



(51) International Patent Classification:

A61F 9/00 (2006.01) A61F 13/12 (2006.01)
A61F 7/02 (2006.01) A61M 35/00 (2006.01)
A61F 7/03 (2006.01) A61F 13/00 (2006.01)
A61F 7/00 (2006.01)

(21) International Application Number:

PCT/US2016/065876

(22) International Filing Date:

9 December 2016 (09.12.2016)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

14/967,116 11 December 2015 (11.12.2015) US
62/266,483 11 December 2015 (11.12.2015) US

(63) Related by continuation (CON) or continuation-in-part (CIP) to earlier application:

US 14/967,116 (CIP)
Filed on 11 December 2015 (11.12.2015)

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS,

[Continued on next page]

(54) Title: COMBINATION TREATMENT SYSTEMS

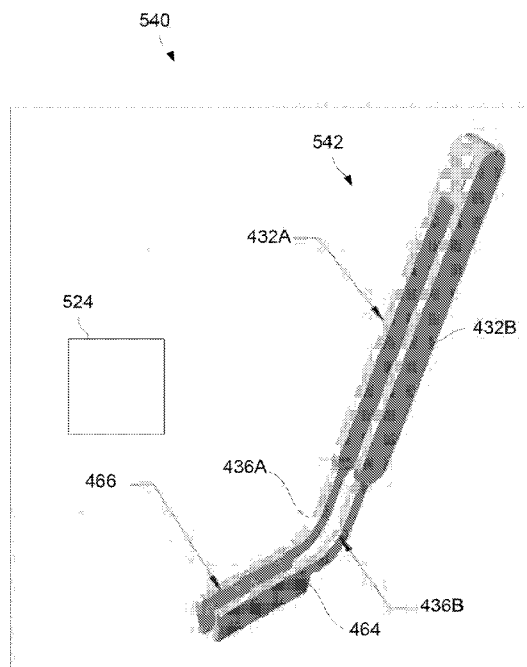


FIG. 59A

(57) Abstract: Controllers for dry eye treatment apparatus and methods are described herein which generally comprise a patch or strip affixed to the skin of the upper and/or lower eyelids to deliver heat to the one or more meibomian glands contained within the underlying skin. The treatment strip or strips include one or more strips configured to adhere to an underlying region of skin in proximity to one or both eyes of a subject such that the one or more strips allow for the subject to blink naturally without restriction from the one or more patches. A controller is in communication with the one or more strips and is programmable to monitor a temperature of the one or more strips to provide a treatment therapy above a threshold temperature. Additionally forceps for mechanically expressing the Meibomian glands may be included with the strips and/or controller.



RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

- (84) **Designated States** (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

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

Published:

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

COMBINATION TREATMENT SYSTEMS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority to U.S. Prov. Patent Application No. 62/266,483 filed December 11, 2015 and is also a continuation-in-part of U.S. Patent Application No. 14/967,116 filed December 11, 2015, which is a continuation-in-part of U.S. Patent Application No. 13/645,985 filed October 5, 2012 (now U.S. Pat. 9,510,972), which is a continuation-in-part of U.S. Patent Application No. 13/343,407 filed January 4, 2012, each of which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to methods and apparatus for treatment of dry eye syndrome and other related conditions. More particularly, the present invention relates to methods and apparatus having a programmable controller for the treatment of dry eye syndrome using adhesive strips which are specifically contoured or shaped to adhere to selected regions around a patient's eyes or peri-orbital region. Additionally, the present invention relates to various forceps embodiments used for meibomian gland expression and the treatment of dry eye syndrome, evaporative dry eye, and meibomian gland disease.

BACKGROUND OF THE INVENTION

[0003] Tears are a complex mixture of water, lipids, mucus, proteins and electrolytes and this mixture helps to maintain a smooth, lubricious, and optically clear optical surface and also helps to protect the eyes from infection. The tear film has three basic layers: oil, water, and mucus and problems or disturbances in any of these layers can cause ocular surface problems including dry eye symptoms.

[0004] The outermost layer of the tear film is typically comprised of an oil layer containing fatty acids and lipids (meibum), which are produced primarily by sebaceous glands called the meibomian glands located along the eyelid margin. The oil layer smoothes the tear surface and retards evaporation of the aqueous or watery middle layer. However, if the meibomian glands fail to produce enough oil, produce suboptimal fatty acid mixtures, or if the glands become obstructed or clogged, the watery layer typically evaporates too quickly causing dry eyes. A blockage or inflammation of the meibomian glands can, among many things, lead to enlarged glands or infections, inspissated secretions, styes, chalazia, hordeolum, or preseptal cellulitis. Dry eyes are thus common

in people whose meibomian glands are obstructed or functioning improperly. The aforementioned are some examples of meibomian gland dysfunction which is also sometimes referred to as evaporative dry eye.

[0005] The middle watery layer of tears is composed primarily of an aqueous solution, which is produced by the lacrimal glands and accessory glands (tear glands). The middle layer cleanses the eyes and washes away foreign particles or irritants, maintains a clear optical medium, and keeps the ocular surface moist. The innermost layer of the tear film is composed primarily of mucus, which helps to spread the tears evenly over the surface of the eyes. A lack of mucus in the tear film is also associated with dry eye syndrome.

[0006] As discussed above, the meibomian glands are oil-secreting glands located within both the upper and lower eyelids. There are approximately 30 to 40 glands along the upper eyelid and approximately 20 to 30 glands along the lower eyelid with the ducts for each of the glands opening along the inner edge of the free margin of the respective lids by minute foramina through which their secretion is released to prevent the lids adhering to each other or to the ocular surfaces. An example of the location of the meibomian glands is illustrated in the cross-sectional view of the upper eyelid **UL** shown in Fig. 1A which illustrates the relative positioning of a single meibomian gland **MG**. Other glands and anatomical features are illustrated for reference, e.g., the glands of Wolfring **GW**, tarsus **TR**, gland of Moll **GM**, gland of Zeis **GZ**, gland of Krause **GK**, upper fornix **UF**, conjunctiva **CN** and cornea **CR** of the eye which is partially covered by the upper eyelid **UL**. As illustrated, the meibomian gland **MG** is positioned along a length of the upper eyelid **UL** (and lower eyelid **LL**) with the duct opening along the inner edge of the eyelid **UL** in proximity to a surface of the underlying eye.

[0007] Fig. 1B illustrates a front view of a patient's eye having the upper eyelid **UL** and lower eyelid **LL** in a closed position, such as when the patient blinks. As shown, the meibomian glands **MG** may be seen aligned adjacent to one another over both the upper **UL** and lower eyelids **LL**. Fig. 1C also shows a perspective view of a patient's eye in the open position to illustrate how the meibomian glands are typically aligned relative to one another when the patient's eye is opened.

[0008] Blinking is thought to be the primary mechanism to open the orifice of the meibomian glands to allow for the release of oil secretions from the glands. The natural blinking motion and blinking force causes the upper lid to pull or drag a sheet of the lipids secreted by the meibomian glands over the two underlying layers of the tear film thus

forming the protective coating which limits the rate at which the underlying layers evaporate. It is estimated that at least 65% of meibomian gland disease or dry eye results from a defective lipid layer or an insufficient quantity of such lipids that results in accelerated evaporation of the aqueous layer. Hence, eyelid closure or blinking disorders, or other disorders that affect proper tear distribution, may also cause or exacerbate meibomian gland dysfunction or dry eye.

[0009] As the eyelids close in a total blink, the superior and inferior fornices, which hold a reservoir of tears, are compressed by the force of the preseptal muscles and the eyelids move toward one another. The upper eyelid, for instance, moves over the eye while exerting upon the eye surface a force which helps to clear the front of the eye of debris, insoluble mucin, and also expresses the oil secretions from the meibomian glands. The lower lid moves horizontally in the nasal direction and pushes debris toward both punctae, the openings that ultimately drain into the nasal cavities.

[0010] As the eyelids open the tear film is redistributed where the upper lid pulls the aqueous phase via capillary action and the lipid layer spreads as quickly as the eyelids move. Hence, eyelid movement is accordingly important in tear-film renewal, distribution, turnover, and drainage.

[0011] For a variety of reasons, the meibomian glands can become blocked, plugged, inflamed, or occluded resulting in meibomian gland dysfunction and dry eye disease. The obstruction that triggers the disease can occur anywhere within the meibomian gland, for instance, at the gland's surface or orifice preventing normal lipid secretions from flowing; in the main channel of the gland which may be narrowed or blocked; or in other locations deeper within the gland that lead to the main channel.

[0012] Treatments for blocked meibomian glands may include a number of conventional treatments. One course of treatment includes the application of soap and cleaning agents, eyelid scrubs, antiseptics, or antibiotics to reduce eyelid inflammation. Antibiotics such as tetracycline, doxycycline, minocycline, metronidazole, azithromycin, bacitracin, or erythromycin can be administered orally or topically to help regulate or improve meibomian gland lipid production. Inflammation on the surface of the eye may also be controlled with topical drugs such as corticosteroids or cyclosporine (RESTASIS®, Allergan, Inc., CA), or other anti-inflammatory compounds or immune-suppressants. Evidence suggests that ocular surface inflammation is not only associated with meibomian gland dysfunction but also with dry eye syndrome.

[0013] Other examples of dry eye treatments may include the application of prescription eye inserts for people with moderate to severe dry eyes symptoms who are unable to use artificial tears. An eye insert, e.g., hydroxypropyl cellulose (LACRISERT®, Merck & Co., Inc., NJ), may be inserted between the lower eyelid and eye. The insert
5 dissolves slowly to release a substance which lubricates the eye. Alternatively, special contact lenses or amniotic membrane transplants may be used to shield the surface of the eye to trap moisture.

[0014] In other treatments, the patient's tear ducts may be closed to prevent the tear film from draining away from the surface of the eye too quickly by procedures such as
10 insertion of punctal plugs into the tear ducts or cauterizing the tissues of the drainage area. Aside from implants or cauterizing treatments, dry eye syndrome may be treated using pharmaceutical agents such as eyedrops, ointments which coat the eyes, etc. Artificial tears, gels, ointments, autologous serum tears, or albumin drops have all been employed in the treatment of dry eye.

[0015] Additionally, warm compresses are also typically placed over the eyes and are used to restore function to the meibomian glands by melting any lipid plugs as well as incorporating massaging of the lids which may further express meibomian gland contents. However, application of warm compresses often can require their application two to three
15 times daily during which time patients may incorrectly target only one of the affected lids and are also prevented from seeing out of the treated eye because of the compresses. Warm compresses pose multiple issues such as noncompliance, poor persistence, or high variability. Compresses may be too hot, further exacerbating inflammation, or they may cool too quickly preventing adequate therapeutic effect.

[0016] Other treatment devices have also been developed which cover the entire
25 affected eye to apply heat and a massaging force directly to the affected eyelids. However, such devices, like the compresses, require that the patient's eyes be temporarily but completely obstructed during the treatment resulting in discomfort, lost productivity, and potentially lower compliance among patients. Additionally, these treatments require visits to a physician or healthcare provider, and thus are labor intensive, inconvenient, expensive,
30 and consequently are not as well-suited for widespread consumer adoption.

[0017] There are also forceps that are used for expressing meibomian glands but these forceps are not customized or optimized for meibomian gland expression. Expression of the meibomian glands typically involves application of compressive force to the glands to express the secretions of the gland, also known as meibum, from the gland

orifice. For instance, such forceps are neither heated nor dimensionally customized for directional expression of meibum.

[0018] Accordingly, there exists a need for methods and apparatus which are relatively simple to routinely use for the patient or physician to use and which also allow for the patient to continue their normal activities, is non-obtrusive and non-disruptive, and which also take advantage of the patient's natural physiological activities to facilitate treatment and which facilitates meibomian gland expression..

SUMMARY OF THE INVENTION

[0019] In treating conditions such as meibomian gland dysfunction or dry eye syndrome, a patch or strip can be affixed to the skin of the upper and/or lower eyelids to deliver heat or other forms of energy, cooling, light, ultrasound, vibrations, pressure, drugs, moisture, etc. (alone or in combination) to the one or more meibomian glands contained within the underlying skin. In particular, the assembly for the treatment strip or strips may generally comprise one or more strips configured to adhere to an underlying region of skin in proximity to one or both eyes of a subject such that the one or more strips allow for the subject to blink naturally without restriction from the one or more patches. Moreover, the one or more strips may be configured to emit energy or therapy to the underlying region of skin and where the one or more strips are shaped to follow a location of one or more meibomian glands contained within the underlying region of skin.

[0020] A programmable controller having a controller board and a processor may be in communication with the one or more strips, where the controller may induce, and monitor a programmable temperature of the one or more heater strips and to provide a treatment therapy. The therapy may be programed to maintain a set point, within a known accuracy, (e.g., 42°C +/- 1°C) above a threshold temperature of, e.g., 39°C, and below a maximum temperature of, e.g., 48°C, over a treatment period of 12 minutes. Other treatment times may be implemented in other variations; for instance, the treatment time may extend from 1 minute to 60 minutes in other treatment variations.

[0021] In use, the one or more strips may be adhered to a region of skin in proximity to one or both eyes of a subject such that the one or more strips allow for the subject to blink naturally without restriction from the one or more patches. While adhered, the strips may treat or emit energy to the region of skin, where the one or more strips are shaped to follow a location of one or more meibomian glands contained within the region of skin. Alternatively, while the strip may not directly overly a meibomian or other ocular

or orbital gland, it may deliver energy or absorb energy from underlying neighboring tissue or vasculature, which ultimately diffuses, or supplies said glands, respectively. In other words, heating or cooling the blood supply to the eyelids, meibomian glands, and/or lacrimal glands using these strips may affect their function and metabolism while not necessarily needing to directly overly them in particular variations.

[0022] The upper strip may thus have an upper curved or arcuate periphery which is shaped to extend and follow the upper (or superior) border of the meibomian glands (such as along or up to the upper eyelid crease) while the straightened periphery of the lower edge may be shaped to extend and follow the lower (or inferior) border of the meibomian glands such as along the free margin of the upper eyelid. Although straightened, the lower edge may be gently curved or arcuate in alternative variations. The lower strip may similarly have an upper straightened periphery to extend and follow the upper (or superior) border of the meibomian glands along the free margin of the lower eyelid and a lower curved or arcuate periphery to extend and follow the lower (or inferior) border of the meibomian glands along the lower eyelid (such as along or up to the lower eyelid crease). Alternatively, the upper periphery of the lower strip may also be gently curved or arcuate in alternative variations as well.

[0023] In other words, with the tarsal plate containing the meibomian glands, which span from proximal to distal, the peripheral edges of the treatment strips may correspond to the distal eyelid margin and proximal peripheral edge and the treatment strips can assume multiple configurations. Generally, the peripheral distal edge of the treatment strip may be relatively straight or assume a gentle curve either of which can follow the underlying distal eyelid margin and tarsal plate while having a proximal peripheral edge that is relatively curved to assume the more curved proximal edge of the underlying tarsal plate.

[0024] The strips may be used individually for placement upon only the upper eyelid or only the lower eyelid depending upon the desired treatment. Moreover, the lengths of the treatment strips may also be varied to target individual meibomian glands for providing a targeted treatment, if desired, and as described in further detail herein. Additionally, while the treatment strips may be sized generally, they may also be custom made or sized for a specific individual's eyelid dimensions.

[0025] Because of the specific contoured sizes and flexibility of the treatment strips the treatment strips may be placed upon the patient to apply therapy to the underlying meibomian glands allowing the patient's eyes to be opened and closed normally without interference from one or both treatment strips. Accordingly, the treatment strips contoured

size, shape, thickness, and flexibility allow for treatment to occur while also allowing for the patient to have one or both eyes remain opened such that normal, physiologic blinking can proceed during the course of treatment. To further reduce the forces on the eyelids, heaters may be decoupled from the forces acting on their connections (such as wires) by the addition of multiple turns (e.g., non-linear regions) in their connection paths that destabilize loads that would otherwise be communicated from power supply cabling to the eyelid(s). Rather than relying on an application of any type of external force, the treatment strips take advantage of the eye's natural mechanism for clearing oil from the meibomian glands via blinking. Hence, the treatment strips may be adhered in place for treatment without any further intervention by the patient or healthcare provider such that the treatment strips may apply, e.g., heat energy, to melt or liquefy any waxy or solid meibomian gland obstructions while the eyes remain unobstructed and are allowed to blink naturally. The treatment strips thus allow for the natural blinking force to clear the glands of the heat-treated softened obstructions before they have re-solidified unlike other treatments which require that the patient keep their eyes closed or obstructed during the course of a treatment and prevent or inhibit the patient from blinking.

[0026] The treatment strip may be configured to have a contact layer (e.g., fabricated from conductive materials such as metals, alloys, porous ceramics, engineering ceramics, woods, polymers, composites, foams, polymer foams, fabrics, elastomers, etc.), which may protect the skin from burns or any other adverse effects. A second heating layer may be positioned above the contact layer (or directly in contact against the skin) for generating the heat energy and an insulative layer may be positioned atop the heating layer for focusing, directing, or reflecting the heat towards the underlying skin surface as well as to protect the patient from contact with the heating layer from other parts of the body. A sensory layer may be positioned on or between any layer to provide system or therapy monitoring and feedback, e.g., temperature, tissue impedance, muscle activity, etc. Multiple sensors may be used in any single heater, and compared via the controller's processor to determine heater state, functionality, regional intra-heater variations, inter-heater variations, and positioning relative to the patient. An insulating layer may accordingly be fabricated from a variety of insulative or reflective materials, e.g., foams, foam tapes, gauze, silicone, microporous polyethylene films, fabrics, polymers, reflectors, etc. for the purpose of directing energy toward the patient, maintaining therapeutic target temperatures, and reduce therapeutic fluctuations based on ambient conditions. An insulating layer may have a thermal load (capacity) to target a thermal response time for the

purpose of tuning temperature variations. For instance, due to the increased thermal mass, the increased heating and cooling times may be considered in the treatment procedures.

[0027] Although the application of heat energy from the treatment strips is described, other variations may alternatively include the application of using the treatment strips for cooling of the underlying skin. Rather than using the heating layer in an exothermic reaction, the layer may be configured to utilize an endothermic reaction, for example, instead to provide for cooling of the skin. Cooling, rather than heating, may be applied for conditions such as reducing inflammation, alleviating allergies or tired eyes, etc. particularly as the patient rests or sleeps. Electromagnetic energy such as light, mechanical energy, vibrations, or ultrasonic energy are some other examples of therapy that can be delivered to target tissues. Energy delivery may be continuous or periodic (cyclical).

[0028] Aside from the application of heat energy from the treatment strips, the strips may also include a layer for the diffusion, directed delivery, or release of one or more pharmaceutical, biological, or chemical agents either alone or in combination with the heat treatment. For instance, the pharmaceutical, biological, or chemical agents may be incorporated into the either the contact layer, insulative layer, or in a separate layer entirely, for transdermal delivery to the meibomian glands or to the areas surrounding the meibomian glands for additional and/or alternative treatments. In the event that the pharmacological or chemical agent is released during the heat treatment, the heat may help to improve penetration of any drugs into the underlying skin.

[0029] While the treatment strips may incorporate various layers into the strips to effect various different treatments, the strips may also be varied in size, shape, contour, etc. depending upon the desired treatment areas so long as the treatment strips are contoured or shaped to follow the location of at least one meibomian gland.

[0030] While the treatment strips may be applied to one or more of the meibomian glands, variations of the strip may also be used to treat other glands such as the sebaceous glands, e.g., for acne treatment, cosmetic purposes, arthralgias, myalgias, wound healing, pain, inflammation, premenstrual pain, breast pain and inflammation. Treatment strips used to treat acne may utilize different pharmacological treatments. Moreover, the treatment strips may be used to potentially treat eye disorders beyond meibomian gland dysfunction.

[0031] Yet another example may include use of the treatment strips for treating disorders of the lacrimal gland and/or palpebral lacrimal gland, which are located above the

eye. Various sized treatment strips, such as lacrimal gland strips, which are sized to have a curved upper periphery, may be sized for placement directly over the skin surface above where the lacrimal glands are located. The lacrimal glands and/or palpebral lacrimal gland may be treated alone or in combination with the treatment strips contoured for treatment of the meibomian glands.

[0032] While the treatment strips may be applied over the meibomian glands to apply the heat energy, the treatment does not require the application of any external force applied by the strip or any other external device but may utilize the natural blinking of the patient to facilitate treatment. However, in additional variations, the treatment strips may be configured to apply both the heat treatment as well as an external force. Any number of mechanisms may be utilized to apply a pinching or biasing force to provide for compression of the underlying skin and of the meibomian glands during application of the heat therapy.

[0033] Aside from a compression force, the strip may be formed with alternative components such as a mechanical, sonic, or ultrasonic, component to impart vibrational energy or other forms of energy to facilitate the expression of the meibomian glands and promote oil secretion. Alternatively, electromagnetic radiation such as visible light, red wavelengths, or infrared wavelengths, as examples, can be delivered as a continuous or cyclical therapy.

[0034] In yet another variation, one or both treatment strips may be configured to incorporate an indicator, e.g., LED light, alarm, vibration element, etc., electrically coupled to a power supply and/or processor to alert the patient when a prescribed treatment has been completed. This feature (and any of the other features) may be combined with any of the other variations of the treatment strips described herein as practicable.

[0035] With the incorporation of a processor or sensors into the treatment strips, treatment times or other parameters such as temperature of the strips may be programmed, monitored, and optionally shut on or off selectively by the patient or automatically. Moreover, other parameters such as the frequency of the heat delivery or other stimulation or therapy may also be programmed by the processor to provide further flexibility in treatment and monitoring.

[0036] In treating conditions such as meibomian gland dysfunction (MGD), which is commonly associated with the evaporative form of dry eye syndrome (DES), the meibomian glands may be mechanically pressed or squeezed to express solidified meibum from the glands in order to help treat MGD. Forceps are typically used to apply pressure

upon the meibomian glands. The forceps may be modified to create a pressure gradient upon the meibomian glands to direct meibum and any other meibomian gland secretions towards the meibomian gland orifices. This pressure gradient may be increased by the optional incorporation of one or more features along the compression surfaces of the forceps. Additionally and/or alternatively, the forceps may be configured to also provide a thermal treatment, e.g., to the eyelid surfaces to simultaneously melt, soften, or liquefy and express meibum to increase its therapeutic efficacy.

[0037] The forceps may be used after (or during) a heat treatment in combination with the heating strips as described herein. Alternatively, the forceps may be used to first apply a heat treatment to melt the meibum plugs contained within the glands and then the forceps may be used to mechanically express the liquefied meibum before it re-solidifies. In another alternative, the forceps may be used to apply a thermal treatment and mechanical expression simultaneously to effectively express the meibum. In treating the meibomian glands, the forceps may also be used to apply heat to other regions, e.g., inner eyelids, outer eyelids, or both. However, when the heating strips are used to apply a heat treatment to a patient, the forceps used for mechanically expressing the glands may be configured to separately heat the glands and/or they may include any number of mechanical features, as described herein, to facilitate mechanical expression.

[0038] The forceps described herein may be used to first apply a heat treatment to melt, soften, or liquefy the meibum plugs contained within the glands and then the forceps may be used to mechanically express the liquefied meibum before it re-solidifies. Alternatively, the forceps may be used to apply a thermal treatment and mechanical expression simultaneously to effectively express the meibum. Alternatively, the forceps may be customized with a single feature, e.g., directional expression or heat treatment but not both. Furthermore, if a thermal treatment (either heating or cooling) is employed, it may be delivered before, during, or after any mechanical intervention, e.g., meibomian gland expression. Moreover, the mechanical intervention and/or heating may be repeated any number of times and may be accomplished in any order, e.g., alternating, simultaneously, etc.

[0039] One variation of the forceps may have a first handle and second handle coupled at a proximal end and optionally positioned to extend in parallel or at an angle such that a respective first bridge and second bridge project and optionally curve relative to the handles such that a first jaw or paddle is aligned in apposition to a second jaw or paddle. The first paddle and second paddle may also be aligned such that a respective first

inner surface and second inner surface are angled relative to one another to impart a directional pressure gradient upon the contacted tissue for facilitating meibomian gland expression. The first and second paddles may be sized for positioning in proximity to the eyes and directly upon the eyelids of a patient and the paddles may also be spaced apart
5 from one another to allow for the positioning of the tissue (e.g., eyelid tissue containing the meibomian glands) in-between. In other variations, the first and second handles may be curved or arcuate provided that the paddles are spaced apart from one another.

[0040] One or both of the paddles may be suitably sized for application to various regions of the body but when configured for treating the meibomian glands, the paddles
10 may have a height ranging anywhere, e.g., between 1 mm to 20 mm with a length ranging anywhere, e.g., between 1 mm to 50 mm. In one variation, one or both paddles may have a height and length of, e.g., respectively, 5 mm by 25 mm.

[0041] In treating the meibomian glands, one or both paddles may be configured to heat up to a predetermined temperature range and optionally for a predetermined period of
15 time. In one variation, the forceps may have heating strips or sleeves which may be attached or secured or otherwise applied as separate elements onto their respective paddles. The heating assemblies, in this variation, may each define a respective first and second receiving cavity or channel, such as a sleeve, into which the first and second paddles may be inserted or attached. The heating elements may be in electrical communication with a
20 controller and/or power supply which may be integrated with the forceps or otherwise externally connected or coupled with the heating elements.

[0042] The controller may incorporate a processor which is programmable as well as a power supply which is rechargeable or disposable, if desired. In yet other variations, the controller may be configured as a mobile device such as a computer, smartphone,
25 tablet, etc. which may communicate wirelessly with the heating elements or other features of the forceps.

[0043] Another variation of the forceps may have the heating element incorporated directly upon or within the paddle. The heating element may be electrically coupled to the controller and/or power supply and may be attached to the paddle through any number of
30 securement mechanisms, e.g., adhesives, magnetic, clips, fasteners, etc. In either variation, the heating element may be used to generate or remove energy from the contacted tissue region being treated by the forceps to create an isolated microenvironment where the energy may be delivered for thermal therapy (or diagnosis) and to confine the area under

treatment so as to prevent or inhibit surrounding tissues from unnecessary treatment or damage.

[0044] When the heating element is incorporated directly into one or both of the paddles, the heating element may be positioned in a number of different configurations.

5 For example, the heating element may be positioned upon or beneath the inner surface which comes into contact with the tissue being treated, mid-way from the inner surface, or upon or beneath an outer surface of the paddle such that the element is positioned away from the inner surface.

[0045] In applying the thermal therapy, the heating element (in one or both
10 paddles) may be heated to a temperature which is effective for melting solidified meibum, e.g., between 35° C to 50° C, or preferably between 38° C to 43° C, or more preferably between 41° C to 43° C. Moreover, the treatment times over which the heated forceps may be applied to the tissue region being treated may also be varied any, e.g., between 0 to 30
15 min., or preferably between 5 to 15 min., or more preferably between 10 to 12 min, in treatments where the forceps may be locked and otherwise secured upon the patient. In other variations, the treatment time may vary, e.g., between 1 to 2 mins. per eyelid, when the eyelids are actively treated and monitored by the user or physician.

[0046] The respective first inner surface and/or second inner surface may be angled relative to one another to impart a directional pressure gradient upon the contacted tissue
20 for facilitating meibomian gland expression when compressed between the paddles. When the paddles are urged towards one another, one or both angled inner surfaces may compress the tissue between the paddles to create the directional pressure gradient, e.g., in a direction perpendicular to the direction of the force applied, which may urge the compressed meibum away from the paddles. Additionally, with continued compression of the forceps,
25 a greater region of the inner surfaces may become apposed thereby allowing for a changing or dynamic pressure gradient.

[0047] One or both of the inner surfaces may define any number of features which facilitate the creation of the directional pressure gradient. For example, one or both of the paddle surfaces may define indentations or grooves, bumps or projections, or grooves or
30 pits or depressions. With any of these features described, they may be utilized in any number of combinations either on the inner surface of a single paddle or both paddles. Moreover, any of these surface features are intended to be utilized in any number of combinations with any of the angled paddle variations as well as with any of the heated paddle variations in any number of configurations.

[0048] Aside from surface features on the paddle inner surface, variations in the paddle shape may also be utilized in any number of combinations. In any of these varying paddle configurations, any of these shapes may be utilized in a uniform complementary configuration or in any other shape combinations where a first paddle has a first configuration and a second paddle has a second configuration different from the first configuration. Moreover, any of the paddle configurations are intended to be utilized in any number of combinations with any of the paddle configurations have surface features and/or in combination with any of the paddles having varying angled configurations and/or in combination with any of the heating element configurations.

[0049] In yet another variation, one or more optional sensors may be positioned along the heating elements or paddles. The sensors may comprise temperature sensors, such as thermocouples or thermistors, while other sensor types (e.g., chemical sensors, oxygen, blood flow, force, pressure, etc.) may also be utilized in other variations. Such sensors may be incorporated along the paddles alone or in any number of combinations with any of the variations described herein.

[0050] Additionally, any of the paddles may also incorporate any number of drugs (e.g., anesthetics, antibacterial agents, etc.) upon the paddle surfaces or through delivery mechanisms which may be infused or placed upon the tissue when contacted by the forceps.

[0051] Furthermore, any of the forceps variations and combinations described herein may be used alone for treating a patient or they may be used in combination with any of the treatment apparatus and methods described in further detail in U.S. Pat. App. 13/645,985 filed October 5, 2012 and U.S. Pat. App. 13/343,407 filed January 4, 2012, which are each incorporated herein by reference in its entirety and for any purpose herein, particularly for treatment of MGD and dry eye syndrome.

BRIEF DESCRIPTION OF THE DRAWINGS

[0052] Fig. 1A shows a cross-sectional side view of an upper eyelid and an example of the location of a meibomian gland.

[0053] Fig. 1B shows a front view diagram of meibomian gland distribution in human eyelids having the upper eyelid and lower eyelid in a closed position, such as when the patient blinks, and the alignment of the meibomian glands over both the upper and lower eyelids.

[0054] Fig. 1C shows a perspective view of a patient's eye in the open position to illustrate how the meibomian glands are typically aligned relative to one another when the patient's eye is opened.

[0055] Fig. 2A shows a front view of a patient's eye in a closed position with an example of treatment strips which adhere onto the upper or lower eyelids (or both) and where the strips are sized or contoured for placement directly over the meibomian glands located in the underlying eyelids.

[0056] Fig. 2B shows the treatment strips of Fig. 2A illustrating how the strips may remain adhered to the patient skin while allowing for the eyelids to retract and allow for the patient to continue blinking while viewing normally out of the eye. While the strips may be applied from eyelid margin to eyelid crease, they may alternatively flex or accordion and/or compress during blinks to prevent impairment of normal blinking and maximize comfort.

[0057] Fig. 3A shows an example of a contoured treatment strips.

[0058] Fig. 3B shows an example of a cross-sectional side view of a treatment strip.

[0059] Fig. 3C shows another variation of a treatment strip which may optionally incorporate sensory capabilities that feed into a controller.

[0060] Fig. 3D shows yet another variation where a treatment strip may be formed into a zig-zag or curved configuration to facilitate the blinking by the patient.

[0061] Fig. 4 shows a front view of another variation of the treatment strip, which is relatively thin and positioned over the upper eyelids.

[0062] Fig. 5 shows a front view of another variation of the treatment strip which is relatively thick for treatment of the targeted meibomian glands as well as the surrounding tissue.

[0063] Fig. 6 shows a front view of another variation of the treatment strip which is contoured to more closely follow the meibomian glands in the upper eyelids.

[0064] Fig. 7 shows a front view of another variation of the treatment strip which may be formed into shortened strips for selective placement along the eyelids.

[0065] Fig. 8 shows a front view of another variation of the treatment strip which is relatively thin and contoured for placement along the lower eyelids.

[0066] Fig. 9 shows a front view of another variation of the treatment strip which is relatively thicker and also contoured for placement along the lower eyelids.

[0067] Fig. 10 shows a front view of another variation of the treatment strip which is relatively thick for placement along the lower eyelids.

[0068] Fig. 11 shows a front view of another variation of the treatment strip which is contoured for the lower eyelids and which may be shortened into various lengths.

[0069] Fig. 12 shows a front view of another variation of the treatment strip which is relatively straightened and selectively shortened.

5 [0070] Fig. 13 shows a front view of another variation of the treatment strip which is contoured and further illustrates how differently sized strips may be used in combination with one another.

[0071] Fig. 14 shows a front view of another variation of the treatment strip which is sized to follow not only the meibomian glands along the lower eyelid but also the
10 surrounding tissue regions.

[0072] Fig. 15 shows a front view of another variation of the treatment strip which is contoured to follow the meibomian glands along the lower eyelid along with the surrounding tissue regions.

[0073] Fig. 16 shows a front view of yet another variation where the strip is
15 contoured to follow at least a portion of the meibomian glands but also to cover selected regions of the surrounding tissue.

[0074] Fig. 17 shows a front view of yet another variation which is contoured to selectively treat particular regions of the underlying tissue.

[0075] Fig. 18 shows a front view of yet another variation where the contoured
20 treatment strips may be used in combination for treating both upper and lower eyelids.

[0076] Fig. 19 shows a front view of yet another variation where the treatment strips may be altered in color to more closely match the underlying skin tone.

[0077] Fig. 20 shows a front view of yet another variation where the treatment strips may be sized to treat specified meibomian glands.

25 [0078] Fig. 21 shows a front view of yet another variation where the strips may be varied in size to selectively treat particular meibomian glands.

[0079] Fig. 22 shows a front view of yet another variation where the treatment strips may be sized to treat individual meibomian glands.

[0080] Fig. 23 shows a front view of yet another variation where the treatment
30 strips may be sized for placement along the lower eyelids.

[0081] Fig. 24 shows a front view illustrating the relative positioning of the lacrimal glands.

[0082] Figs. 25 to 27 show variations of treatment strips which may be contoured and positioned for treating the underlying lacrimal glands.

[0083] Figs. 28 to 30 show variations of treatment strips which may be contoured and sized for treating the meibomian glands in combination with optionally treating the lacrimal glands as well.

[0084] Figs. 31 and 32 show variations on treatment strips which may be sized for selectively treating particular meibomian glands in combination with the lacrimal gland.

[0085] Fig. 33 shows another variation of a treatment strips which may have mechanically biasing features incorporated along the strips for applying a force to the underlying tissue and meibomian glands.

[0086] Fig. 34 shows a detail perspective view of the treatment strip of Fig. 33 illustrating an example of biasing mechanisms incorporated along the strips.

[0087] Fig. 35 shows another variation of treatment strips incorporating one or more transducers for imparting a vibrating force to the underlying tissue and meibomian glands.

[0088] Fig. 36 shows yet another variation of treatment strips incorporating electrodes through the length of the strips.

[0089] Fig. 37 shows yet another variation of treatment strips incorporating microwave antennas, inductive coil, or technology that allows for wireless powering of the strips without physical connections to the controller.

[0090] Fig. 38 shows yet another variation of a treatment strip incorporating a timer and indicator for alerting a user when a treatment has been completed.

[0091] Fig. 39 shows yet another variation of an eyelid treatment system which may be coupled to a portable remote controller such as a smartphone or tablet.

[0092] Fig. 40 shows a perspective view of a controller which is specifically designed and programmed for use with the treatment strip assemblies.

[0093] Figs. 41A and 41B show perspective views of the controller having connectors for respective treatment strip assemblies coupled to the controller.

[0094] Figs. 42A and 42B show perspective views of the controller with the housing shown as transparent for clarity purposes to illustrate some of the internal components.

[0095] Fig. 43 shows a perspective view of a charging station which provides a receiving cradle for holding the controller.

