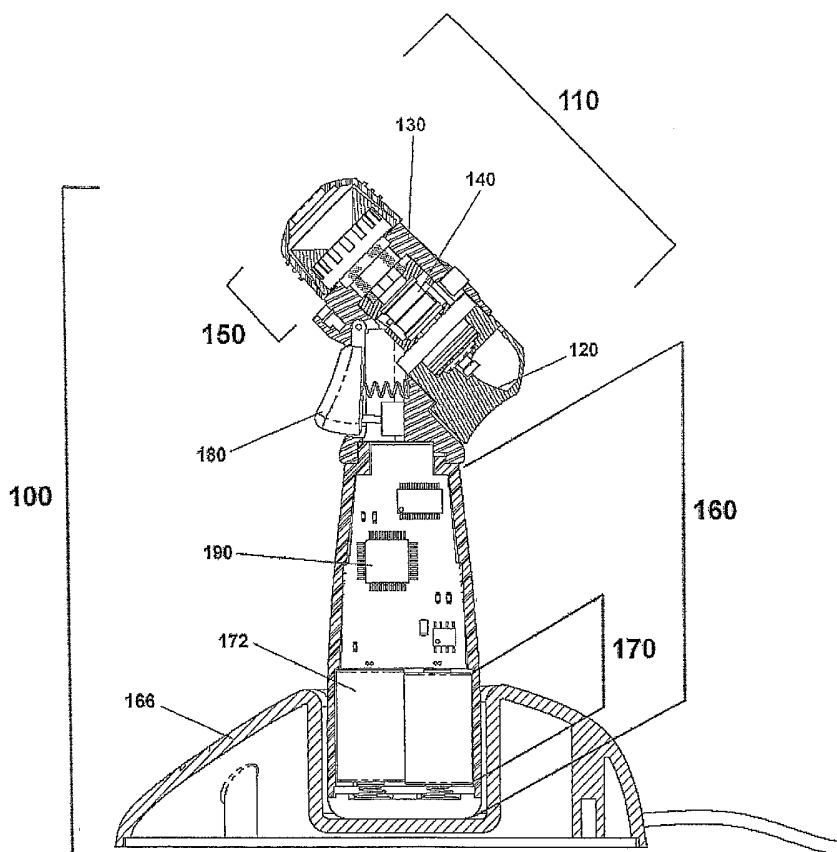
Randal, B. [US/US]; 53 McGilpin Road, Sturbridge, MA 01566 (US). **MELANSON, Jeffrey** [US/US]; 90 Fiske Hill Road, Sturbridge, MA 01566 (US). **HOWARD, Joseph** [US/US]; 148 Brook Street, Bayshore, NY 11706 (US).

(74) Agent: **MAENNER, Joseph, E.**; Monte & McGraw, P.C., P.O. Box 650, 4092 Skippack Pike, Skippack, PA 19474 (US).

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

[Continued on next page]

(54) Title: OPTHALMIC DRUG DELIVERY SYSTEM



(57) Abstract: A fluid atomizer is disclosed. The fluid atomizer comprises a body having a proximal end and a distal end. A removable reservoir containing a fluid disposed therein is connected to the body. A discharge plate is disposed at the distal end, wherein the discharge plate includes a plurality of openings extending therethrough. An ultrasonic oscillator is disposed in the body for transmitting the fluid from the reservoir to the discharge plate and through the plurality of openings, wherein transmission of the fluid through the plurality of openings atomizes the fluid.



(84) **Designated States** (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

— *with international search report*

TITLE OF THE INVENTION
Ophthalmic Drug Delivery System

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims priority from U.S. Provisional Patent Application Serial No. 60/471,883, filed May 20, 2003 and from U.S. Provisional Patent Application Serial No. 60/485,305, filed July 3, 2003.

FIELD OF THE INVENTION

[0002] The present invention relates to drug delivery devices for dispensing liquid as an aerosol or atomized mist and, more particularly, for dispensing medicaments to the eye.

BACKGROUND OF THE INVENTION

[0003] Presently, conventional eye drops are the standard means of delivering medicaments to the eye. This means of ophthalmic drug delivery, however, has numerous problems. For example, the average eye drop (approximately 50 micro liters) far exceeds the eye's capacity (7 micro liters in the pre-corneal tear film and a maximum of about 30 micro liters in the lower cul-de-sac) effectively destabilizing and stripping the natural tear film. This results in a brief period of massive over-dosage, which is quickly cleared by reflex lacrimation, blinking and nasolacrimal drainage, resulting in sub-therapeutic drug levels until the next medication application. This approach represents very inefficient pharmacokinetics. Far smaller volumes of medicament (approximately one tenth of a conventional drop) are desirable and are, in fact, retained by the eye and "bio-available" for a substantially longer time.

[0004] Attempts to prolong ocular contact time by various adaptations, such as the use of particulate suspensions, have led to other drawbacks including ocular irritation and excessively slow drug release. Ointments and gels, though providing prolonged contact time, create obvious visual disturbances.

[0005] Further, local irritations and toxicities often result from the regular use of eye drops. These situations vary widely depending on the pharmacologic agent, preservatives and other additives being used, but this is clearly a very non-physiologic and inefficient system of medication administration. Chronic use of eye drops for such conditions as glaucoma and prolonged infections and inflammations can, in fact, cause substantial morbidity. Additionally, serious and even fatal reactions to sympathomimetic and beta-adrenergic blocking agents have occurred as a result of systemic absorption of eye drops via nasolacrimal drainage.

[0006] Besides the above issues, there are a great many difficulties that patients experience with the mechanics of eye drop administration. Elderly patients, the largest group of eye drop users, often have hand-eye coordination problems, tremors or arthritis, affecting the hands and/or the cervical spine, making eye drop administration difficult if not impossible. Many users report that they have trouble keeping track of their regimens and often repeat doses or miss them entirely, suffering potential consequences in either event. Further, pediatric patients, often unable to comprehend the reasons and benefits behind the administration of eye medication, often fight such application, typically resulting in underdosing due to the patient's attempts to prevent the eye drops from being administered, or overdosing, as a result of the administrator's attempt to ensure that sufficient dosage is being applied.

[0007] Additionally, very few regular users of eye drops, in any age group, actually observe the ideal technique of administration, including tear sac compression, to minimize excretory loss and potential systemic absorption. It is sometimes difficult to tell if the drop was properly instilled. Direct application to the cornea can result in the drop "bouncing" from the eye with little or no benefit.

[0008] Regular eye drop users commonly report using several drops which "missed" the eye until they are sure they properly instilled the drop. Also, many eye drop bottles are fabricated in such a way that loss is unavoidable as soon as the dropper is tilted. Finally, a significant number of regular users put another drop or two in the eye "just to be sure". All of the above represent needless waste of expensive medication (many glaucoma medications cost \$70 - \$80 for a 5 ml bottle) and also increased the risk of side effects, while actually reducing the therapeutic benefit.

[0009] The ophthalmic literature is rife with references to the need for a better means of ophthalmic drug delivery. With an estimate of 25 million users of eye drops in the United States alone, the magnitude of the public health issue is considerable. Accordingly, a new means of ophthalmic drug delivery is needed.

[0010] The concept of "spraying" medicated solutions on to the eye is not a new one. A number of devices have been conceptualized and developed for this purpose. Various means of atomizing and propelling solutions including mechanical pumps, gas-propelled jets and pistons, etc. which have inherent drawbacks relating to difficulties with calibrating the flow velocity, volume and particle size of the emitted spray. See, for example, U.S. Patent Nos. 3,170,462; 5,630,793; and 6,062,212.

[0011] It is hypothesized that the generated mist will expand and "therapeutically alter" but not significantly disrupt the physiologic tear film allowing for a more natural process in the

transmission of therapeutic agents to the surface and the interior of the eye. A much smaller volume of solution can be administered below the blink and lacrimation thresholds, allowing for a prolonged time of application. The aggregate administration of a drug in thousands of 5-micron particles should significantly exceed that of a single eye drop, leading to greater concentrations of the drug (bioavailability). Furthermore, the surface tension of a standard drop is a barrier to "mixing" and tear film incorporation. This problem is expected to be avoided with micronebulization.

[0012] An additional benefit to mist administration of eye medications is the avoidance of dropper bottle contamination which commonly occurs from contact with the eyelid. In the professional office setting, this problem has led to many documented epidemics of viral keratoconjunctivitis. During medication administration via a dropper bottle to a patient with viral keratoconjunctivitis, the bottle tip may inadvertently touch the eye or eyelid of the affected patient, transferring the virus to the bottle tip. Subsequent medication administrations to other patients using the same dropper bottle transmits the virus to those patients.

[0013] Some of the beneficial features of an ophthalmic medication spray dispenser include the following: great ease of use; can be used in any "attitude" (i.e. with patient sitting, erect, lying down, head tilted back, etc.); abbreviated treatment cycle as compared to eye drop usage; improved bioavailability/efficacy; improved safety (reduced local and systemic side effects); improved sterility; increased compliance due to ease of use and "alert" systems; possibility of singular efficacy in the treatment of certain vision threatening infections; conservation of material (reduced volume, diminished waste/loss); and system (fixation target to help ensure proper application).

[0014] It would be beneficial to provide a system for applying the desired small amounts (7 to 10 micro liters) of optical medication, along with at least some of the above-listed beneficial features, while eliminating the drawbacks associated with previous means of drug delivery.

BRIEF DESCRIPTION OF THE INVENTION

[0015] Briefly, the present invention provides a fluid atomizer comprising a body having a proximal end and a distal end. A removable reservoir is connected to the body, wherein the reservoir contains a fluid disposed therein. A discharge plate is disposed at the distal end, wherein the discharge plate includes a plurality of openings extending therethrough. The atomizer further comprises propulsion means for transmitting the fluid from the reservoir to the discharge plate and through the plurality of openings, wherein transmission of the fluid through the plurality of openings atomizes the fluid.

[0016] Also, the present invention provides a fluid atomizer comprising a body having a proximal end and a distal end. A removable reservoir is connected to the body, wherein the reservoir contains a fluid disposed therein. A discharge plate is disposed at the distal end, wherein the discharge plate includes a plurality of openings extending therethrough. The atomizer further comprises propulsion means for transmitting the fluid from the reservoir to the discharge plate and through the plurality of openings, wherein transmission of the fluid through the plurality of openings atomizes the fluid. The atomizer also includes a system controller electronically connected to the propulsion means, wherein the system controller controls operation of the propulsion means.

[0017] Further, the present invention provides a fluid atomizer comprising a body having a proximal end and a distal end. A removable reservoir is connected to the body, wherein the reservoir contains a fluid disposed therein. A discharge plate is disposed at the distal end, wherein the discharge plate includes a plurality of openings extending therethrough. The atomizer further comprises propulsion means for transmitting the fluid from the reservoir to the discharge plate and through the plurality of openings, wherein transmission of the fluid through the plurality of openings atomizes the fluid. The atomizer also includes a means for spacing the discharge plate a predetermined distance from a target.

[0018] Additionally, the present invention provides a fluid atomizer comprising a body having a proximal end and a distal end. A removable reservoir is connected to the body, wherein the reservoir contains a fluid disposed therein. A discharge plate is disposed at the distal end, wherein the discharge plate includes a plurality of openings extending therethrough. The atomizer further comprises propulsion means for transmitting the fluid from the reservoir to the discharge plate and through the plurality of openings, wherein transmission of the fluid through the plurality of openings atomizes the fluid. The atomizer also includes a system controller electronically connected to the propulsion means, wherein the system controller controls operation of the propulsion means. The atomizer also includes a means for adjusting operation of the propulsion means to adjust an amount of the fluid transmitted across the discharge plate, wherein the means for adjusting operation of the propulsion means are operatively connected to the system controller.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] The accompanying drawings, which are incorporated herein and constitute part of this specification, illustrate the presently preferred embodiments of the invention, and,

together with the general description given above and the detailed description given below, serve to explain features of the invention. In the drawings:

[0020] Fig. 1 is a side elevational view, partially broken away, of a mist spraying device according to a first embodiment of the present invention.

[0021] Fig. 2 is an exploded view of the device of Fig. 1.

Fig. 3 is an enlarged side profile view of a first embodiment of a fluid reservoir connected to the device.

[0022] Fig. 4 is a side profile view showing the device being used to spray a mist into a patient's eye.

[0023] Fig. 5 is a side profile view of the first embodiment of the fluid reservoir shown in Fig. 3, having been removed from the device.

[0024] Fig. 6 is an enlarged side profile view of a second embodiment of a fluid reservoir.

[0025] Fig. 7 is an enlarged side profile view of a third embodiment of a fluid reservoir.

[0026] Fig. 8 is a perspective view of the reservoir of Fig. 7.

[0027] Fig. 9 is an enlarged side view, in section, of a prime mover inserted into the device.

[0028] Fig. 10 is an enlarged exploded perspective view of a nozzle assembly of the device.

[0029] Fig. 11 is an enlarged side view, in section, of the nozzle assembly of the device.

[0030] Fig. 12a is an enlarged partial sectional view of a first embodiment of the mesh plate of the nozzle assembly.

[0031] Fig. 12b is an enlarged partial sectional view of a second embodiment of the mesh plate of the nozzle assembly.

[0032] Fig. 12c is an enlarged partial sectional view of a third embodiment of the mesh plate of the nozzle assembly.

[0033] Fig. 12d is an enlarged partial sectional view of a fourth embodiment of the mesh plate of the nozzle assembly.

[0034] Fig. 13a is a top plan view of a first embodiment of a mesh plate.

[0035] Fig. 13b is a top plan view of a second embodiment of a mesh plate.

[0036] Fig. 13c is a side view, in section, of a third embodiment of a mesh plate.

[0037] Fig. 13d is a side view, in section, of a fourth embodiment of a mesh plate.

[0038] Fig. 13e is an enlarged partial sectional view of a fifth embodiment of a mesh plate.

[0039] Fig. 14 is a perspective view of the device showing an optional dosage adjustment feature.

[0040] Fig. 15a is a perspective view of the device showing a first embodiment of the dosage adjustment feature.

[0041] Fig. 15b is a perspective view of the device showing a second embodiment of the dosage adjustment feature.

[0042] Fig. 15c is a perspective view of the device showing a third embodiment of the dosage adjustment feature.

[0043] Fig. 16 is a top plan view showing the targeting device of Fig. 14.

[0044] Fig. 17a is a schematic view of a first embodiment of a targeting mechanism showing the device too close to the target.

[0045] Fig. 17b is a schematic view of the first embodiment of the targeting mechanism showing the device a correct distance from the target.

[0046] Fig. 17c is a schematic view of the first embodiment of the targeting mechanism showing the device too far from the target.

[0047] Fig. 18a is a schematic view of a second embodiment of a targeting mechanism showing the device too close to the target.

[0048] Fig. 18b is a schematic view of the second embodiment of the targeting mechanism showing the device a correct distance from the target.

[0049] Fig. 18c is a schematic view of the second embodiment of the targeting mechanism showing the device too far from the target.

[0050] Fig. 19a is a schematic view of a third embodiment of a targeting mechanism showing the device too close to the target.

[0051] Fig. 19b is a schematic view of the third embodiment of the targeting mechanism showing the device a correct distance from the target.

[0052] Fig. 19c is a schematic view of the third embodiment of the targeting mechanism showing the device too far from the target.

[0053] Fig. 20a is a schematic view of a fourth embodiment of a targeting mechanism showing the device too close to the target.

[0054] Fig. 20b is a schematic view of the fourth embodiment of the targeting mechanism showing the device a correct distance from the target.

[0055] Fig. 20c is a schematic view of the fourth embodiment of the targeting mechanism showing the device too far from the target.

[0056] Fig. 21a is a schematic view of a fifth embodiment of a targeting mechanism showing the device too close to the target.

[0057] Fig. 21b is a schematic view of the fifth embodiment of the targeting mechanism showing the device a correct distance from the target.

[0058] Fig. 21c is a schematic view of the fifth embodiment of the targeting mechanism showing the device too far from the target.

[0059] Fig. 22a is a side elevational view of a mechanical targeting device according to the present invention.

[0060] Fig. 22b is a top plan view of a proximal end of the mechanical targeting device shown in Fig. 22a, being used on a patient.

[0061] Fig. 23 is a schematic view of an electronic control system for the device.

Fig. 24 is a perspective view of an alternative embodiment of the device according to the present invention.

[0062] Fig. 25 is a perspective view of another alternative embodiment of the device according to the present invention.

[0063] Fig. 26 is a perspective view showing self-administration of medication using the device.

[0064] Fig. 27 is a perspective view showing administration of medication by one person to another using the device.

DETAILED DESCRIPTION OF THE INVENTION

[0065] Certain terminology is used in the following description for convenience only and is not limiting. As used herein, the term “distal” is meant to mean the discharge end of the inventive device and the term “proximal” is meant to mean the end of the inventive device held by user. The terminology includes the words above specifically mentioned, derivatives thereof and words of similar import. The embodiments illustrated below are not intended to be exhaustive or to limit the invention to the precise form disclosed. These embodiments are chosen and described to best explain the principle of the invention and its application and practical use and to enable others skilled in the art to best utilize the invention.

[0066] The present invention provides a novel device and method for ophthalmic drug delivery. In preferred embodiments, the present invention provides a small, hand-held, battery or

AC powered device that nebulizes liquid eye medications into a fine mist. The mist from the device is directed at the eye to be treated and the drug is delivered via the mist.

[0067] A preferred means of forming the mist is by ultrasound energy generated by a piezoelectric transducer or other suitable piezo device. A small plume of nebulized solution is generated, consisting of particles measuring what is believed to be an average of about five microns in diameter. The volume of each emission is dependent on the rate of mist generation (typically measured in micro liters per second) as well as the duration of the operation of the device, which may be easily varied by using an electronic control circuit. The shape, dimensions and focus of the emitted mist are proportioned for delivery to the human eye. The momentum of the mist is subliminal to the ocular blink and lacrimation reflexes and may also create a soothing sensation in the eye. The device is equally efficient when used in any "attitude" from a natural, upright head posture to leaning forward or lying back. Application time is significantly abbreviated compared to eye drop usage, which typically requires several maneuvers and careful attention to detail to ensure proper administration.

[0068] One preferred embodiment of the invention is now described with reference to Figs. 1 and 2, which show a hand held device 100 that directs a mist of drug to an eye for treatment. As will be described in more detail below, the device 100 includes a vial or reservoir 120 of the fluid to be delivered to the eye, such as a drug. The user holds the device 100 and, by operating an activation switch, causes the device 100 to generate a mist of the liquid, which is discharged from the head portion 110 of the device 100. The user simply aims the head of the device at the target eye to allow the mist to contact the eye.

[0069] Referring to Figs. 1 and 2, the major components of the device 100 are shown. The components include a head portion 110 and a handle portion 160. The head portion 110 preferably contains, from a proximal to a distal direction, a fluid reservoir 120 to retain a fluid 122 to be administered, a body 130 that houses a prime mover 140 to draw the fluid from the reservoir 120 and propel the fluid 122 out the distal end of the device 100, and a nozzle assembly 150 which aerosolizes the fluid 122 and to form a mist pattern of the fluid 122 as the fluid 122 is directed toward its target. The handle portion 160 preferably contains the power source 170, such as a battery, an activation switch 180 to activate the device, and a system controller 190 that controls the various operational aspects of the device 100.

Head Portion

[0070] The head portion 110 includes the body 130 that connects the reservoir 120, the prime mover 140, and the nozzle assembly 150 together. The head portion 110 is connected to

the handle portion 160 and provides a conduit for electrical leads (not shown) extending from the reservoir 120 and the prime mover 140 to the system controller 190.

