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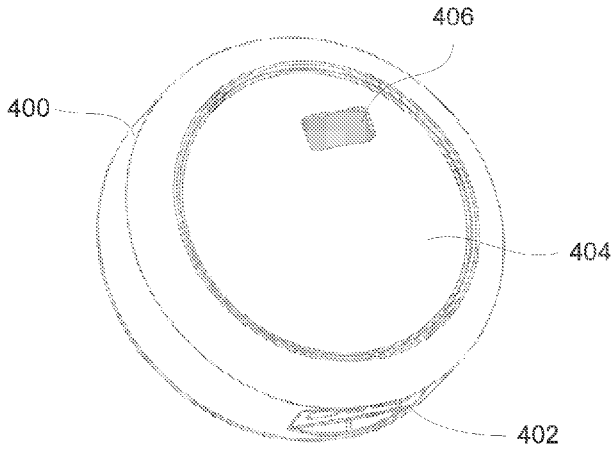


FIG. 44A

(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 of, e.g., 39°C, and below a maximum temperature of, e.g., 48°C, over a treatment period of 12 minutes.

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CONTROLLER WITH IMAGING SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority to U.S. Prov. App. 62/882,792 filed August 5, 2019, 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.

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 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 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 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 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, and consequently are not as well-suited for widespread consumer adoption.

[0017] 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.

SUMMARY OF THE INVENTION

[0018] 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.

[0019] 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.

[0020] 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.

[0021] 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.

[0022] 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.

[0023] 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.

[0024] 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.

[0025] 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 insulting 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.

[0026] 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).

[0027] 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.

[0028] 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.

[0029] 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.

[0030] 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. Variously 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.

[0031] 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.

[0032] 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.

[0033] 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.

[0034] 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.

BRIEF DESCRIPTION OF THE DRAWINGS

[0035] Fig. 1A shows a cross-sectional side view of an upper eyelid and an example of the location of a meibomian gland.

[0036] 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.

[0037] 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.

[0038] 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.

[0039] 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.

[0040] Fig. 3A shows an example of a contoured treatment strips.

[0041] Fig. 3B shows an example of a cross-sectional side view of a treatment strip.

[0042] Fig. 3C shows another variation of a treatment strip which may optionally incorporate sensory capabilities that feed into a controller.

[0043] 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.

[0044] Fig. 4 shows a front view of another variation of the treatment strip, which is relatively thin and positioned over the upper eyelids.

[0045] 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.

[0046] 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.

[0047] 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.

[0048] 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.

[0049] 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.

[0050] Fig. 10 shows a front view of another variation of the treatment strip which is relatively thick for placement along the lower eyelids.

[0051] 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.

[0052] Fig. 12 shows a front view of another variation of the treatment strip which is relatively straightened and selectively shortened.

[0053] 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.

[0054] 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 surrounding tissue regions.

[0055] 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.

[0056] Fig. 16 shows a front view of yet another variation where the strip is contoured to follow at least a portion of the meibomian glands but also to cover selected regions of the surrounding tissue.

[0057] Fig. 17 shows a front view of yet another variation which is contoured to selectively treat particular regions of the underlying tissue.

[0058] Fig. 18 shows a front view of yet another variation where the contoured treatment strips may be used in combination for treating both upper and lower eyelids.

[0059] 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.

[0060] Fig. 20 shows a front view of yet another variation where the treatment strips may be sized to treat specified meibomian glands.

[0061] Fig. 21 shows a front view of yet another variation where the strips may be varied in size to selectively treat particular meibomian glands.

[0062] Fig. 22 shows a front view of yet another variation where the treatment strips may be sized to treat individual meibomian glands.

[0063] Fig. 23 shows a front view of yet another variation where the treatment strips may be sized for placement along the lower eyelids.

[0064] Fig. 24 shows a front view illustrating the relative positioning of the lacrimal glands.

[0065] Figs. 25 to 27 show variations of treatment strips which may be contoured and positioned for treating the underlying lacrimal glands.

[0066] 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.

[0067] 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.

[0068] 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.

[0069] Fig. 34 shows a detail perspective view of the treatment strip of Fig. 33 illustrating an example of biasing mechanisms incorporated along the strips.

[0070] 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.

[0071] Fig. 36 shows yet another variation of treatment strips incorporating electrodes through the length of the strips.

[0072] 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.

[0073] 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.

[0074] 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.

[0075] Fig. 40 shows a perspective view of a controller which is specifically designed and programmed for use with the treatment strip assemblies.

[0076] Figs. 41A and 41B show perspective views of the controller having connectors for respective treatment strip assemblies coupled to the controller.

[0077] 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.

[0078] Fig. 43 shows a perspective view of a charging station which provides a receiving cradle for holding the controller.

[0079] Figs. 44A and 44B show perspective views of controllers having an integrated imager.

[0080] Figs. 45A and 45B show perspective views of controllers also incorporate a light for illuminating the patient's eye and eyelids for image or video capture by the controller. (or ocular surface, tear, tear component or layer, or Meibomian glands)

[0081] Fig. 46 shows a perspective view of a controller incorporating display along with the imager. The display could be on the back side of the controller as shown but will likely be on the front side of the controller that has a touch screen interface (like an iphone

where the touch screen functionality, picture buttons, and image display face the user while the imager and lighting are on the back side of the device away from the user)

[0082] Fig. 47 shows a perspective view of a controller having a display for displaying the image of the eye and/or eyelids being captured by the imager. (or ocular surface, tear, tear component or layer, or Meibomian glands)

[0083] Fig. 48 shows a perspective view of a controller having an indicator for alerting the user whether suitable images of the eye and/or eyelids have been captured by the imager.

[0084] Fig. 49 shows an example of a controller receiving images of the eye and/or eyelids captured by a separate imaging device such as a smartphone which may be in communication with the controller.

DETAILED DESCRIPTION OF THE INVENTION

[0085] 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.

[0086] 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.

[0087] 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.

[0088] 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.

[0089] 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.

[0090] 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.

[0091] 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.

[0092] 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.

[0093] 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.

[0094] 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.

[0095] 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.

[0096] 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.

[0097] 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 applied as a single-use treatment or they may be configured to be robust enough as a re-usable device.

[0098] 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**.

[0099] 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.

[00100] 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.

[0100] 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 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.

[0101] 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 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.

[0102] 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 charged, e.g., by direct electrical contact, induction, etc.

[0103] Other mechanisms which may be incorporated into the heating layer **36** may comprise chemically actuated reactions such 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 use 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 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.

[0104] Yet another example of use in the heating layer **36** may include the use of a 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**.

[0105] 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 placement in a microwave prior to use, and then allowed to release the heat over a specified period of time.

[0106] 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 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 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 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.

[0107] 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.

[0108] 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.

[0109] Other agents may include, e.g., alpha-melanocyte-stimulating hormone or adrenocorticotropic 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.

[0110] 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.

[0111] 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.

[0112] 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.

[0113] 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.

[0114] 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.

[0115] 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.

[0116] 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.

[0117] 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.

[0118] Aside from variations in width of the treatment strips, any of the treatment 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 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 styes.

[0119] Fig. 13 shows yet another variation where the contoured strips **120** may be 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.

[0120] Fig. 14 shows another variation where the contoured strip **130** may have a 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

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 glands, around the peri-orbital regions.

[0121] 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.

[0122] 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**.

[0123] 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.

[0124] 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**.

[0125] 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.

[0126] 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.

[0127] 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. Variously 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.

[0128] 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.

[0129] 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**.

[0130] 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**.

[0131] 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.

[0132] 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 a add compressive force.

[0133] 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.

[0134] 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 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.

[0135] 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 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 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.

[0136] 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., 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.

[0137] Fig. 39 shows yet another variation where the eyelid treatment system **330** 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 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.

[0138] 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**.

[0139] 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.

[0140] 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.

[0141] 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.

[0142] 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.

[0143] 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.

[0144] 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**.

[0145] 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.

[0146] 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.

[0147] 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.

[0148] 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.

[0149] 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.

[0150] 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.

[0151] 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.

[0152] 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.

[0153] 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**.

[0154] 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.

[0155] 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).

[0156] 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.

[0157] 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.

[0158] 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**).

[0159] 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.

[0160] 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.).

[0161] 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.

[0162] 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.

[0163] In yet another variation, the controller may also be configured to incorporate a number of additional functionalities not only for dry eye therapy, but also for dry eye diagnostics (as well as for any number of other eye-related conditions).

[0164] In the variation shown in the perspective view of Fig. 44A, the controller **400** may be configured to integrate an imager **406** such as a camera along a surface **404**, e.g., the opposite surface of the control interface, of the controller **400** as shown. The location of the ports **402** for connecting to the one or more heating strips is also shown

located along an edge of the controller housing. The imager **406** may be positioned along the surface **404** in any location suitable for allowing the imager **406** to view and analyze the eye (one eye individually or both eyes simultaneously) and surrounding eyelids including meibomian glands. The imager **406** in one variation may be positioned near an edge along the surface **404** of the controller housing. In another variation, the imager **408** may be positioned along the surface **404** near or at a center of the controller **400**, as shown in the perspective view of Fig. 44B.

[0165] In other variations, as shown in the perspectview views of Figs. 45A and 45B, the imager **410** may incorporate a light **412** in proximity to the imager **410** or light **422** in proximity to imager **420** to illuminate the eye and surrounding eyelids sufficiently.

[0166] In yet another variation, as shown in the perspective view of Fig. 46, the controller **400** may also incorporate a screen or display **430**, which may also be a touchscreen display, along the surface **404** in proximity to the imager **406** for displaying prompts or other information to the user.