[0096] Fig 44 shows the mating connection of a treatment strip assembly to a reusable cable assembly.

[0097] Fig. 45A shows a perspective view of treatment strip assembly coupled via respective connectors to a common junction for attachment to a cable.

[0098] Fig. 45B shows a perspective view of a treatment strip with a sensing layer exposed, illustrating the positions of various sensors.

5 [0099] Fig. 46 shows a perspective view of one variation of the forceps which are sized and angled for expressing the meibomian glands.

[0100] Fig. 47A shows a side view of another variation where heating strips may be applied upon or over the jaws or paddles of the forceps.

10 [0101] Fig. 47B shows a side view of another variation where the heating element may be applied directly upon the face of the jaws or paddles.

[0102] Figs. 48A and 48B show perspective and end views where the heating element may be positioned upon or in proximity to the inner surface of the jaw or paddle.

[0103] Figs. 49A and 49B show perspective and end views where the heating element may be positioned within the jaw or paddle.

15 [0104] Figs. 50A and 50B show perspective and end views where the heating element may be positioned upon or in proximity to the outer surface of the jaw or paddle.

[0105] Figs. 51A and 51B show perspective and end views of another variation where the jaw or paddle may be angled relative to one another to facilitate meibomian gland expression.

20 [0106] Figs. 52A and 52B show end views of variations of the jaws or paddles which may be angled relative to one another to facilitate meibomian gland expression.

[0107] Figs. 53A to 53E show perspective views of several variations of the face of the jaw or paddle which may incorporate various features to facilitate meibomian gland expression.

25 [0108] Figs. 54A to 54D show perspective views of various forceps jaw or paddle configurations which may be used.

[0109] Figs. 55A to 55E show perspective views of additional forceps jaw or paddle configurations which may be used.

30 [0110] Fig. 56 shows a perspective view of another forceps variation incorporating one or more sensors such as temperature sensors.

[0111] Fig. 57 shows a perspective view of a forceps variation incorporating a reservoir for fluid collection.

[0112] Fig. 58 shows an example of a treatment kit which includes forceps and optionally included additional treatments.

[0113] Fig. 59A shows another example of a treatment kit which includes forceps and one or more heating strips.

[0114] Fig. 59B shows another example of a treatment kit which includes forceps, one or more heating strips, and optionally a controller.

5

DETAILED DESCRIPTION OF THE INVENTION

[0115] In treating conditions such as meibomian gland dysfunction (MGD), which is commonly associated with the evaporative form of dry eye syndrome (DES), a patch, strip or thin adhesive device can be affixed to the skin of the upper and/or lower eyelids to deliver or absorb heat or other forms of energy, pressure, drugs, moisture, etc. (alone or in combination) to the one or more meibomian glands contained within the underlying skin. In particular, the treatment strip or strips may be configured and sized specifically for placement over one or more targeted meibomian glands contained within the skin of the upper and/or lower eyelids. The application of thermal therapy, e.g., heating or cooling, can cross the eyelids quite easily as the eyelids are generally the thinnest skin found on the human body and the tissue is highly vascularized. With the root of the eyelid located proximally and the eyelid margin located distally, the net arterial flow of blood flows from proximal to distal. So wherever these treatment strips are placed, the heating or cooling therapy may easily be carried throughout the eyelid and any structures contained therein, e.g., meibomian glands **MG**, lacrimal glands **LG**, gland of Zeis **GZ**, gland of Moll **GM**, gland of Wolfring **GW**, gland of Kraus **GK**, etc.

[0116] Moreover, because the eyelid is so thin, the heating or cooling therapy can be transmitted to the ocular surface and the eye itself (described in further detail below). Thus, the therapy can impart energy to the conjunctiva, goblet cells, episcleral vasculature, cornea, aqueous humor, iris, ciliary body, and possibly the retina, choroid, optic nerve, anterior vitreous, and lens. Thus, any thermal therapy by the treatment strips may also impact and be used to treat ocular surface disorders and anterior segment diseases, e.g., conjunctivitis, keratitis, keratopathy, iritis, cyclitis, glaucoma, cataract, etc. Also, there may be use in the postoperative state-like after LASIK, PRK, or cataract or corneal surgery or other ocular, peri-ocular, intraocular, or eyelid surgery, as described in further detail below.

[0117] As shown in the front view of Fig. 2A and Fig. 2B, one variation of such treatment strips may be seen as being adhered temporarily upon the upper eyelid **UL** and lower eyelid **LL** over an eye of a patient **P** when closed for illustrative purposes. The

contoured upper strip **10** may be sized for adherence directly upon the skin of the upper eyelid **UL** such that the strip **10** has a configuration and shape which follows the location of the one or more meibomian glands contained within the underlying skin of the upper eyelid **UL**. Likewise, the contoured lower strip **12** may also have a configuration and shape which follows the location of the one or more meibomian glands contained within the underlying skin of the lower eyelid **LL**. In other variations, the contoured strip may stop at the eyelid crease or cross over it as described in other variations below.

[0118] The upper strip **10** may thus have an upper curved or arcuate periphery **14** which is shaped to extend and follow the upper (or superior) border of the meibomian glands (such as along or up to the upper eyelid crease) while the straightened periphery **16** of the lower edge may be shaped to extend and follow the lower (or inferior) border of the meibomian glands such as along the free margin of the upper eyelid **UL**. The lower strip **12** may similarly have an upper straightened periphery **20** to extend and follow the upper (or superior) border of the meibomian glands along the free margin of the lower eyelid **LL** and a lower curved or arcuate periphery **18** to extend and follow the lower (or inferior) border of the meibomian glands along the lower eyelid **LL** (such as along or up to the lower eyelid crease). The use of the terms lower and upper herein refer to the periphery of the treatment strips when placed upon the patient **P** (human or animal) and are used herein for descriptive purposes.

[0119] While the treatment strips **10**, **12** are both shown adhered upon the respective upper eyelid **UL** and lower eyelid **LL**, the strips **10**, **12** may be used individually for placement upon only the upper eyelid **UL** or only the lower eyelid **LL** depending upon the desired treatment. Moreover, the lengths of the treatment strips **10**, **12** may also be varied to target individual meibomian glands for providing a targeted treatment, if desired, and as described in further detail herein.

[0120] While the treatment strips **10**, **12** are shown placed upon the closed eyelids of the patient **P**, the strips **10**, **12** are arc-shaped or flexible enough to assume the curvature of the patient's eyelid margin and may be long enough to cover some or all of the underlying meibomian glands in the tarsal plate. While the treatment strips **10**, **12** may be sized generally, they may also be custom made or sized for a specific individual's eyelid dimensions or shaped to optimize adhesion and/or comfort and/or stability. Generally, the treatment strips **10**, **12** may have a length anywhere from about 1 mm to 50 mm depending upon the desired treatment length as well as the anatomical considerations of the patient since the typical palpebral fissure length in an adult is about 27 mm to 30 mm. Thus, to

cover as many as all of the meibomian glands, the treatment strips **10**, **12** may be sized to have length of, e.g., 25 mm to 30 mm, or if sized to cover just beyond all the meibomian glands, a length of, e.g., 30 mm to 50 mm (or more if needed to optimize coverage / adhesion / comfort / stability). Moreover, one or both treatment strips **10**, **12** can have a width ranging anywhere from about 1 mm to 25 mm since the typical eyelid crease in a Caucasian male is about 8 mm to 9 mm above the eyelid margin while in Caucasian females it is about 9 mm to 11 mm above the eyelid margin (or more if needed for adhesion/comfort and potentially increased efficacy from heating or cooling the inbound blood flow). Customization enables it to fit any particular anatomy, race, ethnicity, etc. Moreover, the treatment strips may be manufactured with varying levels of flexibility to accommodate the ergonomics of the eyelid and eyelid blink for optimal comfort and minimal obtrusiveness or movement.

[0121] Because of the specific contoured sizes and flexibility of the treatment strips **10**, **12**, the treatment strips may be placed upon the patient **P** by the patient himself/herself for consumer use or by a healthcare provider to apply therapy to the underlying meibomian glands allowing the patient's eyes to be opened and closed normally, as shown in Fig. 2B, without interference from one or both treatment strips. While the strips may be applied from eyelid margin to eyelid crease, they may alternatively flex or accordion and/or compress during blinks to prevent impairment of normal blinking and maximize comfort.

[0122] Typical treatment patches, such as for application of a warm compress, are generally sized for placement over the entire eye or eyes such that the patient is unable to open their eyes or blink during a treatment session. Yet, because of the strong association between DES and MGD (for instance, MGD includes the spectrum of MGD, meibomitis, blepharitis, and ocular rosacea), natural blinking by an individual is the mechanism by which meibomian gland secretions are normally released onto the eyelid margin and over the tear. In the absence of blinking, the oil contained within the meibomian glands remain unexpressed within the glands' terminal ducts and fail to contribute to distribution of the oily layer upon the tears.

[0123] Accordingly, the treatment strips **10**, **12** contoured size, shape, and flexibility allow for treatment to occur while also allowing for the patient to have one or both eyes remain opened such that normal, physiologic blinking can proceed during the course of treatment. Rather than relying on an application of any type of external force to express the oil or obstruction from the glands, the treatment strips **10**, **12** take advantage of the eye's natural mechanism for clearing oil from the meibomian glands via blinking.

Hence, the treatment strips **10**, **12** may be adhered in place for treatment without any further intervention by the patient or healthcare provider such that the treatment strips **10**, **12** may apply, e.g., heat energy, to melt or liquefy any waxy or solid meibomian gland obstructions while the eyes remain unobstructed and are allowed to blink naturally. The treatment strips **10**, **12** thus allow for the natural blinking to help clear the glands of the heat-treated softened obstructions before they have re-solidified unlike other treatments which require that the patient keep their eyes closed or obstructed during the course of a treatment and prevent or inhibit the patient from blinking. Delivery of heat may also increase blood flow by promoting vasodilation as increased delivery of blood can affect metabolism, temperature of other tissues, may have effects on inflammation, and can thereby improve tissue function or recovery.

[0124] Because some patients have obstructions or occlusions in their meibomian glands that may not sufficiently melt, loosen, or soften without attaining heightened temperatures at the meibomian glands, the treatment strips **10**, **12** may apply heat or other treatments to the surface of the eyelids for a significant period of time for relatively longer treatment times and at higher treatment temperatures because of the ability of the treatment strips **10**, **12** to remain attached to the patient during any given period throughout the day. Treatment strips may be relatively transparent or skin toned, and thereby inconspicuous, to allow for normal functioning throughout the treatment ranges. Patients can assume their daily activities with their eyes open and eyes blinking and with the comfort of a strip-based treatment. Moreover, patients can affix the treatment strips as many times as needed throughout the day, week, month, etc. until dry eye symptoms subside. This increases the frequency of treatment, convenience of treatment, and thus efficacy of treatment.

[0125] Because of the prolonged treatment times, the application of a separate force beyond the application of the strips may not be needed so long as the patient is able to continue blinking during the course of treatment. Moreover, the treatment frequency may be adjusted or varied depending upon the severity of the condition to be treated. One example for potential treatment frequency may include application of one or both strips, e.g., up to six times per day for ten minutes or up to an hour or more for each treatment. Moreover, because the treatment strips are positioned over the meibomian glands which overlie the ocular surfaces, the application of the heating therapy may also indirectly heat the ocular surface as well and may further reduce any chronic ocular surface inflammation, chronic conjunctival inflammation, or corneal neovascularization.

[0126] Aside from heating of the ocular surface, heat therapy may also optionally be used to potentially provide for indirect heating through the ocular surface as well for heating of the retina to provide a thermal therapy to limit inflammation and neovascularization which are underlying conditions for diseases such as age-related macular degeneration (AMD), retinal vascular occlusions, retinal neovascularization, glaucoma, retinal degenerations and dystrophies, and Diabetic Retinopathy.

[0127] While the treatment strips **10**, **12** may be used throughout the day to take advantage of the patient's physiologic blinking, the treatment strips **10**, **12** may also be used while the patient is resting or sleeping or while the patient simply maintains their eyes closed. The treatment strips **10**, **12** may be applied as a single-use treatment or they may be configured to be robust enough as a re-usable device.

[0128] The treatment strips **10**, **12** are desirably flexible enough to accommodate movement of the upper eyelid **UL** and/or lower eyelid **LL** which may move as much as about 15 mm or more. Thus, the treatment strips **10**, **12** may be fabricated from various materials. Figs. 3A and 3B show front and cross-sectional side views, respectively, in one example of a treatment strip configured to have an adhesive **32** positioned about a periphery of the strip to leave a contact region **30** for direct placement against the skin surface. The contact region **30** may further include a moisturizing layer to interface between the strip and skin to facilitate heat transfer from the strip as well as to provide moisturizing therapy to the skin. Alternatively, the treatment strips may be used with any number of moisturizing agents which may be applied to the underlying skin by the patient **P** or by a practitioner separately from the treatment strips. Moreover, the contact region **30** may be formed to have a surface which is smooth, porous, irregular, corrugated, etc. to facilitate contact and transfer of the heat from the treatment strip to the skin surface. Alternatively, the entire contact region **30**, including its periphery, may be adhesive to maintain good contact. It may be hinged or curved to allow flexing or accordion-like dynamic movement for comfort and better, physiologically-sound ergonomics. In use, the strip may be applied under tension, as shown by the tensioned strip **10'** in Fig. 3D, to further reduce any impairment to blinking and once adhered to the skin the strip may be released to allow for its flexion, as shown by the released strip **10''** also in Fig. 3D, to facilitate blinking by the patient **P**.

[0129] In this variation, the treatment strip **10** may be configured to have a contact layer **34** (e.g., fabricated from conductive materials such as metals, alloys, porous ceramics, engineering ceramics, woods, polymers, composites, foams, polymer foams, elastomers,

etc.) which may protect the skin from burns or any other adverse effects. Such a contact layer 34 may also be comprised of a single-use adhesive layer, soft sticky polymeric material, etc. A second heating layer 36 may be positioned above the contact layer 34 (or directly in contact against the skin) for generating the heat energy and an insulative layer 38 may be positioned atop the heating layer 36 for focusing, directing, or reflecting the heat towards the underlying skin surface as well as to protect the patient from contact with the heating layer 36 from other parts of the body. The insulative or reflective layer 38 may accordingly be fabricated from a variety of insulative or reflective materials, e.g., foams, foam tapes, gauze, silicone, microporous polyethylene films, metals, alloys, reflective materials, mirrors, etc. Moreover, the thickness of the treatment strip 10 may vary, e.g., anywhere from about 1/64" to 1/8" (about 0.397 mm to 3.175 mm) or more, depending upon the heating layer 36 mechanism as well as the desired thermal profile and targeted transmission temperature. Additionally and/or alternatively, the insulative layer 38 may be comprised of a thermochromic material which may change its color when a targeted temperature has been reached by the treatment strip 10 to indicate to the patient that the targeted temperature has been achieved or when the therapy has been completed. With an insulative layer 38, due to the increased thermal mass, the increased heating and cooling times may be considered in the treatment procedures.

[0130] The heating layer 36 may be configured to generate its heat energy, e.g., up to a temperature range of about 20° to 55° C (or more) or between 40° to 50° C, through any number various mechanisms such as mechanical, electrical, or chemical mechanisms. In one variation, the heating layer 36 may comprise an air-activated or oxygen-activated warmer that can increase to an elevated treatment temperature for a period of time lasting, e.g., from 5 minutes up to 24 hours or even longer. An example can include air activated layer incorporating, e.g., iron. Other examples may incorporate a heating layer 36 containing, e.g., cellulose, iron powder, water, activated carbon (to speed up reaction), vermiculite (water reservoir), and salt (catalyst), saw dust, sodium chloride and water, etc. to generate heat from an exothermic oxidation of iron when exposed to air. Other variations may comprise a heating layer 36 which incorporates light-based activation (visible or UV-light powered) or use of a supersaturated solution (crystallization-type) to initiate and/or maintain an exothermic reaction.

[0131] Optionally, aside from use of a thermochromic material to determine when the treatment strip has reached a particular temperature, a separate temperature sensor 39 (e.g., thermocouples or thermistor devices) may be incorporated onto the treatment strip 10,

as shown in Fig. 3B, attached either to the top of the strip or to the bottom of the strip. The treatment strip **10** may also incorporate an optional controller and/or display **37** having a processor which may be programmable and which may incorporate a separate on/off feature, as shown in Fig. 3C. The temperature sensor(s) **39** may be in communication with the controller **37** which may be programmed to regulate the temperature of the heating layer **36** and/or a length of time for a particular treatment. Sensors can provide data to the controller demonstrating any regional variations in temperature, which improve ability to remain in the therapeutic window and also notify a user of suboptimal adherence or heating strip detachment. Multiple temperature sensors may be used to determine the correct application of the strip to the patient, e.g. a sensor not in contact with the patient will register a different temperature compared to a sensor in contact with the patient. The controller **37** may accordingly be programmable by a physician or caregiver or directly by the patient. Alternatively, the controller **37** may be configured to be inaccessible by the patient but may merely provide temperature and/or time indications for display to the patient. In the event that the controller **37** is programmable, the controller **37** may be programmed, e.g., to set a length of a heating period, set treatment times, set predetermined temperature ranges, control a heating temperature profile (such as gradually increasing the heating temperature or decreasing temperature over a predetermined period of time), etc.

[0132] In another variation, the heating layer **36** may generate heat through exothermic crystallization of supersaturated solutions (typically sodium acetate) which are usually reusable. The treatment strips may be recharged by heating them, e.g., by boiling, and allowing them to cool. Heating of these treatment strips may be triggered by snapping a small metal device buried in the treatment strips which generates nucleation centers that initiate crystallization. Heat is required to dissolve the salt in its own water of crystallization and it is this heat that is released when crystallization is initiated.

[0133] In yet another variation, the heating layer **36** may comprise a battery operated warmer which utilizes electrically resistive heating elements that are used to convert electrical energy in the battery to thermal energy. The power supply may be internal or external to the treatment strips and the treatment strips may be charged, e.g., by direct electrical contact, induction, etc.

[0134] Other mechanisms which may be incorporated into the heating layer **36** may comprise chemically actuated reactions such as those used by sodium acetate heating pads. For instance, a single-use chemical reaction utilizing the catalyzed rusting of iron or dissolving calcium chloride may be used where the reagents are maintained in separate

compartments within the treatment strips. When the patient squeezes the treatment strips, the compartments may break and the reagents mixed to produce heat. Examples may include use of a supersaturated solution of sodium acetate (NaCH_3COO) in water where crystallization may be triggered by flexing a small flat disc of notched ferrous metal
5 embedded in the liquid which act as nucleation sites for the crystallization of the sodium acetate into the hydrated salt (sodium acetate trihydrate). Because the liquid is supersaturated, this makes the solution crystallize suddenly [rapidly?] which releases the energy of the crystal lattice.

[0135] Yet another example of use in the heating layer 36 may include the use of a
10 hot gel containing a supersaturated solution of a salt. Heat may be generated when the crystallization of the given salt occurs exothermically. Such heating layer 36 may be reused by forcing the salt back into solution within the heating layer 36.

[0136] Yet other examples for incorporation into the heating layer 36 may also include the use of high specific heat capacity materials which may be heated, e.g., by
15 placement in a microwave prior to use, and then allowed to release the heat over a specified period of time.

[0137] Although the application of heat energy from the treatment strips is described, other variations may alternatively include the application of using the treatment strips for cooling of the underlying skin. Rather than using the heating layer 36 in an
20 exothermic reaction, the layer may be configured to utilize an endothermic reaction instead to provide for cooling of the skin at temperatures ranging, e.g., from about 0° C to 37° C or more particularly from about 25° C to 35° C. One example may include having the layer 36 to incorporate water and ammonium nitrate or ammonium chloride. Mixture of the water and the ammonium may reduce the temperature of layer 36. Another variation may
25 include the use of cooling gel made by adding hydroxyethyl cellulose or vinyl-coated silica gel which may be cooled or frozen prior to use. Alternatively, cooling, including but not limited to thermoelectric cooling, may be achieved by application of a cooling element such as a Peltier junction. Cooling, rather than heating, may be applied for conditions such as reducing inflammation, swelling, alleviating allergies or tired eyes, etc. particularly as
30 the patient rests or sleeps. One example includes treatment for allergic conjunctivitis where application of the cooling treatment may provide relief from any burning or itching sensations by serving as a vasoconstrictor to limit blood flow, reduce blood vessel leakage and permeability thereby reducing acute swelling and inflammation. Yet another example includes reducing inflammation and fibrosis of a conjunctival bleb resulting from a

trabeculectomy or mitigating inflammation generally following any ophthalmic or periocular surgical procedure or treatment.

[0138] Given the multitude of various mechanisms for incorporating a heating layer 36, the treatment strips may be configured to be single-use disposable strips, multiple-use disposable, re-usable strips, selectively actuatable, etc.

[0139] Aside from the application of heat energy from the treatment strips, the strips may also include a layer for the diffusion or release of one or more pharmaceutical, biological, or chemical agents either alone or in combination with the heat treatment. For instance, the pharmaceutical, biological, or chemical agents may be incorporated into the either the contact layer 34, insulative layer 38, or in a separate layer entirely, for transdermal delivery to the meibomian glands or to the areas surrounding the meibomian glands for additional and/or alternative treatments. For instance, examples of some of the various pharmacological agents which may be incorporated into the treatment strips (for use with or without the heat treatment) may include, but are not limited to, anti-inflammatory compounds, antibiotics, topical tetracycline, oral tetracycline, topical corticosteroids, oral corticosteroids, topical androgens, metronidazole, steroid antagonists, topical androgen analogues, TGF- β , omega 3 or omega 6 compounds, vasoconstrictors such as naphazoline, oxymetazoline, phenylephrine, and tetrahydrozoline, enzymes that promote lipid production, agents that stimulate production of enzymes that promote lipid production, agents that act as a secretagogue to enhance meibomian gland secretion, agents that replace or promote production of any tear component, cholinergic, muscarinic, or nicotinic agonists may be used, cosmeceuticals such as retinol or hyaluronic acid (HA) for wrinkled, puffy, or sagging skin in the cosmetics space, retinoic acid for acne, or agents that degrade or break down lipids like lipases, etc.

[0140] Other agents may include, e.g., alpha-melanocyte-stimulating hormone or adrenocorticotrophic hormone or androgens like testosterone to increase tear production, agents which stimulate the underlying muscles like the orbicularis oculi or muscle of Riolan to stimulate blinking, increase frequency of blinking, or maintain longer closure after a blink by inhibiting the levator palpebrae muscle to force a blink or eyelid closure or otherwise mechanically compress the meibomian glands or glands of Zeis or other goblet cells or accessory lacrimal glands.

[0141] Additionally and/or alternatively, other agents for incorporation into the treatment strips may further include, e.g., neurotransmitters, noxious or irritating chemicals or vapors, hormones, oils, lipids, polar lipids, or fatty acids. Use of neurotransmitters may

allow for stimulation to occur via second messenger pathways like activation of the Calcium/Protein Kinase C pathways, G-Protein activation, other calcium related pathways, calcium-calmodulin dependent protein kinases, the cyclic adenosine monophosphate dependent pathways, adenylyl cyclase pathways, inhibition of cAMP dependent phosphodiesterases.

[0142] In the event that the pharmacological or chemical agent is released during the heat treatment, the heat may help to improve penetration of any drugs into the underlying skin.

[0143] Yet another variation may incorporate a treatment strip which applies a heat rub that can be applied via the treatment strips onto the upper UL and/or lower eyelids LL for the treatment of the meibomian glands or which applies a compound which attracts light and heats up accordingly. Each of these variations may allow for the treatment strips 10, 12 to be applied and used while allowing for natural blinking to occur to facilitate the clearing of the ducts of melted oil blockages within the meibomian glands and to facilitate the spreading of the oil onto the tears.

[0144] While the treatment strips may incorporate various layers into the strips to effect various different treatments, the strips may also be varied in size, shape, contour, etc. depending upon the desired treatment areas so long as the treatment strips are contoured or shaped to follow the location of at least one meibomian gland. An example of another configuration for the treatment strips is shown in the front view of Fig. 4, which illustrates a contoured thinned strip 40 sized and shaped for placement along the upper eyelid UL. This treatment strip may have a contoured lower edge 42 as well as a contoured upper edge 44 which follow the positioning of the underlying meibomian glands. Moreover, although the strips 40 are shown placed upon the upper eyelids UL of both eyes of the patient P, a single strip 40 may be used upon a single eyelid to selectively treat the particular meibomian glands in this and other examples shown herein. Additionally, one or both upper eyelids UL may be treated alone or in combination with one or both lower eyelids LL depending upon the desired treatment in this and other examples shown herein.

[0145] Another variation is shown in the front view of Fig. 5 which shows a contoured thickened strip 50 having a contoured lower edge 52 and contoured upper edge 54 for placement upon the meibomian glands as well as the surrounding tissue and glands. In yet other variations, rather than utilizing two separate treatment strips, a singular strip may also be used which extends over the bridge of the patient's nose. Additionally, the thickened strip 50 may cover the portions of skin farther proximally away from the eyelid

margin to facilitate treatment. Because arterial blood supply to the eyelids proceed from proximal to distal of the eyelid margins, the treatment strip may heat (or cool) the blood supply as it continues to flow towards the eyelid margins. This early heating (or cooling) may provide a therapeutic effect for increased comfort to the patient, less impact on eyelid function (such as blinking), and increased safety of application and distance from the ocular surface as well as potentially increased efficacy allowing for more total heating or cooling therapy.

[0146] Fig. 6 shows yet another variation having a contoured thinned strip **60** where the lower **62** edge and upper edge **64** converge to a tapered end **66** for placement upon the meibomian glands. Fig. 7 shows yet another variation where the treatment strips may comprise straightened strips **70** having a first width used in combination with a thinned straightened strip **72** as well. The straightened strips **70** may comprise straightened strips (having optionally rounded corners) which may be selectively placed over the meibomian glands. In this example, a single straightened strip **70** may be applied upon the upper eyelid **UL** of a single eye while the remaining eye may utilize a single straightened strip **70** applied along a first portion of the upper eyelid **UL** and a second straightened strip **72** having a relatively thinner width for placement upon a second portion of the upper eyelid **UL**. Each of the strips may be applied singularly or in various combinations depending upon the desired treatment areas and are shown in this variation as an exemplary combination.

[0147] In the variation of Fig. 8, an example of contoured thinned strip **80** is shown applied along the lower eyelid **LL**. As illustrated, the contoured upper edge **82** and contoured lower edge **84** may be contoured to follow over the underlying meibomian glands. As described above, the treatment strips may be applied singularly over one or both eyes or they may be applied in combination with treatment strips applied over one or both eyes of the upper eyelids. Moreover, any of the treatment strips shown herein may be used in any number of combinations with one another.

[0148] Fig. 9 shows another variation where the contoured thickened strip **90** may be applied over the lower eyelids **LL** and may further have a width which is relatively wider than those treatment strips shown above in Fig. 8. Similarly, Fig. 10 shows yet another variation where the contoured thickened strip **92** may have a width which is relatively wider still for treating not only the underlying meibomian glands but also any glands and tissue surrounding the peri-orbital region. As described above for the variation of Fig. 5, the widened treatment strip may heat (or cool) the blood supply as it continues to

flow towards the eyelid margins. The early heating (or cooling) may provide a therapeutic effect for increased comfort to the patient, less impact on eyelid function (such as blinking), and increased safety of application and distance from the ocular surface.

[0149] Aside from variations in width of the treatment strips, any of the treatment
5 strips may be varied in length as well to selectively target portions of the meibomian glands or particularly selected meibomian glands. For example, Fig. 11 shows one variation where the shortened contoured strip **100** having a first shortened length may be applied upon the lower eyelid **LL** (and/or upon the upper eyelid **UL**). A second contoured strip **102** having a second length which is longer than the shortened contoured strip **100** may
10 also be seen for comparison. Fig. 12 similarly shows a shortened and straightened strip **110** applied upon the lower eyelid **LL** and a second straightened strip **112** having a relatively longer length applied upon the second lower eyelid **LL**. The straightened strips **110**, **112** may incorporate rounded ends and may be varied in length depending upon the desired treatment area. They could also be rounded or circular to cover one or more stytes.

[0150] Fig. 13 shows yet another variation where the contoured strips **120** may be
15 configured to have tapered ends for overlying the meibomian glands. In comparison, thickened contoured strip **122** is also illustrated having tapered ends yet is relatively wider to alter the treatment area.

[0151] Fig. 14 shows another variation where the contoured strip **130** may have a
20 first portion **132** which is relatively wider than a second portion **134** for placement over the meibomian glands of the lower eyelid **LL**. Each of the first **132** and second portions **134** may be varied in width again depending upon the desired treatment areas. Another example is shown in Fig. 15 which shows a contoured strip **140** having a first portion **142** and second portion **144** which are considerably wider for treating not only the meibomian
25 glands along the lower eyelid **LL** but also the surrounding peri-orbital tissue regions such as the underlying maxillary sinus. Fig. 16 shows yet another example of a contoured strip **150** having a first portion **152** and a second portion **154** which is wider than the first portion **152** and where the strip **150** is positioned to cover just a portion of the meibomian glands along the lower eyelid **LL** but also covers various other glands, such as the lacrimal
30 glands, around the peri-orbital regions.

[0152] Fig. 17 shows yet another variation of a treatment strip comprised of a contoured strip **160** having a secondary enlarged portion **162** attached via a connecting strip **164**. While the contoured strip **160** may treat the meibomian glands along the lower

eyelid **LL**, the secondary enlarged portion **162** may treat region of the tissue along the cheeks of the patient.

[0153] In yet another variation, Fig. 18 shows an example where both an upper contoured strip **170** and a lower contoured strip **172** may be applied, respectively, along the upper eyelid **UL** and lower eyelid **LL**. As discussed previously, the contoured strips **170**, **172** are shaped and applied to follow the underlying meibomian glands while enabling the patient **P** to blink normally. Fig. 19 shows a similarly applied upper contoured strip **180** and lower contoured strip **182** where the strips may be varied in color to more closely match a skin tone or shade of the patient **P**. Because the treatment strips may be used throughout the day for any given period of time, the strips **180**, **182** may be made in various colors or tones to either more closely match the skin tone or shade of the patient **P**.

[0154] In yet another variation, Fig. 20 shows another example where the treatment strips may be varied in length to treat specific regions along the upper **UL** or lower eyelids **LL**. In this example, a first upper strip **190** having a first length may be applied adjacent to a second upper strip **192** having a second longer length. Optionally, a third upper strip **194** and/or fourth upper strip **196** having lengths which are relatively shorter may also be applied as well over selected meibomian glands. A lower strip **198** having enlarged distal ends **200**, **202** are also shown for placement along the lower eyelid **LL**. The distal ends **200** may be shaped to facilitate the placement and/or removal of the strip **198** from the skin (or for better adhesion). Yet another example is shown in Fig. 21 which illustrates several shortened treatment strips, e.g., first upper strip **210** and second upper strip **212**, placed selectively along the upper eyelid **UL** along with, e.g., first lower strip **214** and second lower strip **216**, placed selectively along the lower eyelid **LL**. Each of the strips may be varied in length as well as size depending upon the treatment area.

[0155] With the lengths of the treatment strips being variable, multiple strips may be applied adjacent to one another or to overlap horizontally and/or vertically along the eyelids. Moreover, one or more of the treatment strips may be made as a single unit or as a series of panels either horizontally or vertically oriented which may be optionally connected by a backing that is flexible. As shown in the variation of Fig. 22, each of the targeted strips **220** may have a length of, e.g., about 1 mm, to cover as few as a single meibomian gland. One or more of the targeted strips **220** may be applied along the upper eyelid **UL** and/or lower eyelid **LL**. Additionally, one or more of the targeted strips **222** may further comprise a connecting member **224** which functions as a backing to couple each of the individual targeted strips **222** to one another. The individual strips may be

applied selectively at particularly problematic meibomian glands either along the upper eyelid **UL** and/or lower eyelid **LL**. For example, Fig. 23 illustrates the individual targeted strips **222** placed along just the lower eyelid **LL**.

[0156] While the treatment strips may be applied to one or more of the meibomian glands, variations of the strip may also be used to treat other glands such as the sebaceous glands, e.g., for acne treatment. Treatment strips used to treat acne may utilize different pharmacological treatments. Other glands in the underlying eyelids and conjunctiva **CN** for treatment may also include treatment of, e.g., the glands of Zeis **GZ**, goblet cells, accessory sebaceous glands, accessory goblet cells such as the Henle and Manz glands, accessory lacrimal glands of Wolfring **GW** or Krause **GK**, or either one or both lobes of the main lacrimal glands such as the palpebral portion or the orbital portion.

[0157] Moreover, the treatment strips may be used to potentially treat eye disorders beyond meibomian gland dysfunction including, e.g., blepharitis, sjogren's syndrome, dacryoadenitis, conjunctivitis, allergic conjunctivitis, keratoconjunctivitis sicca, keratitis, dacryocystitis, iritis, keratitis, retinitis, sclerokeratitis, uveitis, contact lens related eye problems, post blepharoplasty or eyelid or eye surgical procedures (e.g., cataract surgery, LASIK, PRK, etc.), absent or dysfunctional blinks disorders, conjunctivitis, blepharospasm, exposure keratopathy, corneal abrasions, recurrent corneal erosions, corneal dystrophies, facial nerve palsies or paresis, lagophthalmos, lid myokymia, infections, styes, chalazion, hordeolum, glaucoma, blebs, trauma, etc.

[0158] Yet another example, as mentioned above, may include use of the treatment strips for treating disorders of the lacrimal gland **LG** and/or palpebral lacrimal gland **PL** which are located above the eye as shown in Fig. 24. Various sized treatment strips, such as lacrimal gland strips **230** shown in Fig. 25 which is sized to have a curved upper periphery, may be sized for placement directly over the skin surface above where the lacrimal glands **LG** are located. Other variations are shown in Fig. 26 which illustrates lacrimal gland strips **232** which are relatively thinner in width as well as in Fig. 27 which illustrates lacrimal gland strips **234** which have curved peripheries ending in tapered ends. The treatment strips may deliver heat, e.g., to stimulate the lacrimal gland **LG**, increase gland metabolism, activity, lacrimation, etc. Alternatively, the treatment strips may deliver cooling therapy to reduce inflammation which impairs gland function.

[0159] The lacrimal glands **LG** and/or palpebral lacrimal gland **PL** may be treated alone or in combination with the treatment strips contoured for treatment of the meibomian glands. One variation is shown in Fig. 28 which illustrates contoured strips **240** which are

enlarged in width to cover both the lacrimal glands **LG** as well as the meibomian glands along the upper eyelid **UL**. Contoured treatment strips **242** are also shown placed along the lower eyelids **LL** for treatment of the meibomian glands as well.

[0160] Fig. 29 shows another variation where lacrimal gland strips **250** may be placed over the lacrimal glands **LG** in combination with an integral combined contoured strip **252** which is sized to encircle the eyes entirely while following the location of the meibomian glands along both the upper eyelids **UL** and lower eyelids **LL**. This fully encircling design may also be held in place more tightly against the skin with a strap which may encircle the patient's head, if so desired. Another variation is shown in Fig. 30 which illustrates an integral combined contoured strip **260** which is also sized to encircle the eyes entirely and further having a width suitable for placement over the lacrimal glands **LG**.

[0161] The lacrimal gland strip **270** may be used in combination with any of the treatment strips shown herein. Another example is illustrated in Fig. 31 which shows lacrimal gland strip **270** used in combination with the individual strips **222** while Fig. 32 shows yet another example where lacrimal gland strip **270** may be used in combination with not only the individual strips **222** but also the strips **220** located along respective lower eyelid **LL** and upper eyelid **UL**.