Reservoir

[0071] Referring to Fig. 3, in which an enlarged view of a preferred embodiment of the reservoir 120 is shown, the fluid reservoir 120 may be a vial pre-filled with the fluid 122 to be delivered to the eye. The reservoir 120 may incorporate a scale comprising a clear window 123 with volume graduation markings 124 to indicate fill level or doses of fluid 122 remaining in the reservoir 120. In the present embodiment, the scale is read with the device 100 standing on its base 166, as shown in Fig. 1.

[0072] The reservoir 120 is preferably shaped to maintain contact with the prime mover 140 when the device 100 is held in a preferred operational orientation while spraying into an eye (as shown in Fig. 4), or is tilted in any direction within 45 degrees of horizontal. The reservoir 120 is preferably further shaped to maximize the percentage of the total fill volume that is actually dispensed.

[0073] Referring back to Fig. 3, the reservoir 120 houses the fluid 122 that is used to form the aerosolized mist when the device 100 is operated. The reservoir 120 is preferably a removable and replaceable cartridge 126 that is securably connectable to the body 130 so that the reservoir 120 does not accidentally readily separate from the body 120, yet is easily replaceable when the reservoir 120 is empty or when a reservoir 120 containing a different type of fluid is desired to be connected to the device 100.

[0074] Preferably, the reservoir 120 includes an engagement surface 128 disposed proximate to an upper and a lower side of the reservoir 120. The engagement surface 128 slides over a corresponding extension in the body 130, as shown in Fig. 3, so that the reservoir 120 is retained onto the body 130 with a frictional fit. Preferably, the extension includes a plurality of seals, such as o-rings 134, that provide a sealing engagement between the reservoir 120 and the body 130 and assists in frictionally retaining the body 120 to the reservoir 130. Alternatively, the reservoir 120 may connect with the body 130 by other means known to those skilled in the art, including, but not limited to, threaded connections, bayonet fittings, or other suitable means.

[0075] In the embodiment shown in Fig. 5, which shows the reservoir 120 removed from the remainder of the device 100, the reservoir 120 includes an open face 1210 that is covered by an air impermeable seal 1212. Initially, the open face 1210 allows the fluid 122 to be deposited into the reservoir 120, and then sealed with the seal 1212. Such a seal 1212 may be constructed from thin gauge aluminum, or some other suitable material, with a biocompatible coating disposed on both faces of the seal 1212. The seal 1212 is attached to the reservoir 120

with a biocompatible adhesive. The seal 1212 is designed to maintain sterility of the fluid 122 within the reservoir 120, yet be able to be easily punctured by the proximal end 142 of the prime mover 140 upon connecting the reservoir 120 to the body 130 so that the fluid 122 in the reservoir 120 is put into fluid communication with the proximal end 142 of the prime mover 140, as shown in Fig. 3.

[0076] For a reservoir 120 having a rigid form, such as the reservoir 120 shown in Fig. 5, a vent 1214 is formed in the wall of the reservoir 120, preferably proximate to the top of the reservoir 120, to allow air to be drawn into the reservoir 120 to compensate for the loss volume of fluid 122 as the fluid 122 is drawn out of the reservoir 120 due to operation of the device 100. A filter 1216 covers the vent 1214 to allow ambient air into the interior of the reservoir 120, but prevents fluid 122 in the reservoir 120 from leaking out of the vent 1214. While a presently preferred embodiment of the reservoir 120 envisions the fluid 122 to be prepackaged in the reservoir 120, those skilled in the art will recognize that the reservoir 120 may also be refillable, such as through the vent 1214.

[0077] Alternatively, as shown in Fig. 6, an alternate embodiment of a reservoir 1218 may have a collapsible bladder 1220 that collapses under vacuum as the fluid 122 is drawn out of the reservoir 1218 during operation of the device 100, without any air being able to enter the reservoir 122. The bladder 1220 is preferably supple, biocompatible, and bondable. In the presently preferred embodiment, the bladder 1220 is constructed of aluminum film coated on both sides with a polymer resin. In the presently preferred embodiment, the bladder 1220 is approximately 0.025 to 0.10 mm thick. The bladder 1220 is attached to a rigid bladder neck 1221. The neck 1221 prevents the bladder 1220 from contacting the proximal end 142 of the prime mover 140 as the bladder 120 collapses. Contact with the proximal end 142 would impede the function of the prime mover 140. The bladder neck 1221 may be injection molded or extruded from a material that is rigid, biocompatible, and bondable. A material which meet these criteria includes polyethylene, although those skilled in the art will recognize that other, suitable, biocompatible materials may be used. The bladder 1220 and bladder neck 1221 are housed in a rigid reservoir housing 1222. The housing 1222 is preferably injection molded from low cost polymer resins such as PVC, ABS, or polypropylene.

[0078] An air vent 1223 in the housing 1222 allows the collapsible bladder 1220 to collapse as the fluid 122 is withdrawn from the reservoir 1218, so that no adverse suction forces are generated during operation of the device 100. The air entering the vent 1223 does not need to be filtered, since the bladder 1220 isolates the fluid 122 from the air. In this embodiment, no make-up air is required to enter the bladder 1220.

[0079] Without limiting the type of fluids that could be contained in the reservoir 120, 1218 and dispensed by the present invention, diagnostic agents used by the medical professional that could be delivered with the present invention include mydriatics/cycloplegics, anesthetics, fluorescein and fluorescein/anesthetic combinations, and mydriatic reversal agents. Other agents which could be delivered with the present invention include over-the-counter agents, e.g., ophthalmic decongestants and lubricants, glaucoma medications (prostaglandins, beta blockers, alpha adrenergic agents, carbonic anhydrase inhibitors, miotics), and other ophthalmic medications. Optionally, several different therapeutic agents can be custom formulated in a single fluid to simplify adherence to multiple medication regimens.

[0080] Again, while an envisioned use for the device 100 of the present invention is directed toward ophthalmic use, those skilled in the art will recognize that the device 100 of the present invention may be used in other areas, such as respiratory treatment, and that other fluids, including respiratory medicaments, may be contained in the reservoir 120 instead.

[0081] Preferably, for photo-sensitive medicaments, the reservoir 120 may be tinted to prevent the transmission of certain deleterious wavelengths of light to the fluid 122 to prolong the useful life of the medicament in the reservoir 120. The tint may be a dark brownish tint that is presently used for such medicaments in bottle/eye dropper form.

[0082] Optionally, as shown in Fig. 2 the reservoir 120 may include a self-sealing valve 1224 in a distal wall 1226 of the reservoir 120. The self-sealing valve 1224 allows the reservoir 120 to be inserted into the body 130, and then removed from the body 130 without leaking fluid 122 from the reservoir 120.

[0083] The self-sealing valve 1224 is preferably biased toward a closed position, such as by a helical spring (not shown). A seal, such as an o-ring 1228, seals the valve 1224 against the wall 1226 of the reservoir 120 to eliminate fluid leakage from the reservoir 120 when the valve 1224 is in the closed position. A valve stem 1230 extends distally from the valve 1224. When the reservoir 120 is inserted into the body 130, the proximal end 142 of the prime mover 140 engages the valve stem 1230 and forces the valve stem 1230 into the reservoir 120, opening the reservoir 120 into fluid communication with the prime mover 140.

[0084] An alternative embodiment of a reservoir 1236 is shown in Figs. 7 and 8. The reservoir 1236 is housed in a removable and replaceable cartridge 1237. The reservoir 1236 incorporates a generally coiled tube 1238 that is sized to partially surround the proximal end 142 of the prime mover 140. The tube 1238 may be constructed from polyethylene, although those skilled in the art will recognize that other suitable, biocompatible materials may be used. The tube 1238 preferably has a wall thickness in the range of approximately 0.1 to 0.3 mm thick, and

an inside diameter in the range of approximately 1 to 5 mm. One end 1240 of the tube 1238 is fitted with a filter 1242 to allow makeup air to enter as the fluid 122 in the reservoir 1236 is drawn down. This filter 1242 is a biocompatible, gas-permeable membrane that is impermeable to liquid but permeable to air. One such material that may be used for the filter 1242 is Tyvek®. A distal end 1243 of the tube 1238 is sealed with a fluid impermeable seal 1244 that is broken by the distal end 142 of the prime mover 140 when the reservoir 1236 is connected to the device 100, as shown in Fig. 7.

[0085] As the device 100 is operated and medication is consumed, the fluid 122 is drawn along the tube 1238. The diameter of the tube 1238 is preferably specified in relation to the viscosity of the fluid 122 to insure that surface tension causes the fluid 122 to move in a column along the tube 1238, i.e., no air is drawn in by the prime mover 140 until the fluid 122 is consumed. This design has the advantage of using nearly 100% of the medication loaded into the tube 1238. This configuration has the further advantage of allowing the device 100 to operate in any orientation, even in zero gravity environments. Referring to Fig. 7, a clear window 1245 and a numerical scale 1246 on the side of the cartridge 1237 may indicate how many doses remain in the reservoir 1236. The scale 1246 may be read with the device 100 in any orientation.

[0086] While a design of a reservoir 120 with a collapsible bladder 1220 and a design of a reservoir 1236 with a coiled tube 1238 are shown, those skilled in the art will recognize that other designs of reservoirs may be used.

[0087] Optionally, as shown in Fig. 5, a heater 1248 may be incorporated into the reservoir 120 to heat the fluid 122. The heater 1248 is preferably either an inductance or a resistive heater that is electrically connected to a contact 1249 in the wall of the reservoir 120 that is electrically connectable to a contact (not shown) in the body 130 to provide electrical power to the heater 1248 to heat the fluid 122 in the reservoir 120. However, for many ophthalmic medicines, heating the medicine is not desired, and those skilled in the art will recognize that the heater 1248 may be omitted in its entirety.

[0088] Also optionally, a low level sensor 1250, shown in Fig. 3, may be incorporated into the reservoir 120 to indicate when the fluid 122 in the reservoir 120 is almost depleted. The sensor 1250 is electronically connected to the system controller 190 via electrical connection 1252 to provide an indication of fluid level in the reservoir 120. The sensor 1250 may be electronically connected to an alarm, such as an optical or aural indicator, such as a blinking light or an audible alarm.

Body

[0089] Referring back to Fig. 2, the body 130 houses the prime mover 140 and provides a connection for the fluid reservoir 120 and for the nozzle assembly 150 to engage the prime mover 140. The body 130 includes, at the distal end of the body 130, a bushing 131 that is securely bonded to the body 130, such as by an adhesive or a snap-fit. The bushing 131 includes at least one, an preferably, a plurality of bayonet clips 131a that are adapted to snap into the nozzle assembly 150 to retain the nozzle assembly 150 onto the body 130.

[0090] The body 130 preferably includes a connection device, such as an orifice 132, for attaching to the handle portion 160. However, those skilled in the art will recognize that other connection methods, such as snap fit, bayonet clips, or other suitable mechanisms known to those skilled in the art may be used. Preferably, the body 130 connects to the top 162 of the handle portion 160 in only a single orientation so that electrical contacts in each of the body 130 and the handle portion 160 properly engage each other when the head portion 110 is connected to the handle portion 160.

[0091] The body 130 also includes, at the proximal end of the body 130, a collar spacer 133 that is fixedly connected to the body 130 to provide optimum spacing of the proximal end 142 of the prime mover 140 within the reservoir 120 to optimize the ability of the prime mover 140 to withdraw the fluid 122 from the reservoir 120 during operation of the device 100.

[0092] The body 130 houses the prime mover 140, and provides connection means for the reservoir 120, the nozzle assembly 150, and the handle portion 160. The retainer 135 is fixedly connected to the body 130 and also releasably retains the reservoir 120 so that the reservoir 120 is removable from the remainder of the device 100. As described above, the retainer 135 may include an engagement surface, or alternatively, other connection means, such as threaded connections, or other means known to those skilled in the art.

[0093] The body 130 includes a generally tubular passage 136 that is sized to accept the proximal end 142 of the prime mover 140. A spacer recess 137 is disposed at the distal end of the body 130, preferably below the passage 136. The spacer recess 137 is used to releasably retain a targeting means, which will be described in detail later herein.

[0094] A seal 138 is disposed about the proximal end of the passage 136. The seal 138 prevents any fluid 122 from leaking out of the reservoir 120 when the reservoir 120 is attached to the body 130. In the present embodiment, the seal 138 is formed in the shape of a ring by injection molding or liquid injection molding using medical grade silicones or urethanes with durometers in the range of 5 to 30 Shore A.

[0095] Preferably, the body 130 includes an activation indicator 1310 that is disposed on the top of the body 130. The activation indicator 1310 may be a light, such as an LED, that

provides constant illumination as long as the activation switch 180 is depressed; a light that provides blinking illumination; a sound that provides audible indication, either by constant or by periodic beeping; some combination of these listed indicators, or some other indication that would indicate to the user that the device is ready for operation. The activation indicator 1310 operates when the activation switch 180 is initially depressed by the user. The activation indicator 1310 alerts the user that the device 100 is "ON" and is about to spray the fluid 122 from the nozzle assembly 150. The activation indicator 1310 is electronically connected to the system controller 190 via electrical leads (not shown).

[0096] The body 130 may be machined from solid metal or plastic stock, or may be injection molded with polymer resins such as ABS, styrene, PVC, or other suitable material, as will be recognized by those skilled in the art. The body 130 may be injection molded or manufactured by other methods known by those skilled in the art. Preferably, the body 130 has a durometer within the range of approximately 90 to 100 Shore A.

Prime mover

[0097] Referring still to Fig. 2, as well as to Fig. 9, the prime mover 140 will now be described. The prime mover 140 is shown in Fig. 2 in relation to the nozzle assembly 150 and the reservoir 120. The prime mover 140 is preferably an ultrasonic oscillator formed by a piezoelectric assembly such as that found in the Omron Micro-Air model NE-U03. The NE-U03 is a commercially available nebulizer that is typically used in nebulizers for bronchial therapy. However, the inventors of the present invention have discovered that this particular nebulizer is also suited for delivery of ophthalmic medicine to satisfy the needs that the present invention is intended to satisfy. The preferred piezoelectric assembly is described in detail in U.S. Patent No. 6,651,650, the disclosure of which is incorporated herein by reference. However, those skilled in the art will recognize that the NE-U03 may be substituted for other piezoelectric assemblies, such as those discussed in the article Nebulizers that Use a Vibrating Mesh or Plate with Multiple Apertures to Generate Aerosol, by Rajiv Dhand MD, Respiratory Care, December 2002, Vol. 47, No. 12, which is also incorporated by reference herein. Alternatively, instead of using piezoelectric assemblies, those skilled in the art will recognize that other prime movers that are not piezoelectrically operated may be used. Examples of such other suitable prime movers include electric pumps, manual pumps, compressed gas, or other suitable prime movers, as will be recognized by those skilled in the art.

[0098] The prime mover 140 includes a proximal end 142, a distal end 144, and a central portion 146 disposed between the proximal end 142 and the distal end 144. A longitudinal axis 148 extends along a length of the prime mover 140 between the proximal end

142 and the distal end 144. A longitudinally extending lumen 1410 extends along the longitudinal axis 148 and extends the length of the prime mover 140. Preferably, a perpendicular cross section of the lumen 1410 is generally circular in shape and has a diameter of approximately between 0.25 and 1.0 mm. However, those skilled in the art will recognize that the lumen 1410 may have other cross sectional shapes, such as a generally oblong, oval, or elongated shape.

[0099] The central portion 146 includes at least two generally annular piezoelectric elements 1412, 1414 that surround the lumen 1410. The piezoelectric elements 1412, 1414 are electrically connected to the power source 170, which drives the piezoelectric elements 1412, 1414 during operation of the device 100.

[0100] Referring to Fig. 2, the prime mover 140 is retained within the body 130 by a distal seal 1426. The distal seal 1426 is generally annular in shape and taper from a wider diameter to a smaller diameter from the piezoelectric elements 1412, 1414 toward the proximal end 142 and the distal end 144, respectively. The distal seal 1426, along with the seal 138, restricts movement of the prime mover 140 within the body 130 and prevent fluid 122 that may leak through the device 100 from engaging the central portion 146 of the prime mover 140. Preferably, the seal 1426 is constructed from a biocompatible material, such as medical grade silicon or urethane, although those skilled in the art will recognize that other suitable material may be used.

[0101] Referring back to Fig. 3, the proximal end 142 is immersed in the fluid 122 in the reservoir 120. When the piezoelectric elements 1412, 1414 are excited, such as during operation of the device 100, standing waves are formed which draw the fluid 122 into the proximal end 142 of the prime mover 140 and along the lumen 1410. The standing waves propel the fluid 122 along the lumen 1410 to the distal end 144 of the prime mover 140 and to the nozzle assembly 150, which is in mechanical contact with the distal end 144 of the prime mover 140. As the prime mover 140 vibrates at ultrasonic frequencies, the prime mover 140 transfers a portion of its vibrational power to a mesh plate 156 in the nozzle assembly 150, as will be described in more detail later herein. The fluid 122 that has been propelled along the lumen 1410 contacts the mesh plate 156. The vibration of the plate 156 aerosolizes the fluid 122 and accelerates the fluid 122 away from the device 100 and toward the patient.

Nozzle Assembly

[0102] The nozzle assembly 150 is shown in an exploded perspective view in Fig. 10, as well as in an elevated sectional view in Fig. 11. The nozzle assembly 150 forms the mist that is discharged from the device 100 during operation. The nozzle assembly 150 includes, from a

distal to a proximal direction, a cap 152, a biasing member 154, a mesh plate 156, and a retainer 158.

[0103] The cap 152 is generally annular, with a central opening 1510 disposed along the longitudinal axis 148. Preferably, the body of the cap 152 extends in a distal direction and generally away from the longitudinal axis 148 to form a concave volume 1512 distal of the central opening 1510. The concave volume 1512 reduces the likelihood that a foreign object, such as a user's finger, will touch the mesh plate 156, potentially contaminating the plate 156.

[0104] The cap 152 preferably includes a releasable lock feature, such as a female threaded connection (not shown) that releasably threadingly engages the retainer 158, which has a mating twist lock feature, such as a mating male threaded connection (not shown). However, those skilled in the art will recognize that the cap 152 may engage with the retainer 158 by other means not shown, such as by snap engagement, bayonet means, or other suitable means known to those skilled in the art.

[0105] The mesh plate 156 is biased against the distal end 144 of the prime mover 140 by the biasing element 154, such as a helical spring, that is disposed between the cap 152 and the mesh plate 156. The biasing element 154 ensures that the mesh plate 156 is firmly engaged with the distal end 144 of the prime mover 140 to provide proper dispersion of the fluid 122 through the mesh plate 156 during operation of the device 100. While a helical spring is preferred as the biasing element 154 because a helical spring provides a generally uniform biasing force around its perimeter, those skilled in the art will recognize that other types of biasing elements, such as leaf springs, may be used instead. As shown in Fig. 11, a clearance space 1518 is formed between the proximal side of the mesh plate 156 and the retainer 158 to allow the mesh plate 156 to vibrate during operation.

[0106] The mesh plate 156 is formed of a rigid material that is biocompatible and non-oxidizing, such as alumina ceramics, titanium alloys, or stainless steel alloys. As shown in Fig. 10, an array of openings 1520 is formed in the mesh plate 156. The number, density, size, and shape of the openings 1520 contribute to determining mist parameters such as volume, velocity, and droplet size distribution. The openings 1520 may be drilled by mechanical means, by fine jets of water, or by lasers. The preferred embodiment of the mesh plate 156 is constructed from a ceramic material and measures approximately 9 mm in diameter and 0.1 mm thick, having between 500 and 5000 openings 1520 drilled by laser. The openings 1520 preferably have diameters in the range of approximately 0.5 to 30 microns. A mask (not shown) may be used that enables many openings 1520 to be drilled simultaneously. After each group of openings 1520 is

drilled, the mask or the mesh plate 156 is indexed to a new position and the next set of openings 1520 is drilled. This step-and-repeat process continues until all the openings 1520 are made.