[0167] With the controller **400** configured to obtain an image of the patient's eye and surrounding eyelids, the processor integrated within the controller **400** may be programmed, e.g., with meibography functionality. For instance, the controller **400** may obtain an image of the patient's eyelids (or inner eyelids) and meibomian glands and use the images to compare against any previously obtained image in order to track treatment progress and/or to determine a health condition of the meibomian glands. The controller **400** may also incorporate memory functionality to store a plurality of images and other related data for the eyelids and meibomian glands. The comparison between one or more selected images and analysis may be accomplished selectively when initiated by the patient and/or physician or automatically by the processor within the controller **400**. Additionally, the controller **400** may also incorporate wireless or wired functionality for connection to the internet so that the data and/or images may be transmitted to one or more selected users through interconnected servers.

[0168] Furthermore, in analyzing the images, the controller **400** may be programmed, e.g., to produce a simple diagnostic output or assessment, and/or to produce a trend in physiological or disease markers as treatments progress.

[0169] The controller **400** may not only track, compare, and diagnose a condition of the eyelids and meibomian glands, but the process may also be programmed for ocular surface diagnostic capabilities, e.g., corneal and/or conjunctival staining imaging functionality. Other capabilities may include tear film analysis, interferometry, lipid layer

thickness analysis as well as aqueous layer (tear meniscus height) analysis, and mucin layer analysis. Additional features may also include non-invasive tear break-up time measurements, blinking analysis functionality, and eyelid size and dimension imaging analysis capability that can be used, e.g., to produce custom-sized therapeutic heating strips to individual patients.

[0170] In utilizing meibography, various methods may be utilized, e.g., infrared meibography, laser confocal meibography, contact meibography, non-contact meibography, optical coherence tomographic meibography, etc. Additionally, infrared light can be used for the meibography, e.g., by using an infrared filter and an infrared charge-coupled device camera to image the eyelids.

[0171] Moreover, in imaging the eye and/or eyelids and/or other parameters, a digitally everted eyelid or the inside of the eyelid may also be imaged, e.g., by imaging the morphology of the meibomian glands in vivo. That is, the inside surface which is in contact against the surface of the eye.

[0172] Any one or all of the functionality described may be incorporated in any combination with any of the controller variations described herein. Moreover, any of the heating strip variations may be used in any number of combinations with the various controller embodiments described herein.

[0173] In obtaining the images of the patient's eyelids and meibomian glands, the controller **400** may include functionality for enabling the patient or practitioner (e.g., physician, nurse, etc.) to confirm that their eyelids are being properly imaged by the imager **406**. One variation is shown in Fig. 47 where the controller **400** may incorporate a display **440** for displaying the image of the patient's eye and eyelids **442** being captured by the imager **406** back to the patient. In this manner, the user may ensure that suitable images of their eyelids are being captured by the imager **406** during use. Another variation is shown in the perspective view of Fig. 48 where suitable image detection may be accomplished by the controller **400**. During image capture by the imager **406**, the controller **400** may automatically determine by image analysis whether a suitable image of the user's eye and eyelids are being imaged or captured. An indicator **450**, such as lights or an audible alert, may be provided to the user (either the patient or practitioner) to confirm whether suitable images have been obtained or whether new images are needed.

[0174] In yet another variation, while the controller **400** may incorporate the imager **406** directly on the surface **404**, the controller **400** may additionally and/or alternatively be in wireless communication **462** with a separate imaging device **460** having

an integrated camera and also having wireless capabilities (such as a smartphone, tablet, laptop, etc.). In example, the user may use their smartphone to obtain an image of their eye and/or eyelids and wirelessly transmit this image directly to the controller **400** for meibography analysis. Alternatively, the imaging device **460** may be used to obtain the image and perform the analysis and transmit the results directly to the controller **400** and/or other users.

[0175] 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.

CLAIMS

What is claimed is:

1. A treatment system for determining a condition of a patient, comprising:

a controller having a housing configured for connection to one or more heating strips;

an imager incorporated into the controller and configured to image an eye and/or eyelid of the patient;

wherein the controller is configured to receive the image of the eye and/or eyelid and determine a condition of the eye and/or eyelid.

2. The system of claim 1 further comprising a light for illuminating the eye and/or eyelid.

3. The system of claim 1 further comprising a display along the housing.

4. The system of claim 1 further comprising a visual or auditory indicator along the housing.

5. The system of claim 1 wherein the controller is configured to wirelessly communicate with an external device to receive one or more images of the eye and/or eyelid.

6. The system of claim 1 wherein the controller is configured to track a condition of the eye and/or eyelids over time.

7. The system of claim 6 wherein the controller is configured to compare an image of the eye and/or eyelids with a previously obtained image of the eye and/or eyelids.

8. The system of claim 1 wherein the controller is configured to analyze a condition selected from the group consisting of corneal and/or conjunctival staining imaging, tear film analysis, interferometry, lipid layer thickness analysis as well as aqueous layer (tear meniscus height) analysis, mucin layer analysis, non-invasive tear break-up time measurements, blinking analysis functionality, and eyelid size and dimension imaging analysis.

9. The system of claim 1 wherein the controller is configured to analyze a condition via infrared meibography, laser confocal meibography, contact meibography, non-contact meibography, optical coherence tomographic meibography, and infrared light.

10. The system of claim 1 wherein the controller is further configured to receive the image of an inside of the eye and/or eyelid.

11. The system of claim 1 wherein the controller is programmable to monitor and induce a temperature in the one or more strips to provide a therapy.

12. The system of claim 1 wherein the controller is programmable to maintain a set point above a threshold temperature and below a maximum temperature over a predetermined treatment period.

13. The system of claim 1 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.

14. The system of claim 1 wherein the one or more strips are 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.

15. A method of determining a condition of a patient, comprising:

capturing an image of an eye and/or eyelid of the patient via an imager integrated with a controller having a housing configured for connection to one or more heating strips;

determining a condition of the eye and/or eyelid based on the image obtained by the controller.

16. The method of claim 15 further comprising selecting a treatment based on the determined condition.

17. The method of claim 15 further comprising determining a condition comprises analyzing the condition via a modality selected from the group consisting of infrared meibography, laser confocal meibography, contact meibography, non-contact meibography, optical coherence tomographic meibography, and infrared light.

18. The method of claim 15 further comprising determining a diagnostic assessment based on the image.

19. The method of claim 15 further comprising determining a trend in physiological or disease markers over one or more treatments.

20. The method of claim 15 wherein capturing an image comprises capturing an image of an inner surface of the eyelid.

21. A method for sizing one or more heating strips for a patient, comprising:

receiving one or more images of at least one eyelid from at least one eye of the patient; and

determining one or more dimensions for a heating strip based on the one or more images, wherein the one or more dimensions are sized to conform the one or more heating strips over meibomian glands contained within the at least one eyelid.

22. The method of claim 21 wherein receiving one or more images further comprises imaging the at least one eyelid via a controller having an imager.

23. The method of claim 22 wherein the controller comprises an imager incorporated into the controller and configured to image an eye and/or eyelid of the patient.

24. The method of claim 21 wherein receiving one or more images further comprises imaging the at least one eyelid via a personal imaging device.

25. The method of claim 24 wherein the personal imaging device comprises a smartphone.

26. The method of claim 21 further comprising fabricating the heating strip.

27. A treatment system for sizing one or more heating strips for a patient, comprising:

a controller having a housing configured for connection to one or more heating strips;

an imager incorporated into the controller and configured to image an eye and/or eyelid of the patient;

wherein the controller is configured to receive the image of the eye, ocular surface, tear, and/or eyelid and determine one or more dimensions sized to conform the one or more heating strips over meibomian glands contained within the eyelid.

28. The system of claim 27 wherein the controller is further configured to determine a condition of the eye, ocular surface, tear, and/or eyelid.