[0162] While the treatment strips may be applied over the meibomian glands to apply the heat energy, the treatment does not require the application of any external force applied by the strip or any other external device but may utilize the natural blinking of the patient to facilitate treatment, as described above. However, in additional variations, the treatment strips may be configured to apply both the heat treatment as well as an external force. Any number of mechanisms may be utilized to apply a pinching or biasing force to provide for compression of the underlying skin and of the meibomian glands during application of the heat therapy. One example is shown in the front view of Fig. 33 which illustrates a biased treatment strip **280** which may be comprised of a strip **282**, as previously described, having one or more biasing mechanisms **284** positioned along the strip **282**. The one or more biasing mechanisms **284** may be positioned along either the upper strip or lower strip or both, as shown.

[0163] In this example, the biasing mechanism **284** may locally squeeze or compress the underlying skin to apply a pressure to the meibomian glands **MG** to facilitate the clearing of any obstructions, particularly if applied simultaneously with the heat treatment. An example of a biasing mechanism **284** is illustrated in the perspective view of Fig. 34 which shows how the biasing mechanism **284** may generally comprise portions of

the strip **282** or separate members biased to form corresponding channels **286** which are configured to flex in an open or closed configuration. When the strip is initially placed upon the skin, the ends of the strip may be pulled to open the channels **286** which may then be placed upon the skin surface. As the strip and biasing mechanisms **284** relax, the underlying skin and meibomian glands **MG** may be compressed or pinched by the compression forces **288** induced into the biasing mechanism **284**. The compressive force maybe applied, for instance, by changing the current through a Nitinol wire to change a length of the wire when the current is applied. Additionally, the wire can be used to hold strips to the eyelid or to add compressive force.

[0164] Aside from a compression force, the strip may be formed with alternative components such as a mechanical component to impart vibrational energy to facilitate the expression of the meibomian glands and promote oil secretion. An example is illustrated in Fig. 35 which shows another variation of the contoured strip **290A**, **290B** having one or more vibrating elements **292** (e.g., piezoelectric transducers, electromagnetic actuators, eccentrically coupled rotating elements, etc.) incorporated along the strips **290A**, **290B**. The one or more vibrating elements **292** may be electrically coupled to a power supply and/or processor **294** also contained along the strips **290A**, **290B**. Moreover, the vibrational energy may be imparted separately from heat treatment or in combination with the heat therapy. The power supply may include a micro-battery which can be rechargeable to deliver microcurrents of energy. Such a micro-battery can be integrated either on the strips or separately.

[0165] Aside from the application of a vacuum or suction, mechanical pressure or vibrational energy, other forms of energy may also be delivered by one or more of the treatment strips. Another variation is illustrated in Fig. 36 which shows an upper contoured strip **300A** having a conductive element **302** such as a wire integrated along the entire length (or a partial length) of the contoured strip **300A**. The conductive element **302** may be configured in an alternating pattern or it may be simply aligned along the length of the strip as shown by conductive element **306** (or electrically resistive) along the lower contoured strip **300B**. Each of the conductive elements **302**, **306** may be in electrical communication with a respective power supply and/or processor **304**, **308**. The conductive elements **302**, **306** may be selectively actuated to apply either heat energy or they may be configured to apply radio-frequency (RF) energy, visible light or specific bands or wavelengths thereof, or infrared radiation to the underlying skin and meibomian glands. With respect to the application of electrical energy, one form of electrical energy applicable

by the treatment strips may include use of a transcutaneous electrical nerve stimulation feature, e.g., to deliver neural stimulation to increase tear production. The conductive elements may generate the thermal energy via various power sources, e.g., battery, solar cell, kinetic movement, RF, etc.

5 [0166] Fig. 37 shows yet another variation where the contoured strips **310A**, **310B** may be configured to incorporate an electrode or antenna **312** coupled to a power supply and/or processor **314** for applying, e.g., microwave energy to the underlying meibomian glands. Aside from the electrical or microwave energy, the treatment strips may be configured to apply yet other forms of energy for treating the meibomian glands. For
10 example, other variations may incorporate actuators or transmitters for applying ultrasonic, RF, microwave, magnetic, photonic (light energy in the infrared or visible light spectrum), ultrasound powering with a receiver such as a piezoelectric receiver, electromotive force or electromagnetic radiation powered, thermal, etc. In yet other variations, the conductive elements may be configured to function as electromagnetic elements once actuated or the
15 strips may incorporate ferromagnetic elements to promote closure of the eyelids. The magnetic force could serve to squeeze the meibomian glands and express the oily obstruction as the eyes are opened and re-opened when overcoming the magnetic force.

[0167] In yet another variation, one or both treatment strips **320A**, **320B** may be configured to incorporate an indicator **324**, e.g., LED light, alarm, vibration element, etc.,
20 electrically coupled to a power supply and/or processor **322** to alert the patient when a prescribed treatment has been completed. This feature (and any of the other features) may be combined with any of the other variations of the treatment strips described herein as practicable.

[0168] Fig. 39 shows yet another variation where the eyelid treatment system **330**
25 may be formed into a coupled dual-strip design, e.g., a “wishbone” design, where the dual-strip heating strips may have two heating elements which follow the location of the meibomian glands the upper **UL** and lower **LL** eyelid of a single eye. Depending upon whether both eyes or a single eye and/or both upper and lower eyelids are treated, the system **330** may comprise a first heating strip assembly **332** and a second heating strip
30 assembly **334** for each respective eye. Each of the assemblies **332**, **334** may accordingly utilize an upper and a lower lid treatment heater, e.g., upper lid treatment strip **332A** and lower lid treatment strip **332B**, where each of the upper and lower elements may be coupled to one another via wires **336** (e.g., flexible circuit). Moreover, each of the assemblies **332**, **334** may be coupled via a connecting cable **338** to controller **340** which

may be coupled (e.g., through an input/output port such as a headphone jack, USB port, micro HDMI, or other connection port) to a portable electronic device **342** (e.g., smartphone having a touch screen interface, tablet, PDA, laptop computer, etc.) as shown.

[0169] In other variations, the number of connecting cables may range anywhere from 1-4 connector cables rather than utilizing a single cable **338**. For instance, one cable may be used to provide power and communication to a few or all four heating elements in each of the assemblies **332**, **334**. Alternatively, four connecting cables may provide power and communication to each of the heating elements in assemblies **332**, **334**. Yet in other alternatives, two connecting cables may provide power and communication to each of the assemblies **332**, **334**.

[0170] In other additional variations, any of the treatment strips described may be used in combination with the controller **342** described herein, as practicable. Yet in a further variation, oval or circular shaped heating elements may cover the eye and both eyelids where an outer border of the heating elements or strips may follow the path of the upper and lower meibomian glands. In this case, one treatment strip may cover both eyelids and both sets of meibomian glands and the user may use a total of two (rather than four) round, circular, or oval shaped treatment strips to cover both eyes. Such a variation may be used, e.g., for a night time therapy in bed prior to or during sleep when the eyes need not necessarily be open.

[0171] The assemblies **332**, **334** may generally comprise strips, as previously described, which follow the location of the meibomian glands while still allowing patients to blink easily and proceed in comfort with daily activity. An example of such heaters which may be configured for use with the treatment system **330** may include thin, flexible heaters which are commercially available through companies such as Minco Products, Inc. (Minneapolis, MN) or can be custom designed and manufactured independently or through third party manufacturing. Each individual treatment strip, e.g., treatment strips **332A**, **332B**, may each be sized for a single eyelid, e.g., 28 mm x 7 mm x 0.15 mm, having a bottom chord length of, e.g., 28 mm, with a radius of curvature of, e.g., 75 mm, and having a general configuration of an arcuate rectangle having blunted corners where the nasal or temporal edges may coincide with the radii of the arc. However, these size limitations are intended to be exemplary and not limiting since the treatment strips **332A**, **332B** may be sized to be smaller or larger to accommodate different eye anatomies.

[0172] Moreover, the individual treatment strips **332A**, **332B** may be formed as thin, flexible transparent polymers containing the heating elements while the contact

surface of the strips may be affixed to the respective eyelids with, e.g., a disposable adhesive. Other variations may utilize opaque or colored strips, e.g., skin-tone colors. Moreover, one or more temperature sensors may also be integrated into the treatment strips where the heating elements and sensors may be routed through the connecting cable 338 to a power source and/or controller 340 and/or portable electronic device 342, as shown.

[0173] Controller 340 may generally comprise a hardware/software platform or unit which may be programmed for controlling the therapy treatments. Accordingly, the controller 340 may include a processor as well as a power supply such as a battery (rechargeable or disposable) for providing power to the assemblies 332, 334. The power supply within controller 340 may be optionally rechargeable separate from the portable electronic device 342 or the power supply may draw power for the assemblies 332, 334 and processor directly from the portable electronic device 342 as well.

[0174] In the case where the controller 340 is programmed to provide the therapy treatment protocols, one or several controls for controlling the treatments may be built directly into controller 340. The portable electronic device 342 may interface with the controller 340 to display, in one variation, part of the controls on a screen (e.g., touchscreen) of the electronic device 342 such as controls for starting and/or stopping a treatment. The controller may also have facilities for detecting when leads are not properly connected, measuring power levels, and measuring temperature levels. Accordingly, there will be the capability to notify or alert a user should any of these values fall out of range or the ability to prevent initiation of treatment or cease treatment until these scenarios are explicitly acknowledged or corrected. Alternatively, all of the controls may reside on the controller 340 while a display on the electronic device 342 may serve primarily to show or track various results or treatment parameters, and or treatment status. A separate display and controller combination may also be used.

[0175] In yet another alternative, the all of the controls may reside on the display of the electronic device 342 for controlling the various treatment options and parameters rather than on the controller 340. In this variation, the electronic device 342, in this example a smartphone, may also provide the power to the treatment strip assemblies 332, 334 and may also control the various treatment temperatures and times as well as receive and display temperature feedback or other physiological parameters which may be measured. In this case, the treatment strips 332, 334 and connecting cable 338 may be plugged directly into the mobile or portable consumer electronic device 342. For instance, the electronic device 342 may be used to display treatment parameters and controls such as

an icon or button for initiating therapy. In one example, therapy may be initiated by the user through electronic device 342 to heat one or more of the strips of one or both of the treatment strip assemblies 332, 334. In any of the variations, the electronic device 342, particularly in the case of a smartphone or tablet, may have an optional program or application downloaded onto the device which facilitates the various control and/or display parameters on the electronic device 342 depending upon how the electronic device 342 is used with the controller 340 and assemblies 332, 334. Depending on the variation, the display and control display may reside on the controller 340 itself or on another device separate from the controller 340.

[0176] Additionally, the electronic device 342 may also provide a diagnostic function to allow the user to test for dry eye and/or to determine how treatment is progressing either before, during, or after treatment. Accordingly, the electronic device 342 or controller 340 may leverage, e.g., an integrated camera and/or flash/light source, for purposes of imaging the user's ocular tear film or ocular surface and evaluating commonly used tear assessment criteria such as total tear film layer thickness, and/or tear film mucin layer thickness, and/or tear film lipid layer thickness, and/or tear film aqueous layer thickness, or any combination thereof. Such a camera may also display or "mirror" strip placement for evaluation or adjustment by the user or remotely, either synchronously or asynchronously. In addition to imaging of the user's tear film and/or ocular surface conditions, the mobile application may include other common methods for diagnosing dry eye such as user questionnaires related to the user patient's symptoms, discomfort, and/or improvement or worsening of symptoms that can be completed using the electronic device's touch screen interface, results stored on the electronic device 342 or web application or manufacturer's servers, tracked over time for trend evaluation, and possibly shared with the user's physician.

[0177] Moreover, in any of the variations, the controller 340 and/or electronic device 342 may be programmed or initiated to heat up the assemblies 332, 334 to, e.g., 42.5° C +/- 1° to 2° C. Treatment time may be set to, e.g., 1 to 30 minutes or more such as 60 minutes, and the controller 340 and/or electronic device 342 may further be programmed to shut down when the allotted treatment time has passed or if the measured temperature rises above a predetermined level, e.g., 45° C. Additionally, the controller 340 and/or electronic device 342 may also be programmed or set to indicate various treatment parameters (e.g., the initiation of treatment, warming of the heating elements, completion

of treatment, errors, battery life, etc.) through any number of visual, auditory, or haptic indicators.

[0178] Additionally, the controller 340 and/or electronic device 342 may be used to store and/or transmit various data such as historical treatment data, usage time, total treatment time, temperature data, etc. Furthermore, the controller 340 and/or electronic device 342 may communicate wirelessly with a remote server or additional controller, allowing the controller 340 and/or electronic device 342 to also be programmed remotely, e.g., by a physician or other party. In yet other variations, audio and/or visual information (e.g., advertisements, educational media, social media connectivity, or other media) may also be displayed upon the controller 340 and/or electronic device 342 which may be received from remote servers or various other data may be transmitted to and/or from the controller 340 and/or electronic device 342 as well.

[0179] In yet other variations, although controller 340 is illustrated as being coupled to assemblies 332, 334 via a wired connecting cable 338, other variations may have controller 340 wirelessly connected with assemblies 332, 334. Such a connection may be through any number of wireless protocols such as Bluetooth®, RF, etc.

[0180] This “precision temperature control” mobile heating therapy system may be used for heating other parts of the body as well, where the system remains nearly the same, but the heating element dimensions may be varied and power requirements may also be changed depending on the total surface area being treated, temperature goals, patient comfort, or other situational specifics.

[0181] With the incorporation of a processor into the treatment strips, treatment times or other parameters such as temperature of the strips may be programmed and optionally shut on or off selectively by the patient or automatically. Moreover, other parameters such as the frequency of the heat delivery or other stimulation may also be programmed by the processor to provide further flexibility in treatment.

[0182] In yet another variation, the treatment strip assemblies may be used with a controller 350 which is specifically designed and programmed for use with the treatment strip assemblies. An example of such a controller 350 is shown in the perspective view of Fig. 40 which illustrates the controller 350 which may comprise a housing 352, e.g., a circularly-shaped housing which may weigh less (or more) than 8 ounces, which encloses the power supply and controller board having a programmable processor contained within. The controller housing 352 may incorporate two ports 354 for plugging two heater assemblies, i.e., a first port for connecting a first treatment assembly for the first eye and a

second port for connecting a second treatment assembly for the second eye, although in other variations, a single port may be used for treating a single eye. In cases where the tissues around only the first eye are treated, a single port may be utilized. Connector indicators **358** may be included to provide a visual indicator (and/or auditory indicator) to indicate to the user whether the first and/or second ports **354** have heaters properly connected. A charging port **356** for connecting to a power supply for charging the controller **350** may also be incorporated into the housing **352**. Ports for heater assemblies **354** on the controller may be oriented relative to the charging port **356** such that charging is not possible with any number of heaters connected to the controller.

[0183] A power button **360** may be provided to allow the user to activate the controller **350** on/off and a power indicator **362** may also be provided to show the power level of controller **350**. In addition to the power indicator **362**, a temperature controller **364** may also be provided to allow for the user to adjust the temperature of the strip assemblies during treatment, e.g., by pressing the “+” or “-” as appropriate. Additionally, a timer **366** may also be provided to give feedback like a visual (and/or auditory) countdown of the treatment time. For instance, when a 12 minute timer has been initiated, each indicator bar of the timer **366** may pulse for 1 min then turn off until the entire 12 minute treatment time has elapsed.

[0184] As shown in the perspective views of Figs. 41A and 41B, the controller **350** may provide a visual indication, as indicated by the connector indicators **358**, of when the first connector **370A** for the first treatment strip assembly has been inserted into the first port **354A** and likewise when the second connector **370B** for the second treatment strip assembly has been inserted into the second port **354B**.

[0185] Figs. 42A and 42B illustrate various perspective views of the controller **350** with the housing **352** shown as transparent for clarity purposes to illustrate some of the internal components contained within the housing **352**. For instance, a first and second power source **380A**, **380B**, e.g., rechargeable batteries, may be incorporated into the housing **352** for supplying the power to respective first and second treatment assemblies. Additionally, a controller board **382** having a programmable processor may also be incorporated into the housing **352** for controlling the treatment parameters as well as for controlling various safety features.

[0186] For instance, the controller board **382** and processor may be programmed initiate a therapy session by applying power to the treatment strip assemblies (when connected to the controller **350**) for a treatment time of approximately 12 minutes

(although this treatment time may be altered as needed or desired). The applied voltage provided by the power source **380A**, **380B** may be actuated by the controller board **382** to provide a current through the electrical traces of the heater strips to apply heat to the eyelids at a temperature of approximately 42.5°C. The controller board **382** may be programmed to heat the treatment strips to a therapeutic temperature within, e.g., 20 seconds, of initiating therapy (e.g., in a temperature controlled setting such as room temperature, 20-26 °C).

[0187] The controller board **382** may be programmed to include a temperature sensing feedback loop capable of maintaining a nominal temperature of 42+/- 1°C and may be further programmed to provide a visual and/or auditory warning if the treatment strips drop below a threshold temperature, e.g., 39°C, at any time during treatment. The controller board **382** may also be programmed to prohibit the treatment strip surface temperatures from exceeding a maximum temperature for a predetermined period of time, e.g., 48°C for a cumulative period of time no greater than 5 seconds, during treatment. The controller may be programmed to discern discrepancies in temperatures in any single treatment strip, which may indicate partial application of the strip on a patients face. Each strip may have multiple sensors to provide for accuracy regarding regional temperature differences along the strip and optionally to detect temperatures separate from the strips more accurately and rapidly and to adjust accordingly.

[0188] If the patient determines that the treatment strip assemblies are too hot, the user may adjust the treatment temperature by adjusting the temperature controller **364** or the treatment may be stopped by either 1) momentarily pressing the power button **360** on the controller **350**, 2) turning off the controller **350** (e.g., holding the power button for 3-5 seconds), 3) unplugging the treatment strip assemblies from the controller **350**, or 4) removing the treatment strip assemblies from the patient's eyelids. After the treatment has been completed or stopped, the treatment strip assemblies may be removed from the patient's eyelids, disconnected from the controller **350**, and disposed of.

[0189] The power source **380A**, **380B** within the controller **350** may be sufficient for at least five 12-minute heat treatment cycles and the controller board **382** may be programmed to prevent a treatment cycle from initiating when recharging is required (e.g., less than 25% charge remaining in the power source **380A**, **380B**).

[0190] Additionally, the controller board **382** may also be programmed to automatically shut off power to the treatment strips when the one or both connectors **370A**, **370B** are unplugged from their respective ports **354A**, **354B**. A treatment session may be

paused and the temperature indicator **364** may change in status to provide an indication that a treatment strip is unplugged.

[0191] Additionally, the controller board **382** may be further programmed to provide an automatic shutoff after a period of inactivity, e.g., 15 second, outside of a heating cycle (no start/stop, plugging of heaters or charger, etc.).

[0192] The controller **350** may be rechargeable either via direct connection to a power supply through charging port **356**. Alternatively, a separate charging station **390** may be provided which provides a receiving cradle **392** for holding the controller **350**, as shown in the perspective view of Fig. 43. The charging port **356** may be aligned with a charging port integrated into the receiving cradle **392**. In other variations, the charging station **390** may be configured to wirelessly charge the controller **350**, e.g., via inductive charging, so that the controller **350** may be simply placed into proximity of the charging station **390** rather than being plugged into a charging connector.

[0193] In yet another alternative, the controller **350** may have a replaceable battery pack or packs, which may be recharged external to the controller **350**, and exchanged by the user when one pack has been depleted.

[0194] With respect to the treatment strip assemblies, another variation is shown in the perspective view of Fig. 44 which illustrates heating strips **400A**, **400B** (which may be applied to the upper lid **UL** and lower lid **LL**) which are coupled via respective connectors **402A**, **402B** (e.g., flexible connectors to accommodate the positioning of the heating strips **400A**, **400B** to the patient) to a common junction **404** coupling the heating strips **400A**, **400B**. The junction **404** may be connected to a coupler **410** having a receiving port **412** which is sized to removably receive the junction **404**. The coupler **410** may be connected to a cable **414** (e.g., which may be several feet in length to reach from patient's eyes to the controller **350** when located on the wrist) which is then coupled to the port **354A** or **354B**.

[0195] Because the treatment strip assemblies may be designed for single use, the treatment strips may be marked or otherwise electronically tagged (such as via junction **404** or some other indicator) to prevent their re-use by the controller board **382** when previously used treatment strips are connected to the controller **350**. In one variation, the junction **404** may incorporate a usage tracking mechanism **408** such as a memory chip that may be programmed to have a "0" or "1" memory which may indicate to the controller board **382** that the particular treatment strip assembly has previously been used, as shown in the detail perspective view of Fig. 45A. In another variation, the usage tracking mechanism **408** may comprise a sacrificial fuse located on the junction **404**. A short burst of high energy may

be delivered by the controller to the mechanism **408** to blow the fuse. Then the energy for treatment may be lowered by the controller to deliver the proper temperature therapy.

Optionally, once the treatment strip assembly has been used, the junction **404** may be removed from receiving port **412** and another junction for a new treatment strip assembly may be inserted for another treatment or for another patient.

[0196] In other variations, rather than having a wired connection, the treatment strips may incorporate an antenna and transmitter and/or receiver for communicating wirelessly with the controller board **382**.

[0197] Each of the heating strips **400A**, **400B** may include one or more respective sensors **406A**, **406B**, e.g., thermistors or thermocouples, which may be coupled to a common wire connector or separate wires and positioned upon the strips to provide treatment feedback to the controller board **382** for each eyelid strip, as also shown in Fig. 45A. Each of the heating strips **400A**, **400B**, for instance, may incorporate anywhere from 1-4 temperature sensors on each strip, e.g., one sensor positioned on a first end, a second sensor positioned on the middle, and a third sensor positioned on a second end of the strip. Fig. 45B shows a top view of the heating strips **400A**, **400B** illustrating how each strip may incorporate one or more sensors. As shown, the first strip **400A** may have a first sensor **420A** positioned near or at a first end such as a distal end of the strip, a second sensor **420A'** positioned mid-way along the strip, and a third sensor **420A''** positioned near or at a second end such as the proximal end of the strip. Likewise with the second strip **400B**, a first sensor **420B** may be positioned near or at a first end such as a distal end of the strip, a second sensor **420B'** may be positioned mid-way along the strip, and a third sensor **420B''** may be positioned near or at a second end such as the proximal end of the strip.

[0198] An additional temperature sensor may also be placed upon or in proximity to the patient body, e.g., near the patient's temple, upon an additional treatment strip and away from the treatment strips placed upon the patient's eyelids to measure and monitor an ambient temperature where the patient is being treated. This separate ambient temperature data may help to ensure that the treatment strips themselves are working properly and delivering the targeted temperature therapy. Sensors may be used in a comparative mode to determine if any portion of the treatment strip is not in contact with the patient or is malfunctioning.

[0199] In treating conditions such as meibomian gland dysfunction (MGD), which is commonly associated with the evaporative form of dry eye syndrome (DES), the meibomian glands may be mechanically pressed or squeezed to express solidified meibum

from the glands in order to help treat MGD. Forceps are typically used to apply pressure upon the meibomian glands. The forceps may be modified to create a pressure gradient upon the meibomian glands to direct meibum and any other meibomian gland secretions towards the meibomian gland orifices. This pressure gradient may be increased by the optional incorporation of one or more features along the compression surfaces of the forceps. Additionally and/or alternatively, the forceps may be configured to also provide a thermal treatment, e.g., to the eyelid surfaces to simultaneously melt, soften, or liquefy and express meibum to increase its therapeutic efficacy.

[0200] The forceps may be used after (or during) a heat treatment in combination with the heating strips as described herein. Alternatively, the forceps may be used to first apply a heat treatment to melt the meibum plugs contained within the glands and then the forceps may be used to mechanically express the liquefied meibum before it re-solidifies. In another alternative, the forceps may be used to apply a thermal treatment and mechanical expression simultaneously to effectively express the meibum. In treating the meibomian glands, the forceps may also be used to apply heat to other regions, e.g., inner eyelids, outer eyelids, or both. However, when the heating strips are used to apply a heat treatment to a patient, the forceps used for mechanically expressing the glands may be configured to separately heat the glands and/or they may include any number of mechanical features, as described herein, to facilitate mechanical expression.

[0201] Aside from treating MGD, the forceps may also be used to treat other conditions such as acne, arthralgia, myalgia, hordeolum, styes, chalazion, abscesses, other dermatological conditions, etc. The forceps may also be used for dental applications such as curing adhesives, fillings, etc. Additionally, the forceps may be used for other medical purposes such as tissue ablation, maintaining hemostasis, etc. as well as non-medical purposes such as welding-type applications.

[0202] One variation of the forceps is shown in the perspective view of Fig. 46 which illustrates forceps 430 which has a first handle 432A and second handle 432B coupled at a proximal end and optionally positioned to extend in parallel such that a respective first bridge 436A and second bridge 436B project and optionally curve relative to the handles 432A, 432B such that a first jaw or paddle 434A is aligned in apposition to a second jaw or paddle 434B. The first paddle 434A and second paddle 434B may also be aligned such that a respective first inner surface 438A and second inner surface 438B are angled relative to one another to impart a directional pressure gradient, e.g., in a direction perpendicular to the direction of the force applied, upon the contacted tissue for facilitating

meibomian gland expression, as described in further detail below. Alternatively, the angled surfaces of the paddle may articulate relative to one another, creating a progressive pinching motion or progressive apposition of paddle surfaces from one paddle edge to the other. The first and second paddles **434A**, **434B** may be sized for positioning in proximity to the eyes and directly upon the eyelids of a patient and the paddles **434A**, **434B** may also be spaced apart from one another to allow for the positioning of the tissue (e.g., eyelid tissue containing the meibomian glands) in-between. In other variations, the first and second handles **432A**, **432B** may be curved or arcuate provided that the paddles **434A**, **434B** are spaced apart from one another.

[0203] The forceps **430** may be disposable after a single use or it may be configured to be fully reusable. Alternatively, it may be configured to be partially disposable, e.g., having reusable handles **432A**, **432B** with removably disposable first and second paddles **434A**, **434B** or other portion. Hence, the forceps **430** may be fabricated in part or in whole from any number of various materials, e.g., polymers, metals, composites, ceramics, etc. One or both of the paddles may be suitably sized for application to various regions of the body but when configured for treating the meibomian glands, the paddles may have a height **H** ranging anywhere, e.g., between 1 mm to 20 mm with a length **L** ranging anywhere, e.g., between 1 mm to 50 mm. In one variation, one or both paddles may have a height **H** and length **L** of, e.g., respectively, 5 mm by 25 mm.

[0204] Additionally, one or both paddles **434A**, **434B** may optionally incorporate an insulating or reflective layer **441** which may be used to protect the contacted tissues as well as to increase the efficiency and efficacy of a treatment therapy. The insulating or reflective layer **441** may be integrated on a single or both inner surfaces and they may also be configured to cover a partial surface or the entire surface of the paddle, as needed or desired.

[0205] In treating the meibomian glands, one or both paddles **434A**, **434B** may be configured to heat up to a predetermined temperature range and optionally for a predetermined period of time. In one variation, the forceps **430** may have heating strips or sleeves which may be attached or secured or otherwise applied as separate elements onto their respective paddles. The perspective view of Fig. 47A shows one variation where first heating assembly **442A** and second heating assembly **442B** may each incorporate a respective first and second heating element **446A**, **446B**, e.g., resistive heating wire, upon or within a contact surface of each heating assembly **442A**, **442B**. The heating assemblies **442A**, **442B**, in this variation, may each define a respective first and second receiving

cavity or channel **444A**, **444B**, such as a sleeve, into which the first and second paddles **434A**, **434B** may be inserted or attached. The heating elements **446A**, **446B** may be in electrical communication with a controller and/or power supply **440** which may be integrated with the forceps **430** (e.g., within or along one or both of the handles **432A**, **432B**) or otherwise externally connected or coupled with the heating elements **446A**, **446B**.
5 [0206]

The controller **440** may incorporate a processor which is programmable as well as a power supply which is rechargeable or disposable, if desired. In yet other variations, the controller **440** may be configured as a mobile device such as a computer, smartphone, tablet, etc. which may communicate wirelessly with the heating elements or other features of the forceps **430**. Other forms of communication between the heating elements and the controller or power supply **440** may also be utilized. Examples include various forms of wired or wireless communication such as standard wireless protocols, infrared, radiofrequency, ultrasound, etc. Alternatively, chemically powered heating elements, such as those that rely on exposure of elemental iron to atmospheric oxygen, or other exothermic reactions, can be coupled to the forceps **430**. The controller **440** may also be programmed to incorporate features such as auditory, visual, or haptic alerts which can provide an indication to the user or physician of certain parameters, e.g., when a treatment temperature has been reached, when a predetermined period of time has passed for squeezing of the glands before the forceps are released, etc. Additionally and/or
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20 alternatively, the forceps may incorporate an optional actuator **439** for automatically compressing and releasing the tissue between the forceps paddles while under control via the controller **440** (as shown below in Figs. 47A-47B).

[0207] Fig. 47B shows a side view of another variation of a single handle **432B** and paddle **434B** (for clarity purposes only) where the heating element **448** may be incorporated directly upon or within the paddle **434B**. The heating element **448** may be electrically coupled to the controller and/or power supply **440** and may be attached to the paddle **434B** through any number of securement mechanisms, e.g., adhesives, magnetic, clips, fasteners, etc. In either variation, the heating element may be used to generate or remove energy from the contacted tissue region being treated by the forceps **430** to create an isolated microenvironment where the energy may be delivered for thermal therapy (or diagnosis) and to confine the area under treatment so as to prevent or inhibit surrounding tissues from unnecessary treatment or damage.
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[0208] Additionally and/or alternatively, the forceps **430** may also incorporate various other treatment features, e.g., fluid irrigation, blower or vacuum, etc., for enhancing

the cooling or heating within the treatment region. Moreover, aside from resistive heating elements, other heating modalities may also be incorporated, e.g., infrared, ultrasound, vibrational energy, RF (single or di-pole), electromagnetic radiation such as ultraviolet light or x-rays, inductively transferred energy, thermal conduction, etc. Other mechanisms
5 for heating the heating elements may also be utilized, such as induction heating, chemical mechanisms, fluid flow with a heater reservoir, etc.

[0209] In the event that an electromagnetic radiation is applied between the paddles, an electrical field may be created between the paddles 434A, 434B via electrodes or electrical grid positioned along or within the paddles. The voltage applied may be
10 relatively low level and used to heat the tissue between the paddles and/or for other treatments such as iontophoresis to facilitate the delivery of agents such as drugs into the underlying tissue.

[0210] Additionally and/or alternatively, the treatment applied via the individual paddles may also be configured in a number of different combinations. For instance, the
15 first paddle 434A may be configured to apply a heat treatment while the second paddle 434B may be configured to apply a different energy modality such as vibrational energy, light energy, etc. or it may simply be used to apply the compressive force against the first paddle 434A. Regardless, the energy modality for each individual paddle may be configured to vary from one another as so desired and in any one of the combinations of
20 different features as described herein.

[0211] When the heating element 448 is incorporated directly into one or both of the paddles, the heating element 448 may be positioned in a number of different configurations. Figs. 48A and 48B show perspective and end views of a single paddle 434A, in one example, where the heating element 448 (illustrated in this example as a
25 resistive heating wire or trace wound in an alternating manner) may be positioned upon or beneath the inner surface 438A which comes into contact with the tissue being treated. Another variation is shown in the perspective and end views of Figs. 49A and 49B which show the heating element 448 positioned within the interior of the paddle 434A such that the element 448 is positioned mid-way from the inner surface 438A. Yet another variation
30 is shown in the perspective and end views of Figs. 50A and 50B which show the heating element 448 positioned upon or beneath an outer surface of the paddle 434A such that the element 448 is positioned away from the inner surface 438A.

[0212] In applying the thermal therapy, the heating element 448 (in one or both paddles) may be heated to a temperature which is effective for melting solidified meibum,

e.g., between 35° C to 50° C, or preferably between 38° C to 43° C, or more preferably between 41° C to 43° C. Moreover, the treatment times over which the heated forceps **430** may be applied to the tissue region being treated may also be varied any, e.g., between 0 to 30 min., or preferably between 5 to 15 min., or more preferably between 10 to 12 min, in treatments where the forceps may be locked and otherwise secured upon the patient. In other variations, the treatment time may vary, e.g., between 1 to 2 mins per eyelid, when the eyelids are actively treated and monitored by the user or physician.

[0213] As described above, the respective first inner surface **438A** and/or second inner surface **438B** may be angled relative to one another to impart a directional pressure gradient upon the contacted tissue for facilitating meibomian gland expression when compressed between the paddles **434A**, **434B**. An example is illustrated in the handle **432A** and paddle **434A** of Fig. 51A (a single handle and paddle is shown for clarity purposes only). When the paddles **434A**, **434B** are urged towards one another, one or both inner surfaces **438A**, **438B** may be angled relative to one another, as shown in the end view of Fig. 51B, such that compression of the tissue between the paddles **434A**, **434B** creates the directional pressure gradient **450** which may urge the compressed meibum away from the paddles **434A**, **434B**. Alternatively, the angled paddles may articulate with added pressure, allowing a progressive pinching motion to be applied to the glands during or after heating.

[0214] Fig. 52A illustrates an end view of one variation where both the first paddle **434A** and second paddle **434B** may each be angled relative to one another and relative to a centerline **CL** defined by the forceps such that inner surfaces **438A**, **438B** may define an angle α which creates the directional pressure gradient **450**. Fig. 52B illustrates an end view of another variation where, e.g., the first paddle **434A** may have its inner surface **438A** aligned with the centerline **CL** and the second paddle **434B** may have its inner surface **438B** angled relative to the inner surface **438A** and centerline **CL** to form an angle β . Either angle α or β may range anywhere, e.g., between 0° to 30°, or preferably between 5° to 15°, or more preferably will be about 5°. Regardless of the angle at which the paddles **434A**, **434B** are aligned (or misaligned), the forceps are intended to be combined with any of the heating element variations described herein. The angulation of the paddles may be static, or vary during application of pressure such that the paddles may become parallel at some maximum force applied to the forceps.

[0215] Because the forceps **430** are designed to compress the tissue between the paddles, the forceps may be configured to have locking or non-locking handles.

Additionally, the handles may be manually or automatically actuated to apply the compression forces such that the paddles may be compressed in a sustained continuous manner or in an intermittent or pulsed manner. In the event that the forceps are automatically compressed either in a sustained, intermittent, or pulsed manner, the controller 440 may be programmed to apply the compression in the desired manner, at the desired temperature, and for the desired period of time. The forceps as intended for manual use may be constructed in a manner, or with materials, that limit the maximum amount of compression force on the glands to limit trauma to the patient, this includes but is not limited to travel stops, flexural beams that may sustain known limited loads.