[0107] Enlarged cross sections of several embodiments of openings 1520a, 1520b, 1520c, 1520d, and 1520e in mesh plates 156a, 156b, 156c, 156d, 156e are shown in Figs. 12a, 12b, 12c, 12d, 12e. Referring to Fig. 12a, the mesh openings 1520a in the mesh plate 156a are preferably circular in cross section along a plane parallel to the longitudinal axis 148, with an approximate hourglass cross section along a plane perpendicular to the longitudinal axis 148. Referring to Fig. 12b, the mesh openings 1520b in the mesh plate 156b are wider at the proximal (bottom) end of the plate 156b and narrower at the distal (top) end of the plate 156b. Referring to Fig. 12c, the mesh openings 1520c in the mesh plate 156c are narrower at the proximal (bottom) end of the plate 156c and wider at the distal (top) end of the plate 156c. Referring to Fig. 12d, the mesh openings 1520d in the mesh plate 156d have a generally constant diameter between the proximal (bottom) end of the plate 156d and the distal (top) end of the plate 156d.

[0108] The mesh plate may 156 incorporate one of several designs of openings 1520 as shown in Figs. 13a through 13e. In the top plan view of the design shown in Fig. 13a, a mesh plate 156e is generally planar, with a plurality of openings 1520 in a generally circular pattern, with a center of the generally circular pattern along the longitudinal axis 148. In the top plan view of the design shown in Fig. 12b, a mesh plate 156f is generally planar, with a plurality of openings 1520 in a generally elongated pattern, such as a rectangle or an oval. Alternatively, a mesh plate 156g may be generally convex, as shown in the side sectional view of the mesh plate 156g in Fig. 13c, to disperse the fluid 122 at a relatively wide angle to increase the field of dispersion of the fluid 122. In yet another alternative, a mesh plate 156h may be concave, as shown in the side sectional view in Fig. 13d, to disperse the fluid 122 in a relatively small area. For each of the mesh plates 156g, 156h in Figs. 13c and 13d, the pattern of openings may be circular, as shown in Fig. 13a, or elongated, as shown in Fig. 13b. The pattern of openings 1520 is aligned with the central opening 1510 in the cap 152 so that the fluid 122 that is dispersed through the mesh plate 156 passes through the central opening 1510 and forms a mist for deposition into the eye of the patient.

[0109] In an alternate embodiment, shown in Fig. 13e, a mesh plate 156i includes a generally flat plate with openings 1520i that are angled toward the longitudinal axis 148. This design provides the benefits of an easy to produce mesh plate that directs the fluid to a focused point.

[0110] It is preferred that the openings 1520 in the mesh plate 156 generates mist particle sizes in the average range of between approximately 0.5 and 10 microns in diameter. It

is also desired that the mist generated through the nozzle assembly 150 preferably extends about 7.5 to 10 cm in a mist plume diverging with a solid angle of approximately 10-20 degrees and traveling at a velocity of between approximately 4 and 30 cm per second, discharging approximately between 2 and 20 microliters per second, and preferably, between 7 and 10 microliters of fluid per second.

[0111] Referring back to Fig. 11, the retainer 158 preferably connects to the body 130 via the plurality of bayonet fittings 131a that snap into the retainer 158, although those skilled in the art will recognize that other means for connecting the retainer 158 to the body 130, such as by threaded connection, adhesive, or other suitable means, may be used.

[0112] The mesh plate 156 is removable from the remainder of the device 100 for cleaning, such as in an alcohol or other cleaning solution. To clean the mesh plate 156, the retainer 158 is removed from the body 130, releasing the cap 152, the biasing element 154, the mesh plate 156, and the retainer 158 from the remainder of the device 100. The biasing element 154 biases the mesh plate 154 against the retainer 158, keeping the nozzle assembly 150 intact. After cleaning, the nozzle assembly 150 is reconnected to the remainder of the device 100. The distal end 144 of the prime mover 140 engages the mesh plate 156, forcing the mesh plate 156 away from the retainer 158 so that the mesh plate 156 may be able to vibrate when excited by the prime mover 140.

[0113] Optionally, as shown in Figs. 2 and 11, an overcap 1522 may be disposed over the distal end of the cap 152 to keep the mesh plate 156 clean between uses. The cap 152 may include a peripherally spaced groove 1523 that is engageable with a corresponding protuberance 1523a for a snap fit connection that securely retains the overcap 1522 onto the cap 152, yet allows the overcap 1522 to be removed from the cap 152 with a minimum of effort. Alternatively, the overcap 1522 may attach to the cap 152 with a snap action, a thread, a bayonet, or other simple fastening means. The overcap 1522 may be machined from solid metal or plastic stock, or may be injection molded with polymer resins such as ABS, styrene, or PVC. The overcap 1522 may optionally be tethered to the device 100 with a lanyard made of wire cable or plastic filament. Alternatively, the overcap 1522 may be attached to the nozzle assembly 150 with a hinge (not shown). The hinge may incorporate a spring or other biasing member that automatically retracts the overcap 1522 away from the distal end of the cap 152 when a latch is released.

Dosage adjustment

[0114] Different medications and/or ophthalmic treatment regimens may require different amounts of a medication to be administered with each use of the device 100.

Alternatively, a larger patient may need a larger dose of a medication than a smaller patient. Therefore, an ability to adjust dosage amount may be required. The device 100 may optionally be equipped with user-accessible adjustments for flow rate (mist volume) and total flow (dose). These adjustments may be electro-mechanical (knobs or wheels operating potentiometers), or electronic (buttons or keys providing digital data to the system controller 190).

[0115] In one embodiment of a dosage adjustment, a dosage adjuster 1530, 1530a may be disposed on the nozzle assembly 150, such as is shown in Figs. 14 and 15a- 15b. The dosage adjuster 1530 includes a potentiometer 1532 rotatably connected to the cap 152. The potentiometer 1532 may include an infinitely positionable pot that is movable across a resistive film 1536, as shown in Fig. 15a, or a discretely positionable pot that is movable across a resistive film 1538 as shown in Fig. 15b. For either film 1536, 1538, rotation of the potentiometer 1532 changes the resistance of the potentiometer circuit, as is well known to those skilled in the art. The change in resistance changes a dosage voltage signal that is transmitted to the system controller 190 via a circuit (not shown). The system controller 190 interprets the voltage signal received and in turn transmits an operation duration signal to the prime mover 140, which controls the amount of time that the prime mover 140 operates when the activation switch 180 is engaged, thereby controlling the amount of fluid 122 that is discharged from the device 100.

[0116] While the dosage adjuster 1530 may be disposed on the nozzle assembly 150 as shown, those skilled in the art will recognize that a dosage adjuster 1530a may be disposed on the handle portion 160, as is alternately shown in Fig. 15c. The dosage adjuster 1530a preferably operates similarly to the dosage adjuster 1530 described above. Preferably, the dosage adjuster 1530a is disposed in an inconvenient location, such as behind a panel (not shown). It is typically not desirable to be able to easily adjust the dosage adjuster 1530a so that the user does not accidentally adjust the dosage while picking up or holding the device 100. The flow rate of fluid 122 dispensed as a mist from the device 100 is preferably adjustable between about 10 to 100 microliters/sec.

[0117] In order to ensure that dosing is consistent, the location of the nozzle assembly 150 relative to the eye during dispensing of medication may also need to be controlled. Various targeting mechanisms have been developed for this purpose. Referring back to Fig. 14, a first embodiment of a targeting mechanism 1540 may be incorporated into the nozzle assembly 150. The targeting mechanism 1540 is used to provide the user with an optimum distance to space the nozzle assembly 150 from the patient's eye to maximize effectiveness of the device 100. The targeting mechanism 1540 includes two projection lenses 1542, 1544 that are disposed on the nozzle assembly 150, preferably spaced 180 degrees from each other on either side of the

longitudinal axis 148. The lenses 1542, 1544 are angled toward the longitudinal axis 148 such that projections from the lenses 1542, 1544 intersect at the longitudinal axis 148 at an optimum distance for spacing the nozzle assembly 150 from the patient's eye, as shown in Fig. 16. A light source 1546, 1548 is disposed proximal of each lens 1542, 1544, respectively, with each light source 1546, 1548 being directed along the projection line of each respective lens 1542, 1544. The light sources 1546, 1548 may be LEDs, incandescent sources, lasers, or other suitable light source, as will be recognized by those skilled in the art. The light sources 1546, 1548 are electrically connected to the activation switch 180 so that the light sources 1546, 1548 activate upon initial engagement of the activation switch 180.

[0118] Preferably, the light sources 1546, 1548 and the lenses 1542, 1544 form a pattern on the target eye when the device 100 is aimed at the eye and the activation switch 180 is depressed. The pattern may be formed by separate masks 1550, 1552 that are disposed between each light source 1546, 1548 and its respective lens 1542, 1544, as shown in Fig. 16, or, alternatively, the mask may be formed on each lens 1542, 544 (not shown). In either embodiment, the targeting mechanism 1540 forms one of three general patterns on the iris or the sclera of the eye. When the device 100 is too far from the eye, a pattern similar to a pattern formed in one of Figs. 17a, 18a, 19a, 20a, 21a is formed. When the device 100 is a correct distance from the eye, a pattern similar to the pattern formed in one of Figs. 17b, 18b, 19b, 20b, 21b is formed. When the device 100 is too close to the eye, a pattern similar to the pattern formed in one of Figs. 17c, 18c, 19c, 20c, 21c is formed. Those skilled in the art will recognize that the patterns shown in Figs. 17a-21c are exemplary only, and that numerous other patterns may be formed.

[0119] In addition to assisting in determining the optimum distance for spacing the device 100 from the eye, the targeting mechanism 1540 also aids in accurately aiming the device 100 at the eye, so that the mist generated by the device 100 is directed toward the middle of the eye, and not off to the side.

[0120] While the targeting mechanism 1540 described above is useful for a professional practitioner to use to aim the device 100 at a patient, those skilled in the art will recognize that an alternative embodiment of a targeting mechanism (not shown) may be used to by a patient on himself/herself by directing the targeting mechanism onto his/her retina.

Handle portion

[0121] Referring back to Figs. 1 and 2, the handle portion 160 contains the bulk of the electronics, as well as the activation switch 180 and the power supply 170. As described previously above, the handle portion 160 may also include a dosage adjuster 1530a (shown in

Fig. 15c) for adjusting the amount of fluid 122 that is discharged per use. The handle portion 160 includes an elongated body 162 having a top end 164, which is connected to the body portion 130, as well as a bottom end 165, which is configured for removable insertion into a base 166.

[0122] In a non-use operation, the device 100 is preferably disposed in the base 166, as shown in Figs. 1 and 2. The base 166 typically rests on a desktop and holds the device 100 such that the device 100 can simply be lifted from the receiver for use. The base 166 includes a cavity 167 that is sized and shaped to securely receive the bottom end 165 of the handle portion 160. The base 166 may also be weighted to keep the device 100 from toppling over after the device 100 is inserted into the base 166. Alternately, the base 166 may include an adhesion device, such as a suction cup or an adhesive (not shown), to keep the device 100 from toppling over.

[0123] Preferably, the handle portion 160 and the base 166 may be separately machined from solid metal or plastic stock, or may be injection molded with impact resistant polymer resins, such as ABS, polycarbonate, PVC, or other suitable material, as will be recognized by those skilled in the art. The handle portion 160 may optionally include a rubberized grip 168, at least along a length of the handle portion 160 facing the distal end of the device 100. The rubberized grip 168 is softer for the user and helps prevent the user from accidentally dropping the device 100. The grip 168 may also include indentations for a user's fingers to enhance ergonomics. The grip 168 may be manufactured from a material having a hardness in the range of 10-50 Shore A that may be molded separately and bonded onto the handle portion 160.

[0124] Referring now to Figs. 22a and 22b, an optional mechanical targeting means 1620, for setting an optimum distance between the nozzle assembly 150 and the patient's eye, is shown. In lieu of the electronic targeting means 1540 shown and described with respect to Figs. 14 and 17a-21c, the targeting means 1620 may be mechanically incorporated into the device 100.

[0125] The targeting means 1620 includes a generally elongated member 1622 that includes a connected end 1624 that is releasably inserted into the spacer recess 137, and a free end 1628 that is disposed away from the connected end 1624. As shown in Fig. 22b, the free end 1628 is generally "Tee-shaped" and is preferably formed in the shape of an eyelid depressor to depress the tear sac under the eye and to provide a larger ocular surface area for contact with the fluid 122 being dispensed from the device 100. Since the free end 1628 engages the patient and the patient's eye area, it is preferred that the targeting means 1620 is disposable between uses to avoid any contamination from one patient to the next.

[0126] Preferably, the elongated member 1622 is constructed from impact resistant polymer resins, such as ABS, polycarbonate, PVC, or some other suitable rigid material to minimize deflection of the elongated member 1622 during operation. Also preferably, the free

end 1628 is either coated with or constructed from a soft material, such as rubber in order to reduce the likelihood of eye injury in the event that the free end 1628 accidentally engages the eye.

Power

[0127] A preferred power source 170 for the device 100 is battery power. As can be seen in Figs. 1 and 2, a battery 172 is removably inserted into the bottom end 165 of the handle portion 160. A cover 169 retains the battery 172 in the handle portion 160. The cover 169 is removable so that the battery 172 may be easily replaced. The cover 169 may be releasably connected to the handle portion 160 by clips, threaded fasteners, or other means known to those skilled in the art.

[0128] The battery 172 may be a single-use lithium ion or alkaline type, or the battery 172 may be rechargeable lithium-ion, nickel-cadmium, nickel-metal-hydride, or other battery type. The battery 172 may be a single battery or a plurality of batteries electrically connected in series. For example, two lithium photo batteries NEDA/ANSI type CR2 (e.g. Duracell Ultra CR2 Li/MnO₂) may be connected in series will be used to power the device 100. The batteries 172 are preferably rated for 3V and approximately 2000mAh. The batteries 172 are connected in series to provide a total capacity 2000mAh at 6V. The batteries 172 preferably have a peak current rating of at least 1.8A.

[0129] If a rechargeable battery is used, a charger is required. Those skilled in the art will recognize that the charger may be integrated into the device 100 or enclosed in a separate enclosure, such as in the base 166. The base 166 includes a standard 110V electrical cable 1610 extending therefrom that is electrically connected to an AC/DC converter (not shown) in the base 166 that converts 110V AC supply to 6V DC. The base 166 also includes a pair of contacts (not shown) that engage recharger contacts (not shown) in the bottom end 165 of the handle portion 160 when the device 100 is inserted into the base 166.

[0130] Alternatively, the device 100 may be designed such that the battery 172 can be easily removed from the device 100 and charged in a separate charger (not shown). A further alternative is to replace the battery with an AC-to-DC converter, and power the device 100 through a line cord connected to an AC source.

Activation switch

[0131] An activation switch 180 extends through the handle portion 160 to activate the device 100 upon a user engaging the activation switch 180. The activation switch 180 is preferably a button, as is shown in Fig. 2, or some other suitable device, such as a trigger, as will be recognized by those skilled in the art. Alternatively, the activation switch may be a foot

switch (not shown) that is electronically connected to the system controller 190 to activate the device 100, such as by an electrical line.

[0132] The activation switch 180 is electronically connected to the system controller 190 via leads 182, 184. Preferably, the activation switch 180 is a three-position switch such that, when the activation switch 180 is depressed an initial amount from an open position to an initially closed position, the device 100 is activated. This activation illuminates the activation indicator 1310 to indicate that the device 100 is about to operate. When the activation switch 180 is completely depressed, the activation switch 180 transmits a signal, through the system controller 190, to operate the prime mover 140 for a period of time determined, through the system controller 190, by the settings on the dosage adjuster 1530. Preferably, the time period for operation extends between approximately 0.5 and 5 seconds. However, operation time of the prime mover 140 is not dependent on the duration of time that the activation switch 180 is depressed, but on the settings of the dosage adjuster 1530. However, it is preferred that, if the activation switch 180 is depressed for an extended period of time, such as greater than two seconds, the system controller 190 interprets the signal received from the activation switch 180 as a signal to run the device 100 continuously for a predetermined, extended period of time, such as thirty (30) seconds, such as to run a cleaning solution such as saline, through the device 100 to clean the device 100. Alternatively, if the activation switch 180 is depressed for longer than the predetermined period of time, the system controller 190 will provide power for the prime mover 140 to operate as long as the activation switch 180 is fully depressed.

Electronics

[0133] The primary function of the system controller 190 is to energize the prime mover 140, which is preferably a piezoelectric transducer assembly or other piezo device, as described above. When energized, the prime mover 140 generates a mist of fluid droplets from the fluid 122. The energizing signal for the prime mover 140 must excite the prime mover 140 at the proper resonant frequency, and must supply enough energy to the prime mover 140 to cause misting. A simple user interface, such as the activation switch 180, is required for operation and control of the prime mover 140. A microprocessor 192 will be used to provide intelligence for the interface between the activation switch 180 and the prime mover 140, and to supervise the circuits driving the prime mover 140, as well as all of the electronic features.

[0134] The system controller 190 controls operation of the device 100 and includes a microprocessor 192, preferably in the form of a PCBA (Printed Circuit Board Assembly), to incorporate of the electronics for operation of the device 100. Fig. 23 shows an electronic block diagram for a preferred embodiment of the system controller 190. The microprocessor 192 is

housed in the system controller 190, through which a majority of the operation of the device 100 passes. The system controller 190 preferably also contains a non-volatile memory, input/output (“I/O”) devices, digital-to-analog (“D/A”) and analog-to-digital (“A/D”) converters, driver circuits, firmware, and other electronic components, as will be described in detail herein.

Alternatively, those skilled in the art will recognize that simple logic components may be used.

[0135] The activation switch 180 is part of a normally open (“NO”) circuit that includes the activation indicator 1310. As described above, the activation switch 180 is a three-position switch, with the first position in the NO condition. The second position, when the activation switch 180 is depressed part way, powers the activation indicator 1310 to indicate to the user that the device 100 is on. The third position, when the activation switch 180 is fully depressed, activates the device 100 to operate the prime mover 140 to generate a mist from the nozzle assembly 150 for medication dispensing to the patient. To conserve power and lengthen operational battery life, all circuits are disconnected from power while the activation switch 180 is open.

[0136] A power management & low battery indicator 194 includes an electronic circuit that automatically measures the battery voltage and provides a visual or audible (beeping) indication if the voltage has dropped below a preset level. Power management chips (also known as “gas gages”) are commercially available for various battery types, or such a circuit may be constructed from discrete components. Preferably, the circuit also provides “sleep” or “hibernate” modes, as are known to those skilled in the art, in which battery life is extended by reducing power consumption when the device 100 has been inactive for a preset amount of time.

[0137] An optional power conditioning circuit 196 provides a constant and regulated voltage to the rest of the system controller 190. Power conditioning chips are commercially available for various voltage and current requirements, or alternatively, such a circuit may be constructed from discrete components.

[0138] A voltage step-up & driver (VSD) circuit 198 powers the prime mover 140. For a prime mover 140 that includes the piezo device described above, the purpose of the VSD circuit 198 is to drive the piezoelectric crystal contained in the piezo device at a desired resonant frequency. Different crystals and piezoelectric assemblies have different resonant frequencies, as well as different Q-factors, so the VSD circuit 198 is preferably custom designed to match the operating characteristics of the particular piezo device. The VSD circuit 198 contains an oscillator formed of integrated and/or discrete components such as power transistors, power diodes, capacitors, and coils.

[0139] Preferably, the piezo device is driven by a square wave at its resonant frequency in the range of 50 KHz to 70 KHz. Since each piezo device has a slightly different resonant frequency, the circuit will use a Phase Lock Loop (PLL) or other feedback technique with a Voltage Controlled Oscillator (VCO) to lock on to the piezo resonant frequency and to automatically adjust the drive signal frequency as the resonant frequency varies. The piezo device is preferably driven by a peak-to-peak signal in the range of 200V, or as appropriate to provide sufficient misting. Using the preferred Omron piezoelectric device described above, the mist volume produced with this method is in the range of approximately 10 to 100 microliters/second.