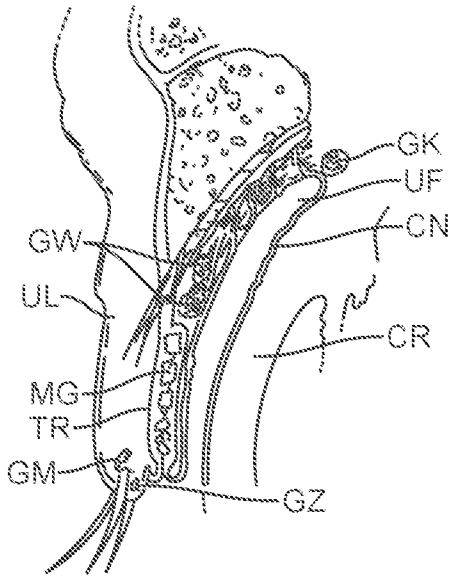


FIG. 1A

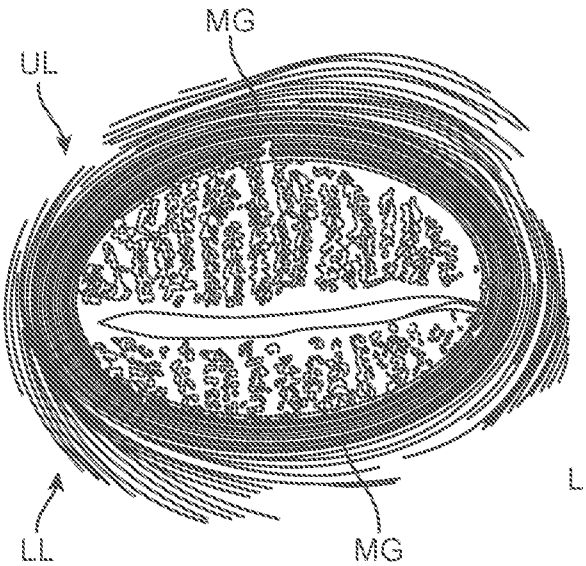


FIG. 1B

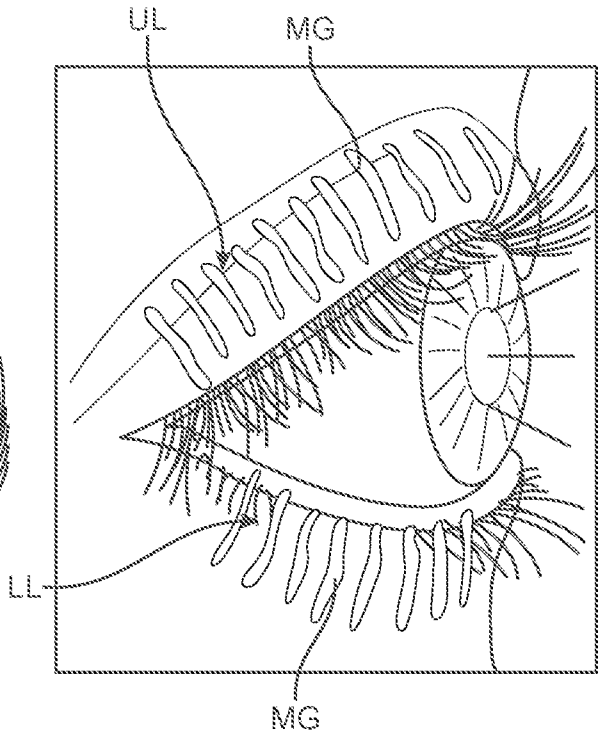


FIG. 1C

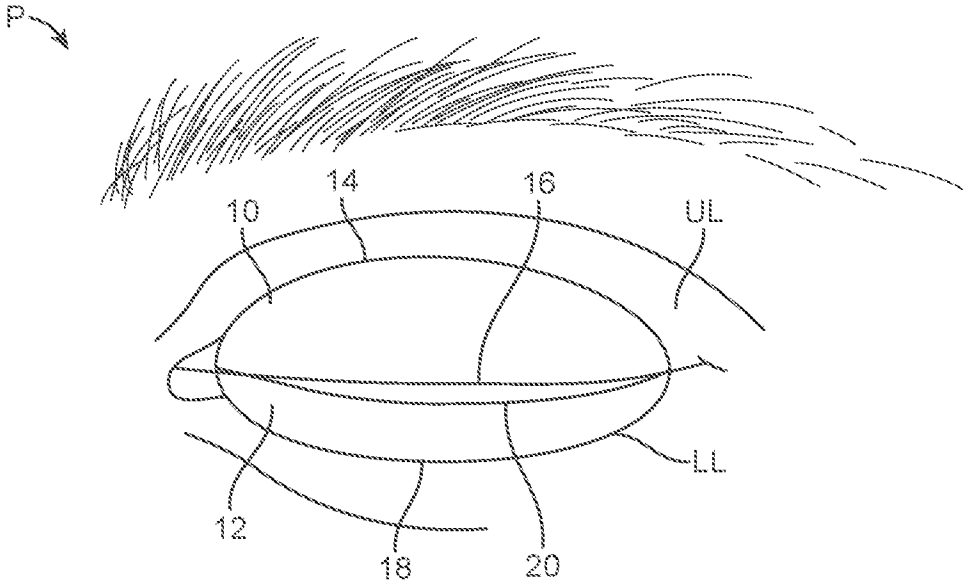


FIG. 2A

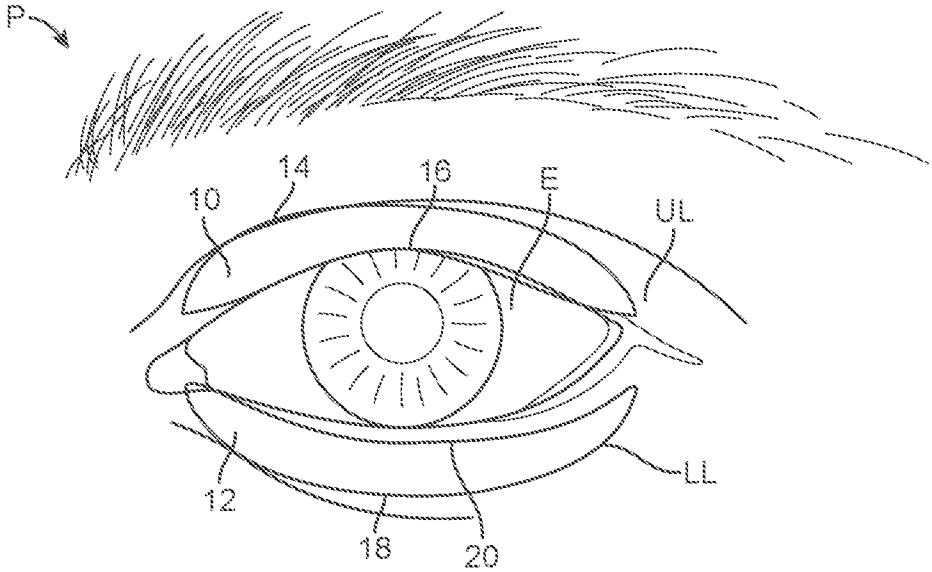


FIG. 2B

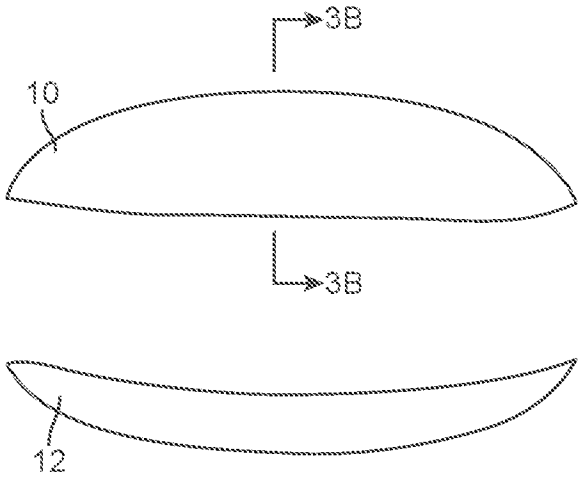


FIG. 3A