[0216] Fig. 53A shows a perspective view of forceps which may incorporate another optional feature upon the paddles 460A, 460B. One or both of the inner surfaces may define any number (e.g., one or more) of features which facilitate the creation of the directional pressure gradient 450 described above. The variation of Fig. 53A illustrates one feature where one or both of the paddle surfaces may define indentations or grooves 462 which are aligned in parallel with the directional pressure gradient 450, e.g., in the direction of the paddle height. The grooves 462 shown may extend partially within the inner surface and may extend at least partially over the inner surface from the upper edge shown. Fig. 53B shows another variation where grooves 466 may similarly extend over the inner surface of paddle 464 in a parallel manner but with alternating grooves having different lengths to create a differential pressure gradient. Fig. 53C shows a perspective view of another variation where the inner surface of paddle 468 may define bumps or projections 470. The projections 470 may be uniform in size and dimension and may also be uniformly positioned over the inner surface. Alternatively, as shown, the projections 470 may range in size from relatively larger to smaller the closer the projections 470 are located to the upper edge of the paddle 468. In yet another variation shown in the perspective view of Fig. 53D, the paddle 472 may define grooves or pits or depressions 474 which extend into the inner surface rather than projecting outwardly. Similarly, the pits or depressions 474 may be uniform in size as well as uniform in positioning relative to one another. Alternatively, as shown, the pits or depressions 474 may range in size from relatively larger to smaller the close the pits or depressions 474 are located to the upper edge of the paddle 472. Fig. 53E shows yet another variation where paddle 476 may define pits or depressions 478 which progressively increase in size from the lower edge to the upper edge of the paddle 476. Such a design may further facilitate the creation of the pressure gradient in facilitating treatment of the meibomian glands. The features may be

formed of a solid construct (single component) or of multiple components that allow relative movement of the features and or permit motion of the feature across the membranes, (e.g., ball bearings forming bumps, rollers forming projections/groves). Alternatively, the grooves/projections **462**, **466**, **470**, **474** may be capable of translation across the face of the paddle, in parallel or at some angle to long-axis of the paddle, creating a dynamic pressure gradient.

[0217] With any of these features described, they may be utilized in any number of combinations either on the inner surface of a single paddle or both paddles. For example, the grooves **466** of Fig. 53A or 53B may be defined along both paddles while in other variations, the projections **470** of Fig. 53C may be defined on a first paddle while the pits or depressions **474** of Fig. 53D may be defined on the second paddle such that the two apposed inner surfaces create interlocking contact surfaces. Additionally, features such as the grooves may be configured to mirror the anatomy of the meibomian glands to further facilitate engagement with the tissue and expression of the meibum. Moreover, any of these surface features are intended to be utilized in any number of combinations with any of the angled (or non-angled) paddle variations as well as with any of the heated paddle variations in any number of configurations.

[0218] Aside from surface features on the paddle inner surface, variations in the paddle shape may also be utilized in any number of combinations. Fig. 54A shows a perspective view of one variation where the forceps **480** may utilize a first paddle **482A** and a second paddle **482B** which are configured to have a curved or arcuate shape. In yet another variation, shown in the perspective view of Fig. 54B, paddles **484A**, **484B** may be shaped to have a rectangular configuration while Fig. 54C shows another configuration where the paddle **486** may extend along its height equidistant in either direction from bridge **436A** to present an enlarged inner surface. Fig. 54D also shows another configuration of a paddle **488** also having a rectangular shape but where the height extends away from the bridge **436A** in an “upward” direction as opposed to the height extending away from the bridge **436A** in a “downward” direction as shown in Fig. 54B.

[0219] Fig. 55A shows yet another variation in forceps **490** where first and second paddles **492A**, **492B** are configured into a square configuration, as shown in the detail view of Fig. 55B, rather than a rectangular shape. Fig. 55C shows yet another variation where the first and second paddles **494A**, **494B** may be shaped into an elongated configuration. Fig. 55D shows another variation where the first and second paddles **496A**, **496B** may be shaped to extend from the bridge as a cylindrical shape optionally have a number of

projections extending from the paddles. Fig. 55E shows yet another variation where the first paddle **498A** may be shaped into a rectangular or square configuration while the second paddle **498B** may be configured into another shape, such as a T-shaped configuration. Additionally, other paddle types may also be used with any of the variations described herein, for example, where the paddles may be replaced with a phaco-needle type forceps.

[0220] In any of these varying paddle configurations, any of these shapes may be utilized in a uniform complementary configuration or in any other shape combinations where a first paddle has a first configuration and a second paddle has a second configuration different from the first configuration. Moreover, any of the paddle configurations are intended to be utilized in any number of combinations with any of the paddle configurations have surface features and/or in combination with any of the paddles having varying angled configurations and/or in combination with any of the heating element configurations.

[0221] In yet another variation, Fig. 56 shows a perspective view of another variation where the forceps **480** may incorporate heating elements **500A**, **500B** along the respective paddles **482A**, **482B** along with one or more optional sensors positioned along the heating elements or paddles. In the variation, a first sensor **502** may be positioned along a distal portion of the paddle, a second sensor **504** may be positioned mid-way along the paddle, and a third sensor **506** may be positioned along a proximal portion of the paddle. Although three sensors are shown in this example, a fewer number of sensors or a greater number of sensors may be utilized at different locations. The sensors in this variation may comprise temperature sensors, such as thermocouples or thermistors, while other sensor types (e.g., chemical sensors, oxygen, blood flow, force, pressure, impedance, etc.) may also be utilized in other variations. Such sensors may be incorporated along the paddles alone or in any number of combinations with any of the variations described herein.

[0222] Additionally, any of the paddles may also incorporate any number of drugs (e.g., anesthetics, antibacterial agents, etc.) upon the paddle surfaces or through delivery mechanisms which may be infused or placed upon the tissue when contacted by the forceps.

[0223] Another variation is shown in the perspective view of Fig. 57 which illustrates paddles **434A**, **434B** optionally incorporating collection reservoirs **510A**, **510B** which may define one or more specimen collection vias or ports such that the reservoirs are

in fluid communication with the contacted tissue positioned between the paddle inner surfaces. Although two reservoirs **510A**, **510B** are shown, a single reservoir may be incorporated. The reservoirs **510A**, **510B** may be used to collect any gland expression for testing and analysis in either real time or after a treatment procedure has been completed.

5 The pores or texture on the inner surfaces of the paddles may be designed such that expressed fluids maintain their position relative to individual glands that produced fluids, which may then be used for evaluation of disease progression.

[0224] While any of the forceps or forceps combinations described herein may be packaged and distributed individually, they may also be packaged into kits **520**, as shown
10 in Fig. 58, to include not only the forceps **430** but also various combinations of additional devices or treatments. In one example, a pharmaceutical treatment **522** (e.g., eyedrops, ointments, medications, etc.) may be included as well as optional heating strips **524** which may be applied to the skin surface of the patient's eyelids (or in proximity to the eyelids) for heating and/or pre-heating the meibomian glands prior to or during gland expression
15 with the forceps **430**. Such a kit **520** may provide a complete treatment solution.

Moreover, while pharmaceutical treatment **522** and optional heating strips **524** are shown included in the kit **520** along with the forceps **430**, any combination of these may be included within the kit **520** as well as various other treatments or devices.

[0225] Another example of a kit **540** is shown in Fig. 59A which illustrates one or
20 more heating strips **524** provided in combination with forceps **542**. In this variation, the forceps **542** may be configured with paddles **464** which define grooves **466** extending over the inner surface(s) between the lower and upper edges of one or both paddles **464** to facilitate mechanical expression after (or before) the heat treatment. Optionally, the heating strips **524** may be single-use and disposable, if so desired.

25 [0226] Fig. 59B shows yet another example of a kit which includes the one or more heating strips **524** and forceps **542**, as described above, but which also optionally includes a controller **350** for controlling the heat treatment of the one or more heating strips **524**. The controller **350** may be a re-usable unit while the heating strips **524** and/or forceps **542** may be optionally configured as single-use and disposable, if so desired.

30 [0227] As discussed, any of the forceps variations and combinations described herein may be used alone for treating a patient or they may be used in combination with any of the treatment apparatus and methods described in further detail in U.S. Pat. App. 13/645,985 filed October 5, 2012 and U.S. Pat. App. 13/343,407 filed January 4, 2012, which are each incorporated herein by reference in its entirety and for any purpose herein,

particularly for treatment of MGD and dry eye syndrome. These references also describe the heating strips 524 in further detail for optional inclusion with any of the kits.

[0228] The applications of the devices and methods discussed above are not limited to the treatment of dry eye syndrome but may include any number of further treatment applications. Moreover, such devices and methods may be applied to other treatment sites within the body where acute or chronic inflammation causes a disease or condition. The treatment strips can be accordingly custom-designed to follow the path of the underlying physiology, e.g. custom designed and contoured cooling or heating treatment strips to treat the sinuses and acute or chronic sinusitis, respectively, rhinitis and allergic rhinitis, joint aches and inflammation, arthritis, muscle aches, back pain, headaches, wounds, sports injuries, etc. Modification of the above-described assemblies and methods for carrying out the invention, combinations between different variations as practicable, and variations of aspects of the invention that are obvious to those of skill in the art are intended to be within the scope of the claims.

15

CLAIMS

What is claimed is:

1. A treatment system, comprising:

one or more strips configured to adhere to an underlying region of skin in proximity
5 to one or both eyes of a subject such that the one or more strips allow for the subject to blink naturally with minimal, or no restriction from the one or more strips; and

a controller in communication with the one or more strips, wherein the controller is programmable to monitor and induce a temperature in the one or more strips to provide a therapy,

10 wherein, the controller is further programmable to maintain a set point above a threshold temperature and below a maximum temperature over a predetermined treatment period,

wherein the one or more strips are configured to emit thermal energy to the underlying region of skin, and wherein the one or more strips are shaped to follow a
15 location of one or more meibomian glands contained within the underlying region of skin.

2. The system of claim 1 wherein the controller comprises a temperature controller.

3. The system of claim 1 wherein the threshold temperature is 39°C.

20 4. The system of claim 3 wherein the maximum temperature is 48°C.

5. The system of claim 4 wherein the treatment period is 12 minutes.

25 6. The system of claim 1 wherein the controller is programmed to provide a treatment temperature of 42°C +/- 1°C.

7. The system of claim 1 wherein the controller is programmed to maintain a treatment therapy at the temperature of 48°C for a cumulative period of time no greater
30 than 5 seconds.

8. The system of claim 1 further comprising a power source having a charge sufficient for at least five 12-minute heat treatment cycles.

9. The system of claim 8 wherein the controller is programmed to prohibit a treatment therapy when the power source is below a threshold value.

5 10. The system of claim 1 wherein the controller is programmed to automatically shut power off from the one or more strips when a connector coupled to the one or more strips is disconnected from the controller.

10 11. The system of claim 1 wherein the controller is programmed to provide an automatic shutoff after a period of inactivity.

12. The system of claim 1 wherein the one or more strips comprise a contact surface for placement against the region of skin.

15 13. The system of claim 1 wherein the one or more strips comprise a heating layer in thermal communication with the region of skin.

20 14. The system of claim 1 wherein the one or more strips each have a first curved or arcuate periphery which is shaped to extend and follow a border of the one or more meibomian glands and a second curved or arcuate periphery which is shaped to extend and follow a free margin of an upper or lower eyelid.

15. The system of claim 1 wherein the controller is programmed to provide an auditory, visual, or haptic indicator for communicating with the user.

25 16. The system of claim 1 further comprising a usage tracking mechanism in communication with the controller.

30 17. The system of claim 1 wherein the controller is programmed to detect a partial application of the one or more strips on the region of skin.

18. The system of claim 1 further comprising a forceps for mechanically expressing the one or more meibomian glands.

19. The system of claim 18 wherein the forceps comprise:

a first handle and a second handle coupled to one another near or at respective proximal ends;

a first paddle coupled to the first handle and defining a first inner surface;

a second paddle coupled to the second handle and defining a second inner surface

5 which is positioned in apposition to the first inner surface,

wherein the first inner surface and/or the second inner surface define one or more grooves such that a directional pressure gradient is created between the first and second inner surfaces when the surfaces are approximated towards one another.

10 20. The system of claim 19 further comprising at least one heating element integrated or secured upon at least one of the first paddle and second paddle.

21. The system of claim 20 wherein the at least one heating element is positioned upon the first inner surface and/or second inner surface.

15

22. The system of claim 20 wherein the at least one heating element is positioned upon an outer surface of the first paddle and/or second paddle.

23. The system of claim 19 wherein the first inner surface and second inner surface
20 form an angle of between 0° to 30° .

24. The system of claim 19 wherein the first paddle and/or second paddle are configured in a rectangular shape.

25 25. The system of claim 19 wherein the first paddle and/or second paddle are configured in a curved or arcuate shape.

26. The system of claim 19 further comprising one or more sensors positioned upon the first paddle and/or second paddle.

30

27. The system of claim 19 wherein the first paddle and/or second paddle further comprise a reservoir in fluid communication for collecting a fluid specimen expressed from tissue.

28. A treatment system, comprising:

one or more strips configured to adhere to an underlying region of skin in proximity to one or both eyes of a subject such that the one or more strips allow for the subject to blink naturally with minimal, or no restriction from the one or more strips, wherein the one or more strips are configured to emit thermal energy to the underlying region of skin, and wherein the one or more strips are shaped to follow a location of one or more meibomian glands contained within the underlying region of skin; and
a forceps for mechanically expressing the one or more meibomian glands.

29. The system of claim 28 wherein the forceps comprise:

a first handle and a second handle coupled to one another near or at respective proximal ends;
a first paddle coupled to the first handle and defining a first inner surface;
a second paddle coupled to the second handle and defining a second inner surface which is positioned in apposition to the first inner surface,
wherein the first inner surface and/or the second inner surface define one or more grooves such that a directional pressure gradient is created between the first and second inner surfaces when the surfaces are approximated towards one another.

30. The system of claim 28 further comprising:

a controller in communication with the one or more strips, wherein the controller is programmable to monitor and induce a temperature in the one or more strips to provide a therapy,
wherein, the controller is further programmable to maintain a set point above a threshold temperature and below a maximum temperature over a predetermined treatment period.

31. The system of claim 30 wherein the controller comprises a temperature controller.

32. The system of claim 30 wherein the threshold temperature is 39°C.

33. The system of claim 32 wherein the maximum temperature is 48°C.

34. The system of claim 33 wherein the treatment period is 12 minutes.

35. The system of claim 30 wherein the controller is programmed to provide a treatment temperature of 42°C +/- 1°C.

5

36. The system of claim 28 wherein the one or more strips each have a first curved or arcuate periphery which is shaped to extend and follow a border of the one or more meibomian glands and a second curved or arcuate periphery which is shaped to extend and follow a free margin of an upper or lower eyelid.

10

37. A method of treating a subject, comprising:

adhering an upper strip to an upper eyelid of a subject such that the upper strip has a flexibility sufficient to accommodate movement of the upper eyelid to allow for the subject to blink naturally without restriction from the upper strip while covering one or more meibomian glands contained within the upper eyelid with the upper strip, wherein the upper strip has a first curved or arcuate periphery which is shaped to extend and follow a border of the one or more meibomian glands contained within the upper eyelid and a second curved or arcuate periphery which is shaped to extend and follow a free margin of the upper eyelid;

15

initiating a treatment with the upper strip via a controller transmitting electrical energy to the upper strip via a connecting cable;
emitting thermal energy from the upper strip to the upper eyelid; and
expressing the one or more meibomian glands.

20

38. The method of claim 37 further comprising adhering a lower strip to a lower eyelid of the subject such that one or more meibomian glands contained within the lower eyelid are covered by the lower strip.

25

39. The method of claim 38 wherein the lower strip has a first curved or arcuate periphery which is shaped to extend and follow a border of the one or more meibomian glands contained within the lower eyelid and a second curved or arcuate periphery which is shaped to extend and follow a free margin of the lower eyelid.

30

40. The method of claim 38 wherein the upper strip and lower strip are electrically coupled to one another.

41. The method of claim 37 wherein emitting thermal energy comprises applying
5 thermal energy from a heating layer in the upper strip.

42. The method of claim 37 wherein initiating comprises programming the upper strip via a controller attached to the upper strip.

10 43. The method of claim 37 wherein the method of treating comprises treating one or more conditions selected from the group consisting of dry eye, evaporative dry eye, and Meibomian gland dysfunction.

44. The method of claim 37 wherein the method of treating comprises treating to
15 improve one or more conditions selected from the group consisting of an ocular surface, tear quality, lipid layer of tears, and tear break up time.

45. The method of claim 37 wherein the method of treating comprises treating to
20 reduce Meibomian gland inflammation or ocular surface inflammation.

46. The method of claim 37 further comprising monitoring a temperature of the upper strip via one or more temperature sensors incorporated into the upper strip.

47. The method of claim 37 wherein emitting thermal energy comprises heating the
25 upper strip for at least 10 minutes or more.

48. The method of claim 37 wherein emitting thermal energy comprises heating the upper strip for up to 15 minutes.

30 49. The method of claim 37 wherein expressing comprises expressing the one or more meibomian glands via a forceps.

50. The method of claim 49 further comprising:

positioning a tissue region having the one or more obstructed meibomian glands between a first paddle having a first inner surface and a second paddle having a second inner surface, wherein the first inner surface and second inner surface define one or more grooves; and

5 urging the first paddle and second paddle towards one another such that the tissue region is compressed between the first inner surface and second inner surface and a directional pressure gradient is created within the tissue region, and wherein meibum is expelled from the one or more obstructed meibomian glands.

10 51. The method of claim 50 further comprising maintaining the first paddle and/or second paddle within a predetermined temperature range while contacting the tissue region.

52. The method of claim 50 wherein the first inner surface and second inner surface are aligned at an angle of between 0° to 30°.

15

53. The method of claim 37 further comprising collecting the meibum excreted from the one or more obstructed meibomian glands.

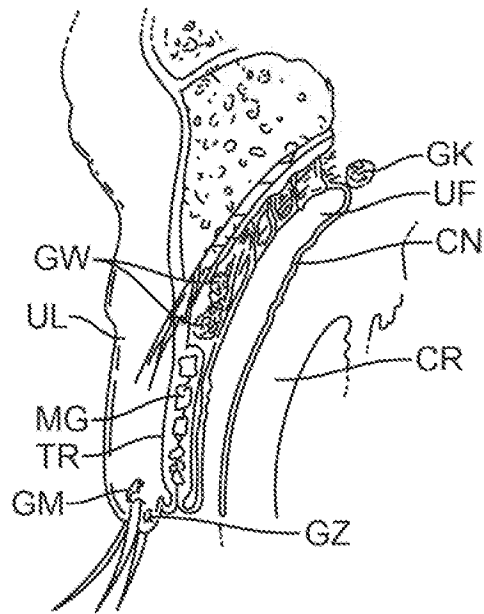


FIG. 1A

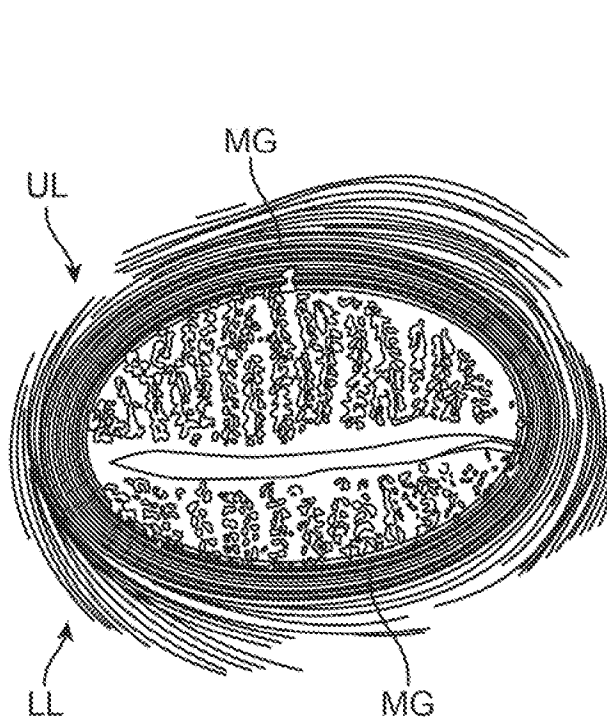


FIG. 1B

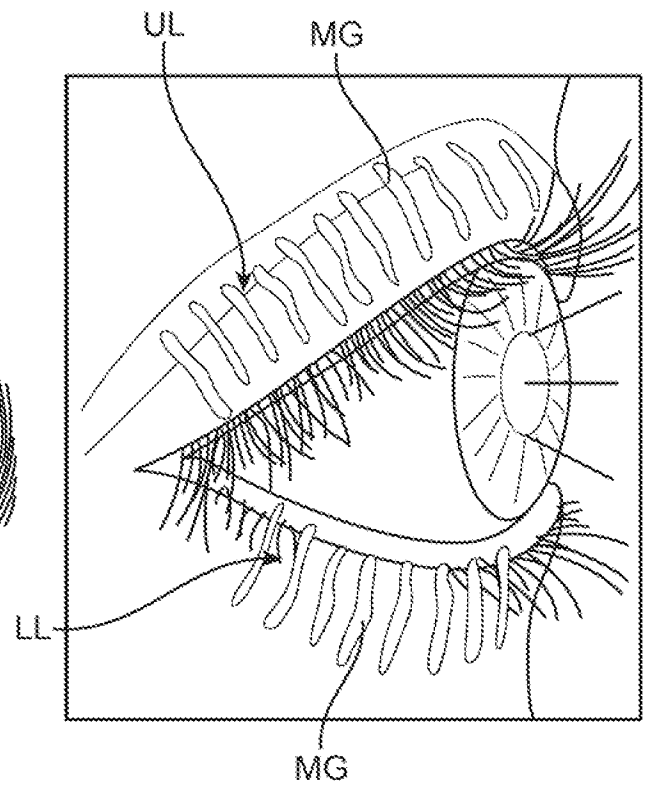


FIG. 1C

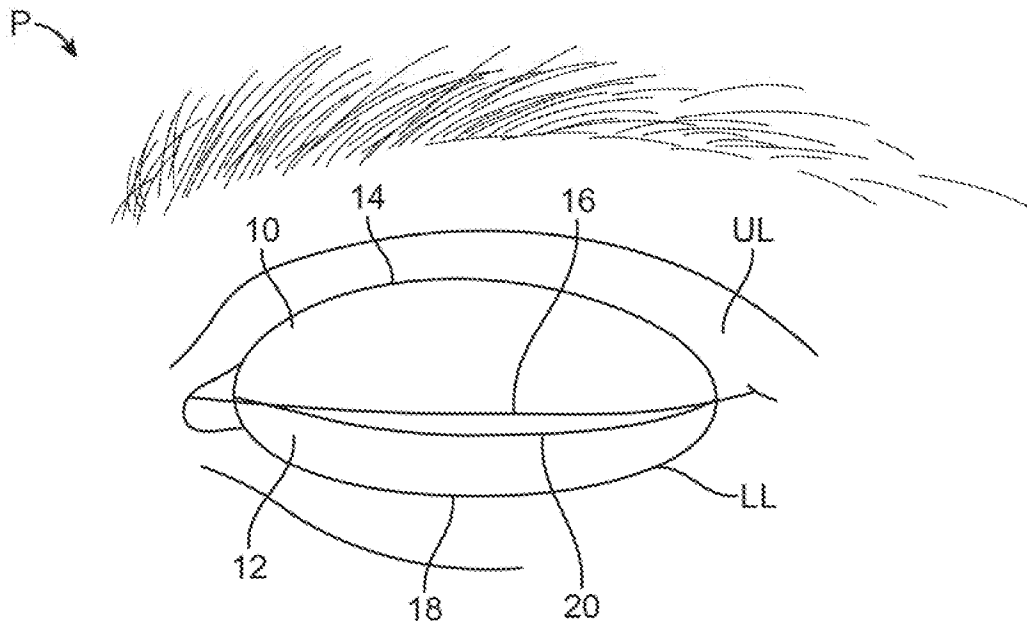


FIG. 2A

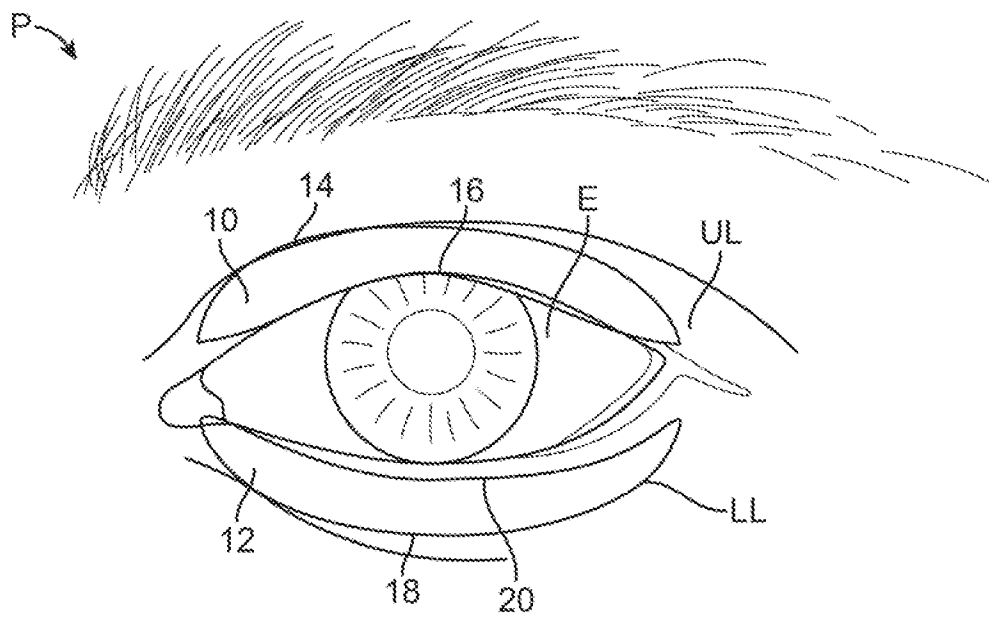


FIG. 2B

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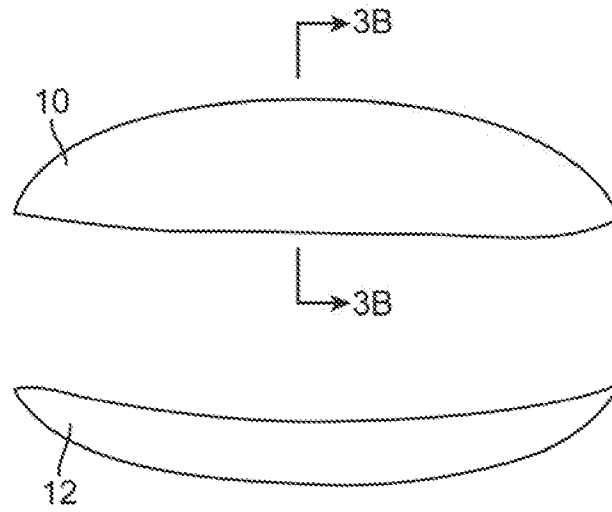