[0140] The system controller 190 also optionally includes a heater control 1910 and that is electronically connected to the optional reservoir heater 1248 to heat the fluid 122 in the reservoir 120, as desired. The heater control 1910 includes a feedback loop to control the desired temperature of the fluid 122 in the reservoir 120. A heater power supply 1912 is also electronically connected to the system controller 190 to provide a power supply to the optional heater 1248.

Low fluid level

[0141] If the device 100 includes the low level sensor 1250 in the reservoir 120 as described above, the device 100 also includes a low fluid level alarm 1914 that is set to alarm when the fluid 122 in the reservoir 120 is depleted to a predetermined level. The low reservoir sensor 1250 is programmed to transmit a signal to the system controller 190 when the fluid level reaches the predetermined level. The system controller 190 in turn transmits a signal to the alarm 1914. The alarm 1914 may be a visual alarm, such as a blinking light, or the alarm 1914 may be an audible alarm, such as a beep.

Dosage adjustment

[0142] A manual method and apparatus for adjusting dosage amount dispensed during operation of the device 100, using the dosage adjuster 1530, 1530a has been previously described. Adjustment of the dosage adjuster 1530, 1530a transmits a signal to a dose control circuit 1916 to determine the length of time that the prime mover 140 operates to dispense the fluid 122 from the reservoir 120 to the patient. The system controller 190 also includes a flow volume control circuit 1918 that determines the volume of the fluid 122 per unit time that is dispensed through the prime mover 140. The total amount of the fluid 122 dispensed is determined by the value of the flow rate as determined by the flow volume control circuit 1918 times the length of time of operation of the prime mover 140 as determined by the dose control circuit 1916. Preferably, the flow volume control circuit 1918 is preprogrammed into the system

controller 190, while the dose control circuit 1916 may be manually adjusted based on the type of medication and the dosage that the prescribing physician determines is necessary based on the patient's condition.

[0143] Alternatively, instead of manually adjusting the dosage amount, the dosage amount may be adjusted electronically, such as by external calibration of the system controller 190 to adjust operational values of the dose control circuit 1916 and the flow volume control circuit 1918 based on need.

Dosage complete indicator

[0144] The system controller 190 also includes a "dosage complete" indicator 1920 that indicates when the device 100 has dispensed the prescribed amount of fluid 122 from the reservoir 120. The indicator 1920 may be a visual alarm, such as a blinking light, or the indicator 1920 may be an audible alarm, such as a beep. The indicator 1920 preferably is activated after a slight time delay, such as approximately 0.5 second, after the device 100 ceases to dispense the fluid 122 from the nozzle assembly 150. This delay ensures that the user does not remove the device 100 from in front of the patient's eye until all of the prescribed dose of medication has been dispensed from the device 100. Since the system controller 190 controls operation of the prime mover 140, the system controller 190 is able to calculate the desired delay time between stopping operation of the prime mover 140 and sending the signal to the indicator 1920 to indicate that the dosage is complete.

Targeting optics

[0145] If the optional electronic targeting mechanism 1540 is used, depressing the activation switch 180 to the first position transmits a signal to the system controller 190 to activate the targeting mechanism 1540, illuminating the light sources 1546, 1548 to project images on the patient's eye. The targeting mechanism 1540 remains activated when the activation switch 180 is depressed to the second position. When the activation switch 180 is released, signal to the system controller 190 ceases, and the targeting mechanism 1540 is deactivated by the system controller 190.

Outside communications

[0146] Optionally, the device 100 may include an input/output (I/O) device 1922 for transmitting information between the device 100 and an outside device, such as a personal computer, PDA, or other such electronic device that is capable of displaying information transmitted from the device 100. Information that may be transmitted from the device 100 includes, but is not limited to, usage information, such as the number of times the device 100 was used, and at what times; dosage amount per application; and current and voltage draw of the

device 100 during use, as well as other operational information about the device 100. Further, information may be transmitted from the outside device to the device 100. Such information may include, but is not limited to, clearance information to clear the system controller 190 memory of previous information that has already been downloaded to the outside device; operational information that allows the device 100 to be used with particular medicament reservoirs; temperature settings for the heater control 1910; and operational duration information to adjust the dose control circuit 1916 and the flow volume control circuit 1918 to adjust dosage amounts, as well as other information that may be transmitted to the system controller 190.

[0147] As shown in Fig. 2, the I/O device 1922 may include a port 1612 on the handle portion 160 for physically connecting the device 190 to the outside device, such as by a cable. The port 1612 may be a standard Universal Serial Bus (USB) port, or some other suitable port as will be recognized by those skilled in the art. The port 1612 is electronically connected to the system controller 190 by a port cable 1614 that transmits information between the port 1612 and the system controller 190. Alternatively, the I/O device 1922 may include an infrared transmitter/receiver (not shown) that allows the device 100 to be placed near, but not physically connected to, the outside device to exchange information such as the information described above.

[0148] A pediatric version of a device 200 according to an alternate embodiment of the present invention, shown in Fig. 24, may include a façade 204 at the distal end 202 of the device 200 that encourages younger patients to look in the direction of the device 200. For example, for ophthalmic delivery, the façade 204 may include a clown face or an animal face that catches the attention of the patient and distracts the patient from the medicament that is being dispensed from the device 200. In the embodiment shown in Fig. 24, the nose of the façade is the mesh plate 156. Alternatively, the façade 204 may include moving parts to distract the patient during operation of the device 200.

[0149] Alternatively, a veterinary version of a device 300 according to yet another alternate embodiment of the present invention, shown in Fig. 25, may include a façade 304 at the distal end 302 of the device 300 that distracts the animal that is being medicated. The façade 304 may include a moving element for the animal to focus upon during administration of the medicament.

[0150] The embodiments shown and described above may be offered in a reusable configuration. In this event, the parts may be injection molding from clear polymer resins that withstand repeated sterilization by steam autoclave, such as autoclaveable versions of acrylics, styrenes, and polycarbonates.

[0151] Alternatively, the embodiments shown may be offered as a sterile disposable. In this case it may be injection molded from a wide variety of clear polymer resins, including acrylics, styrenes, urethanes, PMMA, and polycarbonates. These resins are generally compatible with industrial sterilization by e-beam, gamma, and EtO.

Use

[0152] Between uses, the device 110 is typically stored in the base 166, with the bottom end 165 of the handle portion 160 inserted into the cavity 167 in the base 166. The electrical cable 1610 is connected to an external power supply to provide electrical power to the batteries 172 to charge/recharge the batteries 172. The heater 1248, if used, heats the fluid 122 in the reservoir. The temperature of the fluid 122 is controlled by the heater controller 1910 to maintain the fluid 122 at a desired temperature.

[0153] The device 100 is designed so that it can be used by one person to self administer medicament, such as a patient in his/her home, or, the device 100 can be used by one person to administer medicament to a second person, such as a medical professional treating a patient in a medical office or a hospital setting.

[0154] For self use, the user removes the device 100 from the base 160 and aims the discharge end of the nozzle assembly 150 toward the eye into which the user intends to insert the eye medication. If the optional mechanical targeting means 1620 is connected to the device 100, the user inserts the connected end 1624 into the spacer recess 137. The user then uses the free end 1628 of the targeting means 1620 to depress the eyelid. When the device 100 is in the desired position, the user then uses his/her thumb, as shown in Fig. 26, to depress the activation switch 180. By pressing the activation switch 180 to the first position, the activation indicator 1310 is illuminated, indicating that the device 100 is ready for operation.

[0155] For professional use on a patient, the user, such as an optometrist or an ophthalmologist, removes the device 100 from the base 160 and aims the discharge end of the nozzle assembly 150 toward the eye into which the user intends to insert the eye medication. If the optional mechanical targeting means 1620 is connected to the device 100, the user inserts the connected end 1624 into the spacer recess 137. The user then uses the free end 1628 of the targeting means 1620 to depress the eyelid. When the device 100 is in the desired position, the user then uses his/her index finger, as shown in Fig. 27 to depress the activation switch 180. By pressing the activation switch 180 to the first position, the activation indicator 1310 is illuminated, indicating that the device 100 is ready for operation.

[0156] If the optical targeting mechanism 1540 is used, the user aims the device 100 generally toward the patient's eye and, using his/her forefinger, as shown in Fig. 27, depresses

the activation switch 180 to the first position. The activation indicator 1310 is illuminated, indicating that the device 100 is ready for operation. Also, the light sources 1546, 14538 on the targeting mechanism 1540 are illuminated, projecting images onto the patient's eye. Preferably, the images are any of the images shown in Figs. 17a-21c. The user can adjust the distance and aim of the device 100 relative to the patient's eye based on the images projected onto the patient's eye.

[0157] The remainder of the description of the operation of the device 100 is the same whether the device 100 is being used for self-administration of medication or whether the device 100 is being used by a professional to administer medication to a patient.

[0158] The user presses the activation switch 180 to the second position and then releases the activation switch 180, transmitting a signal to the system controller 190 to operate the prime mover 140. An electronic operational signal is transmitted through the power management circuit 194 and the VSD circuit 198 to the prime mover 140 which, in the case of the piezoelectric device described above, causes the piezoelectric device to vibrate, preferably at an ultrasonic frequency, along its longitudinal axis 148. The prime mover 140 is operated for a predetermined amount of time, preferably between approximately 0.5 and 2 seconds, as programmed into the system controller 190 prior to use. The prime mover 140 operates for the predetermined amount of time, regardless of how long the activation switch 180 is depressed, unless the activation switch 180 is depressed in excess of a predetermined period of time, such as 5 seconds, as will be described in more detail later herein.

[0159] The vibration of the prime mover 140 draws fluid 122 from the reservoir 120 and through the lumen 1410. The fluid 122 exits the distal end 144 of the prime mover 140 and passes through the openings 1520 in the mesh plate 156, where the fluid 122 is broken into micron-sized particles, which are directed toward the patient's eye. After the prime mover 140 has operated for the predetermined period of time, the system controller 190 ceases to transmit the operational signal and the prime mover 140 stops. At this time, the system controller 190 transmits a signal to the dose complete indicator 1920 to indicate to the user that the dosage is complete.

[0160] If the user is using the mechanical targeting means 1620, the user preferably removes the connected end 1624 from the spacer recess 137 and discards the elongated member 1622 to ensure that any bacteria from the patient's eye is not transmitted to the targeting means 1620 and then retransmitted to the next patient.

[0161] If the level of the fluid 122 in the reservoir 120 drops below a predetermined level, the low reservoir sensor 1250 transmits a signal to the system controller 190, which in turn

transmits a signal to the low reservoir indicator 1914, informing the user that the reservoir 120 must be removed and a new reservoir must be inserted into the body 130.

[0162] If the low battery indicator 194 indicates that the power source 170 is at lower power, the user may insert the device 100 into the base 166 to charge the power source 170, or alternatively, replace the power source 170.

[0163] In the event that the user desires to change medication in the reservoir 120, it is recommended that the device 100 be “flushed” after removing the original medication but before using the new medication, so as not to contaminate the new medication with the old medication. In such an instance, the user inserts a reservoir containing a cleaning fluid, such as a saline solution into the body 130, and depresses the activation switch 180 in excess of a predetermined period of time, such as 5 seconds. The system controller 190 recognizes the extended depression of the activation switch 180 as the start of a cleaning cycle and operates the prime mover 140 for an extended period of time, such as for 30 seconds, or some other predetermined time, as desired. At the end of the cleaning cycle, the dose complete indicator 1920 may activate, alerting the user that the device 100 is clean, and that a new medication may now be used in the device 100.

[0164] While the embodiments of the present invention described above are preferably used to deliver medicament to a patient’s eye, those skilled in the art will recognize that the embodiments of the present invention may be used with a respiratory medication instead of an ophthalmic medication, and that the invention may be used in the treatment of respiratory ailments instead of ophthalmic ailments.

[0165] It will be appreciated by those skilled in the art that changes could be made to the embodiments described above without departing from the broad inventive concept thereof. It is understood, therefore, that this invention is not limited to the particular embodiments disclosed, but it is intended to cover modifications within the spirit and scope of the present invention as defined by the appended claims.

CLAIMS

What is claimed is:

1. A fluid atomizer comprising:
 - a body having a proximal end and a distal end;
 - a removable reservoir connected to the body, wherein the reservoir contains a fluid disposed therein;
 - a discharge plate disposed at the distal end, wherein the discharge plate includes a plurality of openings extending therethrough; and
 - propulsion means for transmitting the fluid from the reservoir to the discharge plate and through the plurality of openings, wherein transmission of the fluid through the plurality of openings atomizes the fluid.
2. The fluid atomizer according to claim 1, further comprising means for selectively determining an amount of the fluid to be transmitted through the plurality of openings during operation of the fluid atomizer.
3. The fluid atomizer according to claim 1, wherein the body further comprises a handle having a trigger mechanism that is alternatively operable by one of a thumb of a first user wherein the distal end is pointed toward the first user and by the other of a finger of the first user wherein the distal end is pointed toward a second user.
4. The fluid atomizer according to claim 1, further comprising a heater element disposed proximate to the fluid such that the heater element heats the fluid.
5. The fluid atomizer according to claim 1, wherein the propulsion means comprises a piezoelectric device.
6. The fluid atomizer according to claim 5, wherein the piezoelectric device comprises a lumen having an elongated shape.
7. The fluid atomizer according to claim 1, wherein the wherein the plurality of openings are arranged in the discharge plate in an elongated shape.

8. The fluid atomizer according to claim 1, wherein the atomizer discharges the fluid having a velocity of between approximately 4 and 30 centimeters per second.
9. The fluid atomizer according to claim 1, wherein the atomizer discharges between approximately 2 and 20 microliters per second.
10. The fluid atomizer according to claim 9, wherein the atomizer discharges between approximately 7 and 10 microliters per second.
11. The fluid atomizer according to claim 9, wherein the atomizer operates for approximately 0.5 to 5 seconds.
12. The fluid atomizer according to claim 1, wherein the atomizer discharges the fluid having average particle sizes between approximately 0.5 and 10 microns in diameter.
13. The fluid atomizer according to claim 1, further comprising a system controller operatively connected to the propulsion means for controlling operation of the propulsion means.
14. The fluid atomizer according to claim 13, further comprising means for transmitting data between the system controller and an external device.
15. The fluid atomizer according to claim 13, further comprising means for operating the atomizer for a period in excess of five seconds.
16. The fluid atomizer according to claim 13, further comprising a low level alert operatively connected to the system controller, wherein the low level alert transmits a signal that the fluid is at a low level in the reservoir.
17. The fluid atomizer according to claim 13, further comprising means for adjusting operation of the propulsion means to adjust an amount of the fluid transmitted across the discharge plate.
18. The fluid atomizer according to claim 17, wherein the means for adjusting operation of the propulsion means are operatively connected to the system controller.

19. The fluid atomizer according to claim 1, wherein the discharge plate is releasably connected to the body.

20. The fluid atomizer according to claim 1, wherein the propulsion means comprises an operating switch operable among an off position, a first operating position, and a second operating position.

21. The fluid atomizer according to claim 20, further comprising a system controller operatively connected to the propulsion means for controlling operation of the propulsion means.

22. The fluid atomizer according to claim 21, wherein, upon engaging the operating switch in the second operating position, the system controller transmits an operating signal to the propulsion means for no more than five seconds.

23. The fluid atomizer according to claim 21 wherein, upon engaging the operating switch in the first operating position, the system controller transmits a signal to a user that the device is ready for operation.

24. The fluid atomizer according to claim 1, wherein the reservoir is tinted.

25. A fluid atomizer comprising:
a body having a proximal end and a distal end;
a removable reservoir connected to the body, wherein the reservoir contains a fluid disposed therein;
a discharge plate disposed at the distal end, wherein the discharge plate includes a plurality of openings extending therethrough;
propulsion means for transmitting the fluid from the reservoir to the discharge plate, wherein transmission of the fluid across the discharge plate atomizes the fluid; and
a system controller electronically connected to the propulsion means, wherein the system controller controls operation of the propulsion means.

26. The fluid atomizer according to claim 25, further comprising a low level alert operatively connected to the system controller, wherein the low level alert transmits a signal that the fluid is at a low level in the reservoir.

27. A fluid atomizer comprising:

a body having a proximal end and a distal end;

a reservoir connected to the body, wherein the reservoir contains a fluid disposed therein;

a discharge plate disposed at the distal end, wherein the discharge plate includes a plurality of openings extending therethrough;

propulsion means for transmitting the fluid from the reservoir to the discharge plate and through the plurality of openings, wherein transmission of the fluid through the plurality of openings atomizes the fluid; and

means for spacing the discharge plate a predetermined distance from a target.

28. The fluid atomizer according to claim 27, wherein the means for spacing the discharge plate comprises a spacer bar releasably connected to the body.

29. The fluid atomizer according to claim 27, wherein the means for spacing the discharge plate comprises at least one light projected onto the target.

30. The fluid atomizer according to claim 27, wherein the reservoir is removable.

31. The fluid atomizer according to claim 27, wherein the reservoir is refillable.

32. A fluid atomizer comprising:

a body having a proximal end and a distal end;

a removable reservoir connected to the body, wherein the reservoir contains a fluid disposed therein;

a discharge plate disposed at the distal end, wherein the discharge plate includes a plurality of openings extending therethrough;

propulsion means for transmitting the fluid from the reservoir to the discharge plate, wherein transmission of the fluid across the discharge plate atomizes the fluid;

a system controller electronically connected to the propulsion means, wherein the system controller controls operation of the propulsion means; and

means for adjusting operation of the propulsion means to adjust an amount of the fluid transmitted across the discharge plate, wherein the means for adjusting operation of the propulsion means are operatively connected to the system controller.