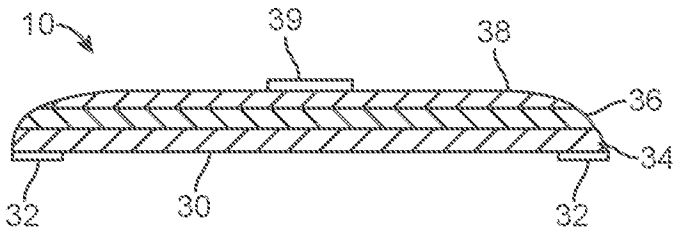


FIG. 3B

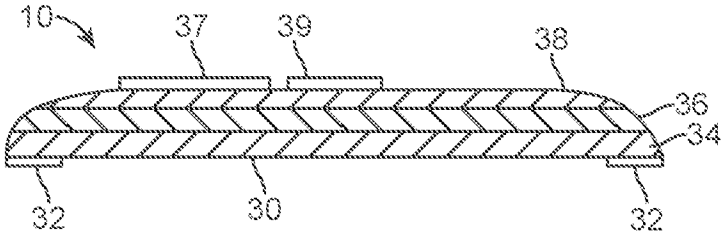


FIG. 3C

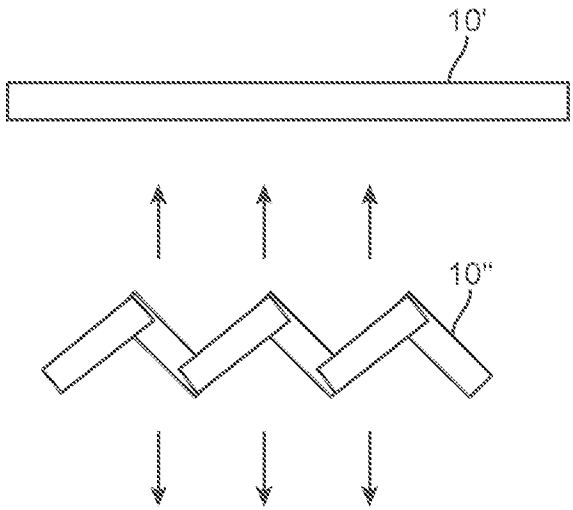


FIG. 3D

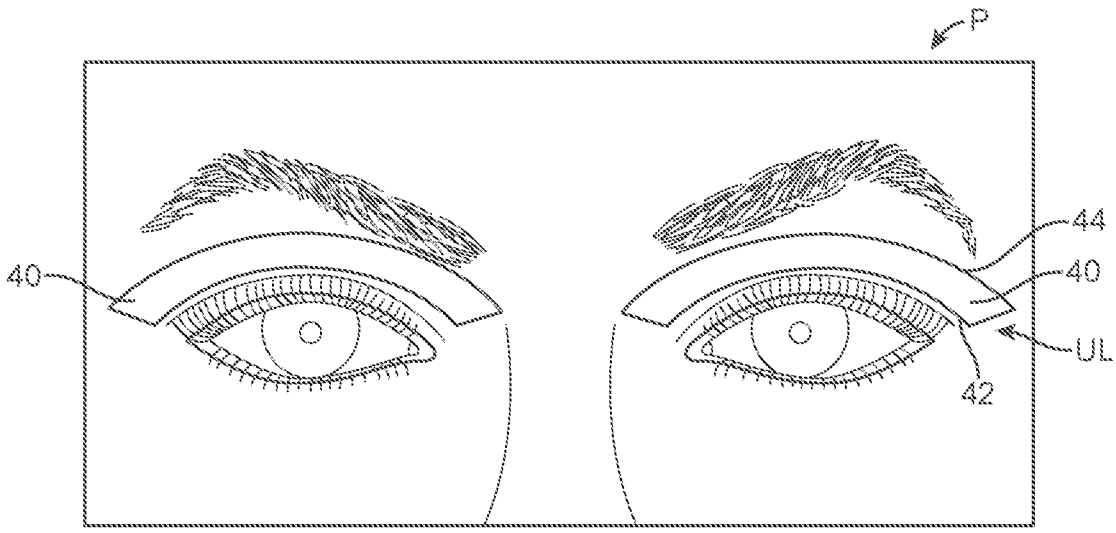


FIG. 4

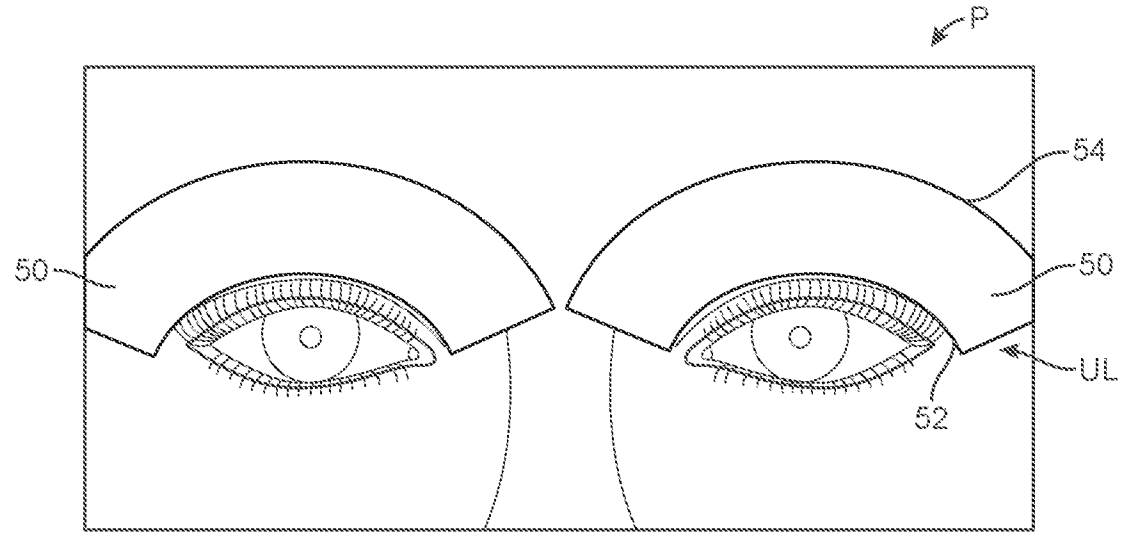


FIG. 5

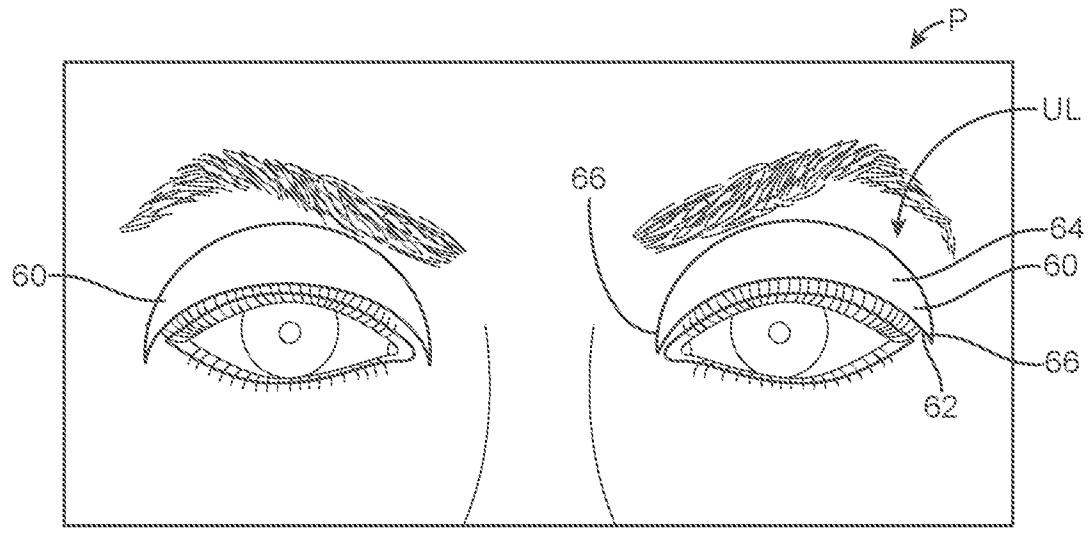


FIG. 6