FIG. 3A

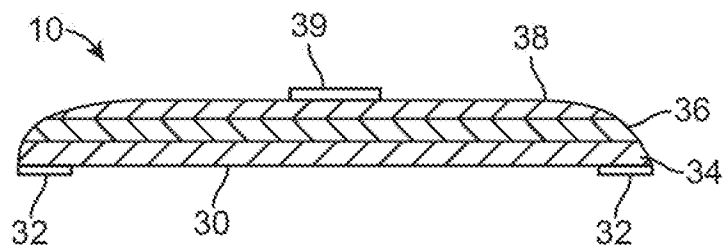


FIG. 3B

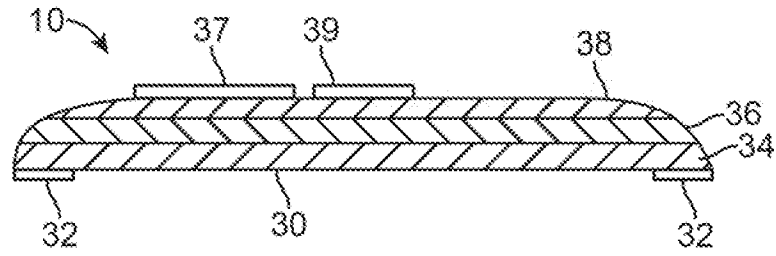


FIG. 3C

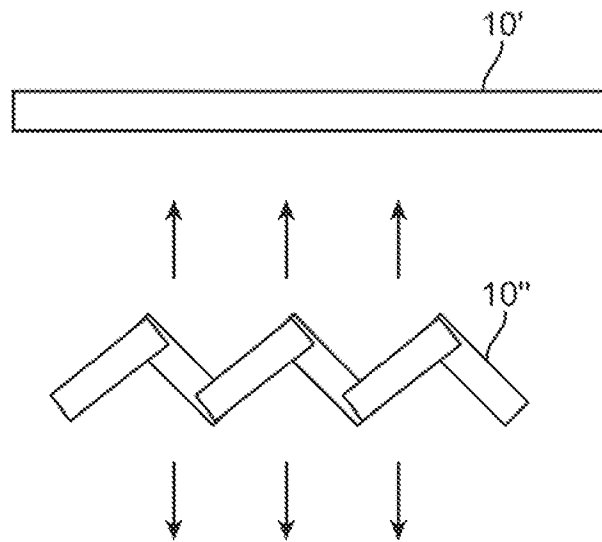


FIG. 3D

5/39

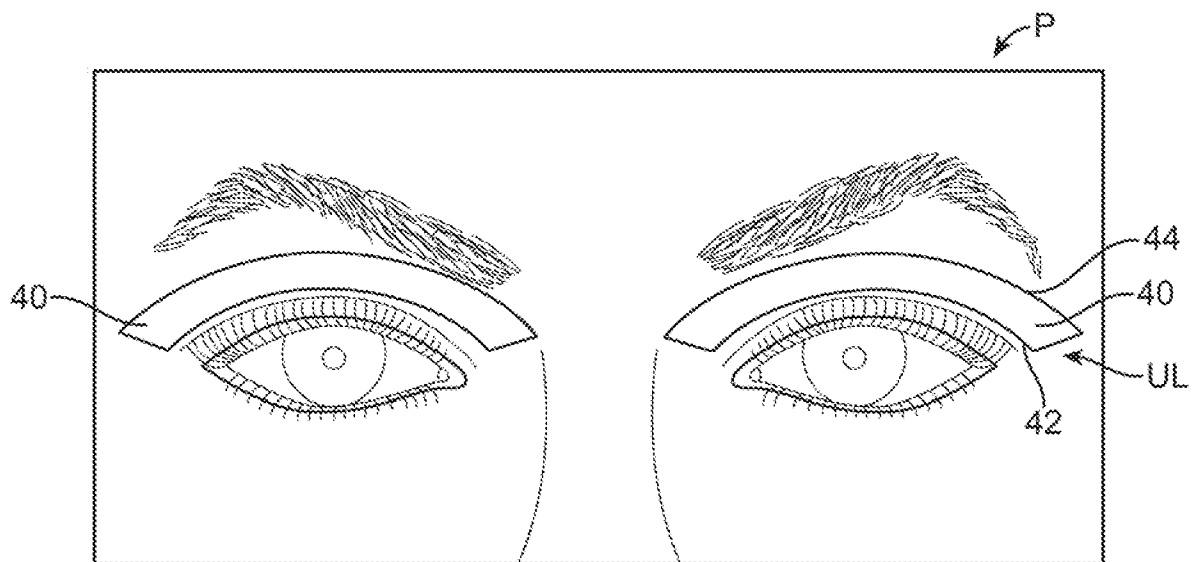


FIG. 4

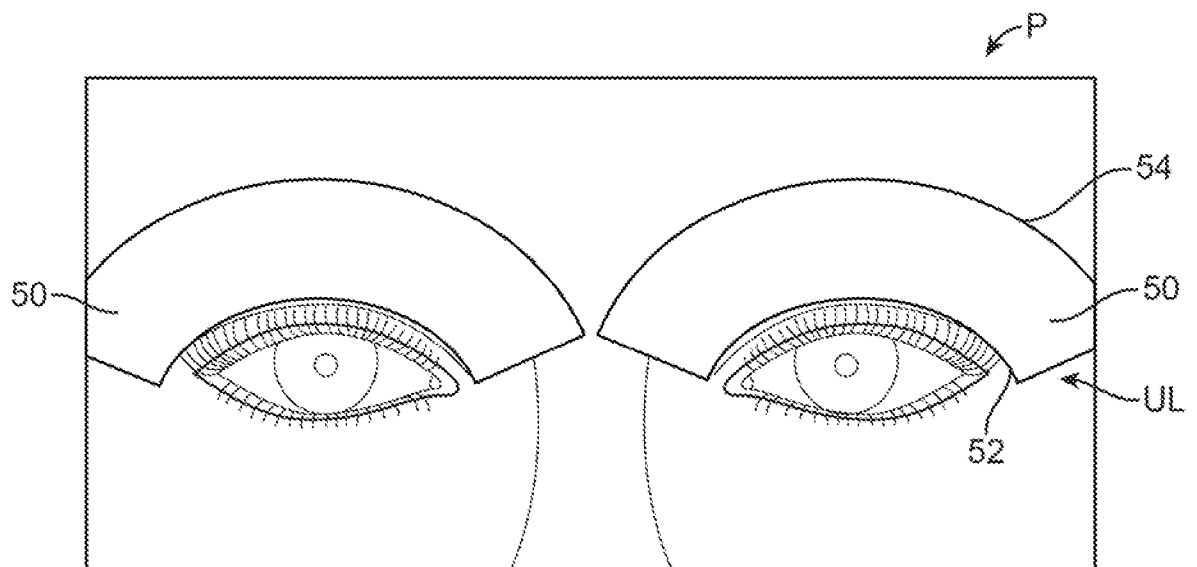


FIG. 5

6/39

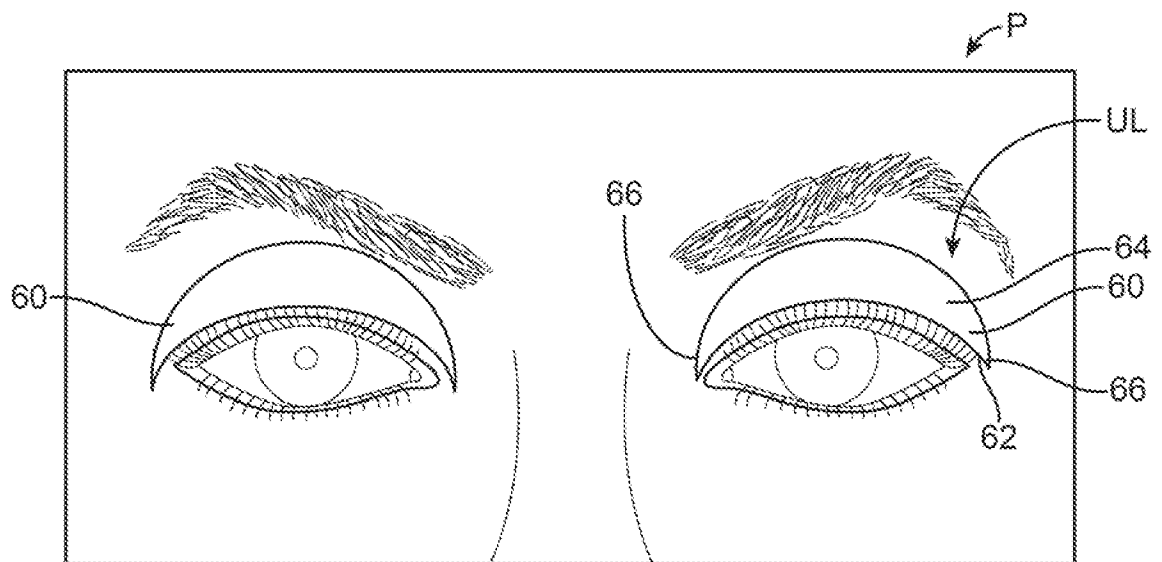


FIG. 6

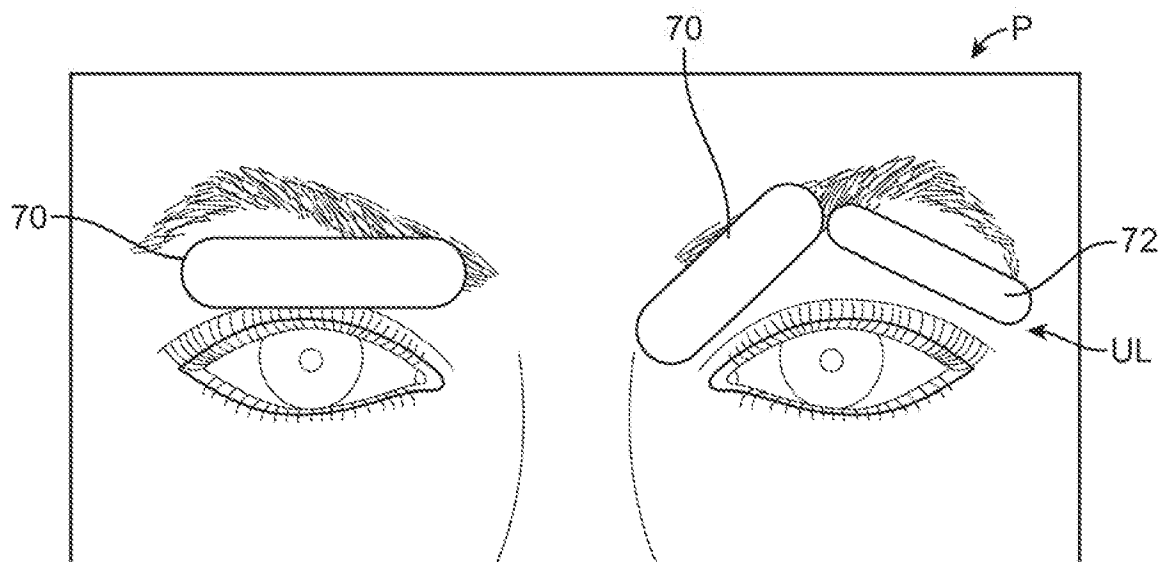


FIG. 7

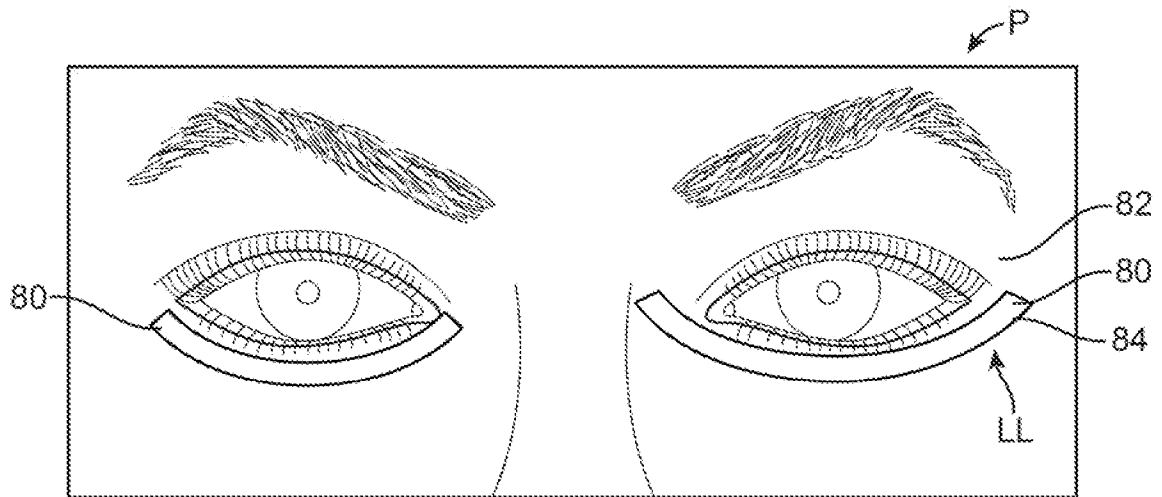


FIG. 8

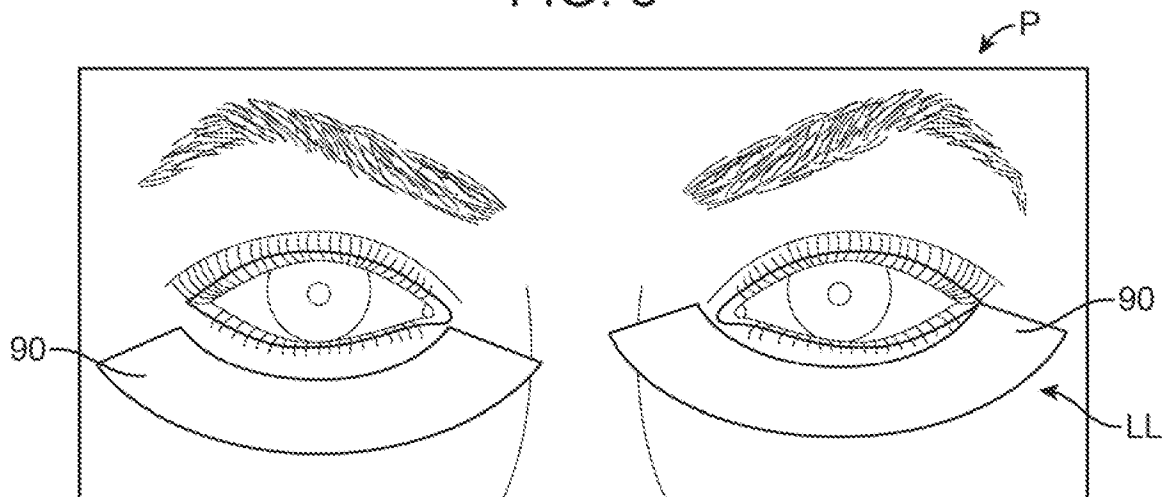


FIG. 9

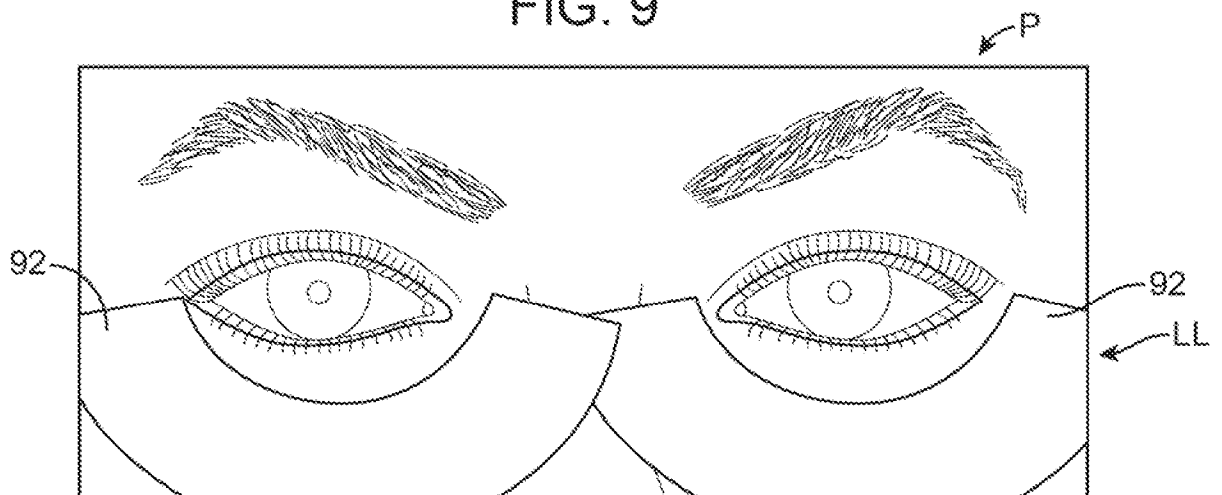


FIG. 10

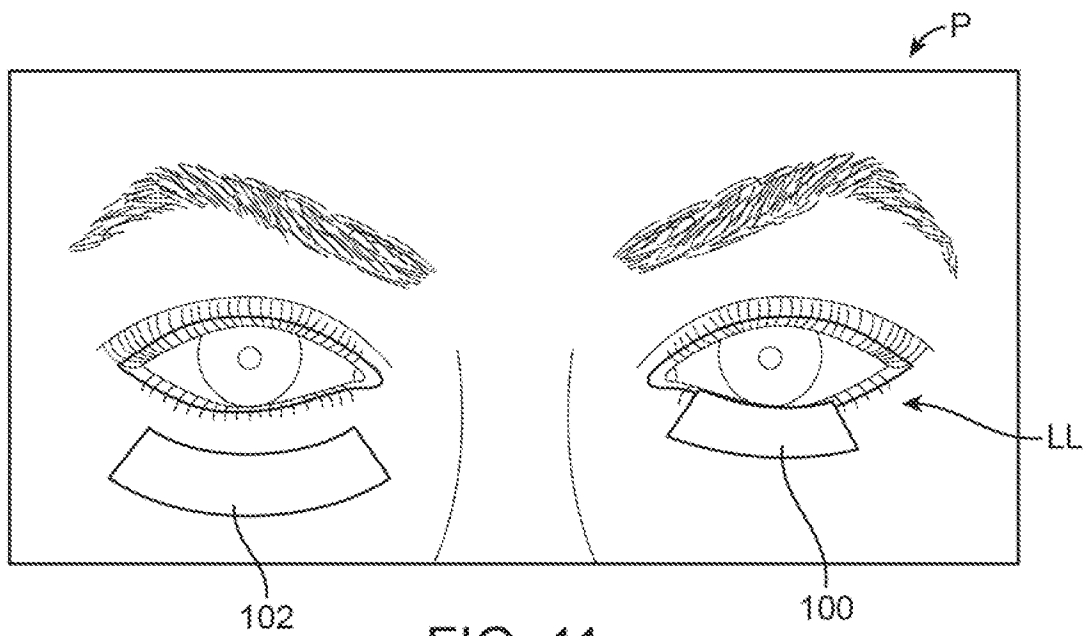


FIG. 11

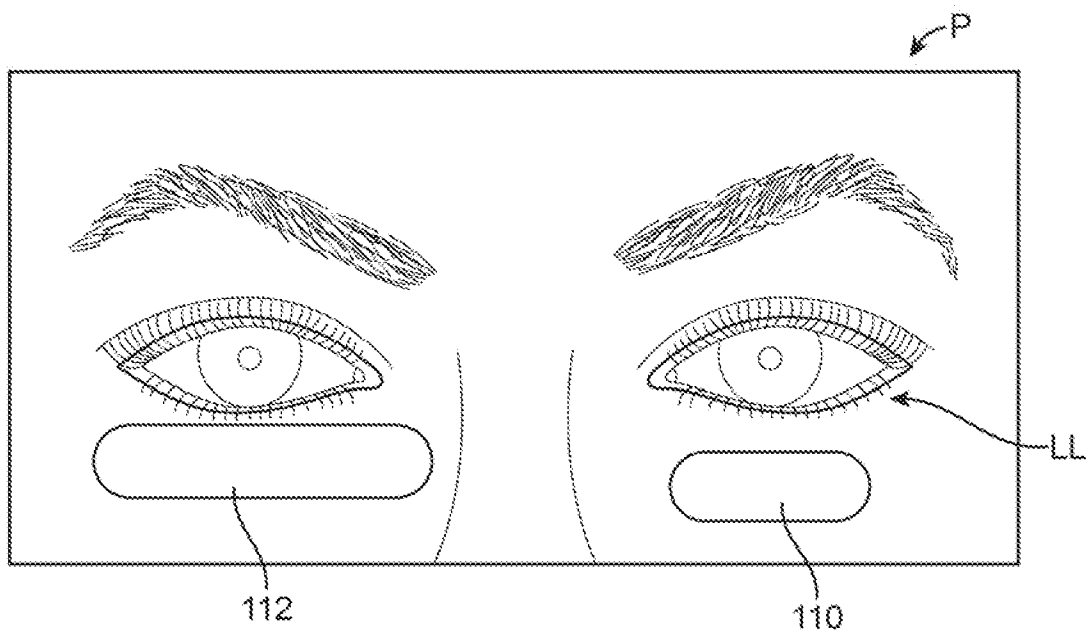


FIG. 12

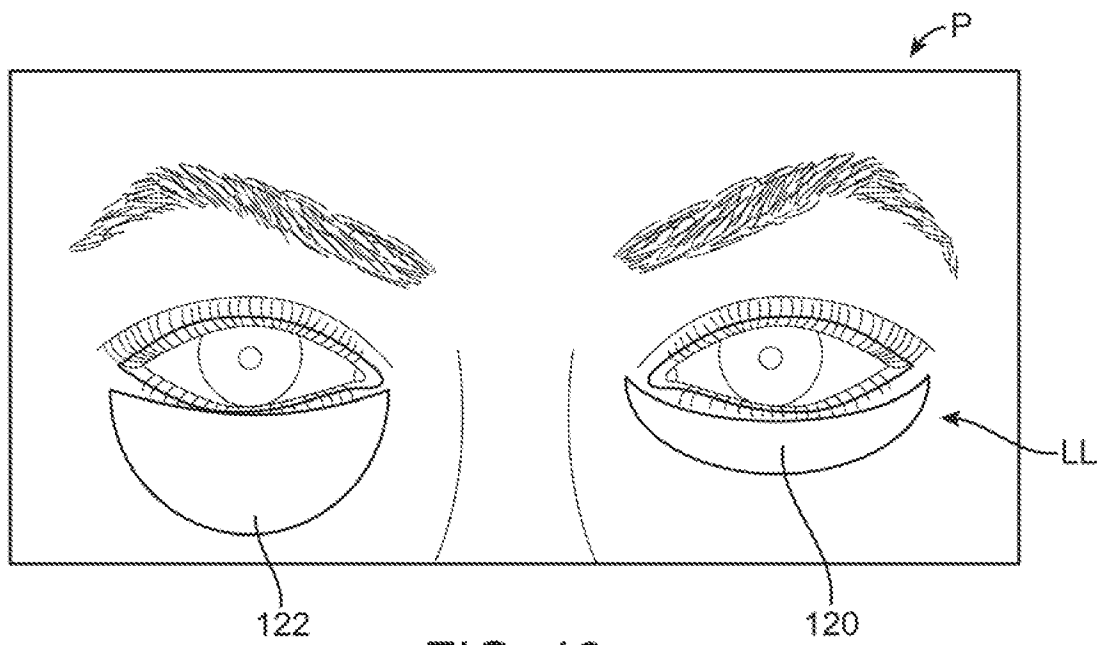


FIG. 13

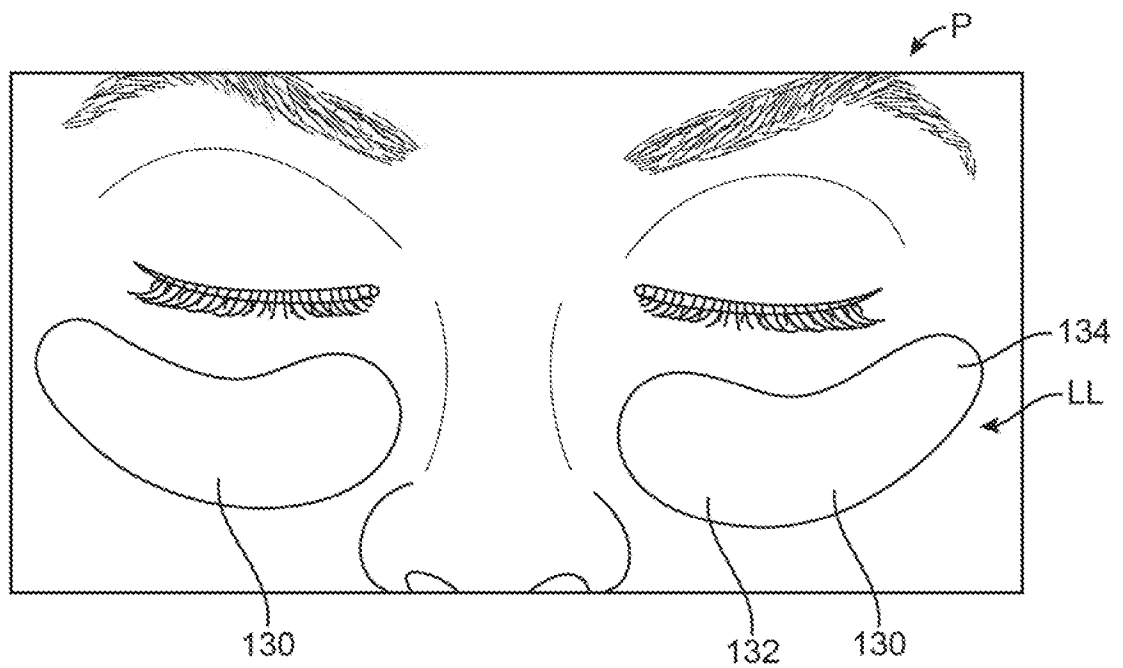
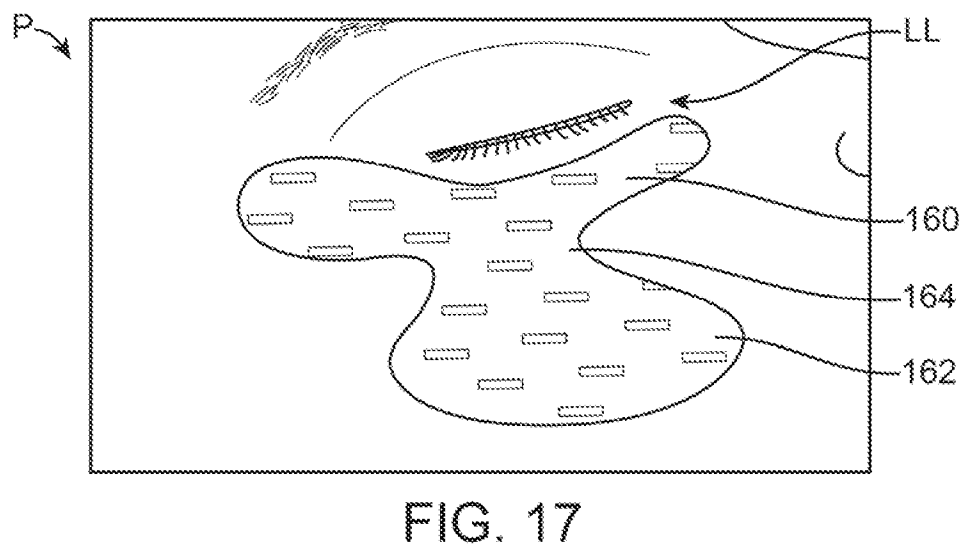
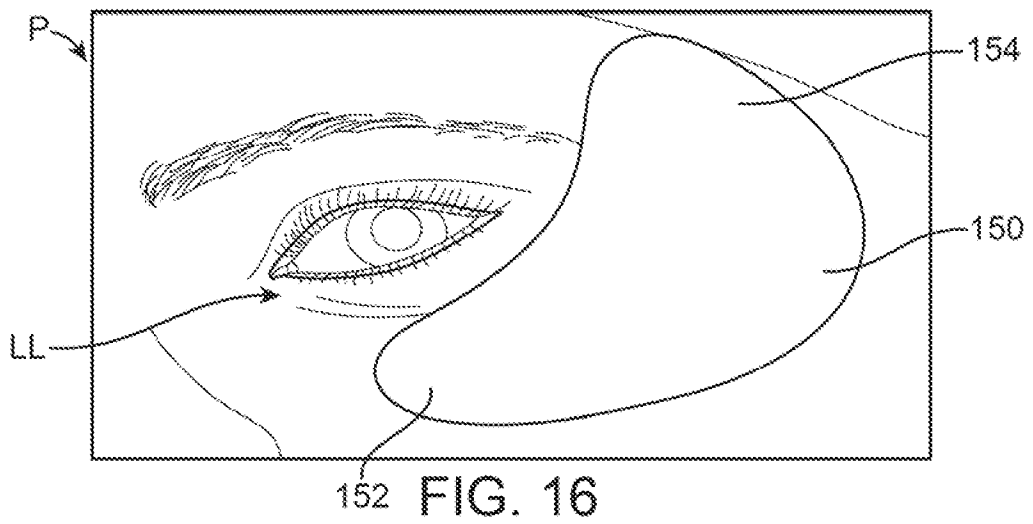
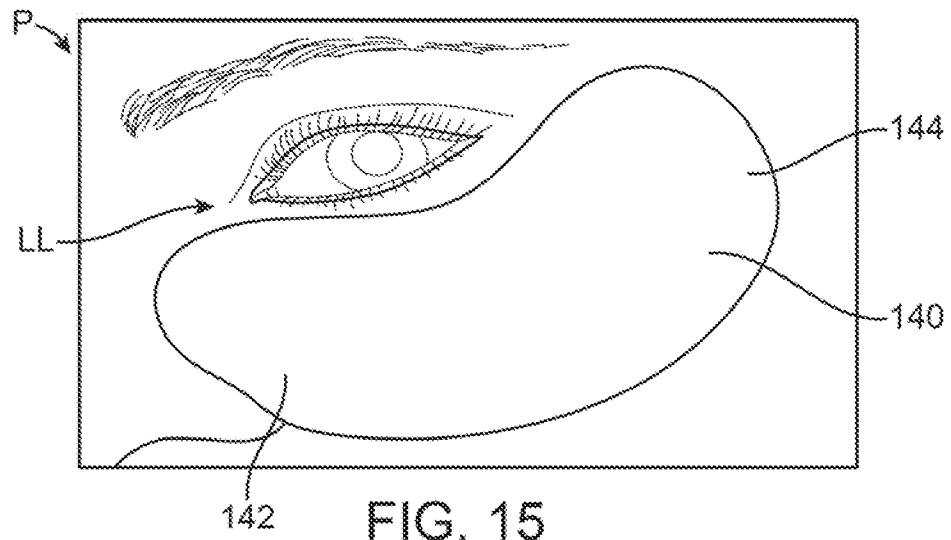