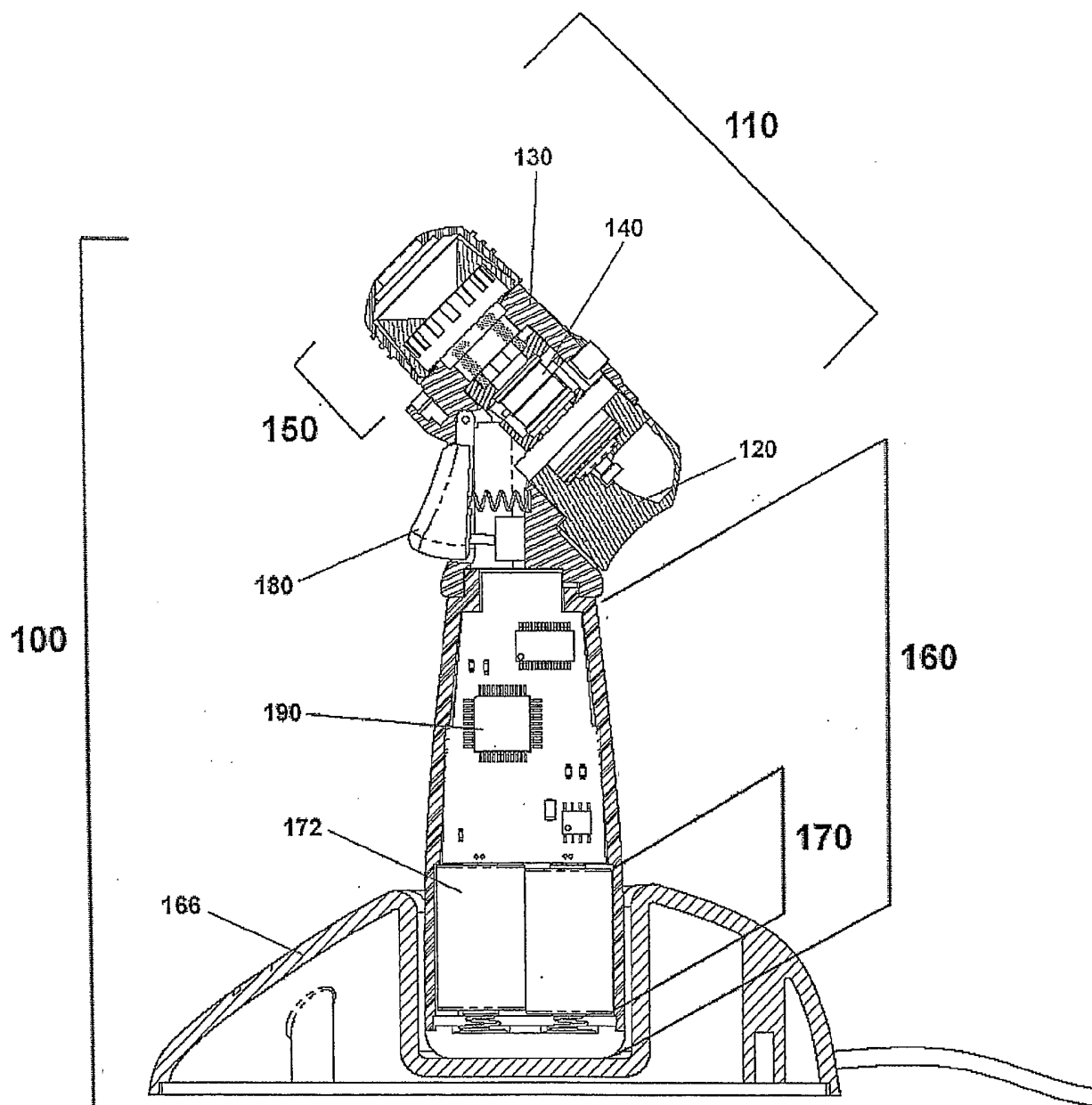


Fig. 1

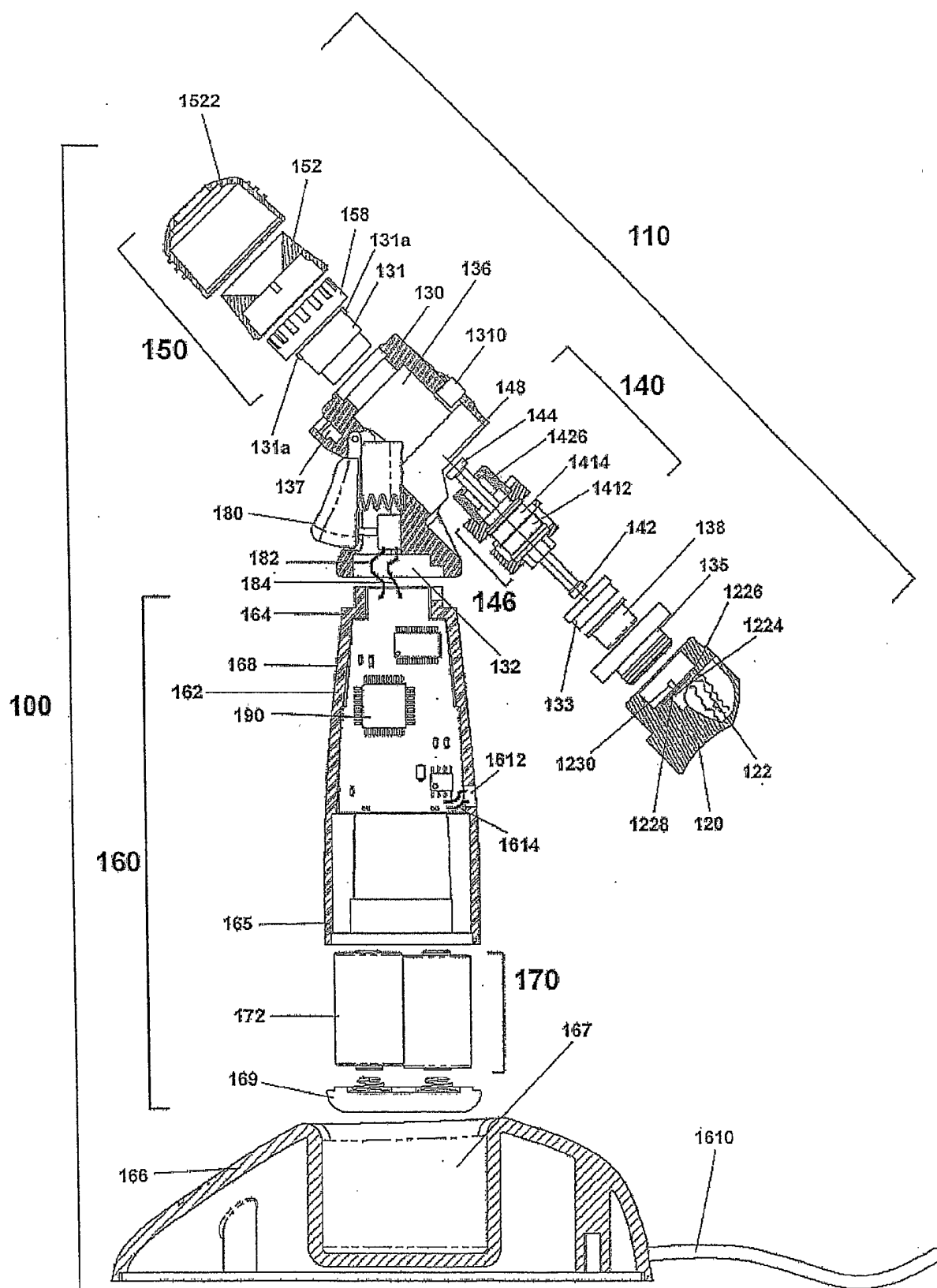
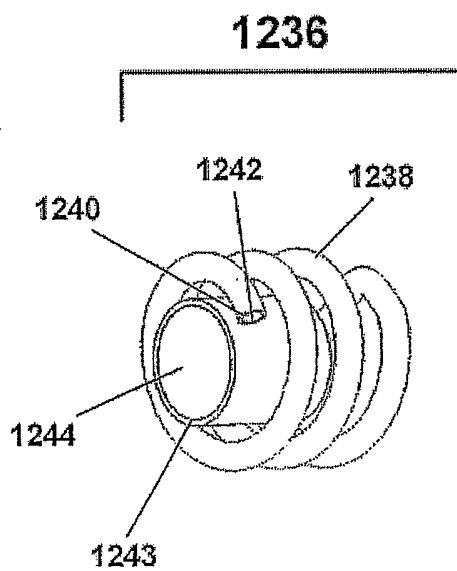
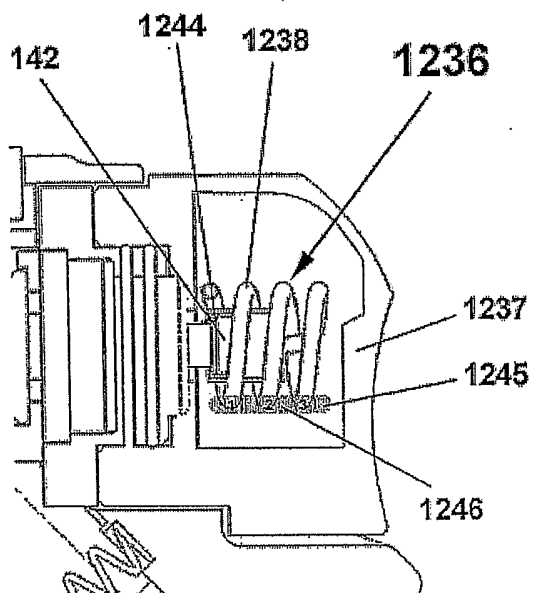
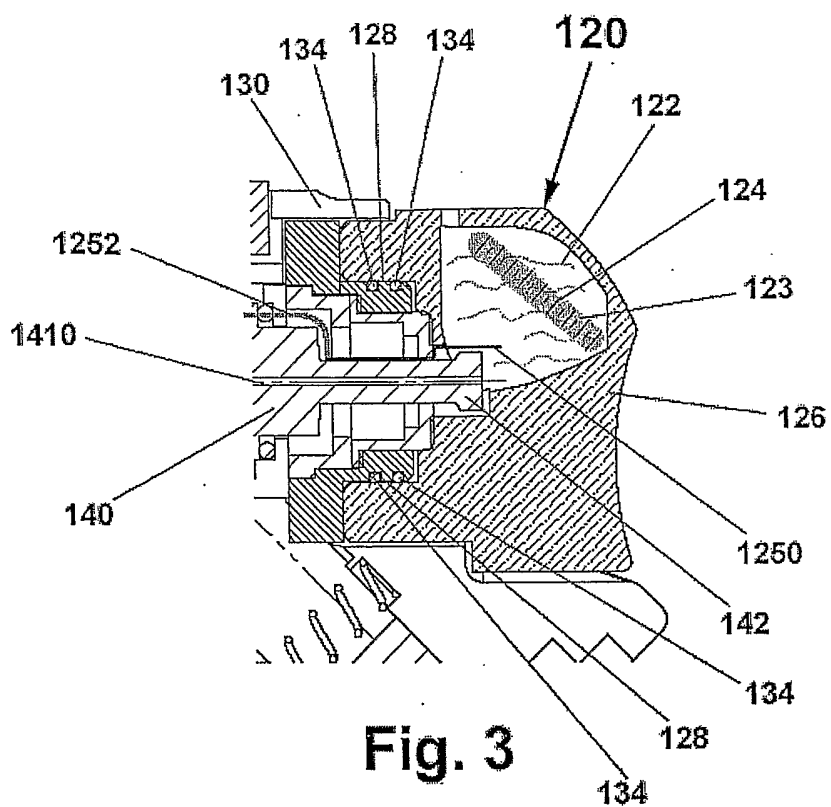