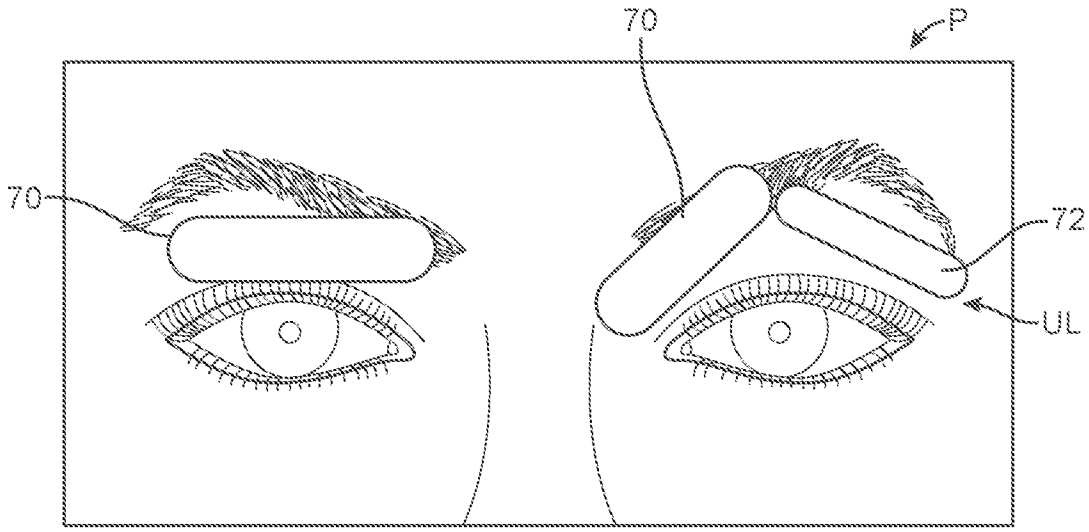


FIG. 7

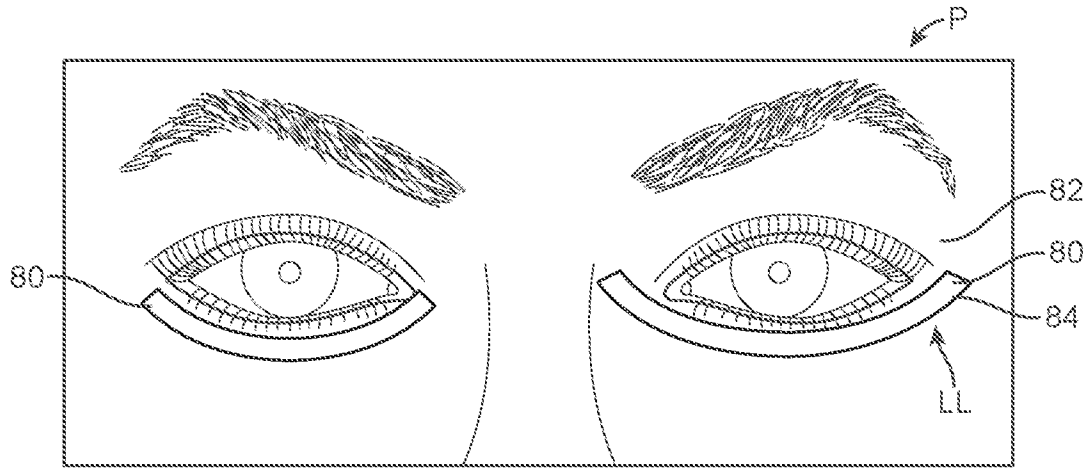


FIG. 8

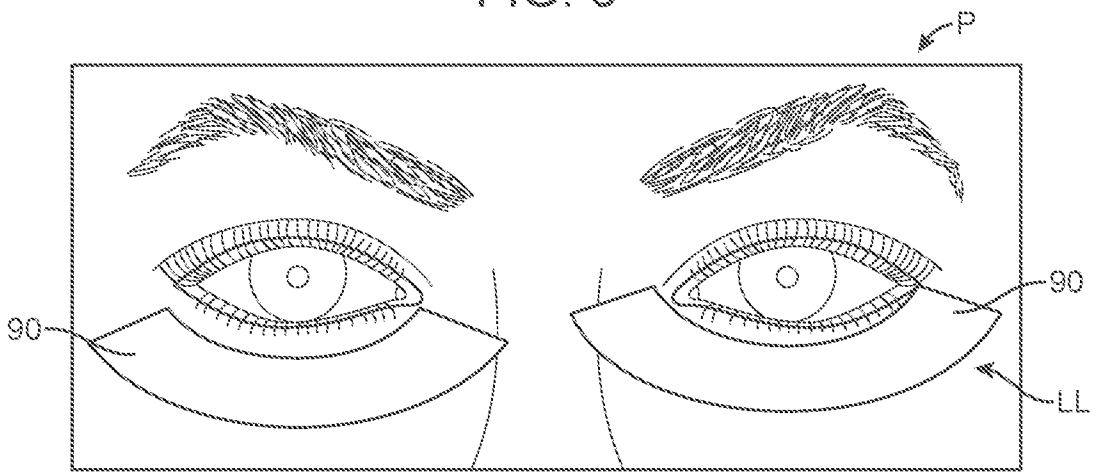


FIG. 9

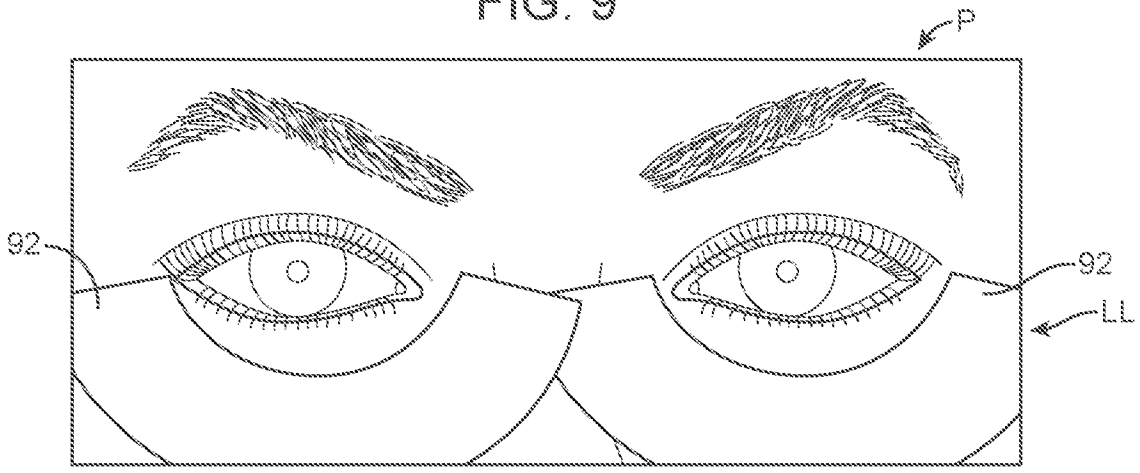


FIG. 10

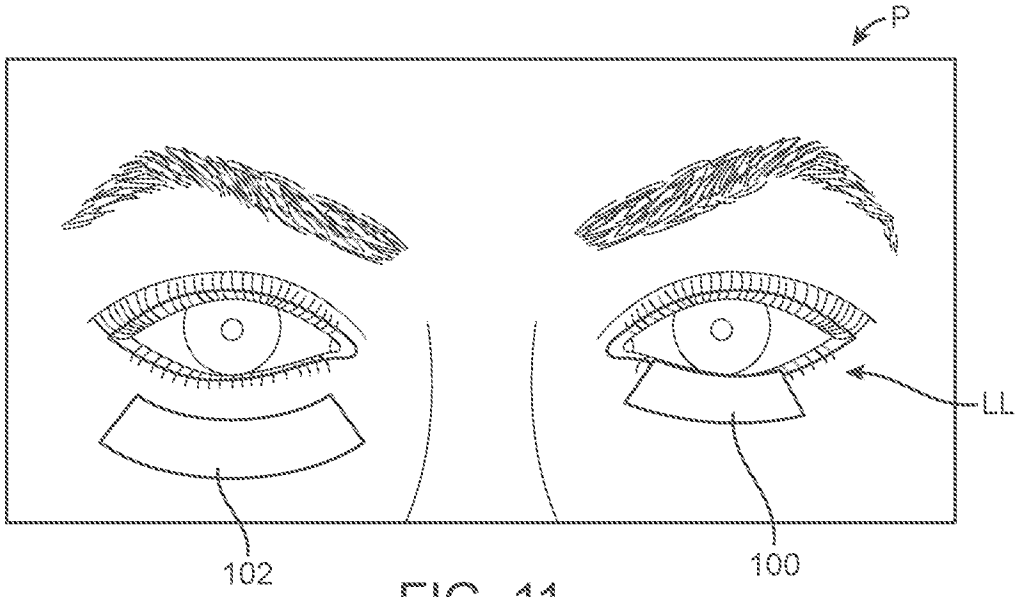


FIG. 11

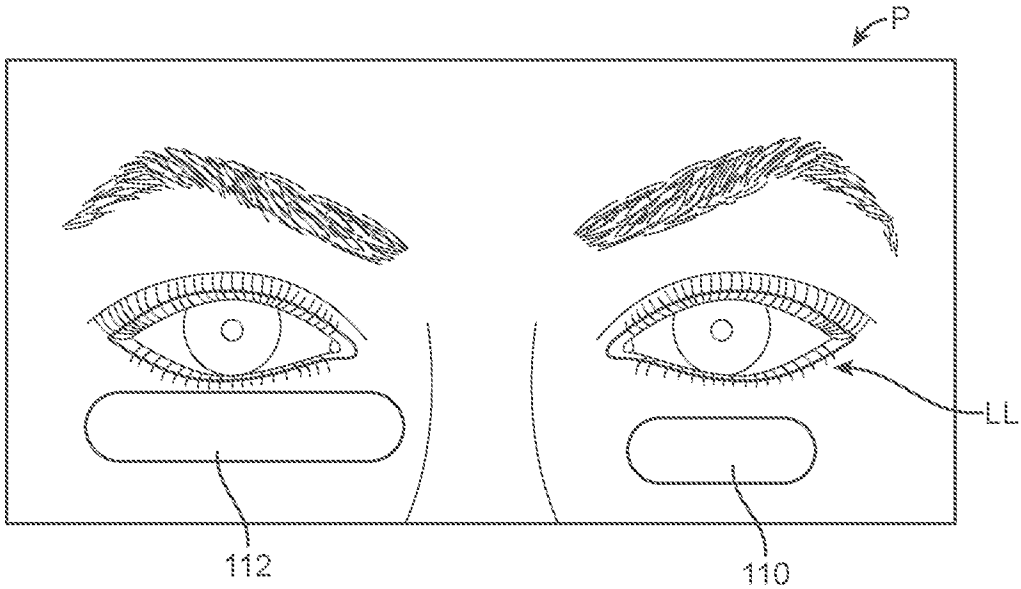


FIG. 12