FIG. 14



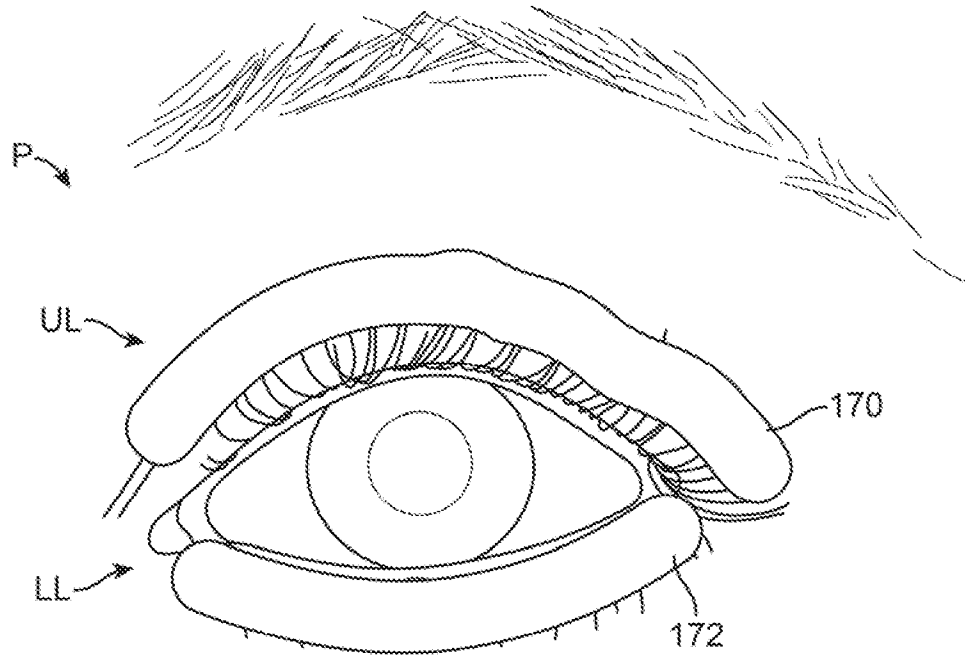


FIG. 18

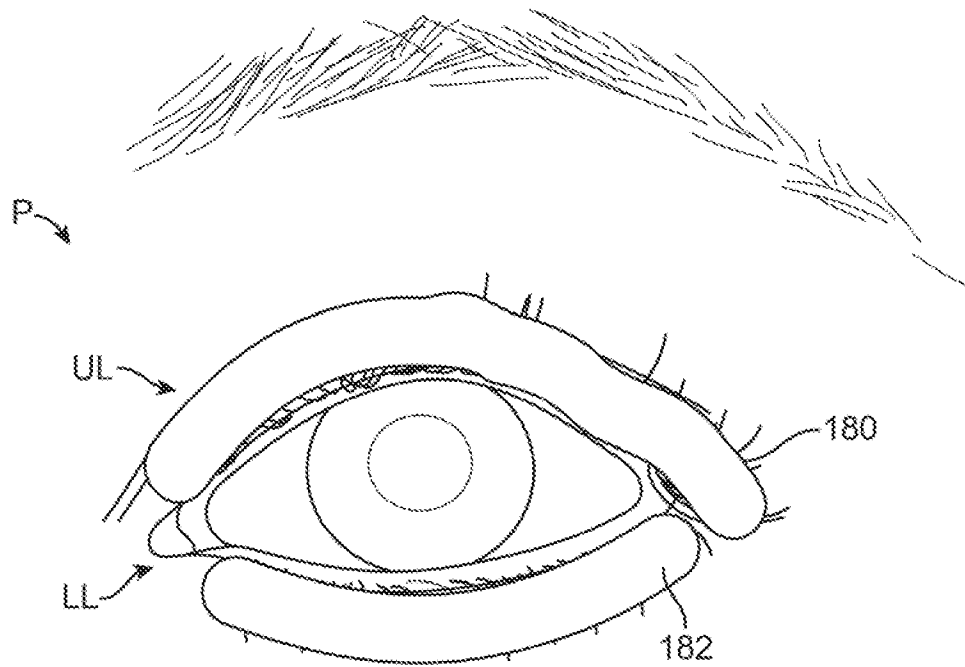


FIG. 19

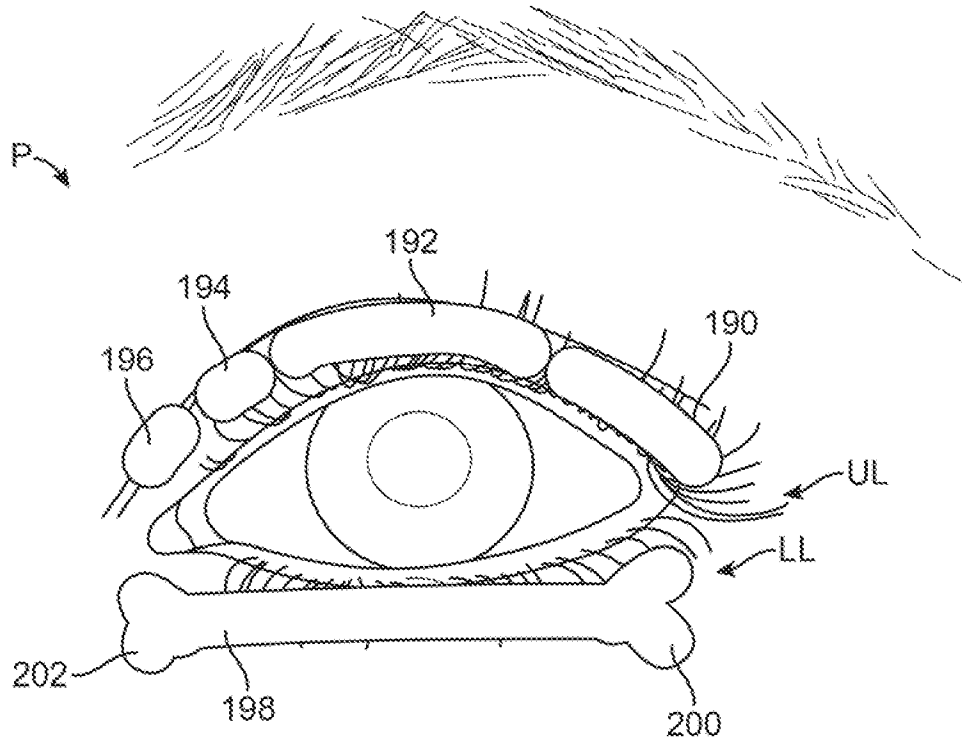


FIG. 20

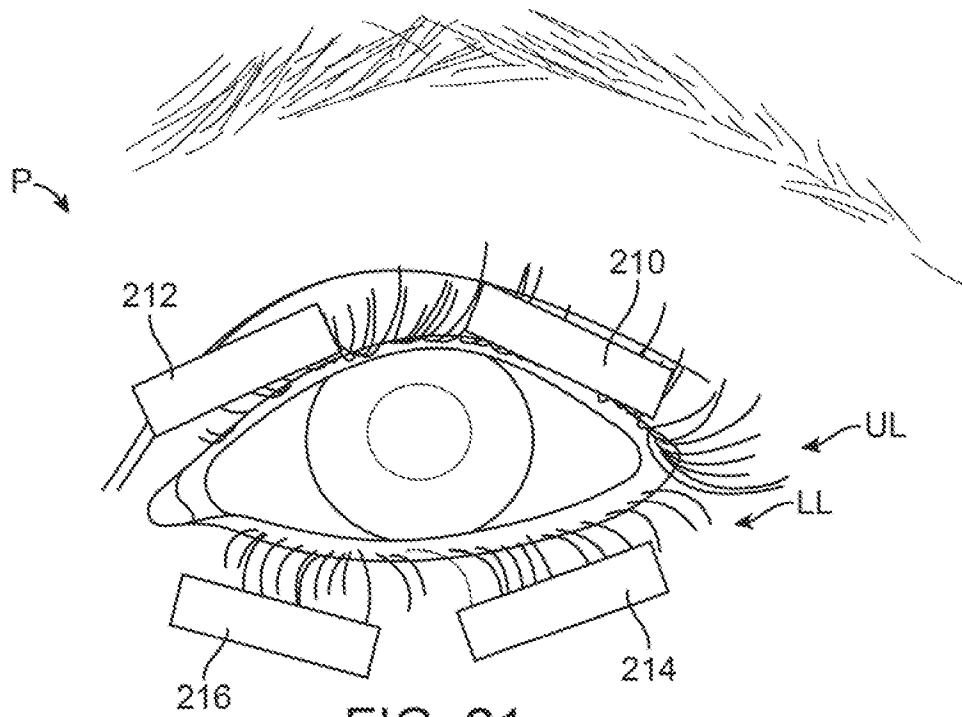


FIG. 21

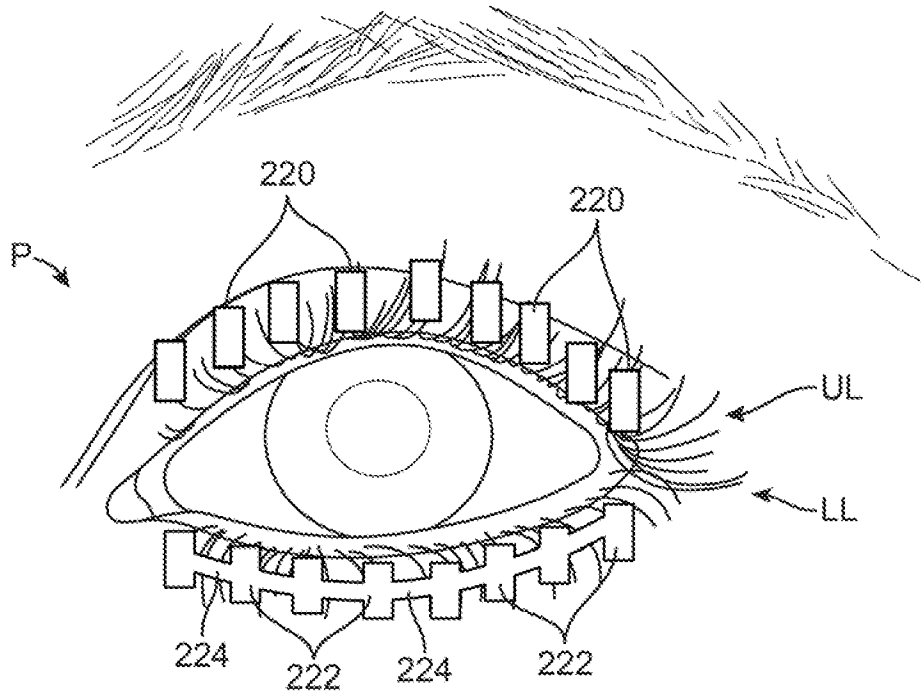


FIG. 22

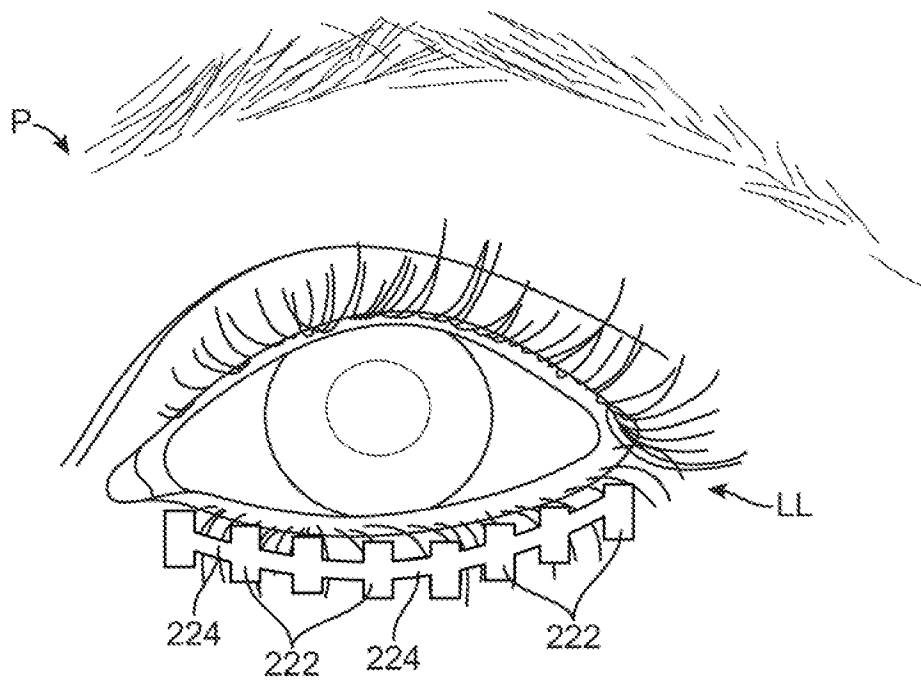


FIG. 23

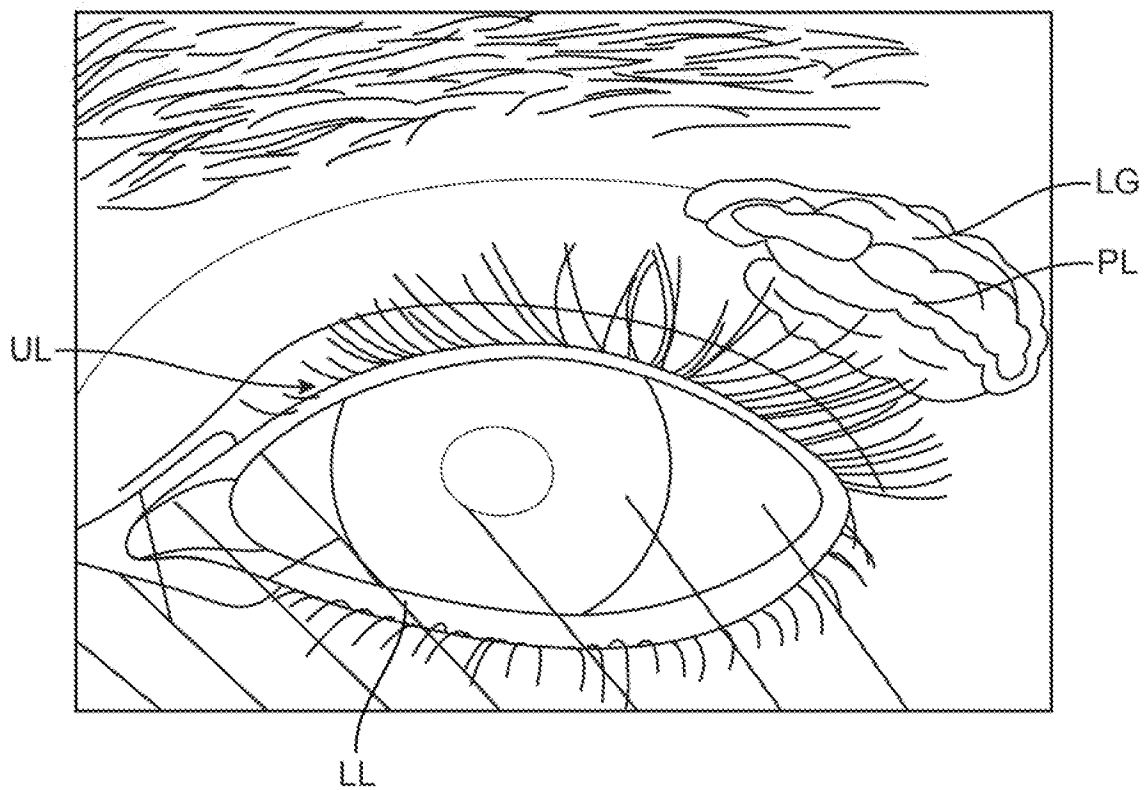


FIG. 24

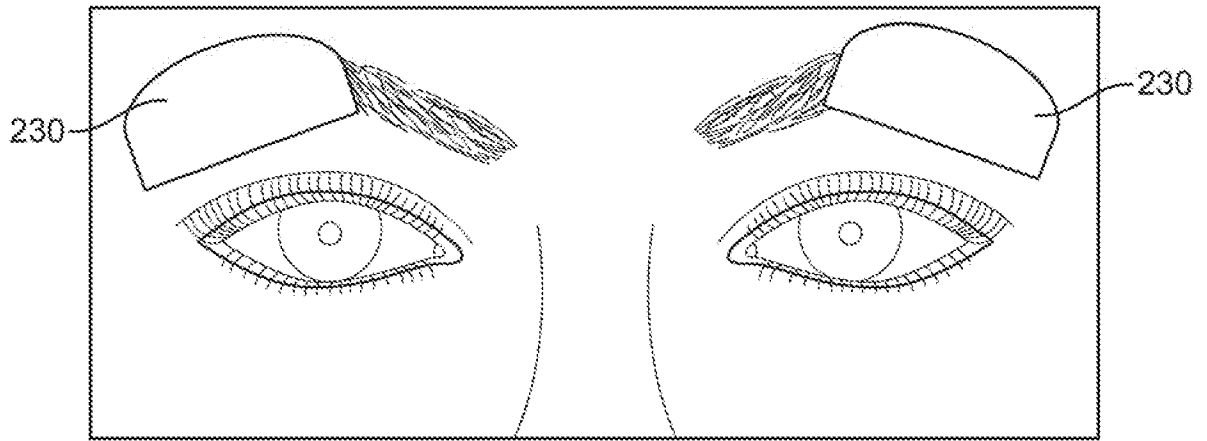


FIG. 25

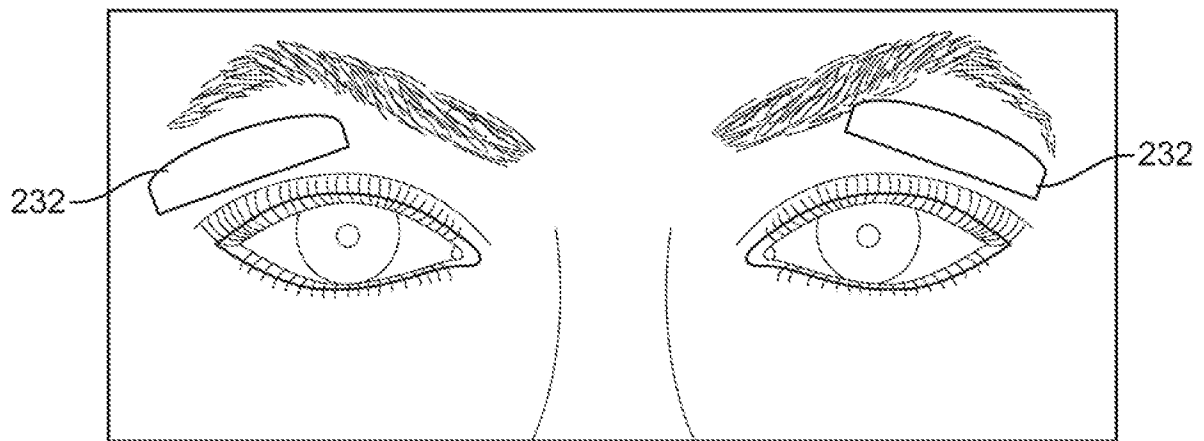


FIG. 26

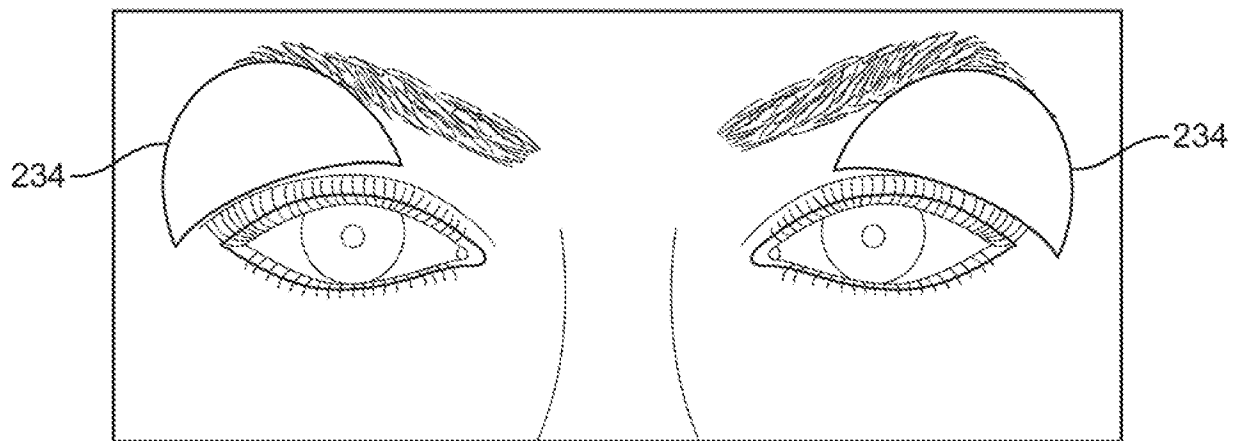


FIG. 27

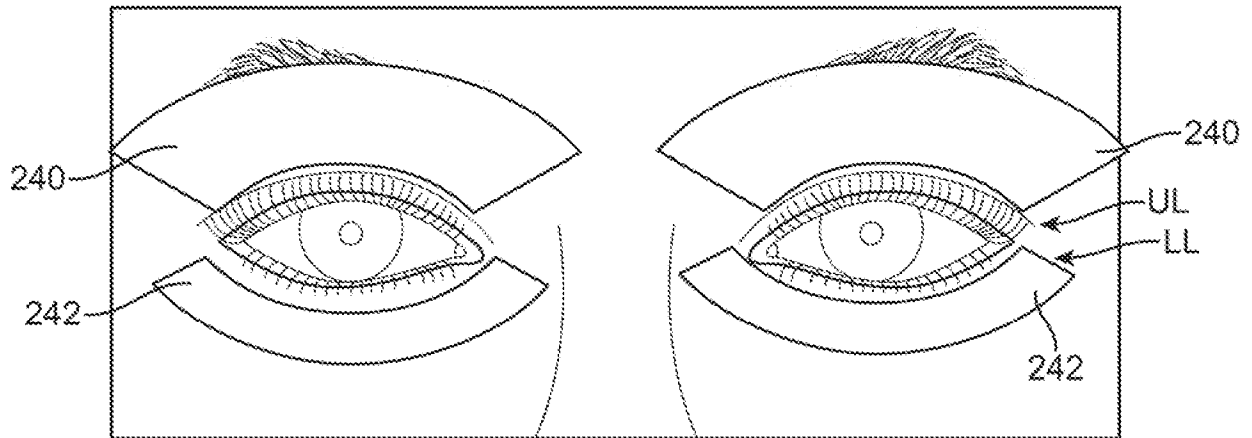


FIG. 28

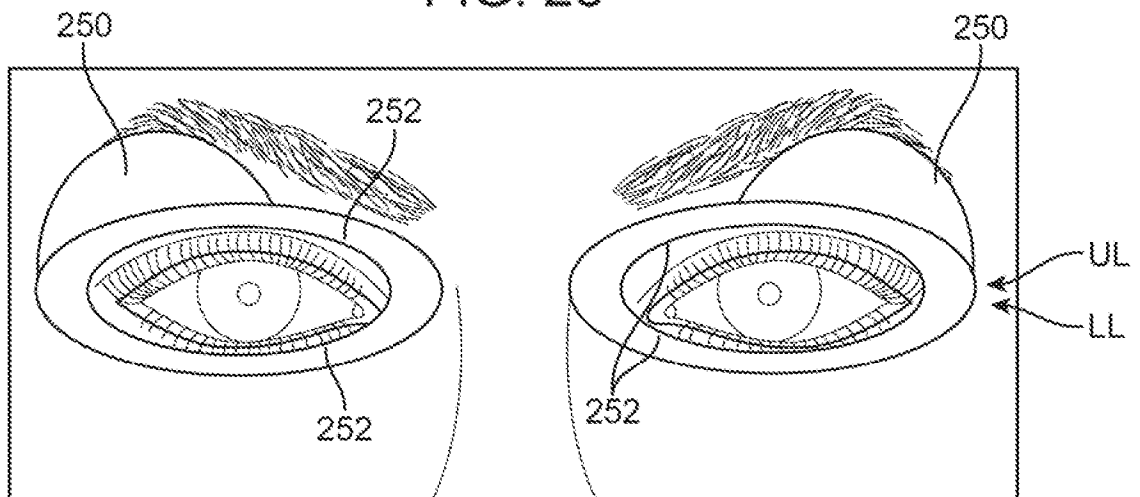


FIG. 29

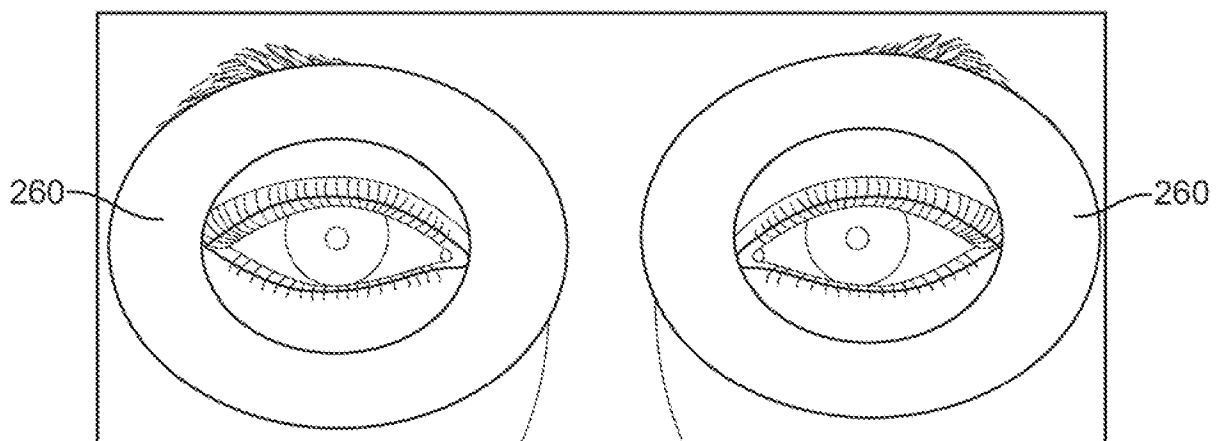


FIG. 30

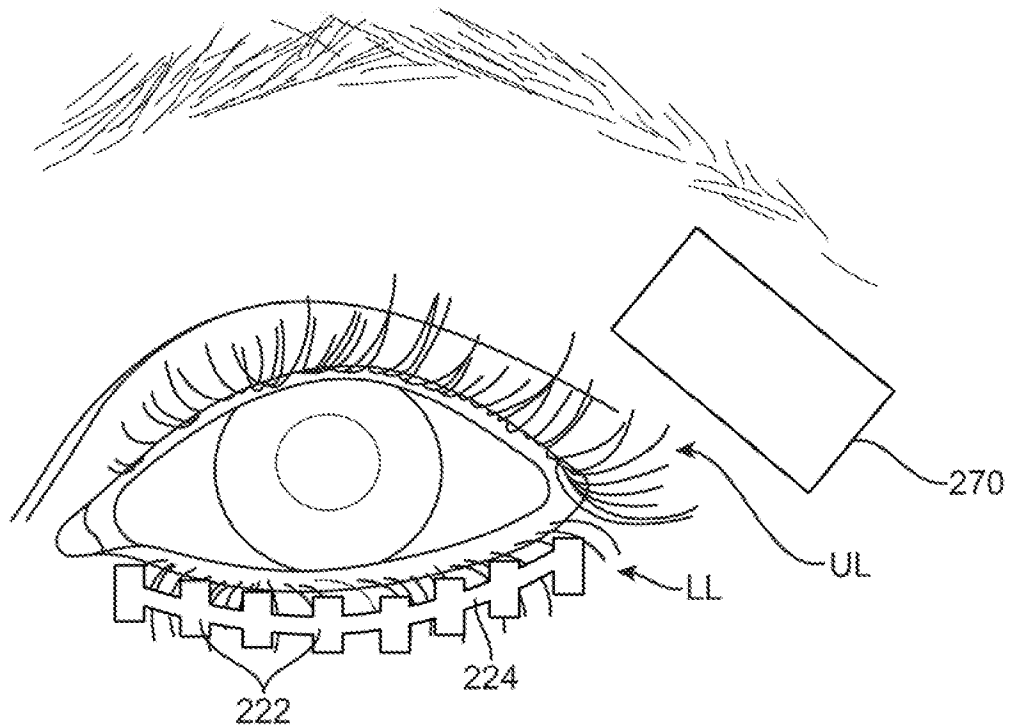


FIG. 31

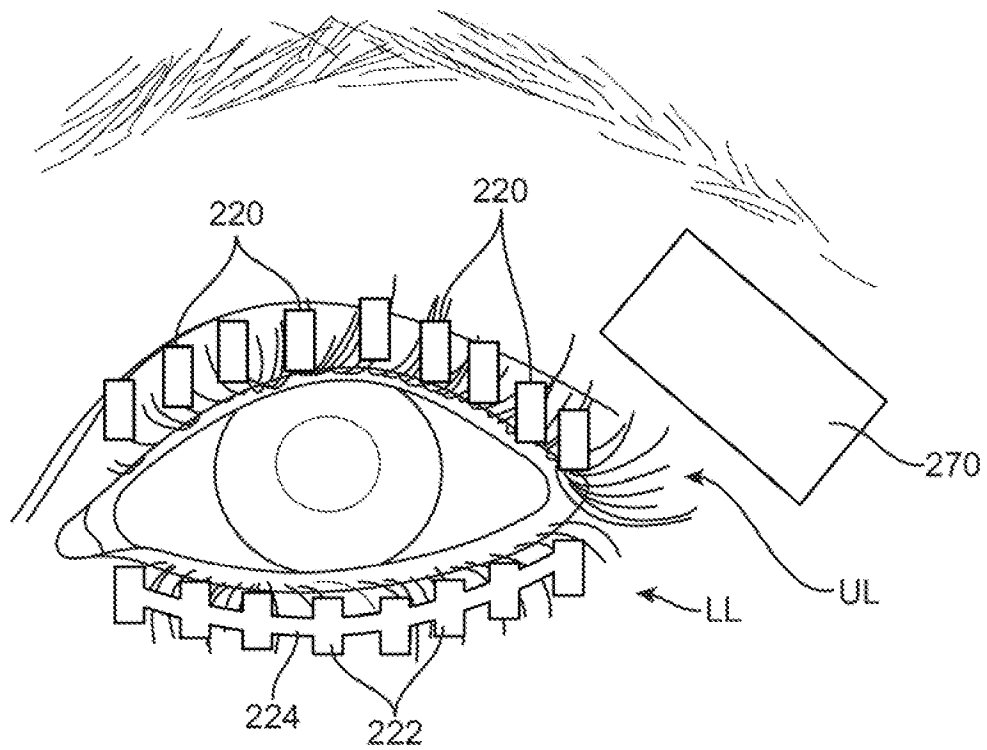


FIG. 32

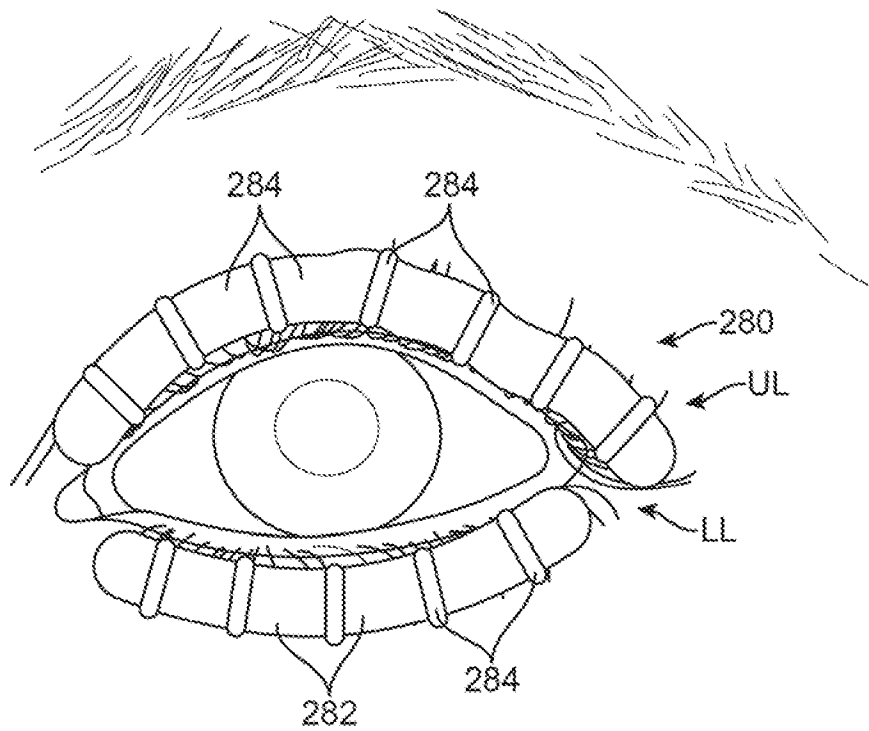


FIG. 33

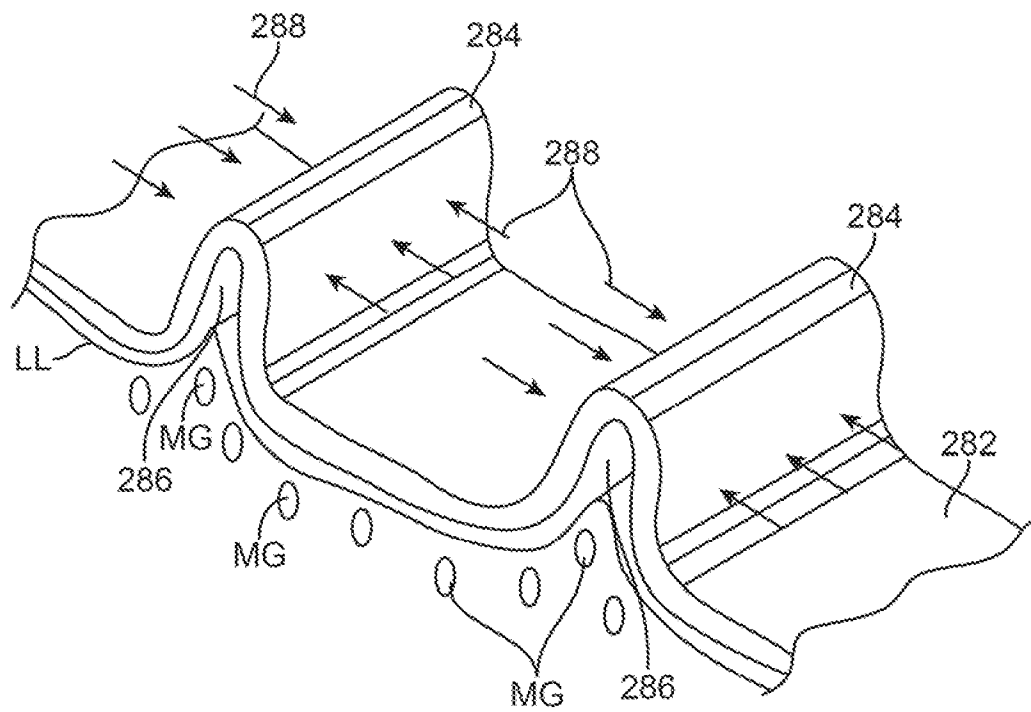


FIG. 34

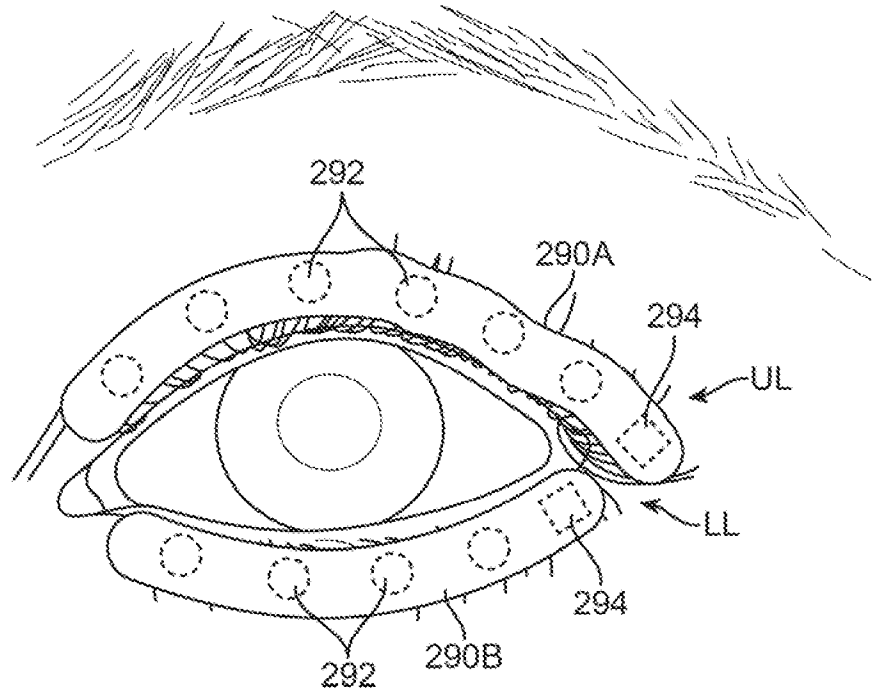


FIG. 35

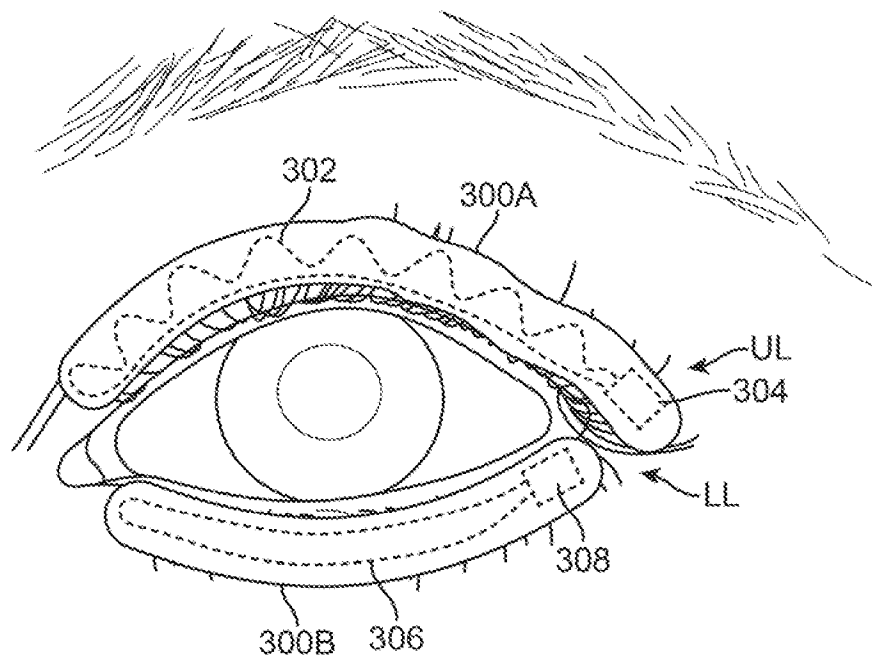


FIG. 36

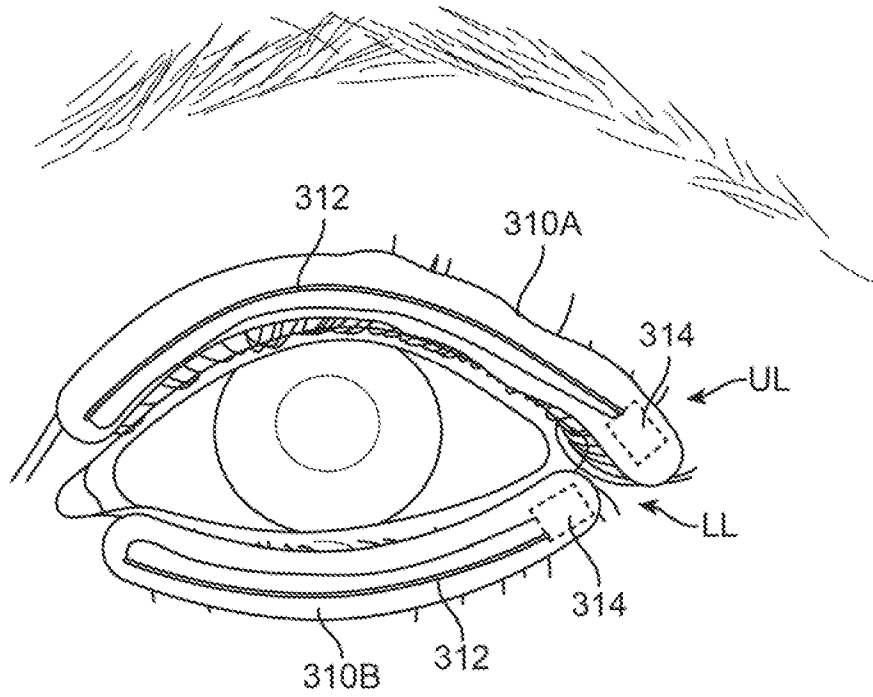


FIG. 37

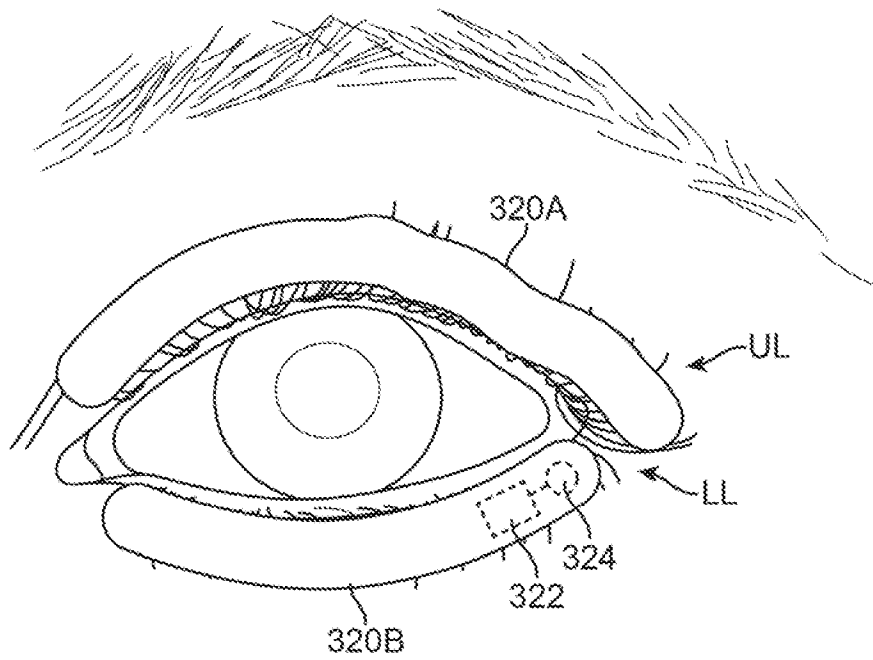


FIG. 38