Fig. 2



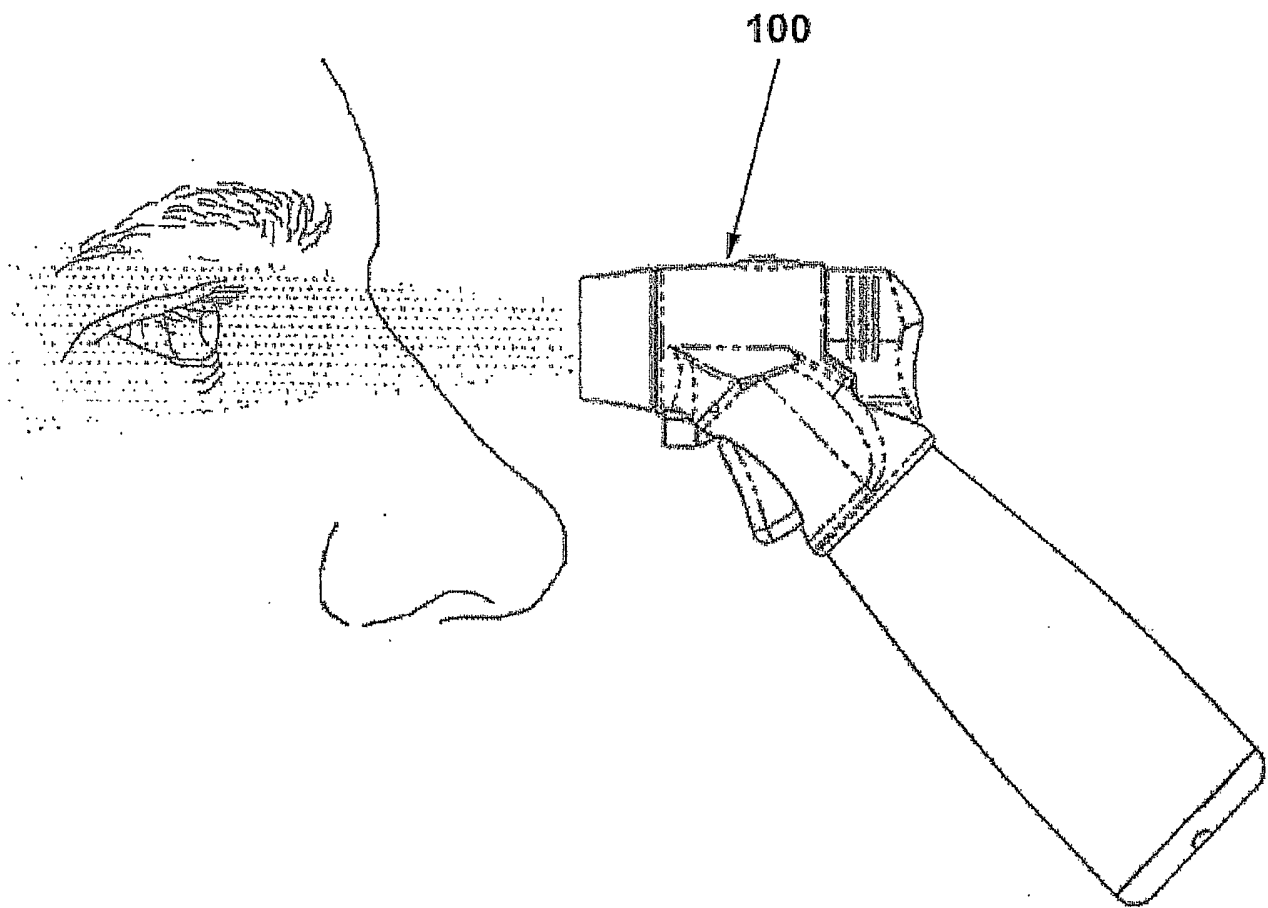


Fig. 4

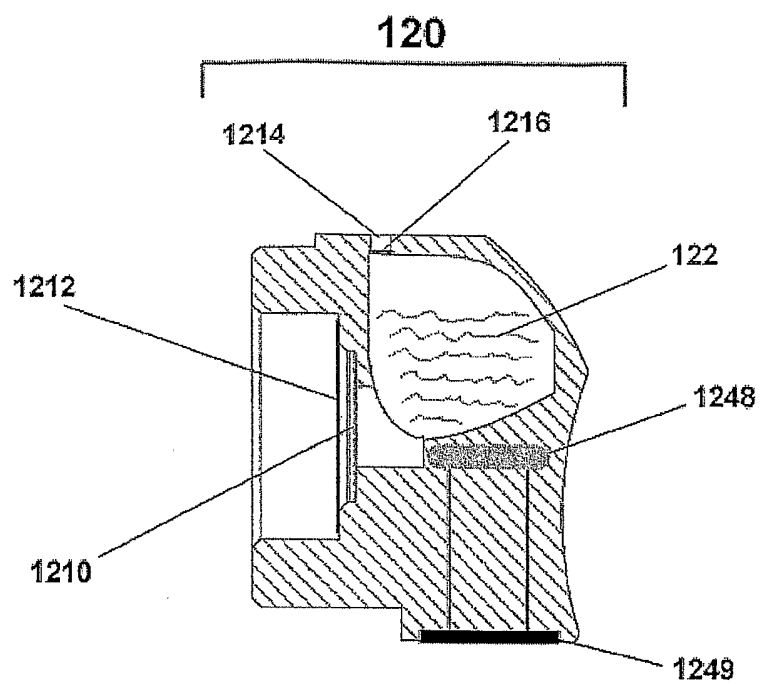


Fig. 5

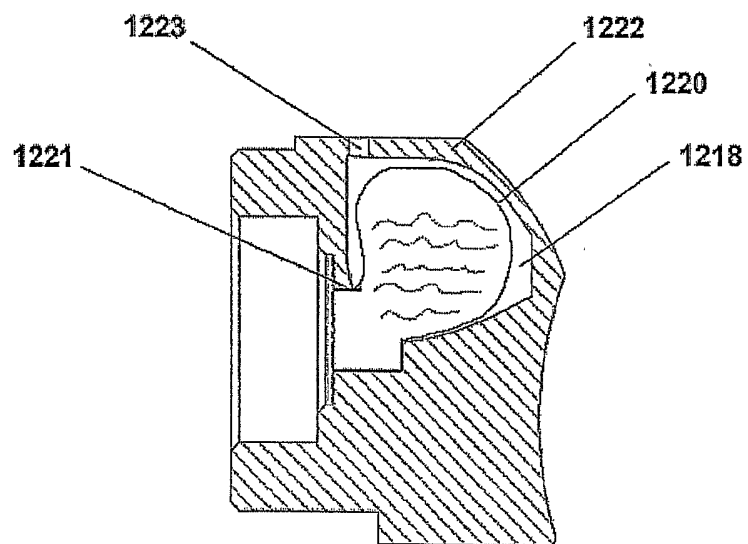


Fig. 6

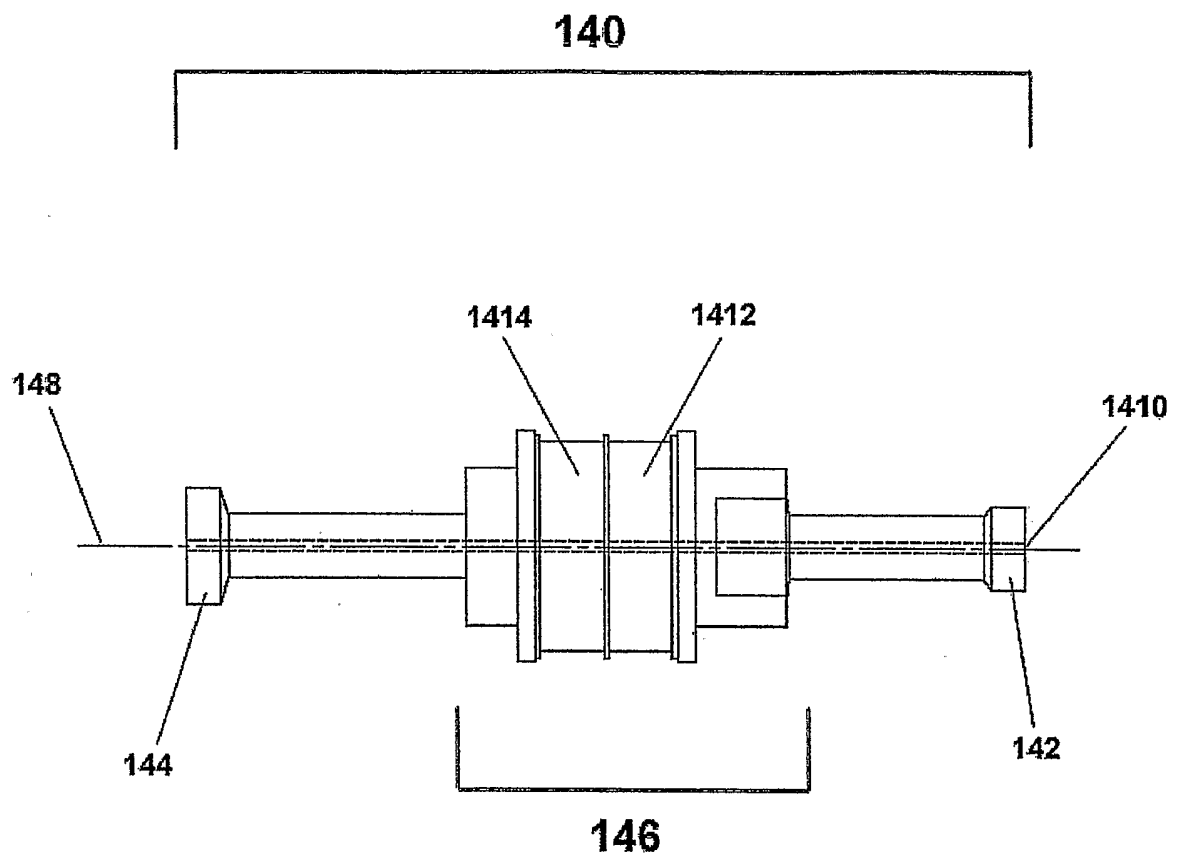
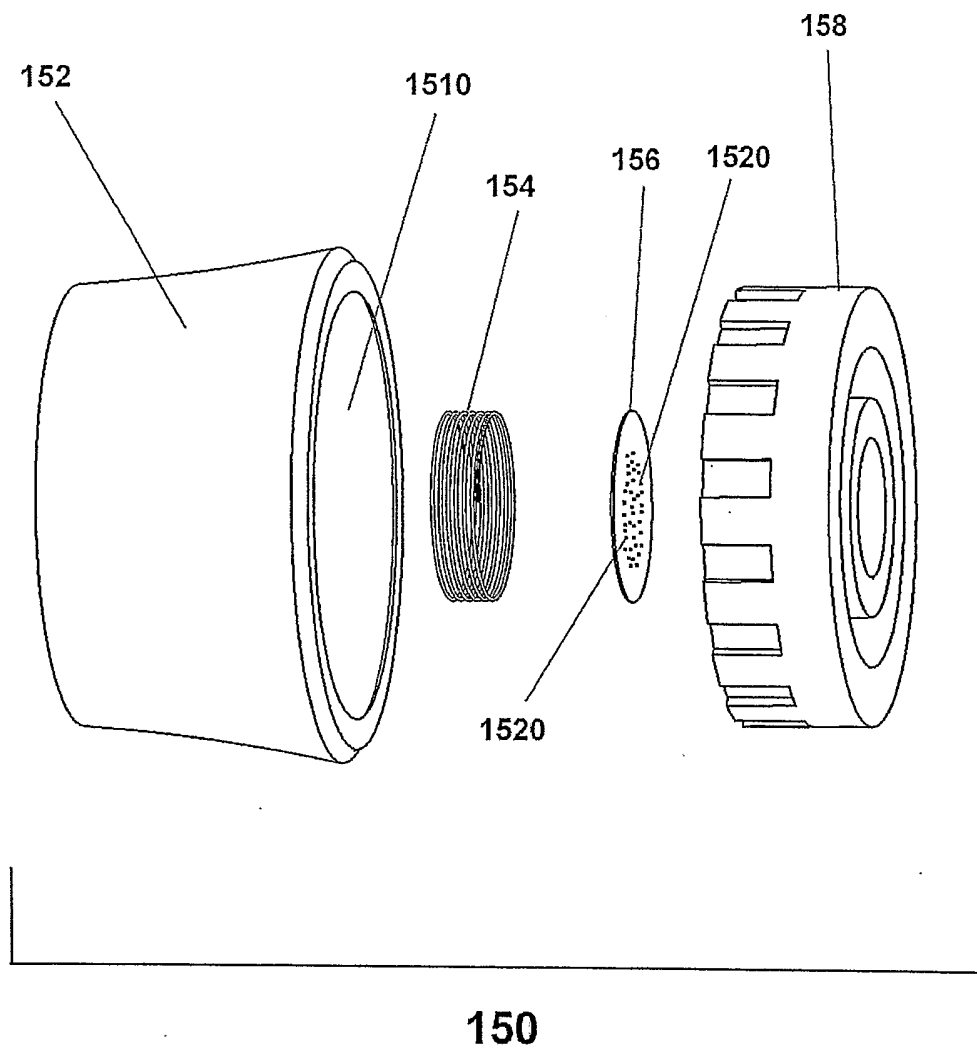


Fig. 9

**Fig. 10**

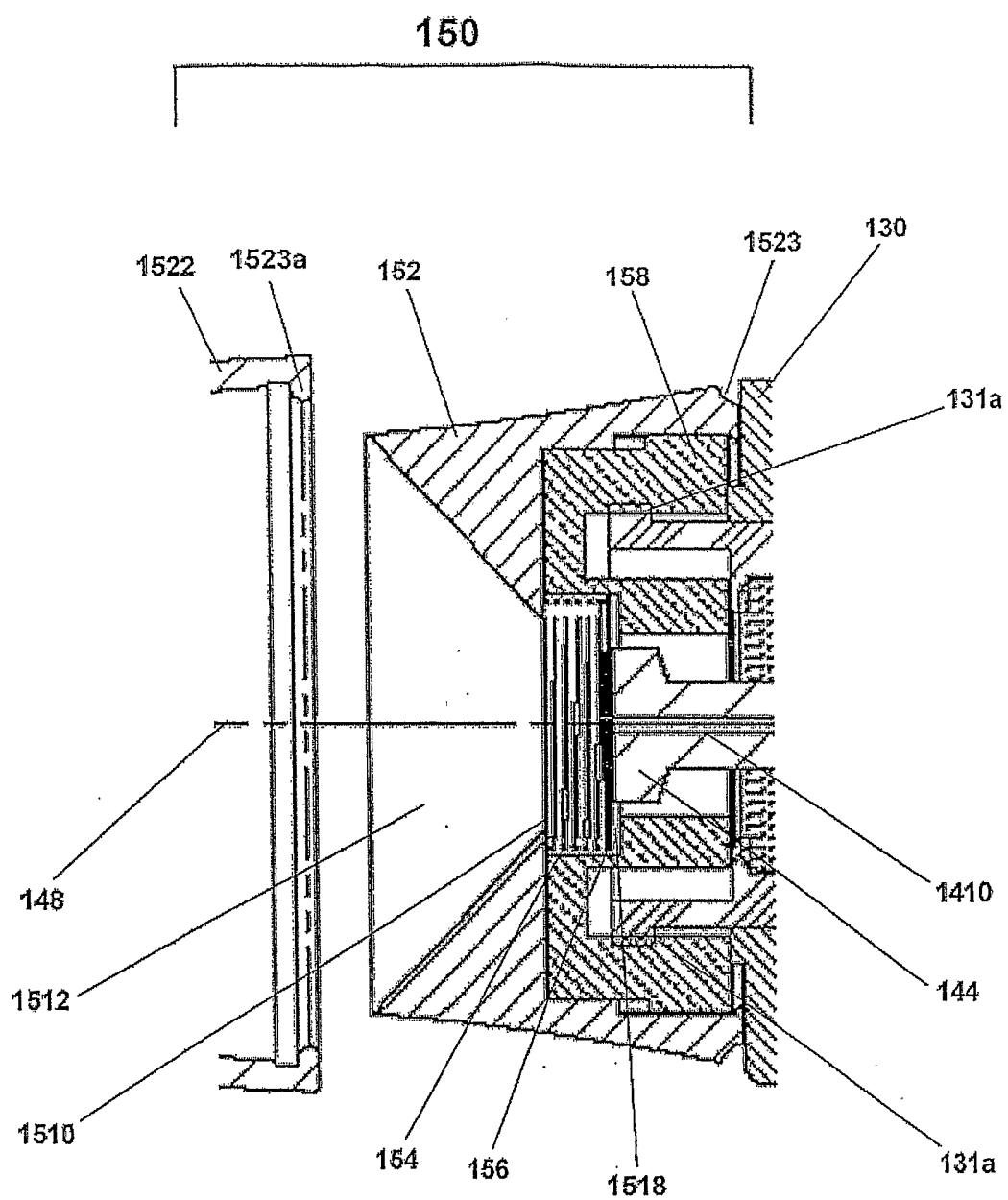
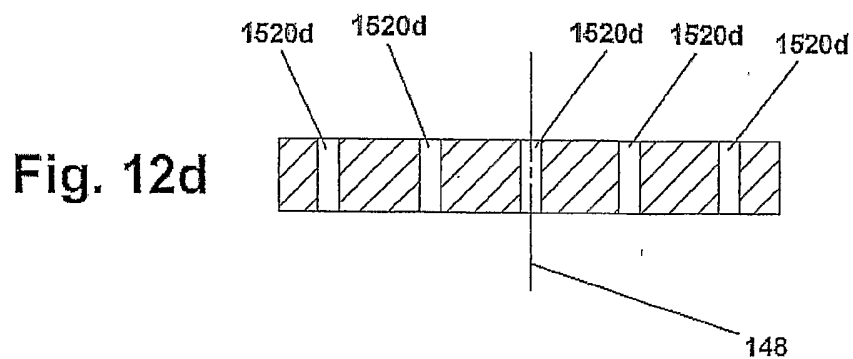
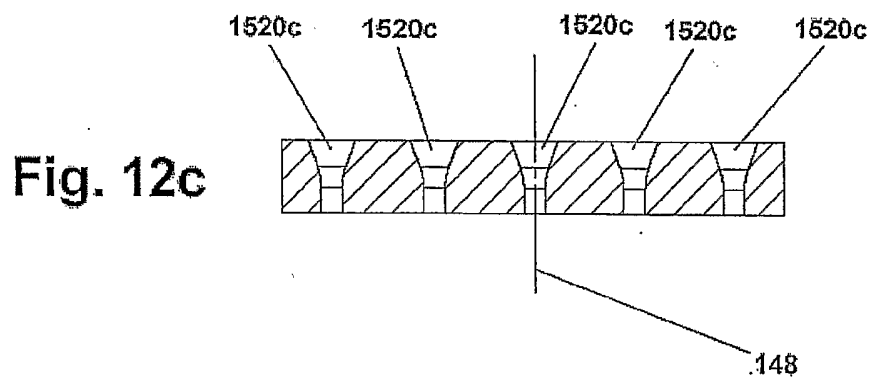
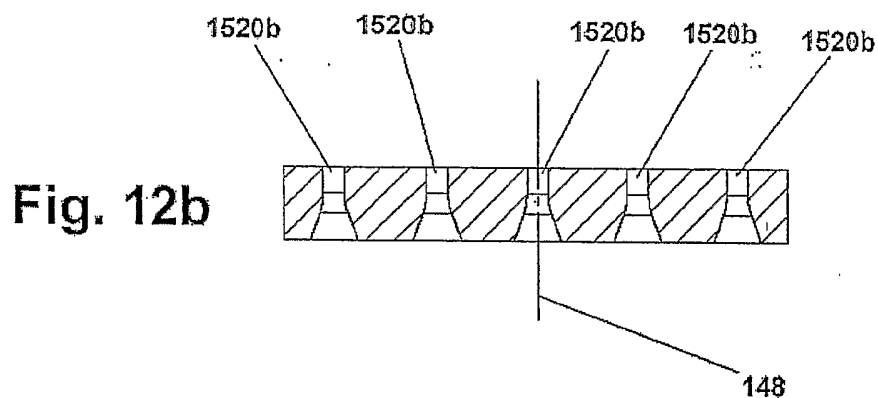
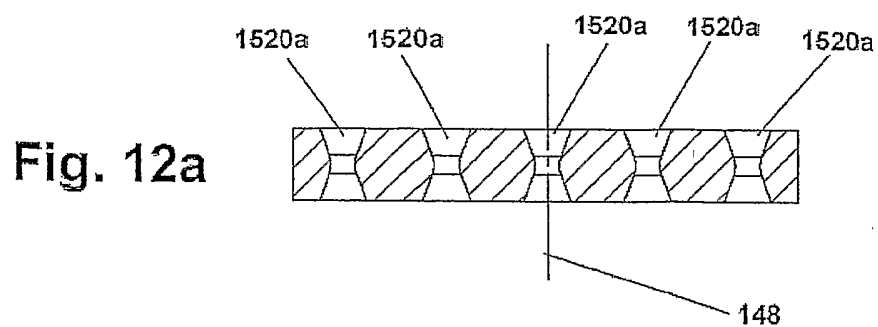