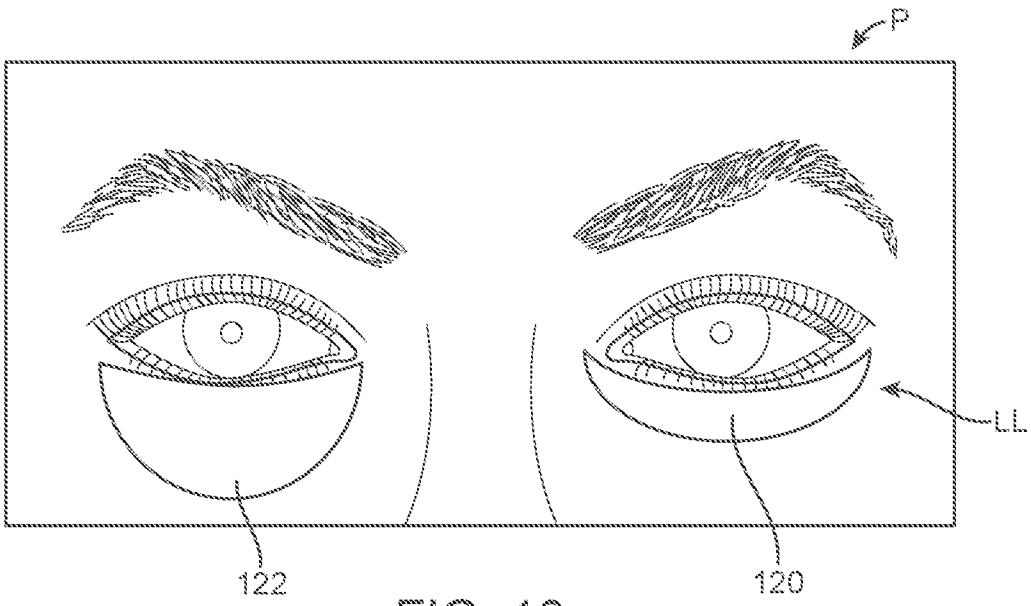


FIG. 13

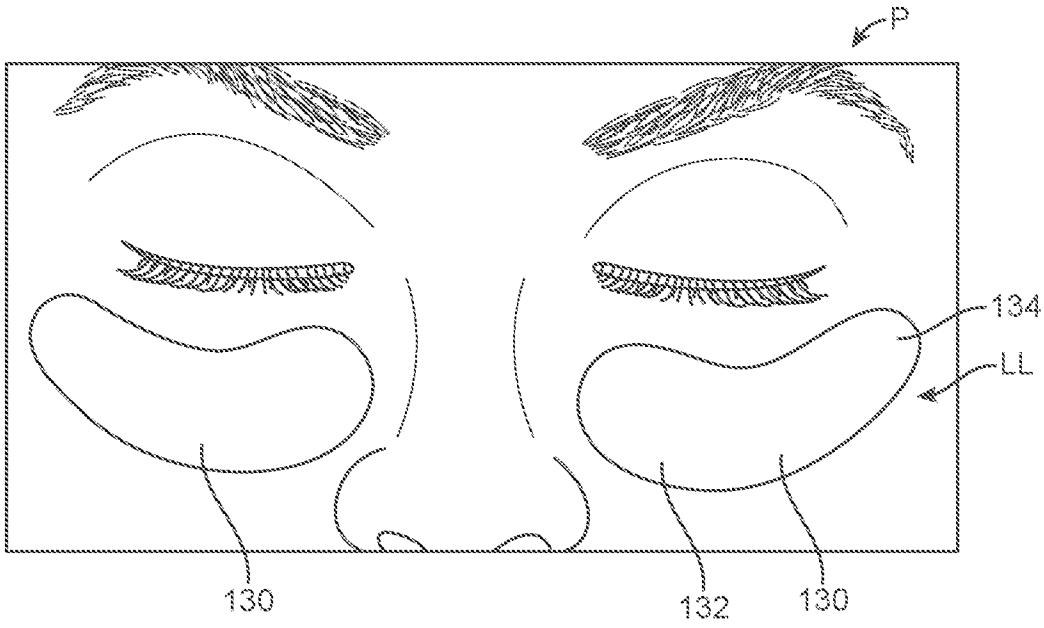


FIG. 14

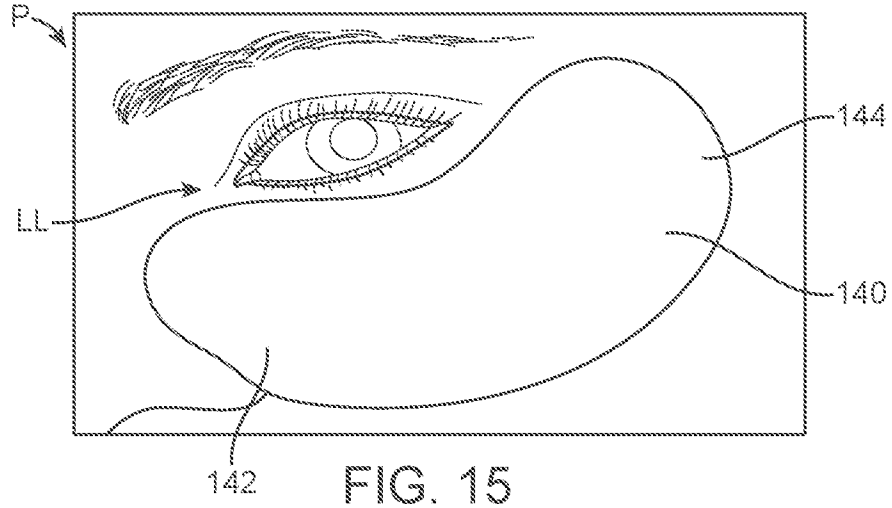


FIG. 15

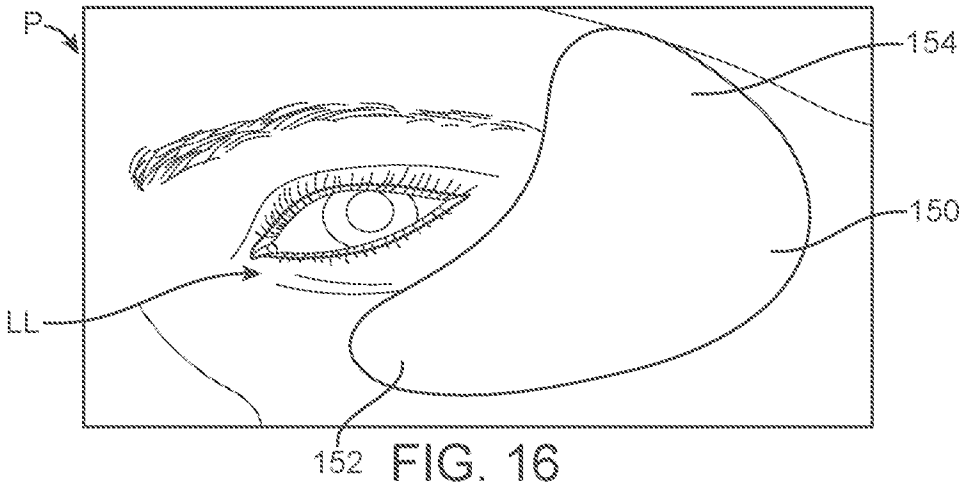


FIG. 16

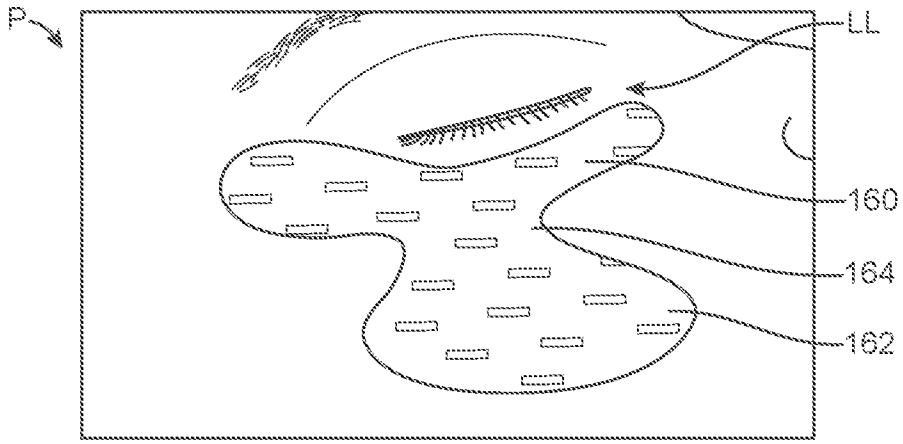


FIG. 17

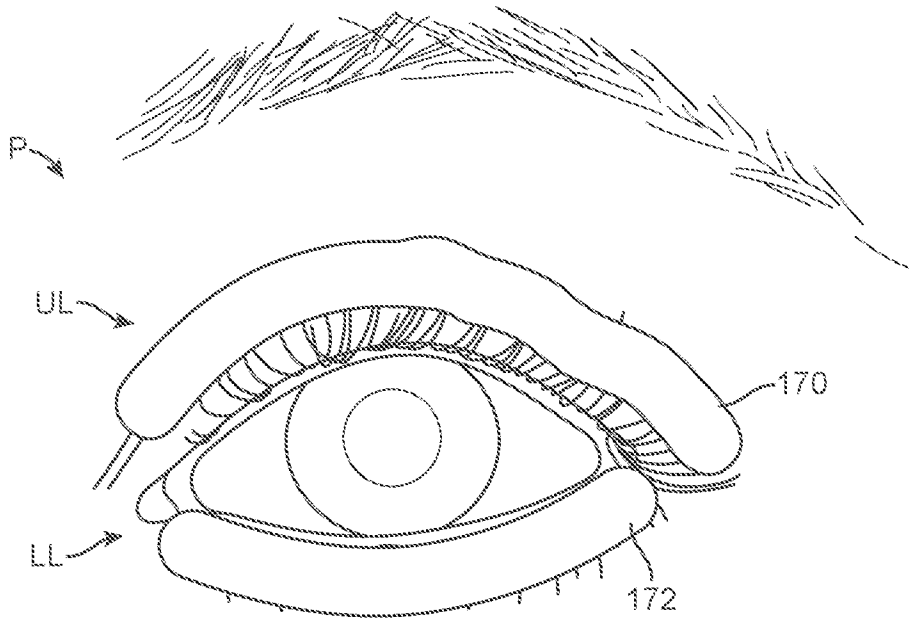


FIG. 18