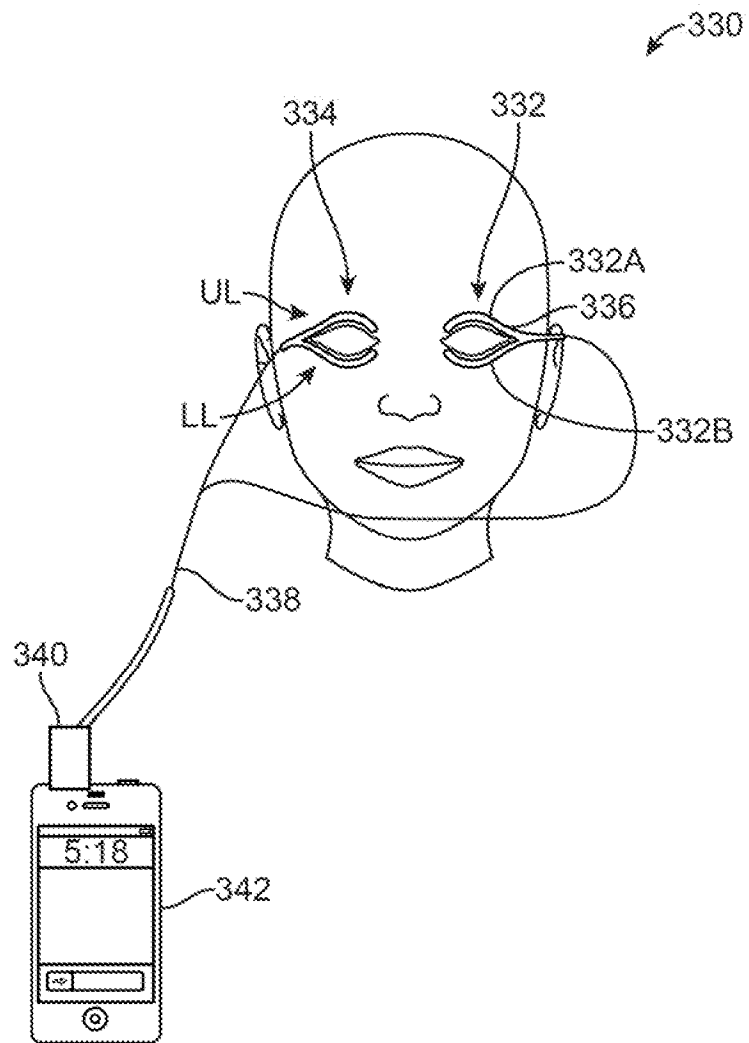


FIG. 39

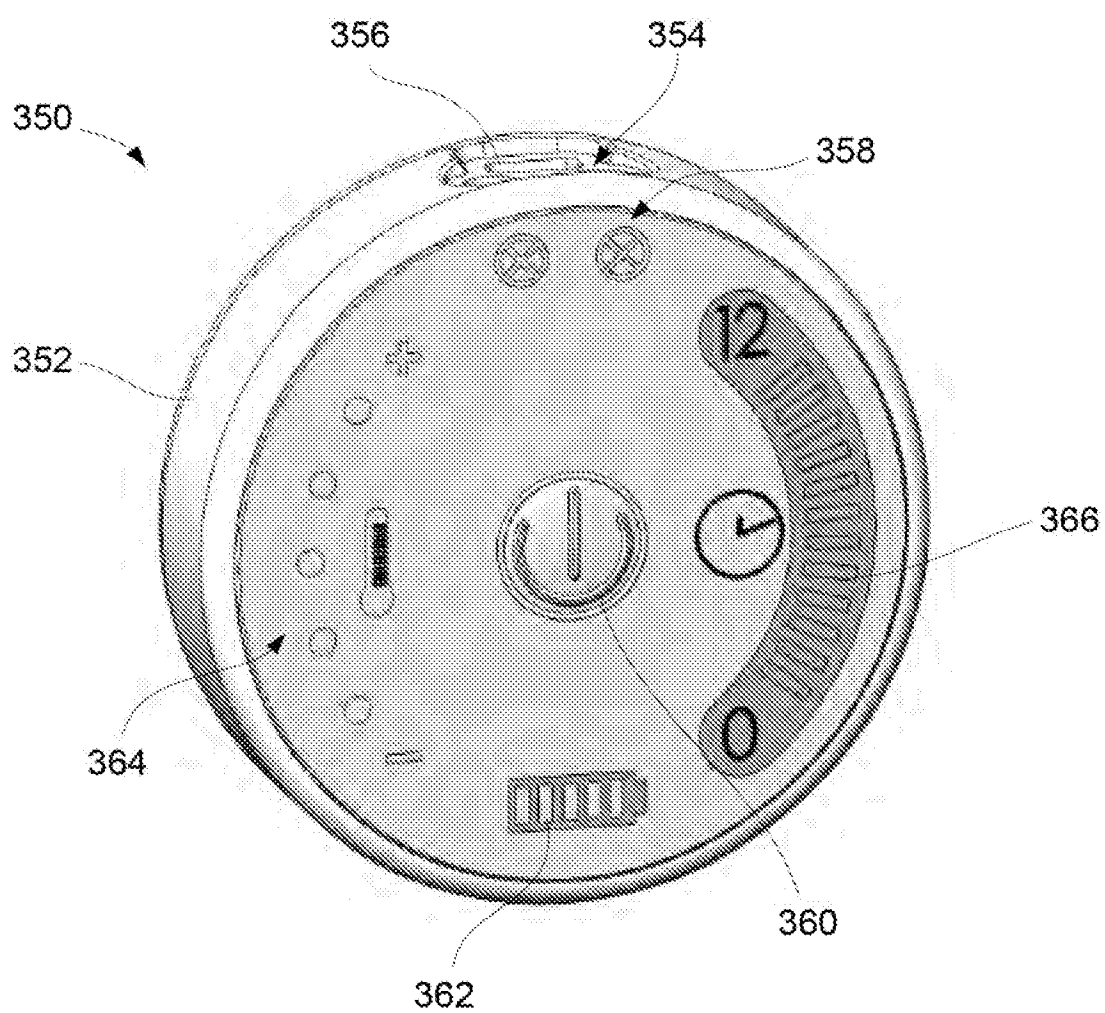


FIG. 40

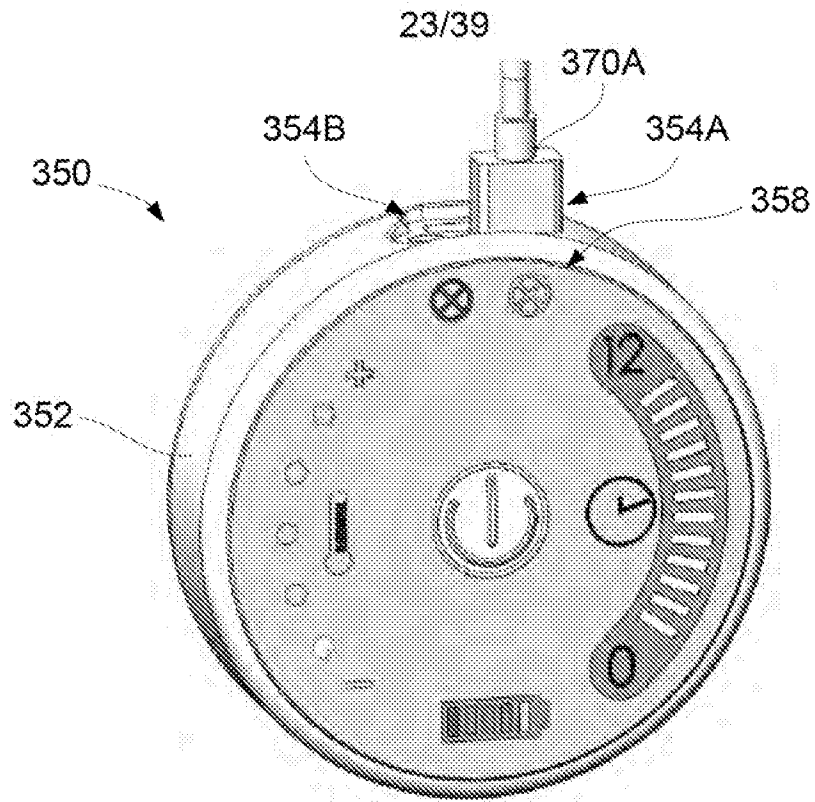


FIG. 41A

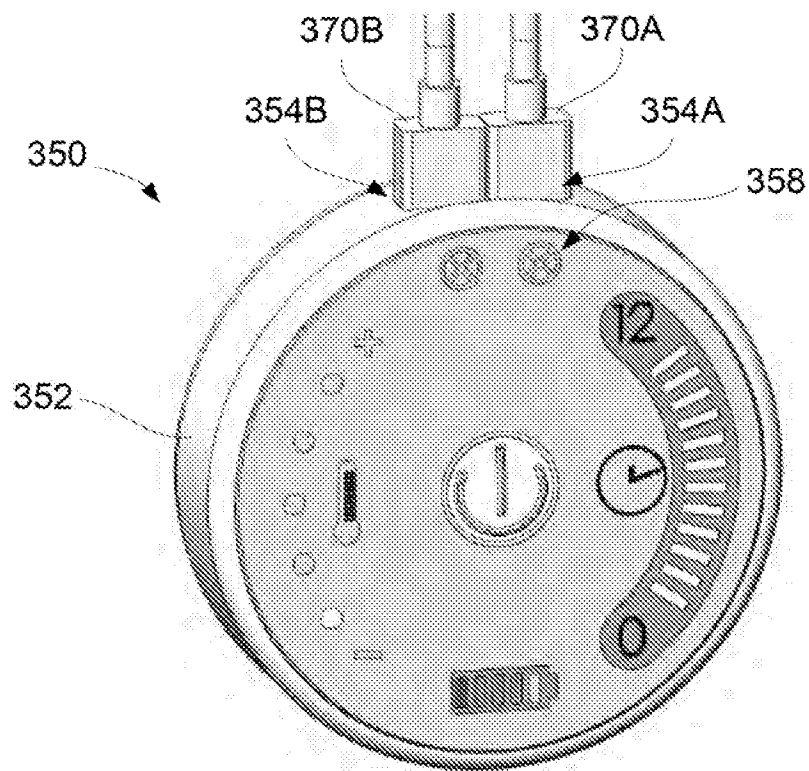


FIG. 41B

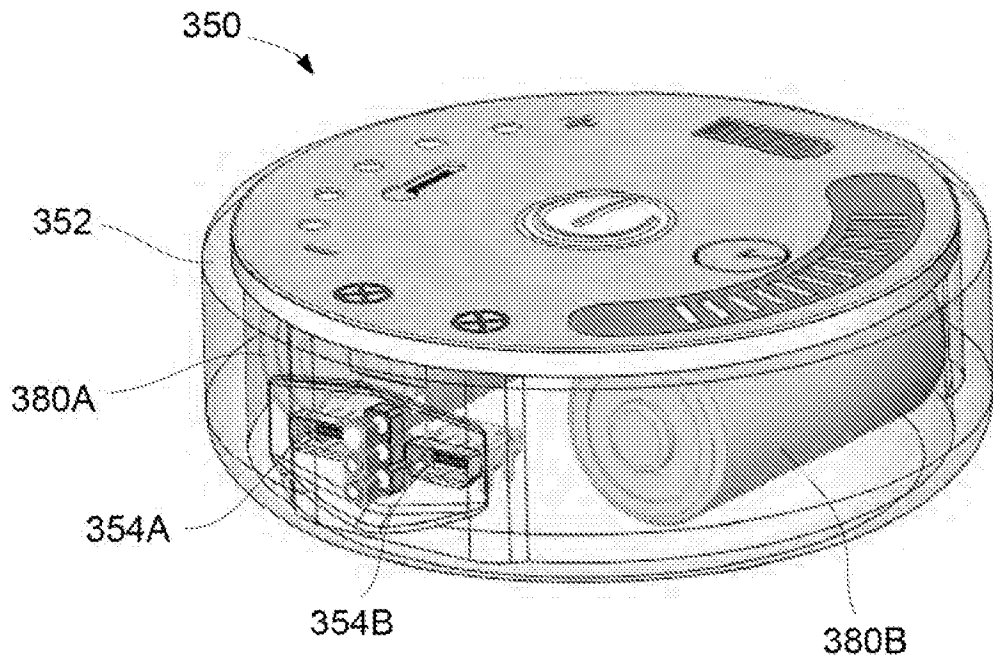


FIG. 42A

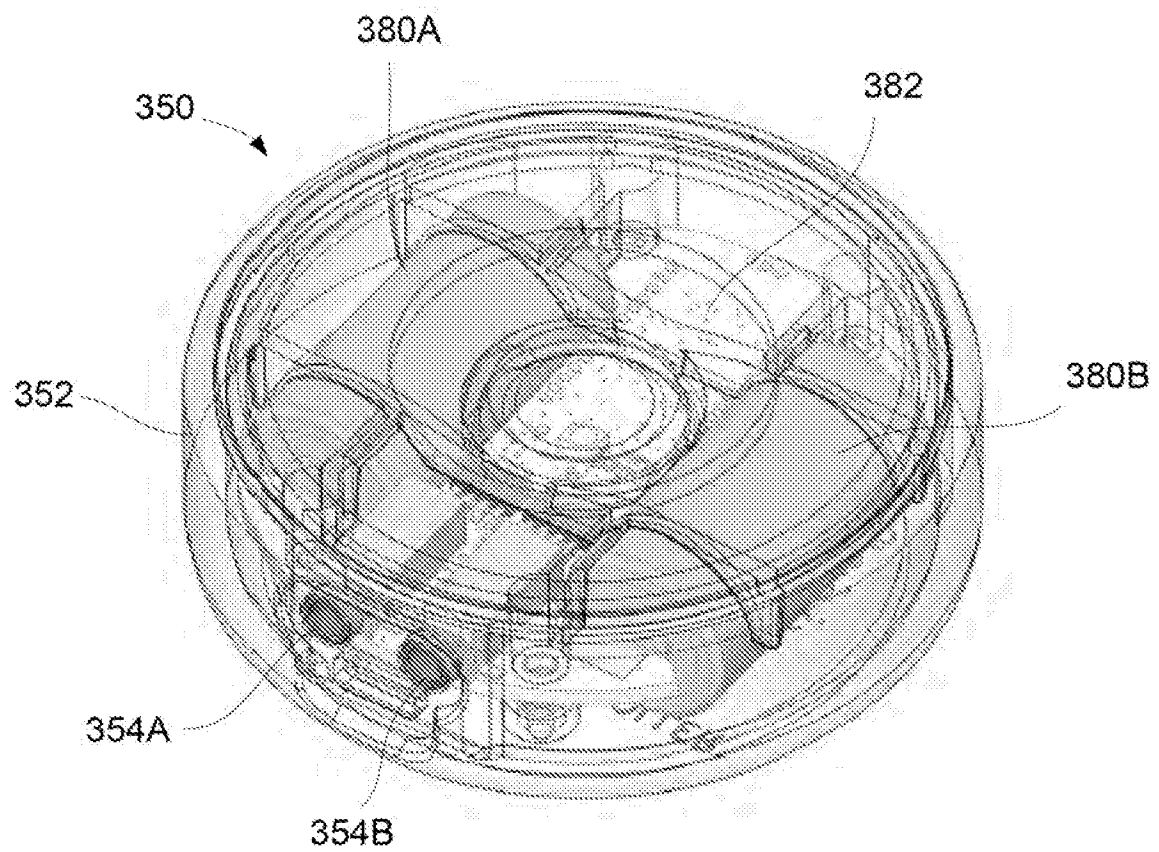


FIG. 42B

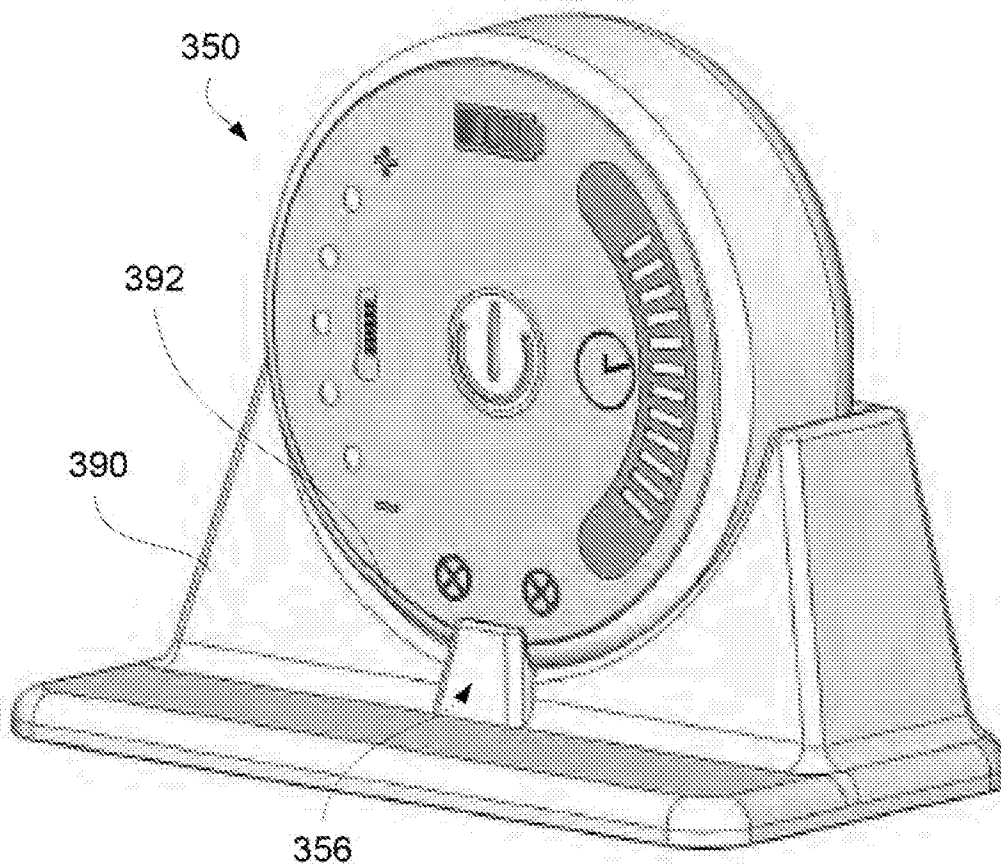


FIG. 43

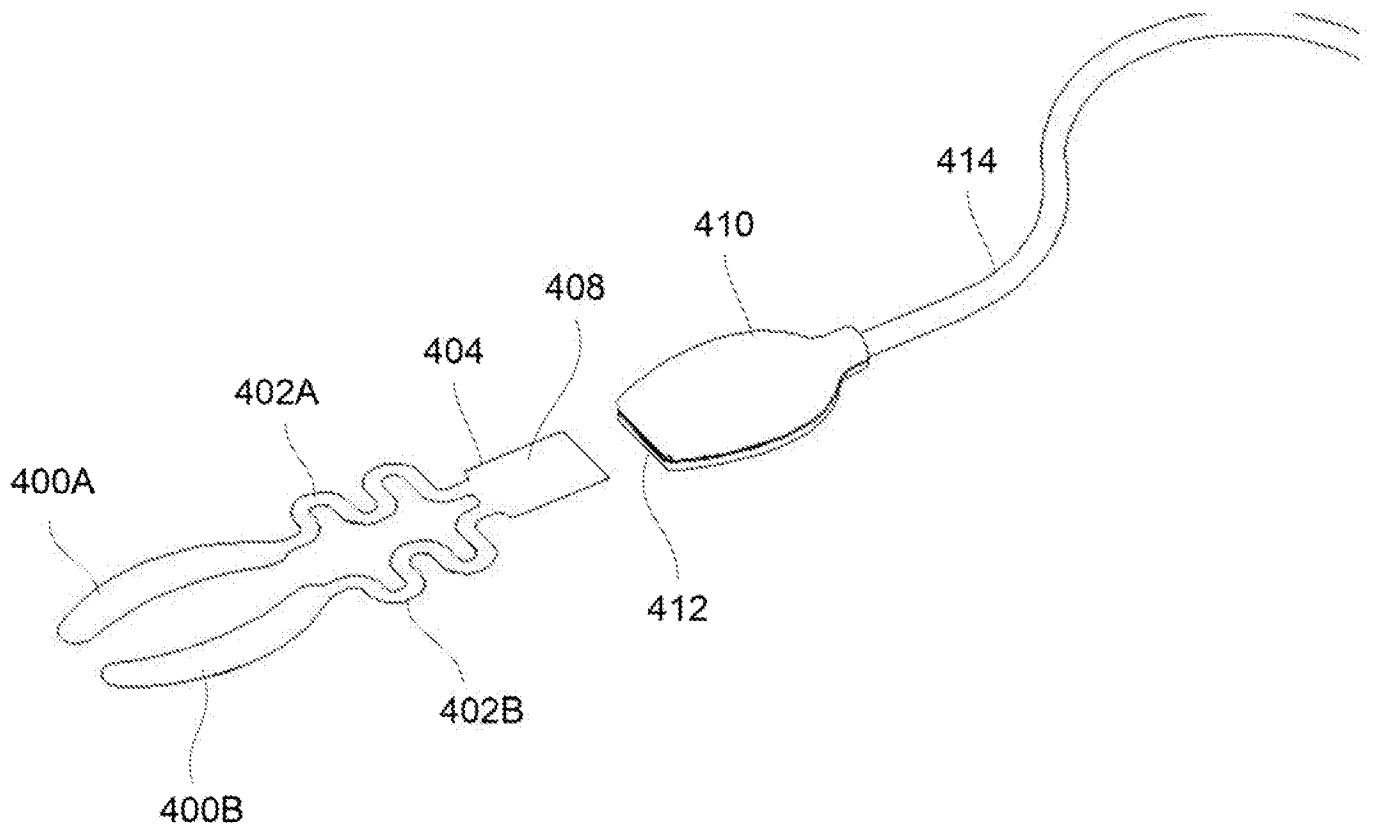


FIG. 44

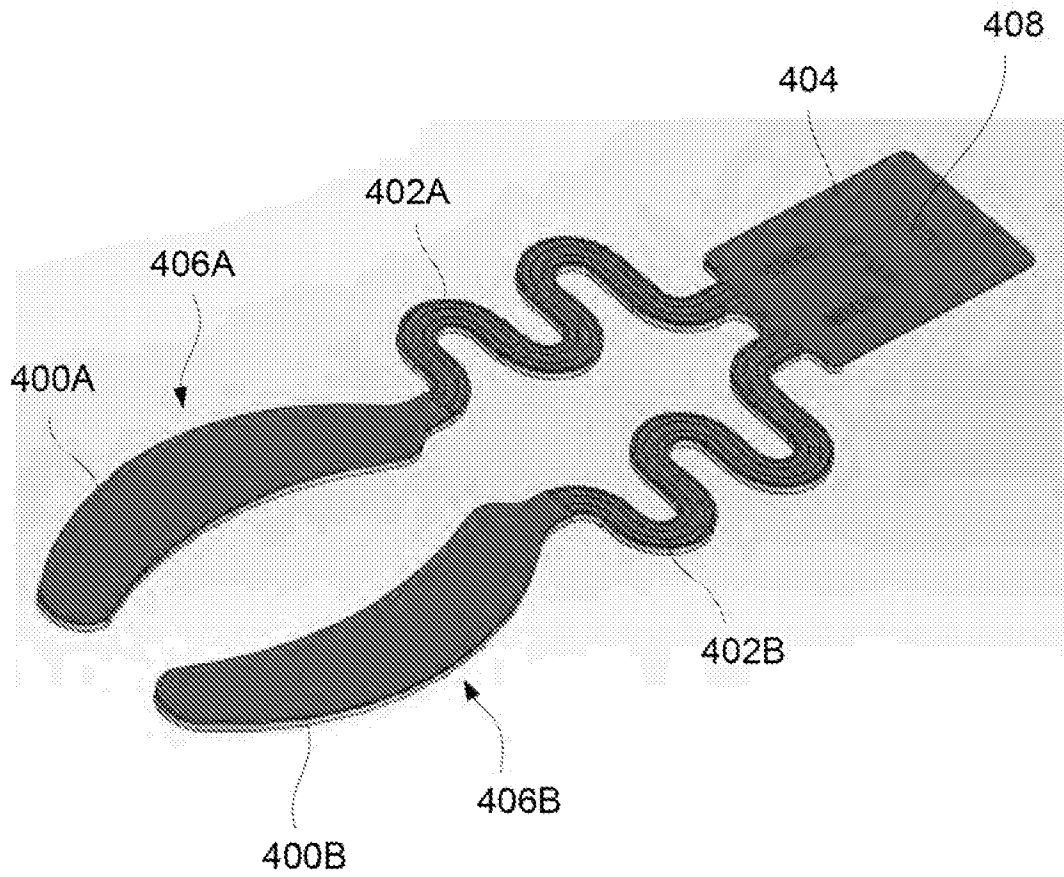


FIG. 45A

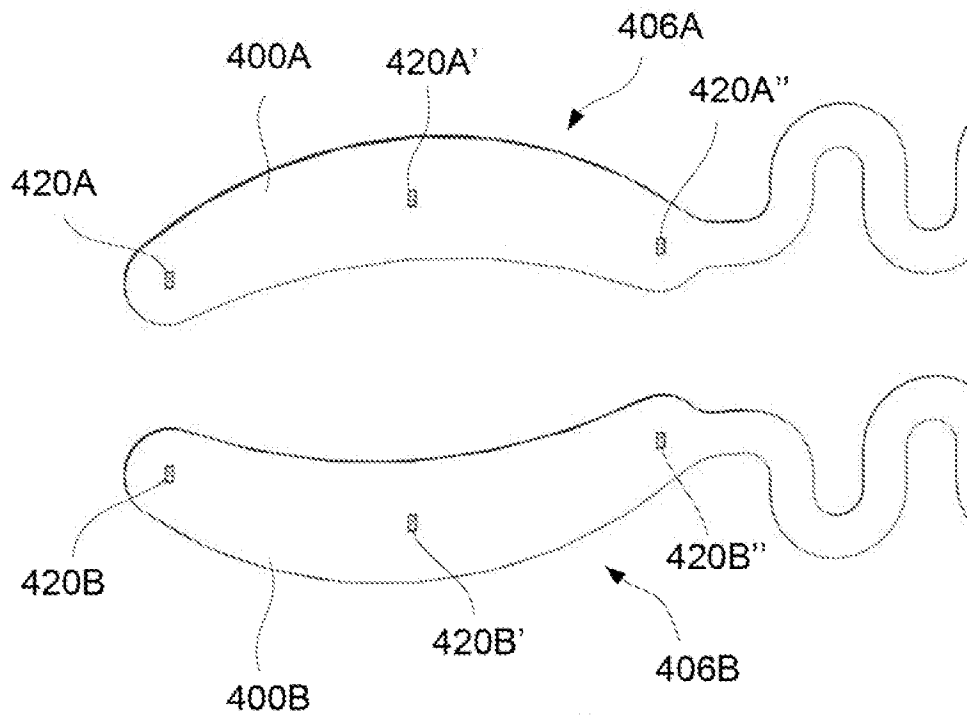


FIG. 45B

28/39

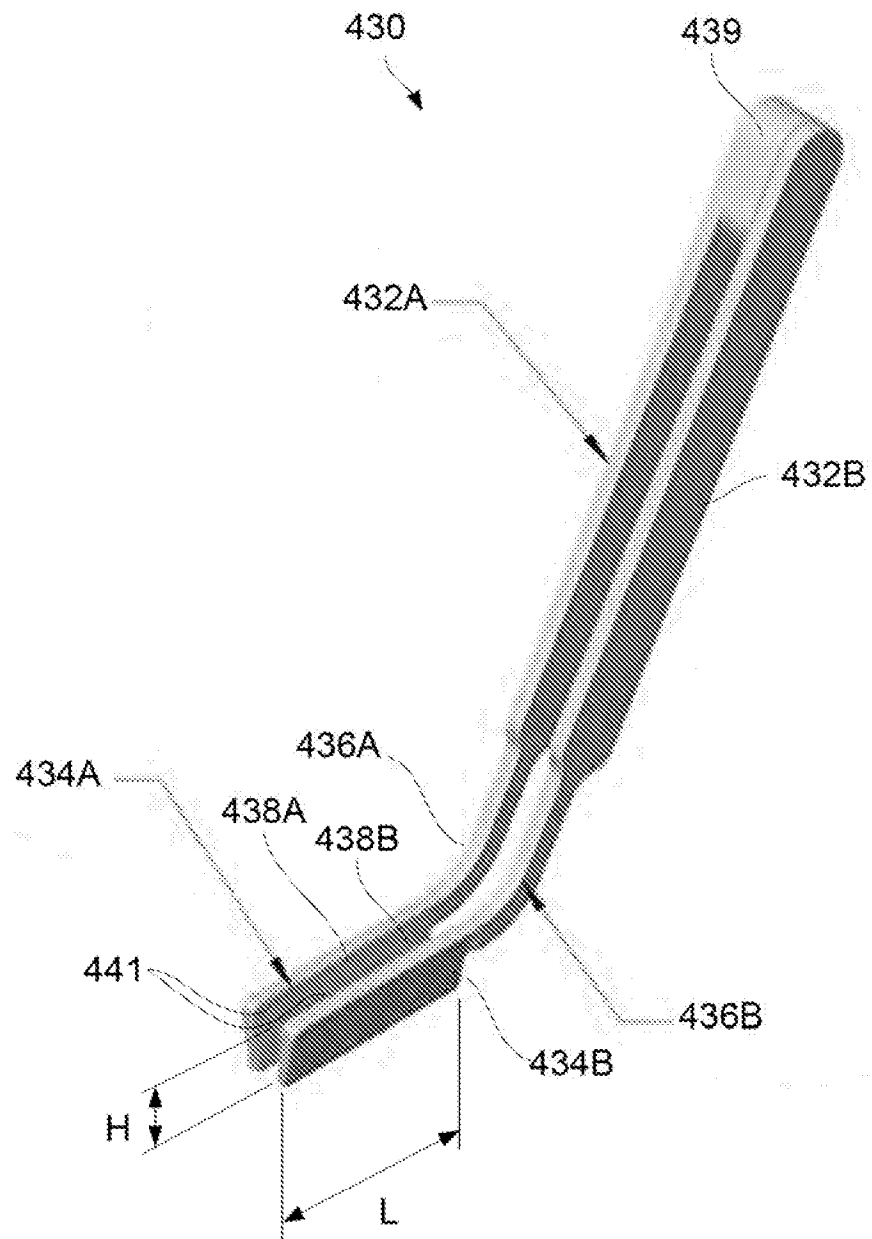
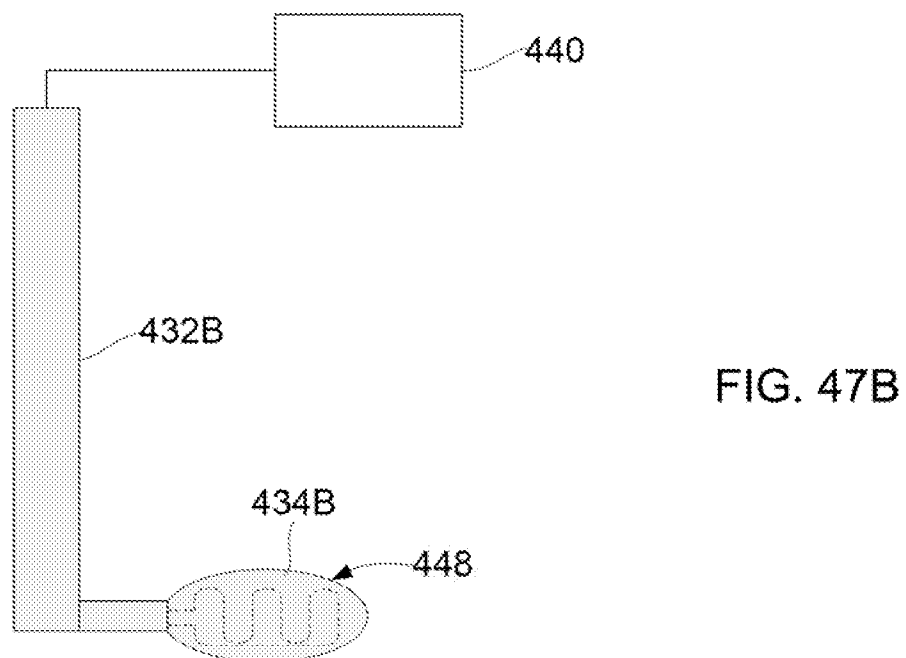
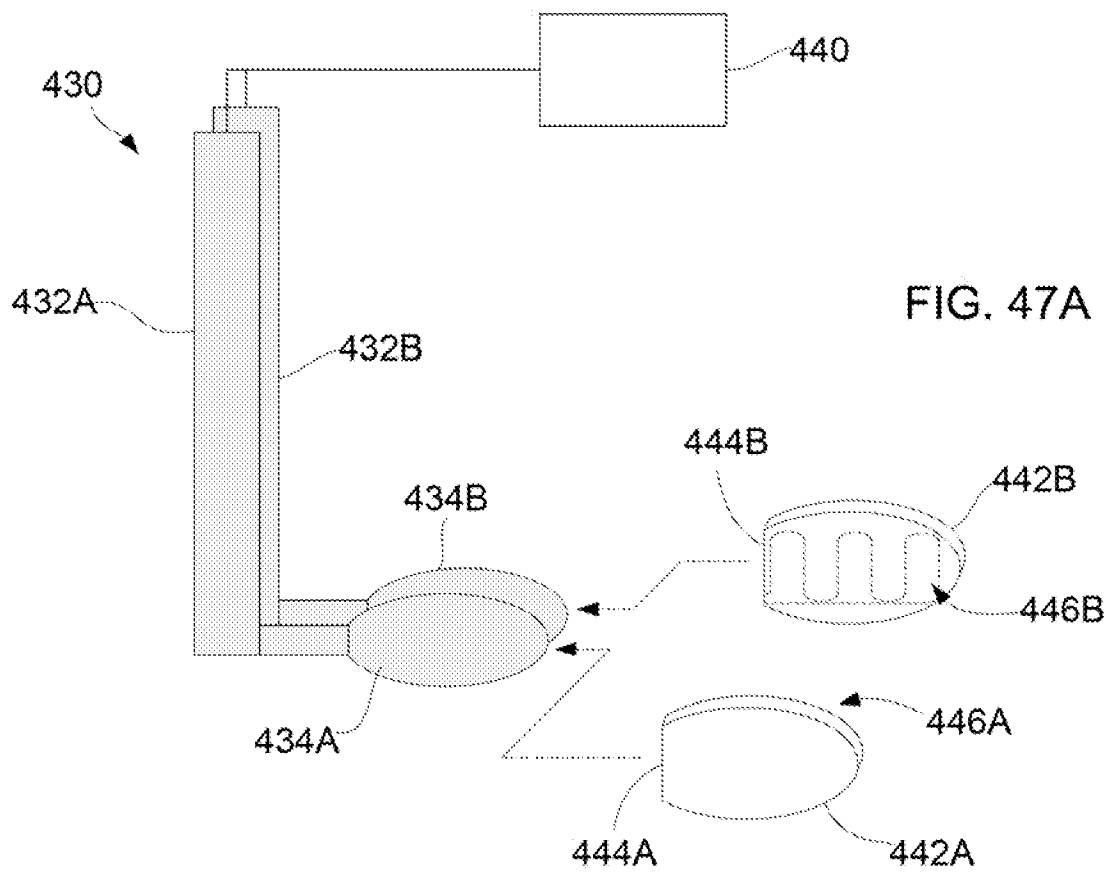


FIG. 46

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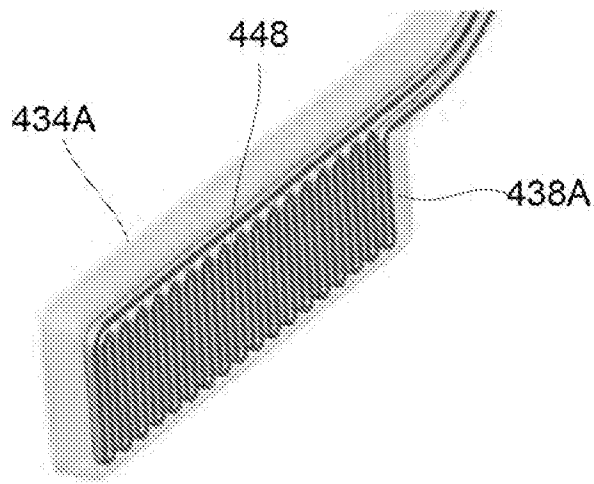


FIG. 48A

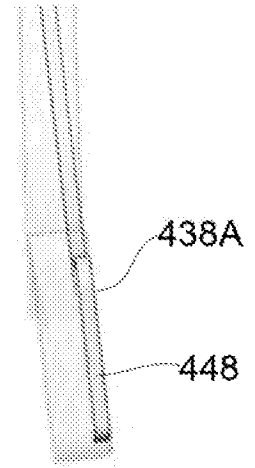


FIG. 48B

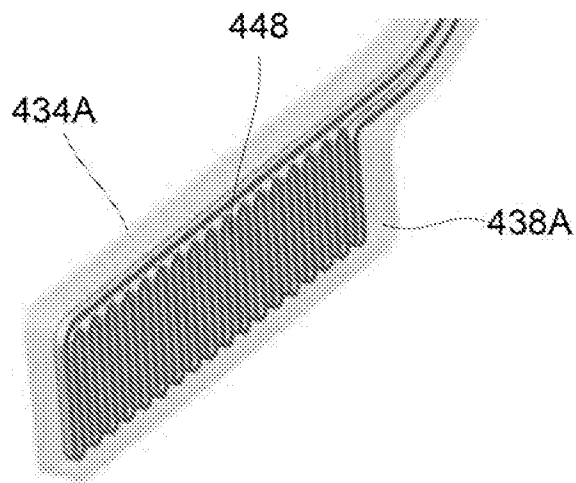


FIG. 49A

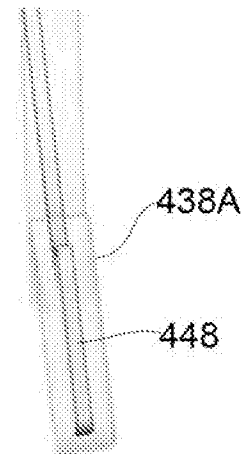


FIG. 49B

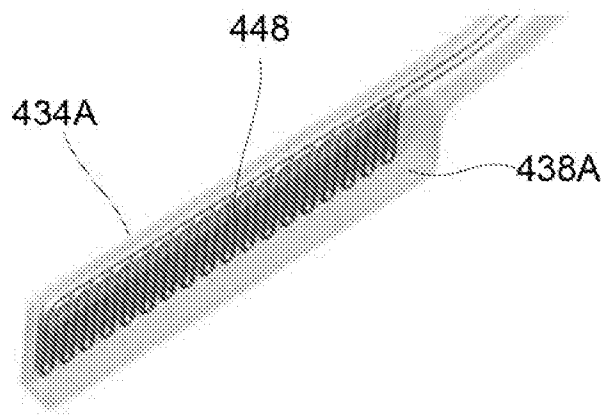


FIG. 50A

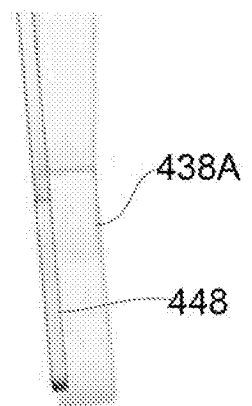


FIG. 50B

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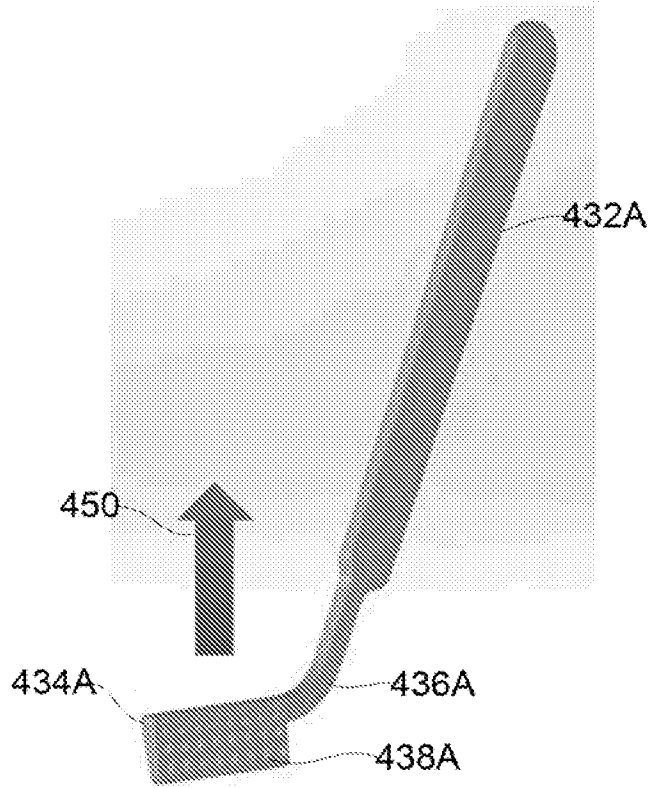