Fig. 11



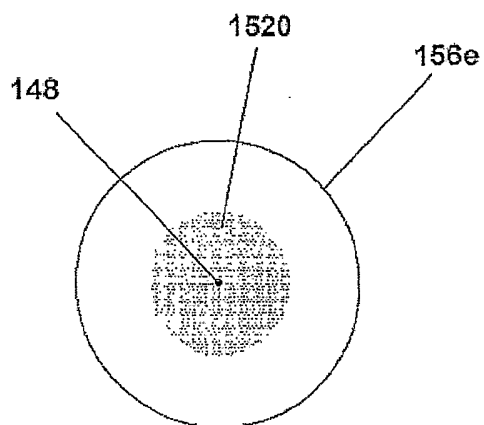


Fig. 13a

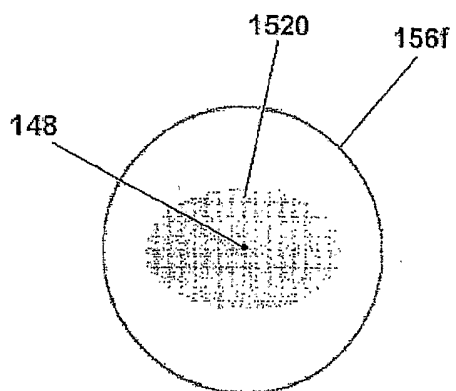


Fig. 13b

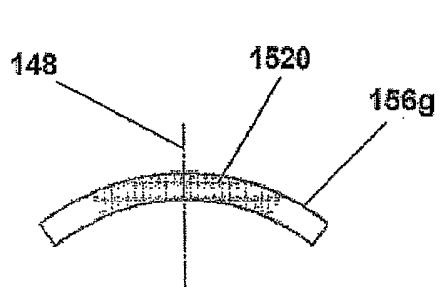


Fig. 13c

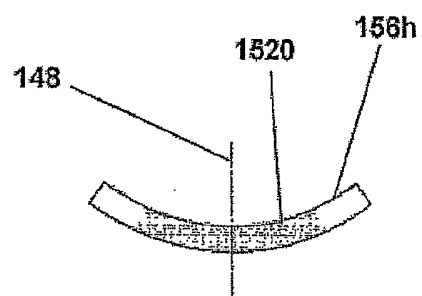


Fig. 13d

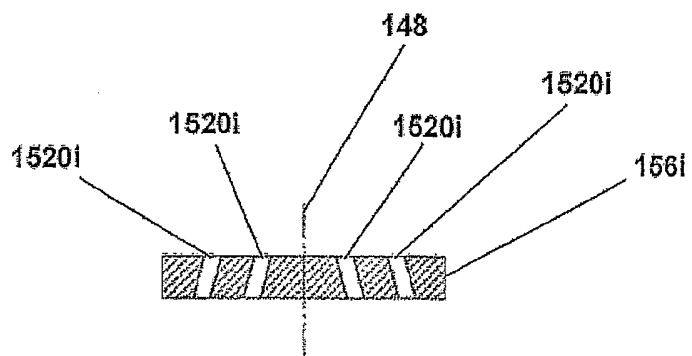


Fig. 13e

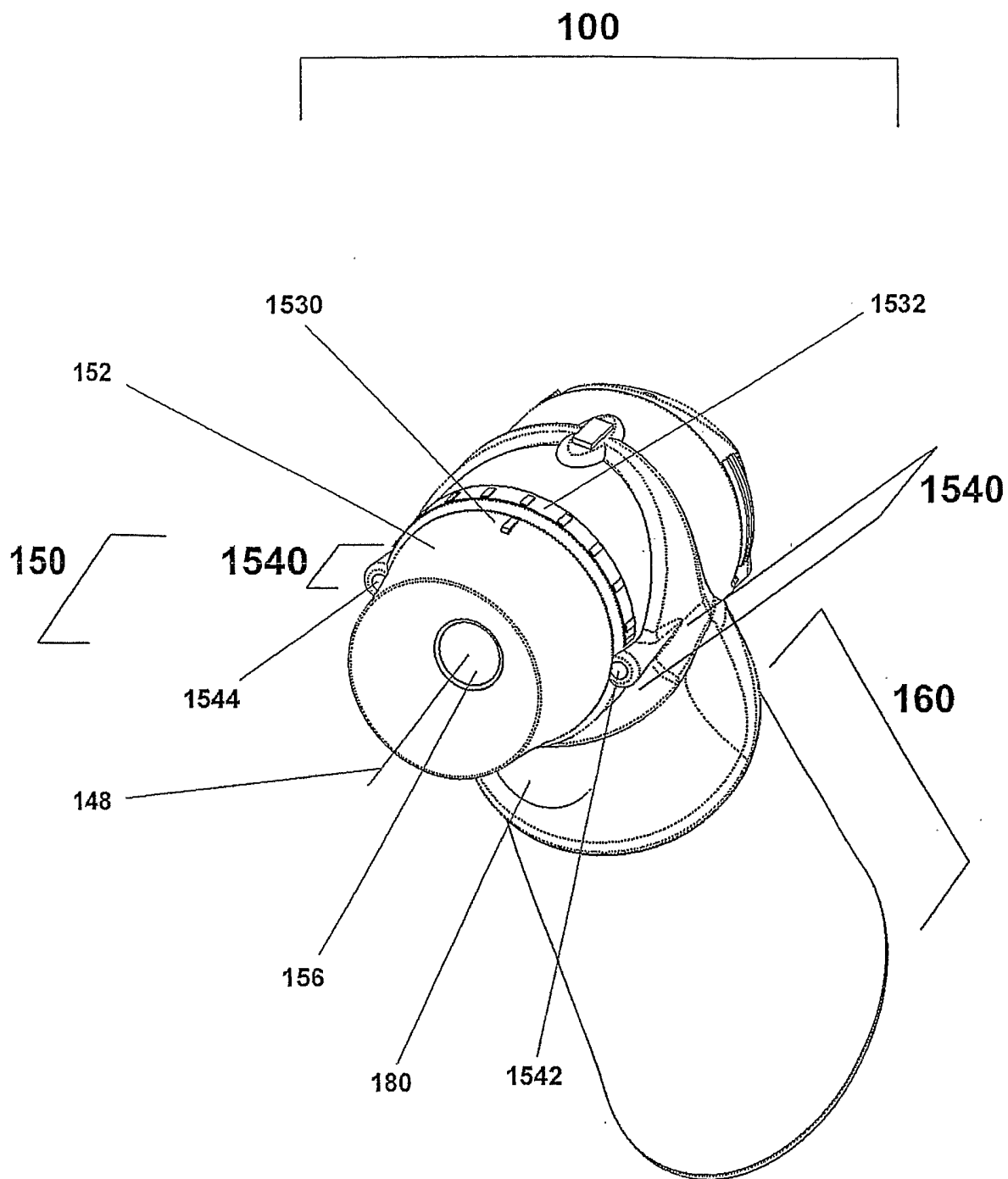


Fig. 14

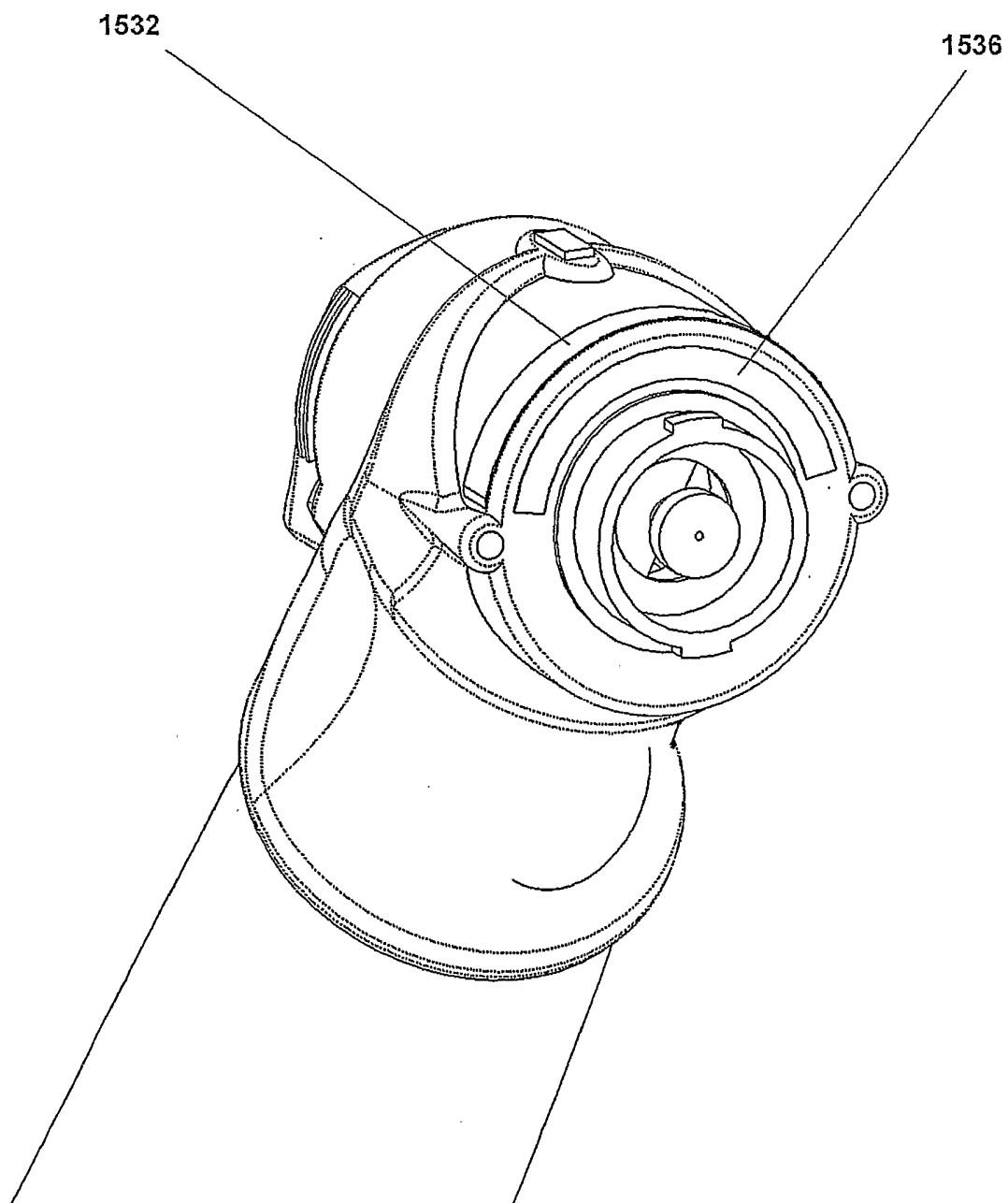


Fig. 15a

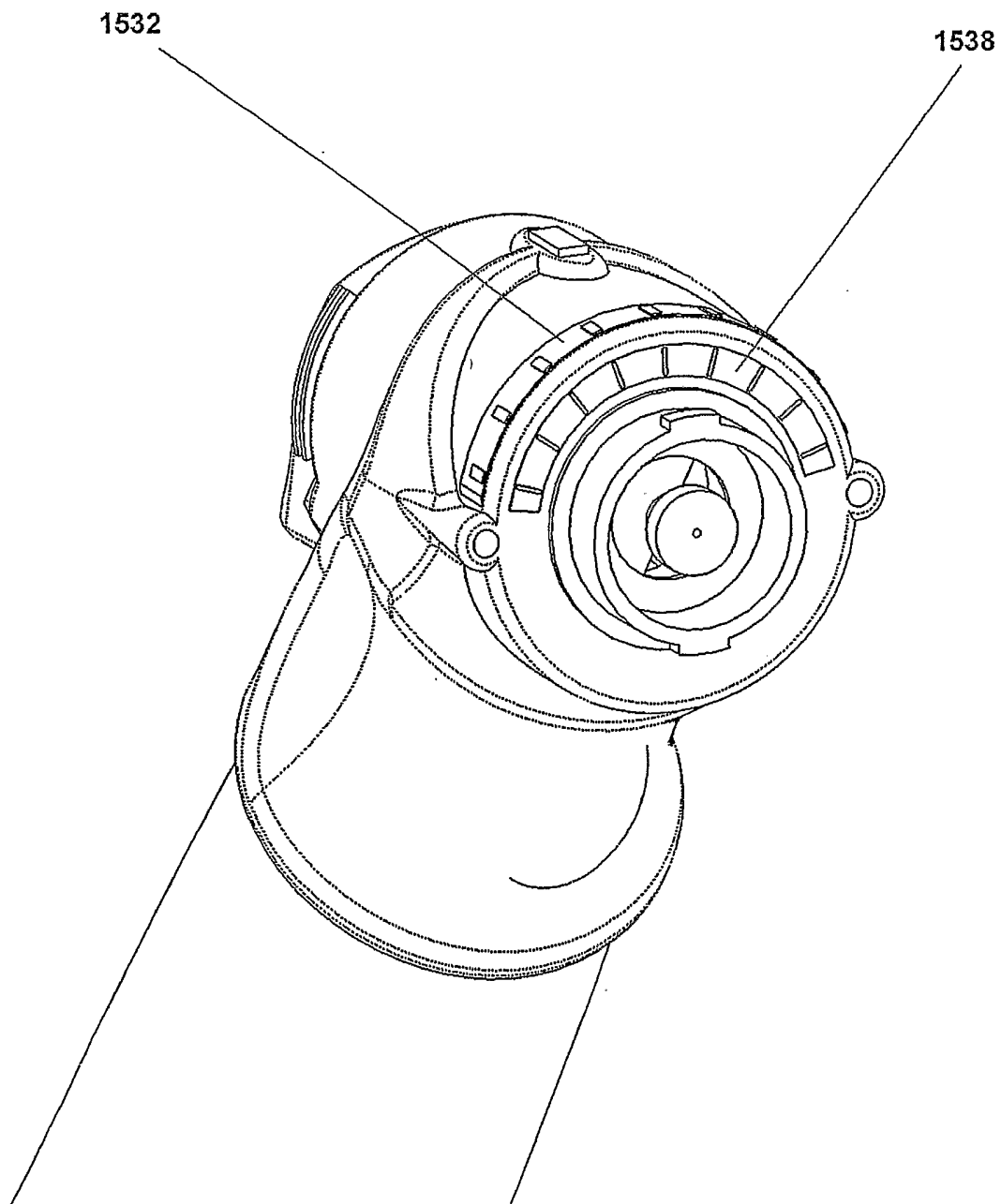


Fig. 15b

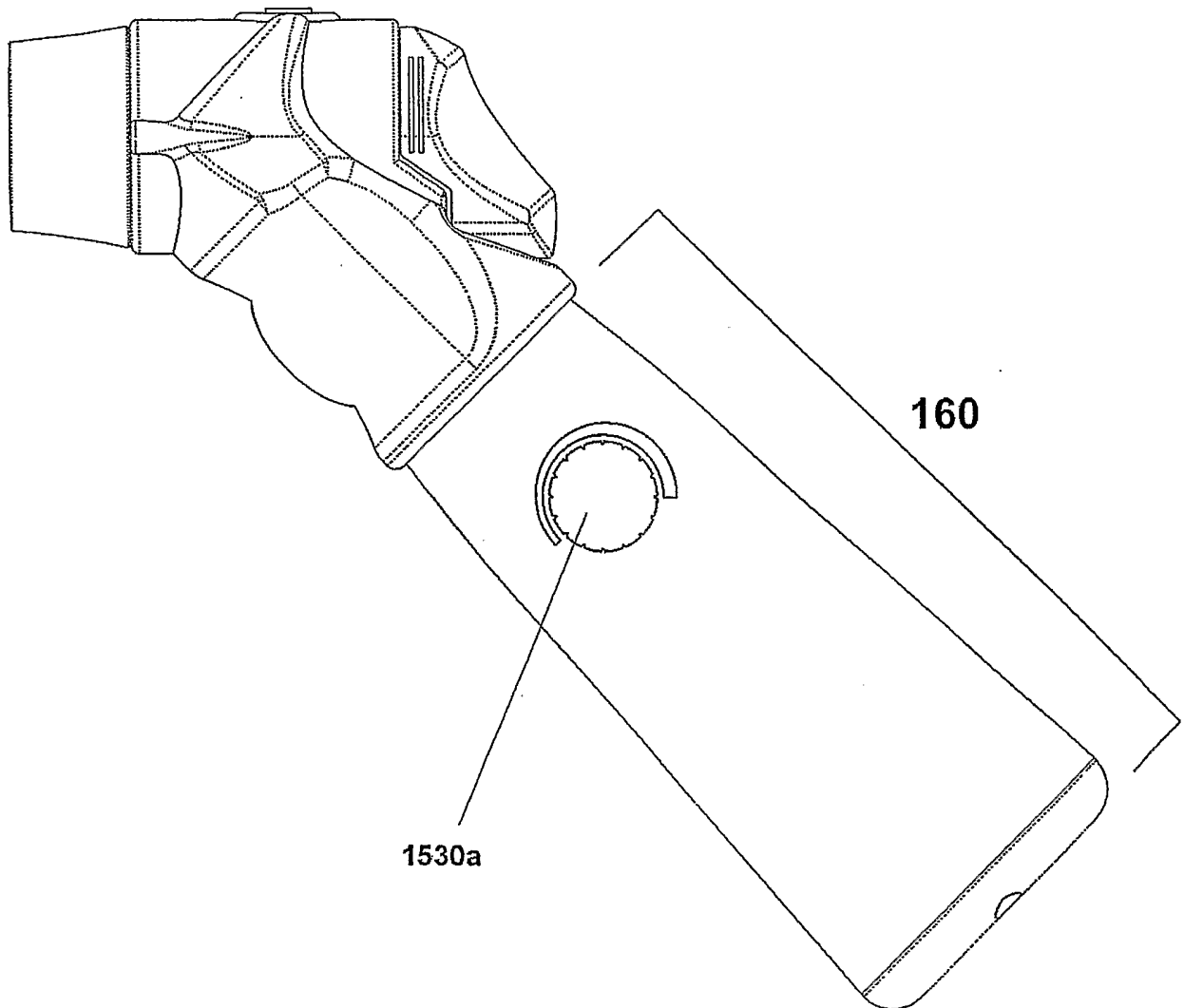
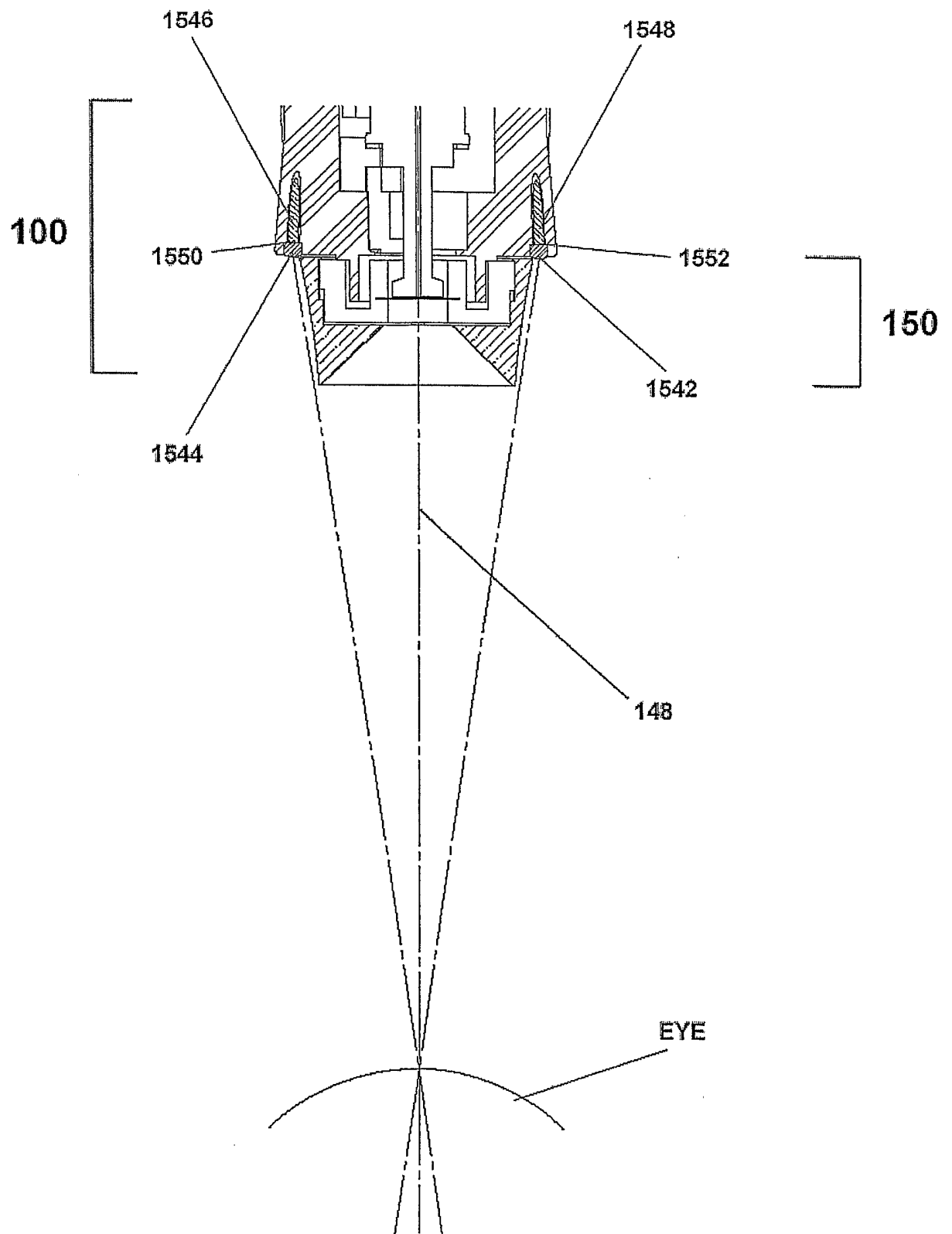