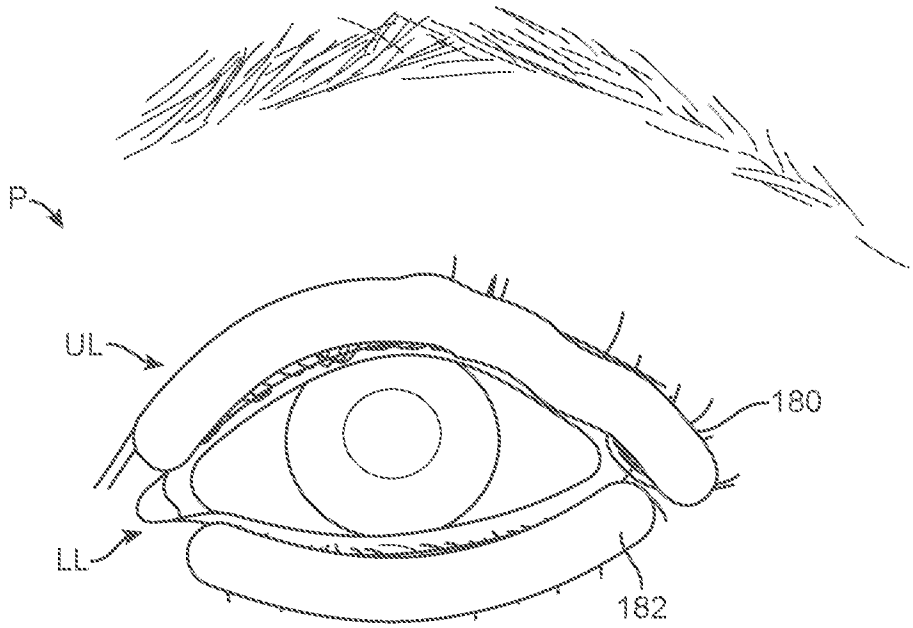


FIG. 19

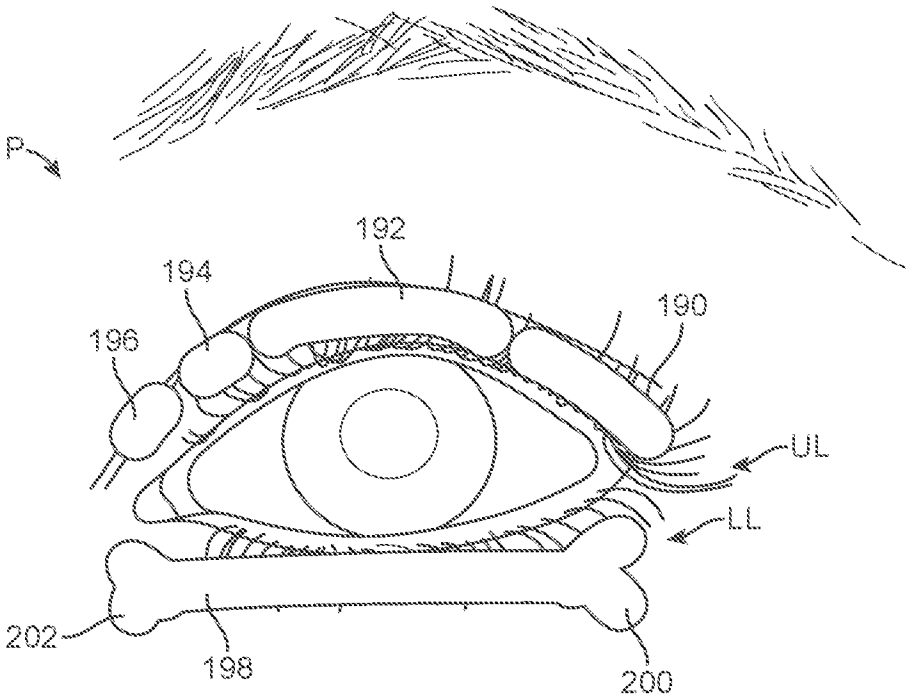


FIG. 20

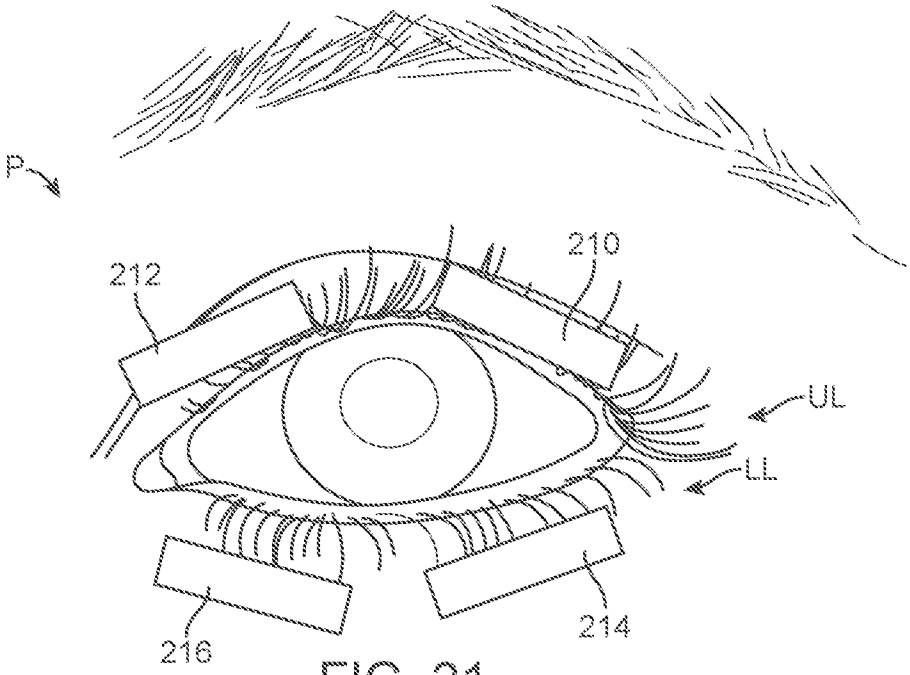


FIG. 21

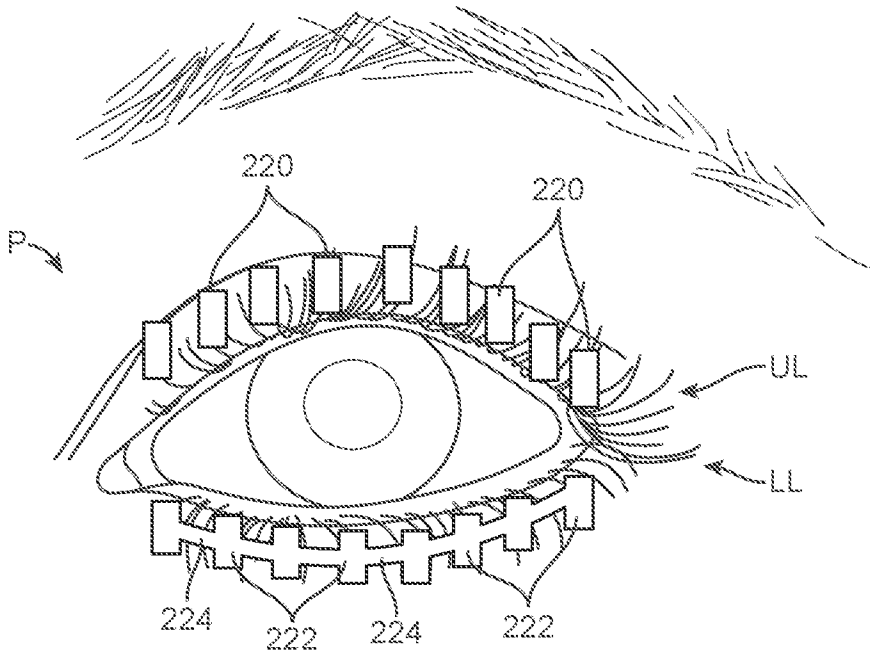


FIG. 22

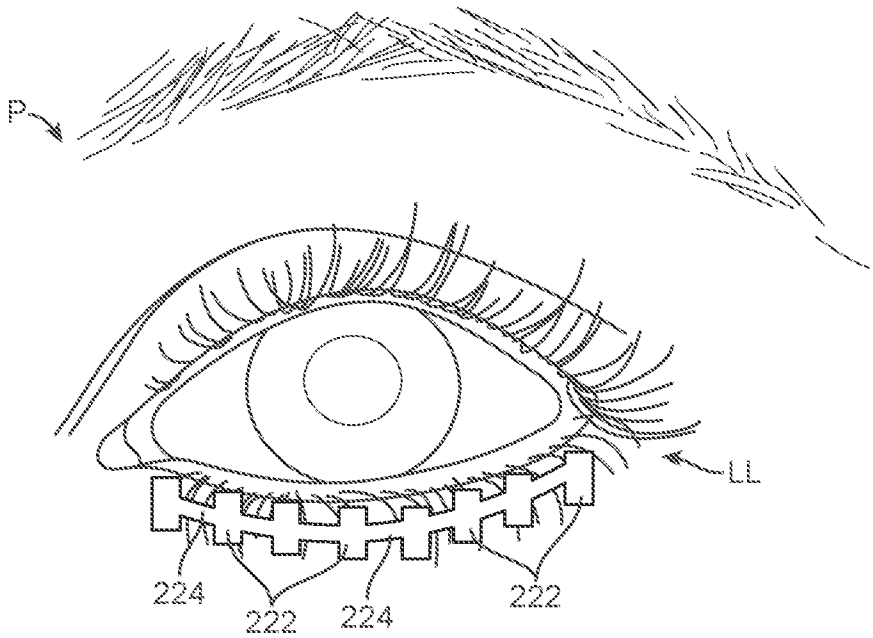


FIG. 23

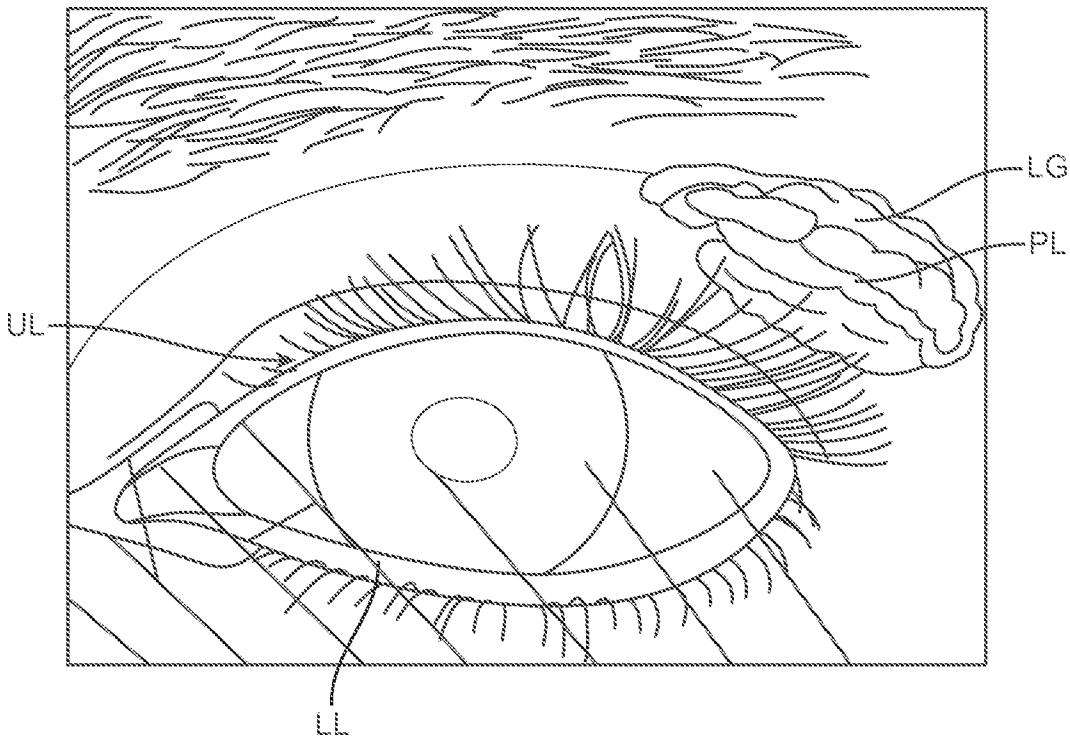


FIG. 24