FIG. 51A

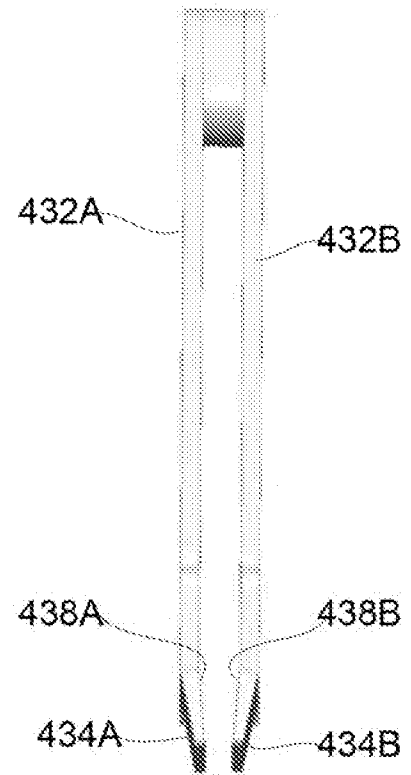


FIG. 51B

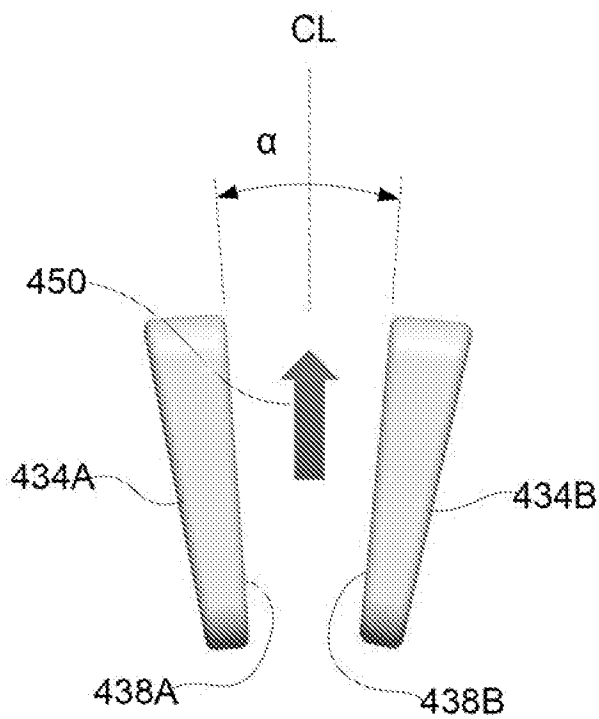


FIG. 52A

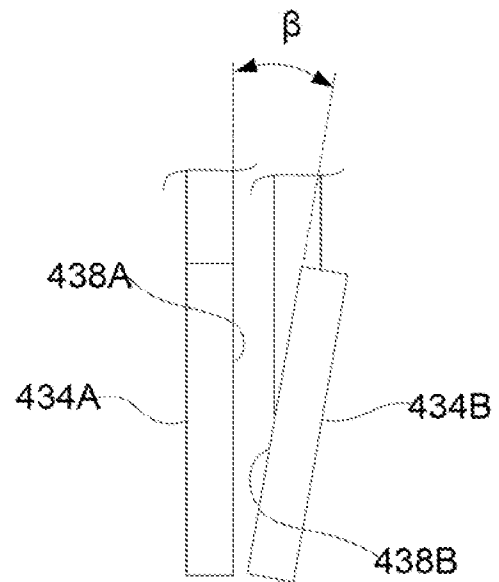


FIG. 52B

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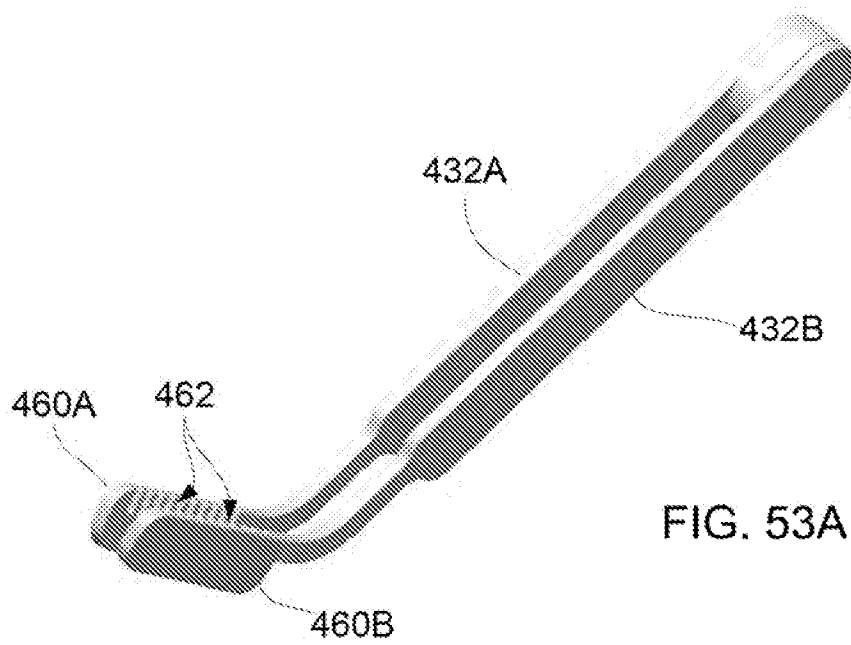


FIG. 53A

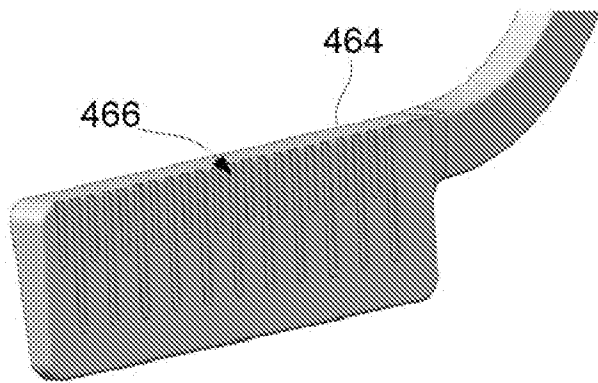


FIG. 53B

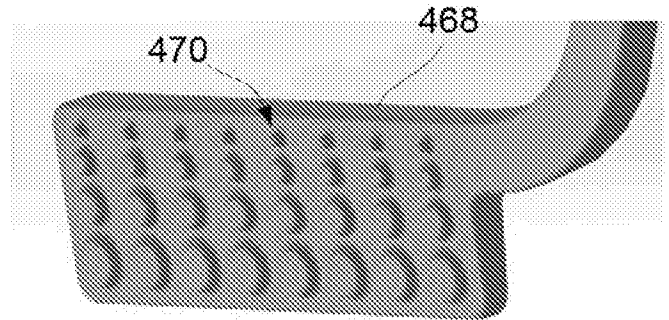


FIG. 53C

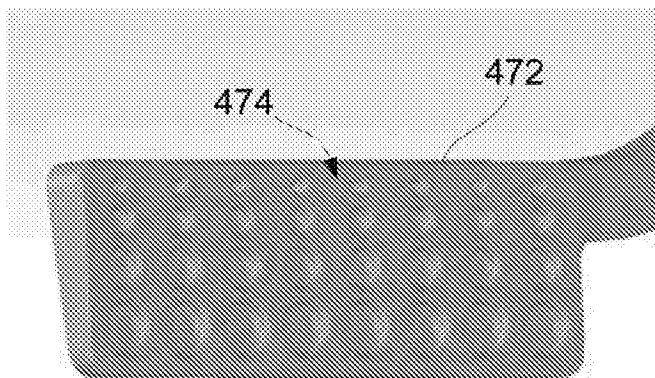


FIG. 53D

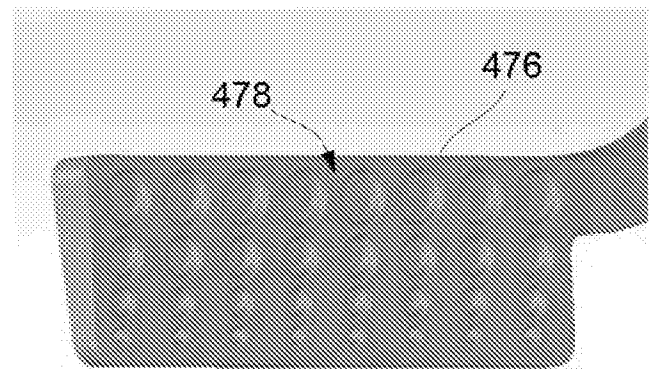
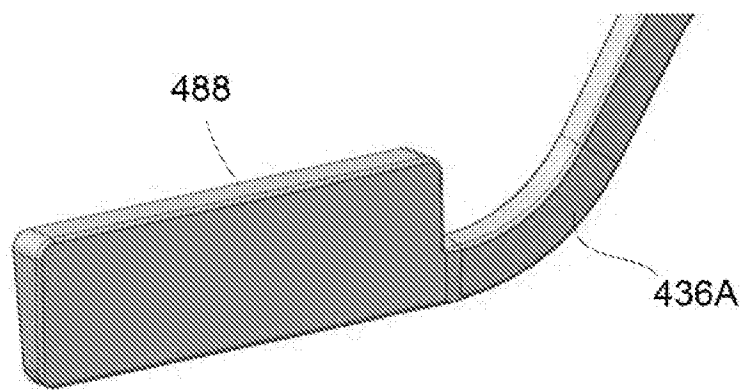
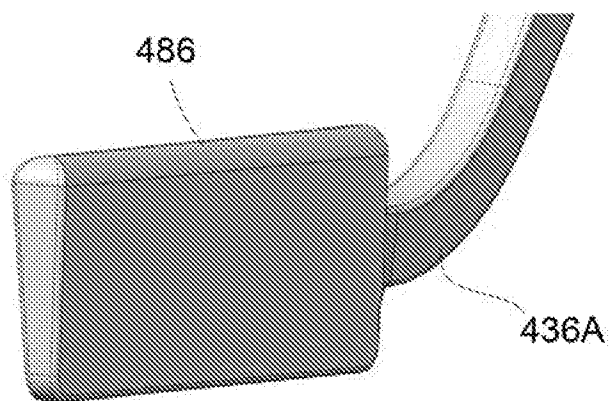
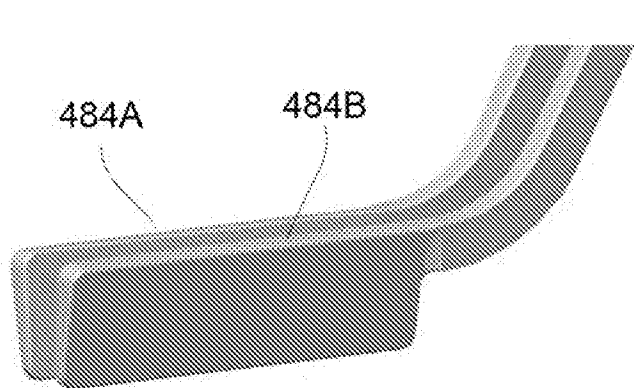
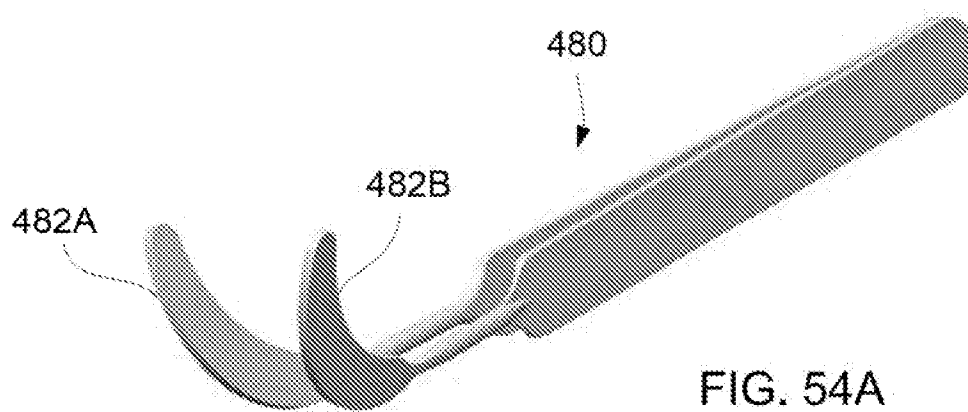


FIG. 53E

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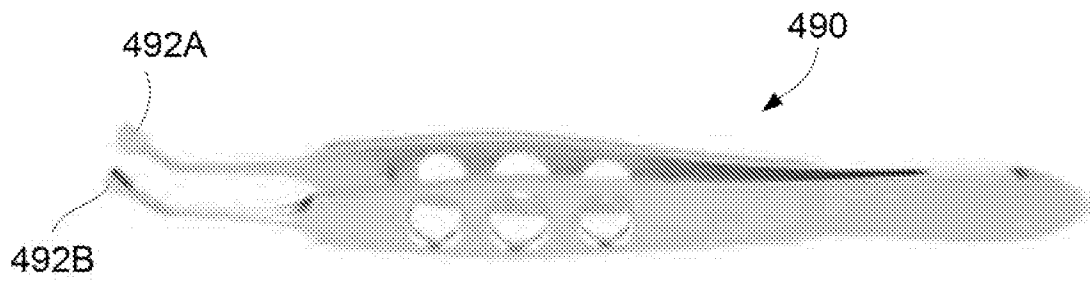


FIG. 55A

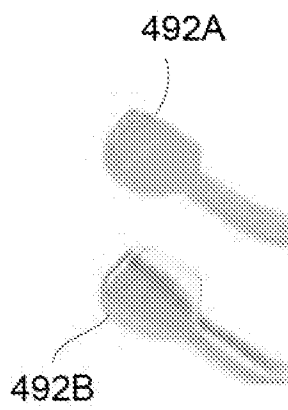


FIG. 55B

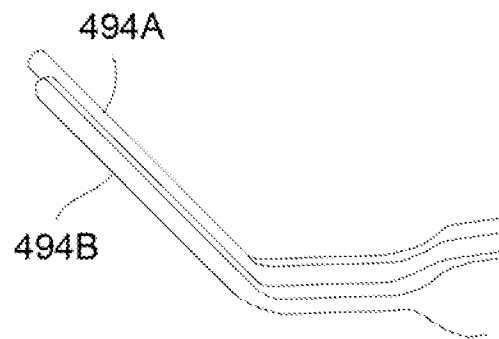


FIG. 55C

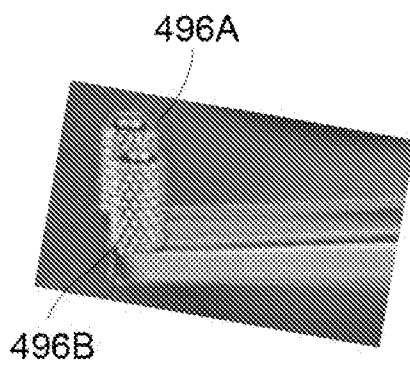


FIG. 55D

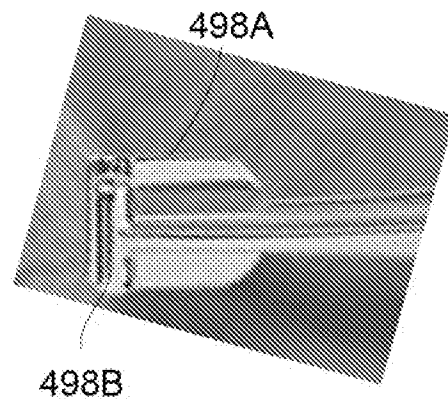


FIG. 55E

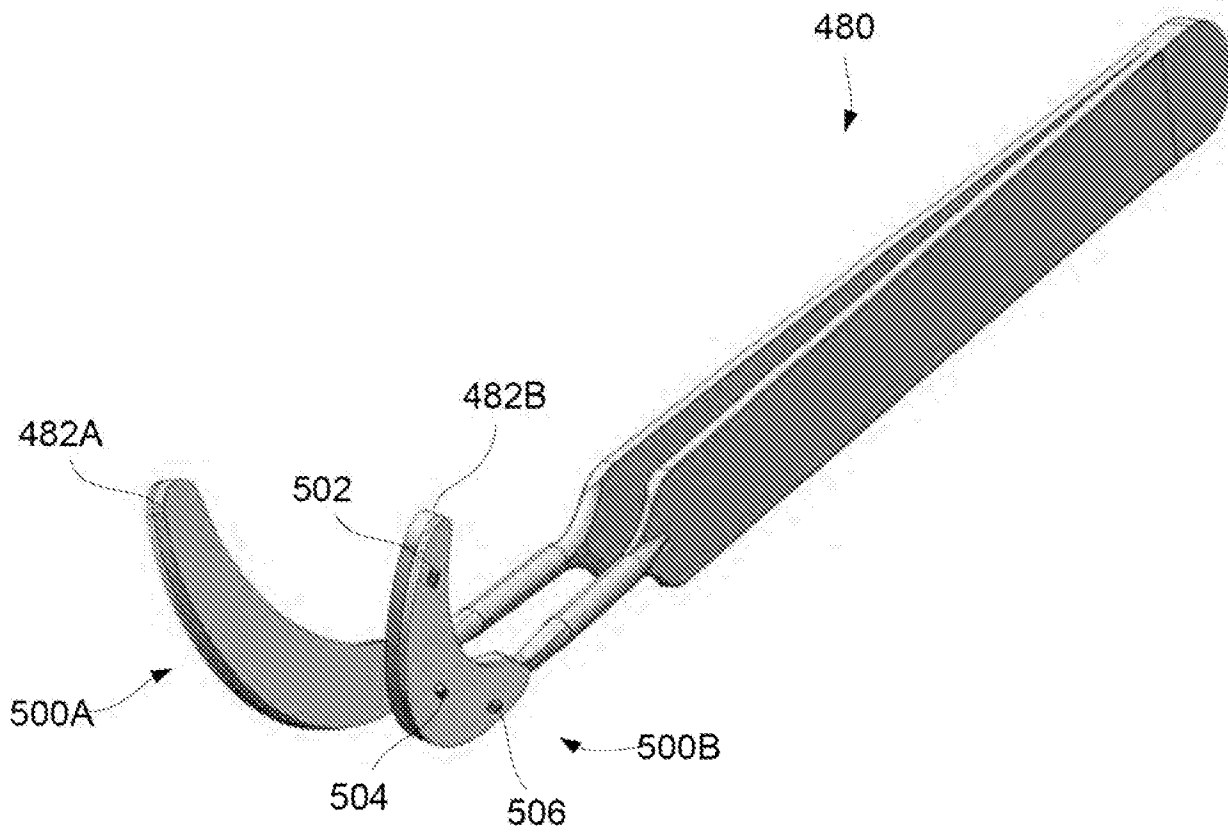


FIG. 56

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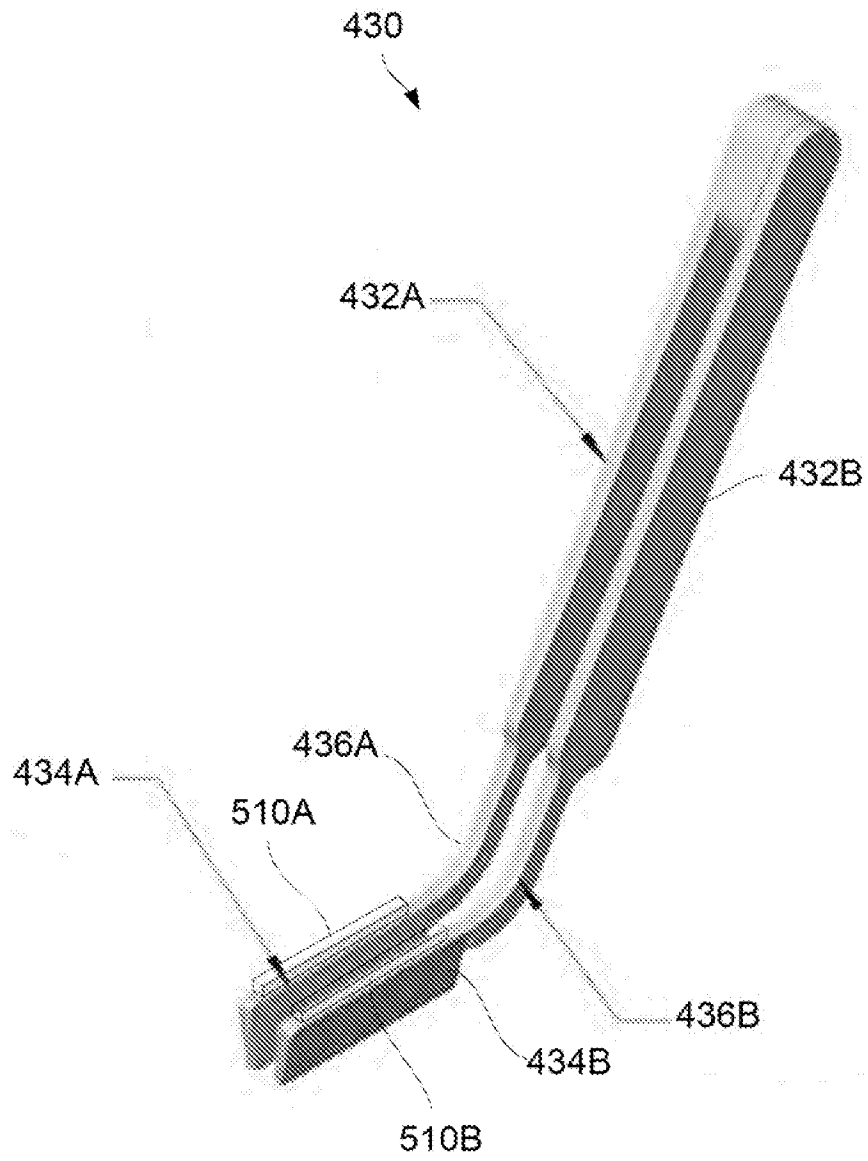


FIG. 57

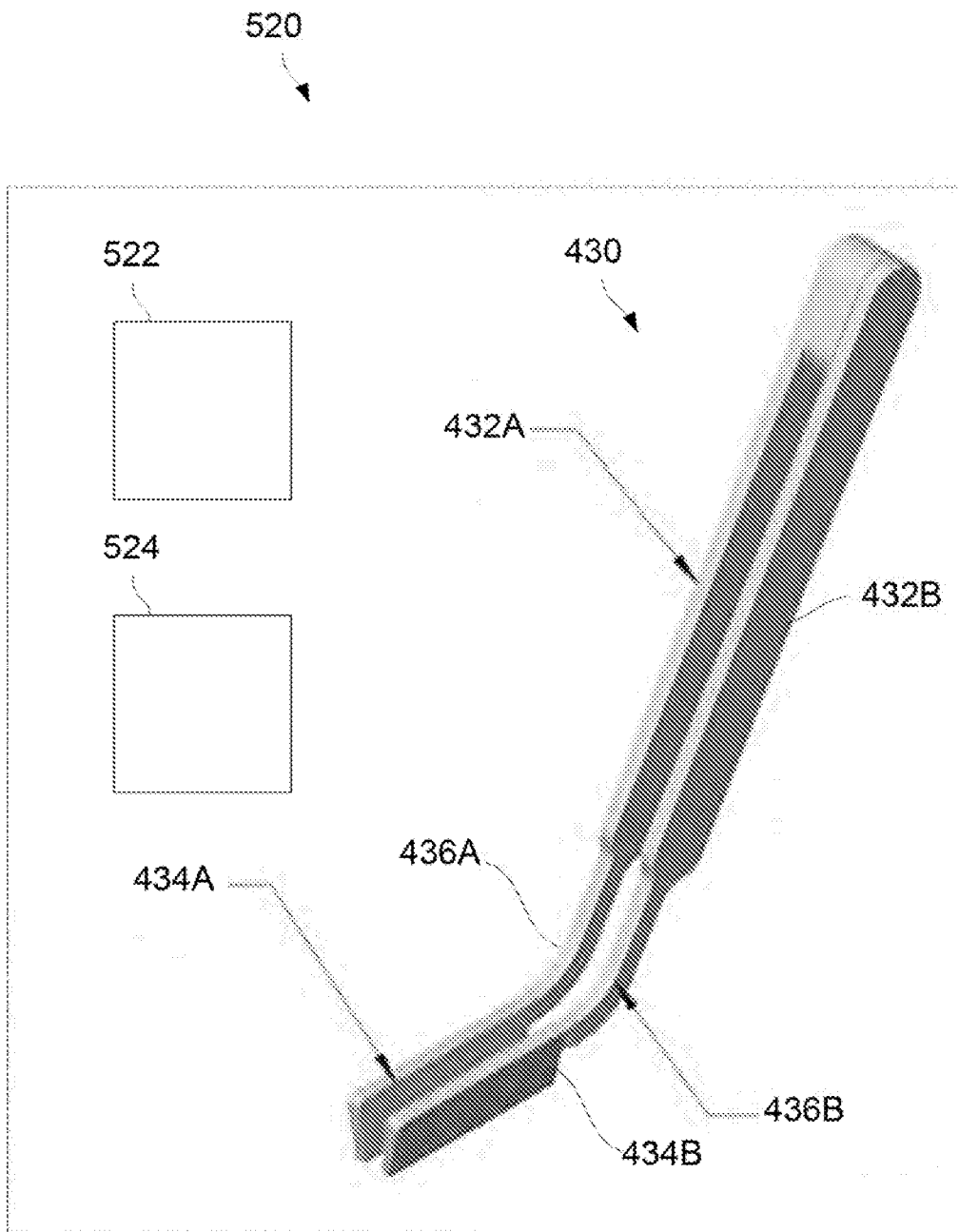


FIG. 58

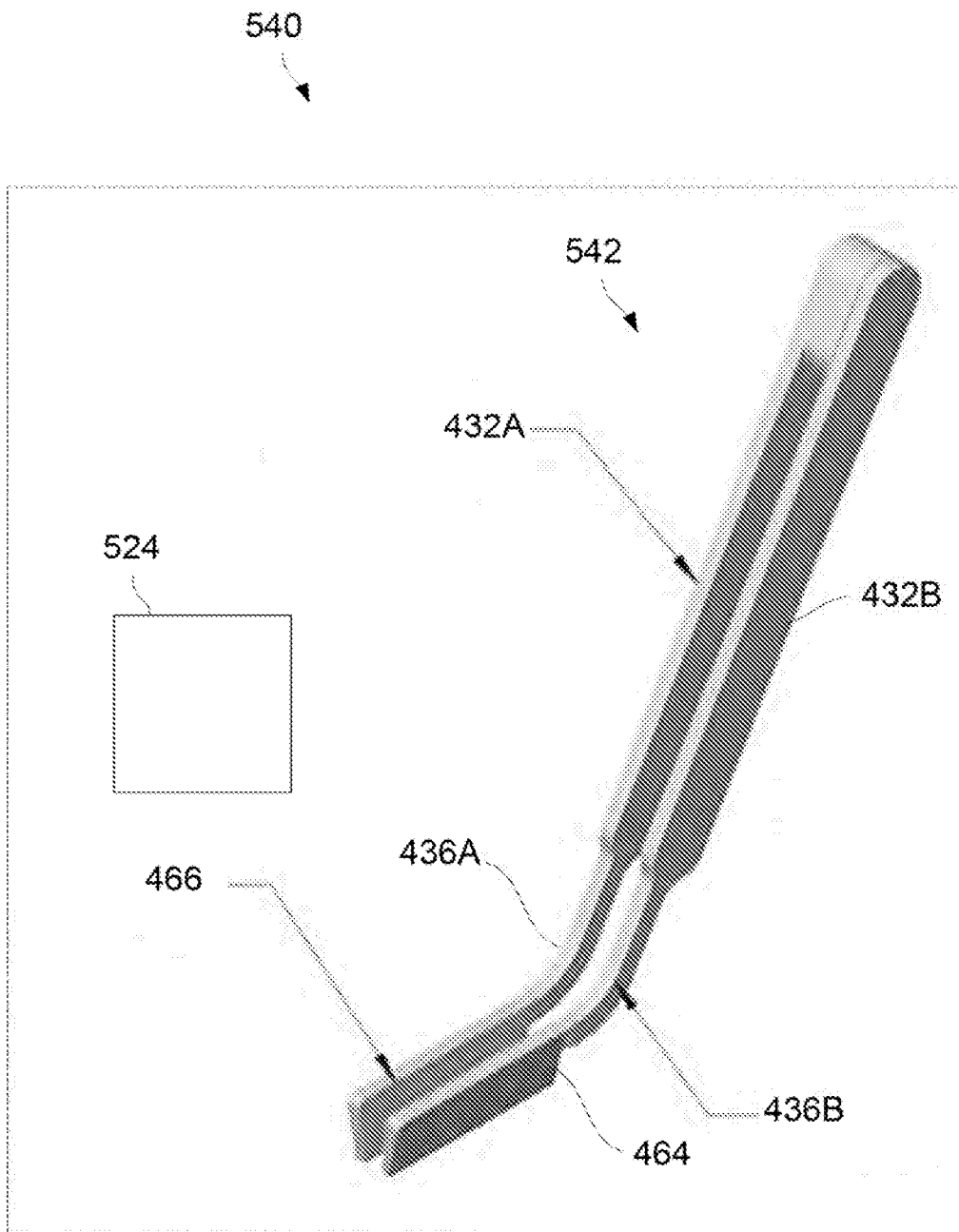


FIG. 59A

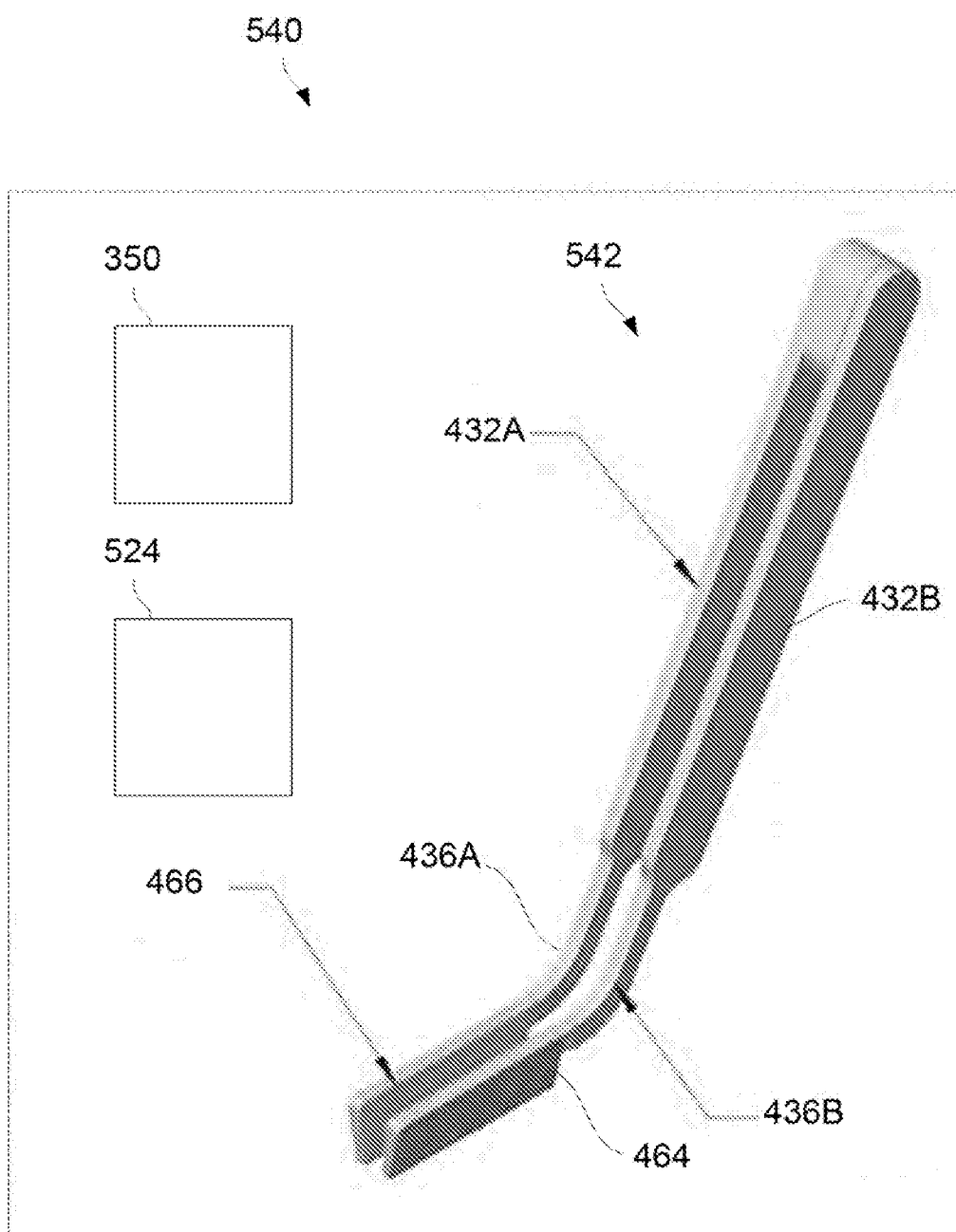


FIG. 59B

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 16/65876

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 9/00, A61F 7/02, A61F 7/03, A61F 7/00, A61F 13/12, A61M 35/00, A61F 13/00 (2017.01)

CPC - A61F 2007/0244, A61F 2007/0095, A61F 2007/0086, A61F 2007/0226, A61F 13/124, A61F 7/007, A61F 7/02, A61F 2007/0004

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)

See Search History Document

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

See Search History Document

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

See Search History Document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2013/0172829 A1 (BADAWI) 04 July 2013 (04.07.2013), entire document	1-17, 37-48
Y		18-26, 49-52
A		27, 53
Y	CN 203564408 U (ZHANG et al.) 30 April 2014 (30.04.2014), entire document	18-24, 26, 49-52
A		27
Y	US 2008/0114421 A1 (KORB et al.) 15 May 2008 (15.05.2008), entire document	25
A	US 2013/0046367 A1 (CHEN) 21 February 2013 (21.02.2013), entire document	1-27, 37-53
A	US 6,860,880 B2 (TREAT et al.) 01 March 2005 (01.03.2005), entire document	1-27, 37-53
A	US 7,108,694 B2 (MIURA et al.) 19 September 2006 (19.09.2006), entire document	1-27, 37-53
P, X	CN 205234758 U (XIANGYANG CENTRAL HOSPITAL) 18 May 2016 (18.05.2016), entire document	1-27, 37-53

☐ Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

30 January 2017

Date of mailing of the international search report

28 APR 2017

Name and mailing address of the ISA/US

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P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-8300

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 16/65876

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

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

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

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

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

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

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-27 and 37-53, directed to a treatment system, comprising one or more strips configured to adhere to an underlying region of skin with a controller in communication with the one or more strips.

Group II: Claims 28-36, directed to a treatment system, comprising one or more strips configured to adhere to an underlying region of skin with a forceps for mechanically expressing the one or more meibomian glands.

See Extra Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Group I: Claims 1-27 and 37-53

Remark on Protest

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

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 16/65876

Continued from: Box No. III

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of a controller in communication with the one or more strips, wherein the controller is programmable to monitor and induce a temperature in the one or more strips to provide a therapy, wherein, the controller is further programmable to maintain a set point above a threshold temperature and below a maximum temperature over a predetermined treatment period, not required by the claims of Group II.

The invention of Group II includes the special technical feature of a forceps for mechanically expressing the one or more meibomian glands, not required by the claims of Group I.

COMMON TECHNICAL FEATURES

Groups I-II share the common technical features of a treatment system, comprising:
one or more strips configured to adhere to an underlying region of skin in proximity to one or both eyes of a subject such that the one or more strips allow for the subject to blink naturally with minimal, or no restriction from the one or more strips; wherein the one or more strips are configured to emit thermal energy to the underlying region of skin, and wherein the one or more strips are shaped to follow a location of one or more meibomian glands contained within the underlying region of skin. However, this shared technical feature does not represent a contribution over prior art as being anticipated US 2013/0172829 A1 to BADAWI. Badawi discloses a treatment system, comprising: one or more strips configured to adhere to an underlying region of skin in proximity to one or both eyes of a subject (Claim 1) such that the one or more strips allow for the subject to blink naturally with minimal, or no restriction from the one or more strips (Claim 1); wherein the one or more strips are configured to emit thermal energy to the underlying region of skin (Claims 1, 2), and wherein the one or more strips are shaped to follow a location of one or more meibomian glands contained within the underlying region of skin (Claim 1).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical feature that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.