Fig. 15c

**Fig. 16**

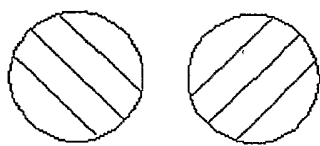


Fig. 17a

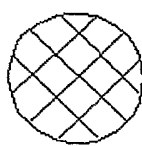


Fig. 17b

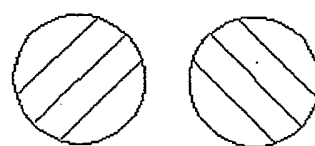


Fig. 17c

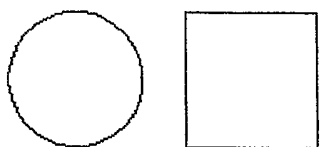


Fig. 18a

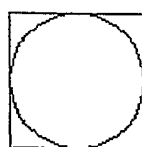


Fig. 18b



Fig. 18c

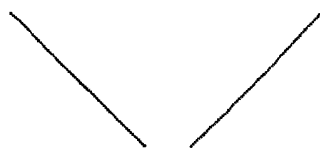


Fig. 19a



Fig. 19b

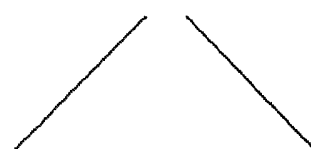


Fig. 19c



Fig. 20a

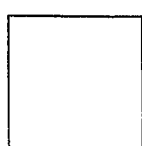


Fig. 20b

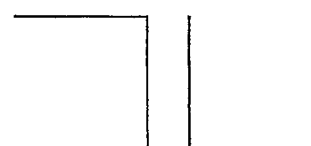


Fig. 20c

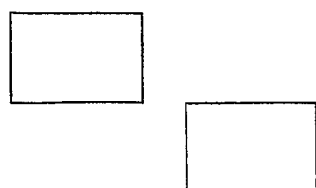


Fig. 21a



Fig. 21b

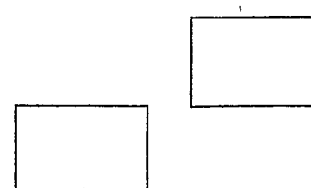


Fig. 21c

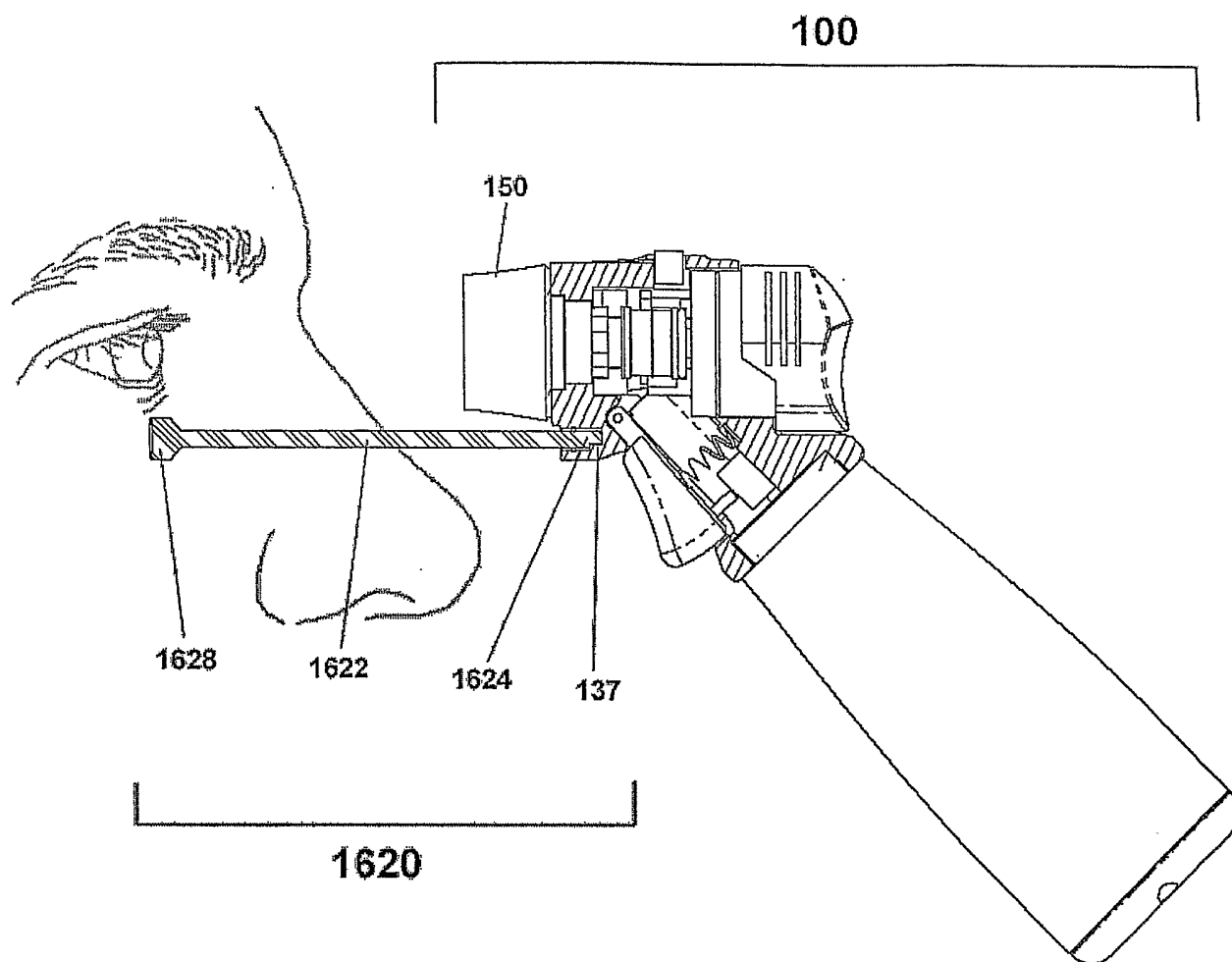


Fig. 22a

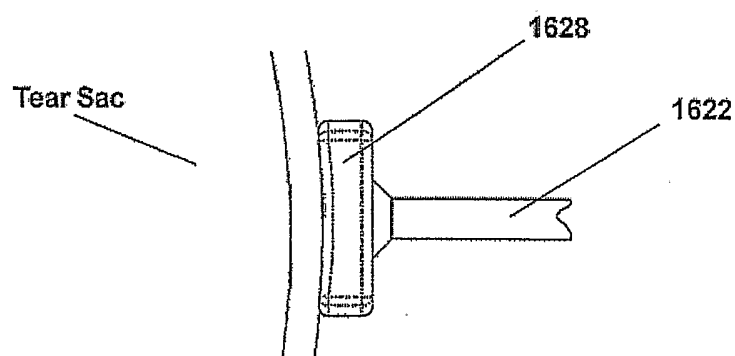


Fig. 22b

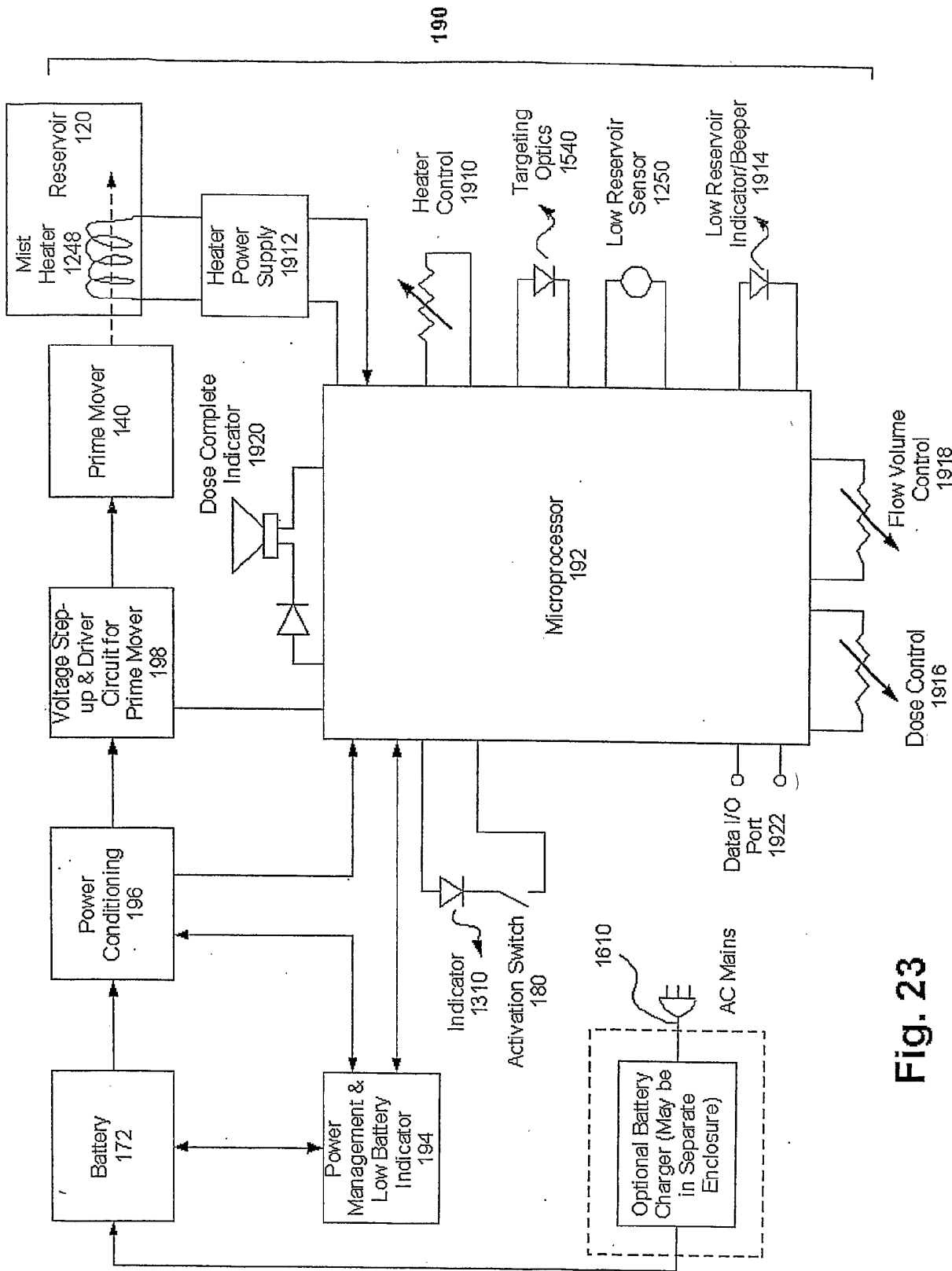


Fig. 23

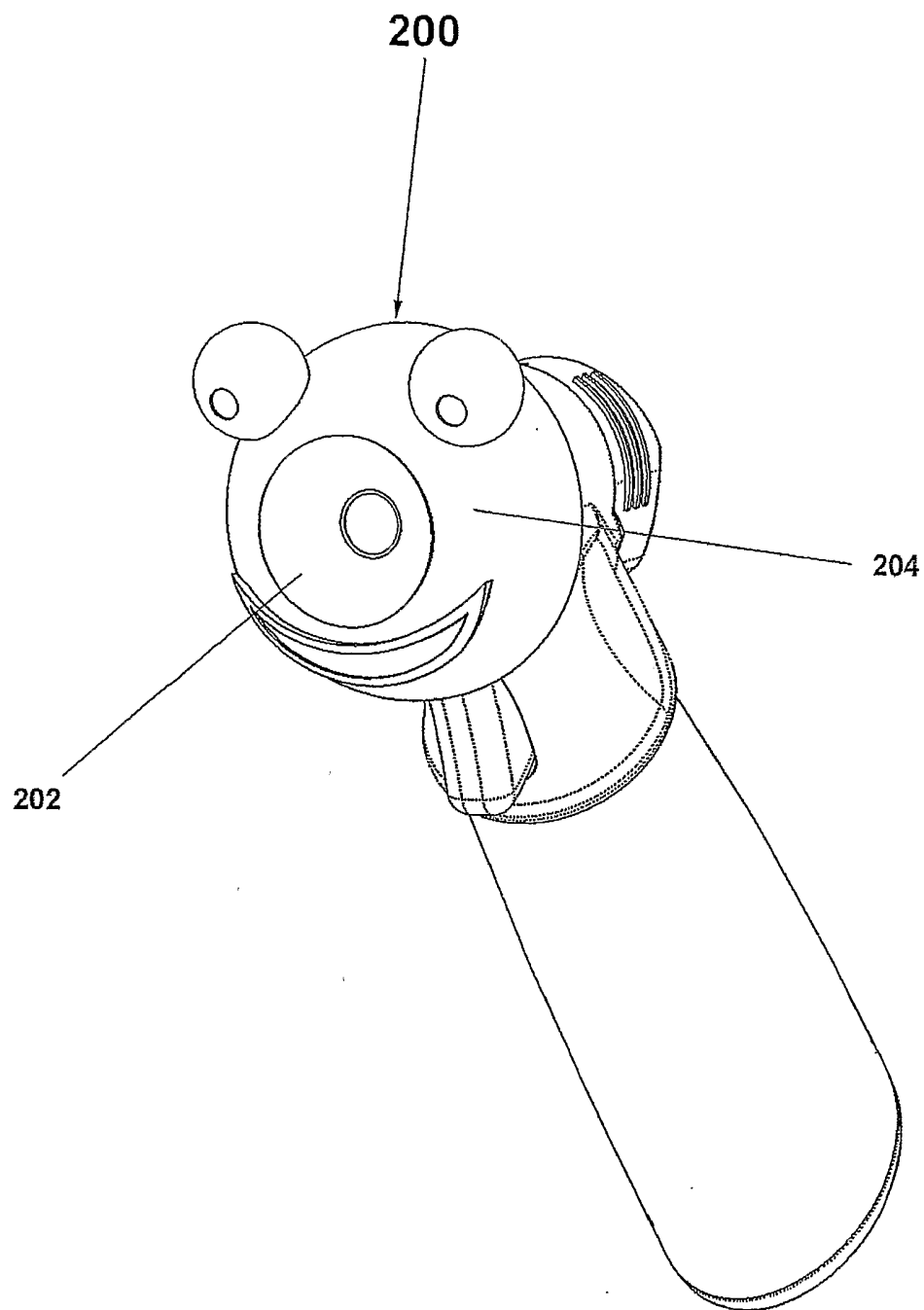


Fig. 24

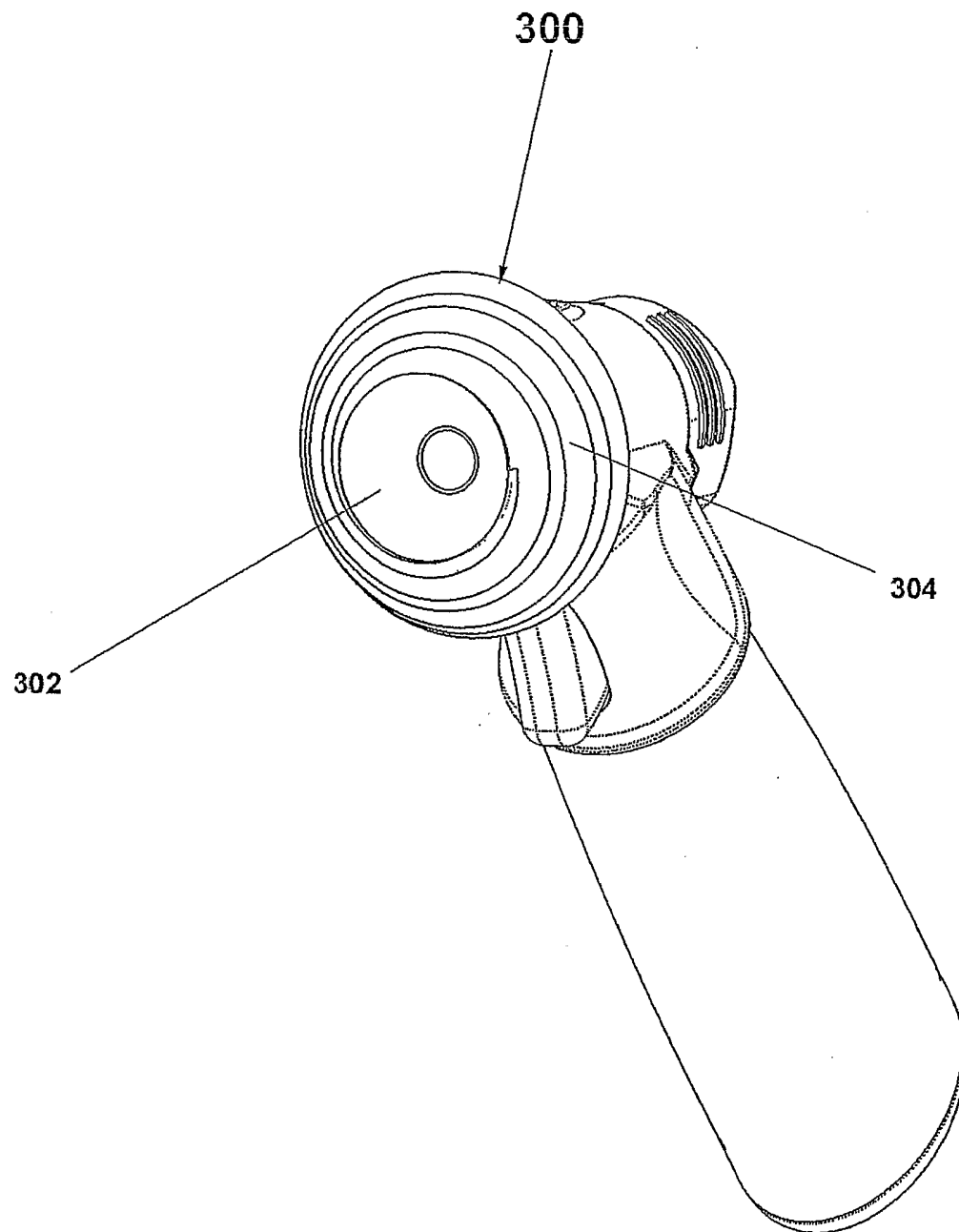


Fig. 25

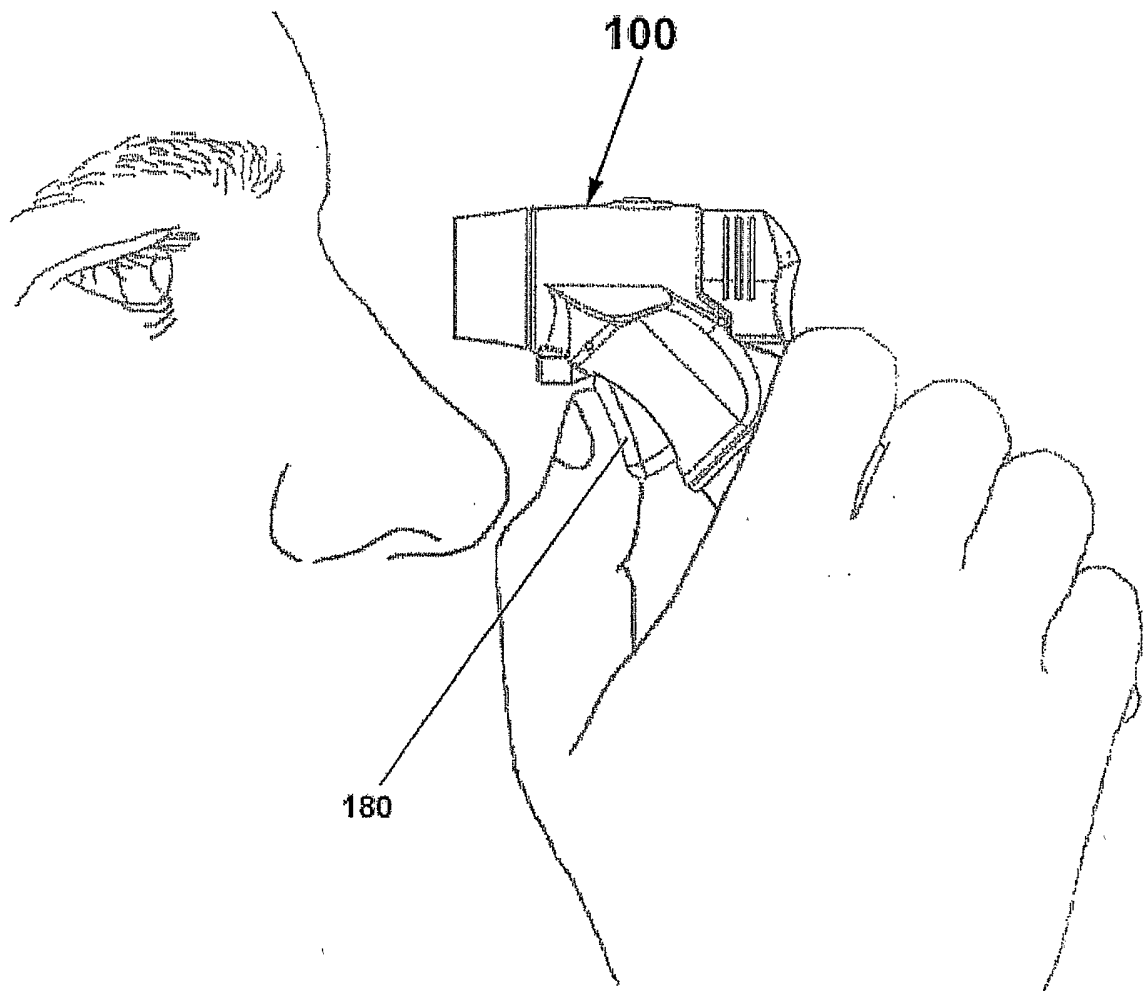


Fig. 26

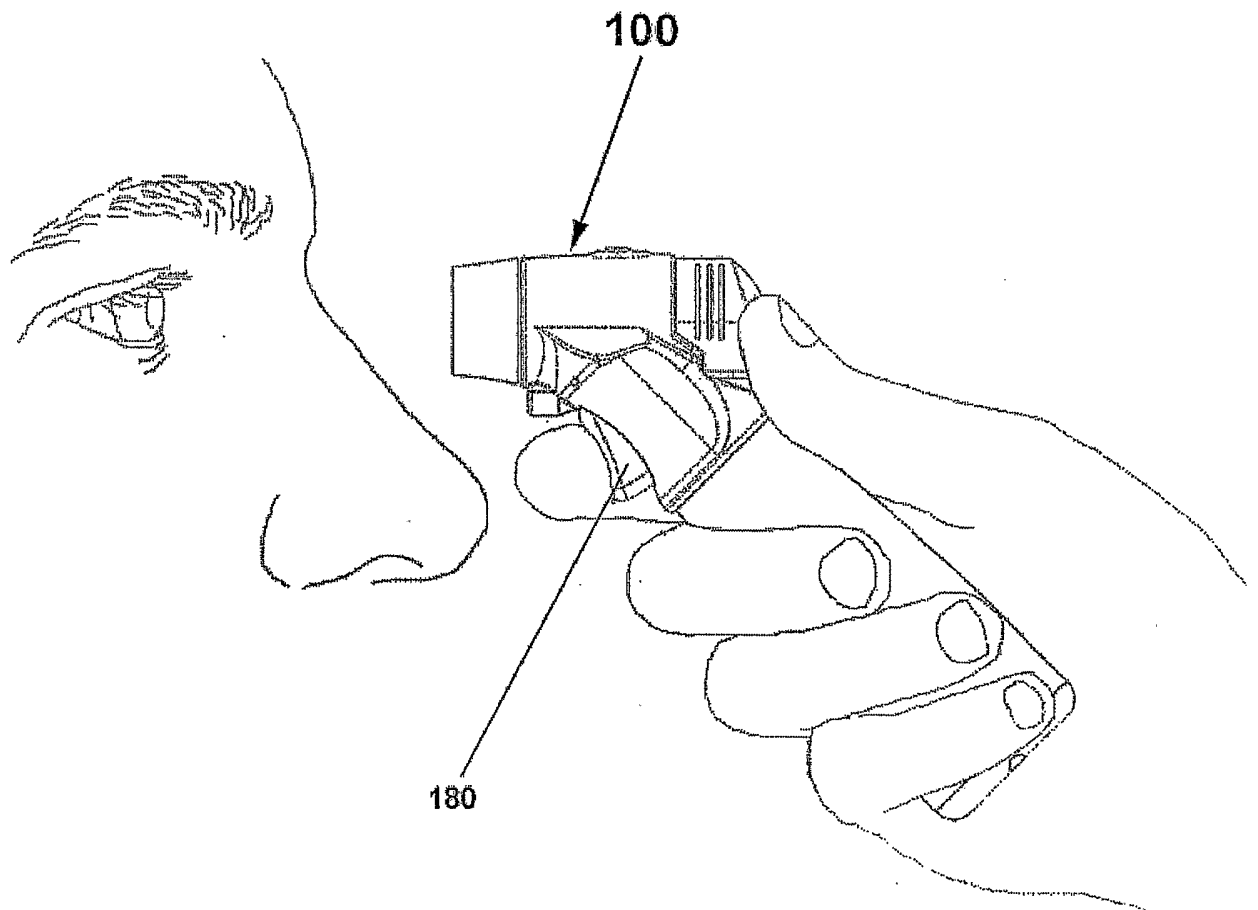


Fig. 27

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/16181

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A62C 13/62

US CL : 239/302

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)

U.S. : 239/302, 552, 553.3557, 559, 596, 102.1

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,152,456 A (ROSS et al) 06 OCTOBER1992 (06.10.1992). See the entire document.	1-32
X	US 5,435,282 A (HABER et al) 25 JULY 1995 (25.07.1995). See the entire document.	1-32

☐ 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 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

06 August 2004 (06.08.2004)

Date of mailing of the international search report

02 SEP 2004

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer

Dinh Q Nguyen

Telephone No. 703-305-0248

Sheila H. Veney
Paralegal Specialist
Tech. Center 3700