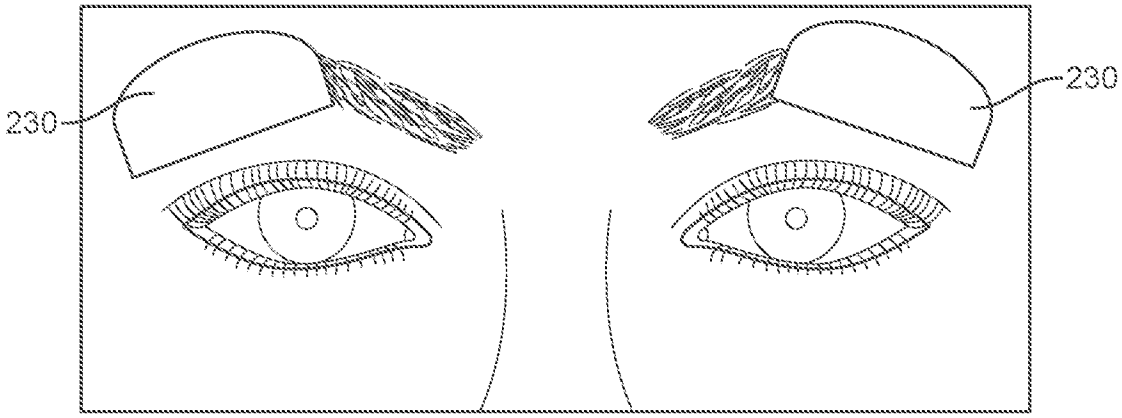


FIG. 25

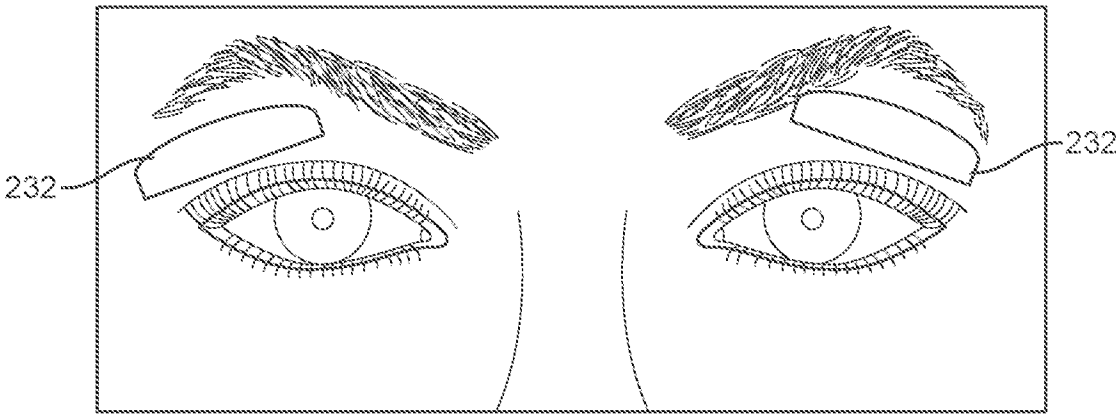


FIG. 26

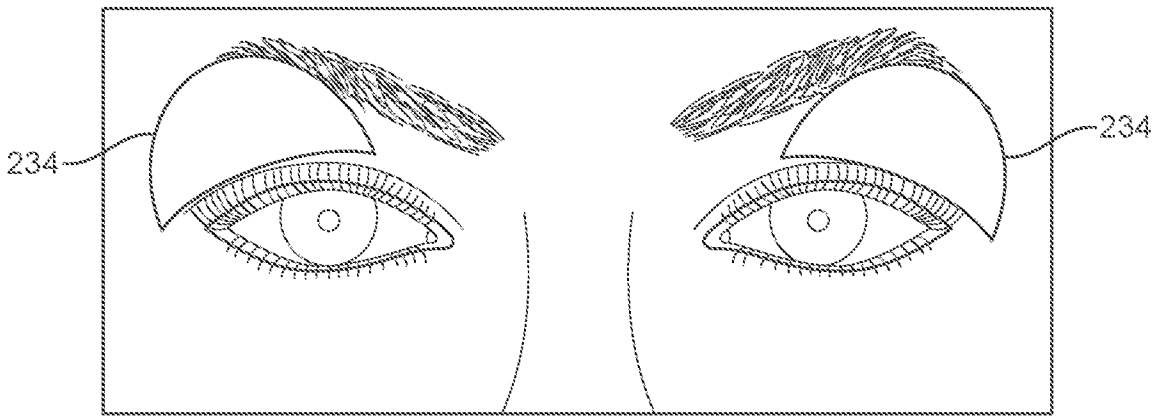


FIG. 27

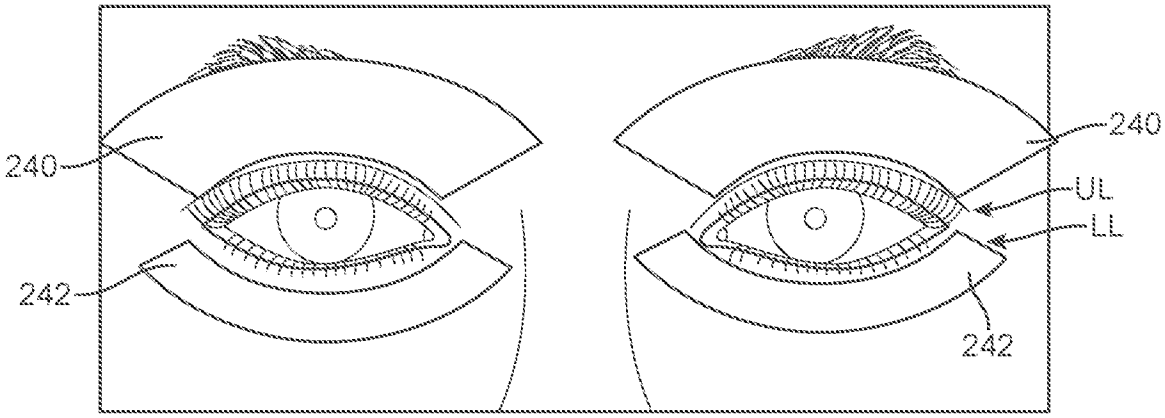


FIG. 28

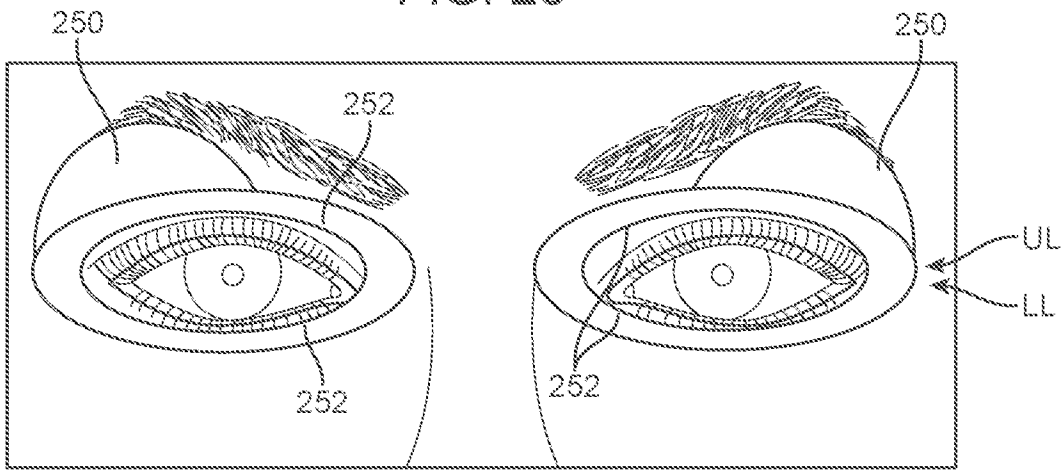


FIG. 29

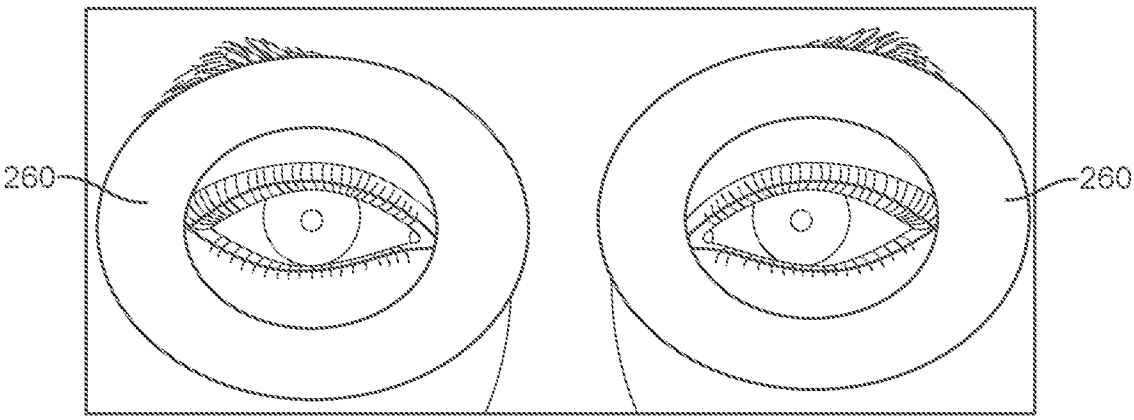


FIG. 30

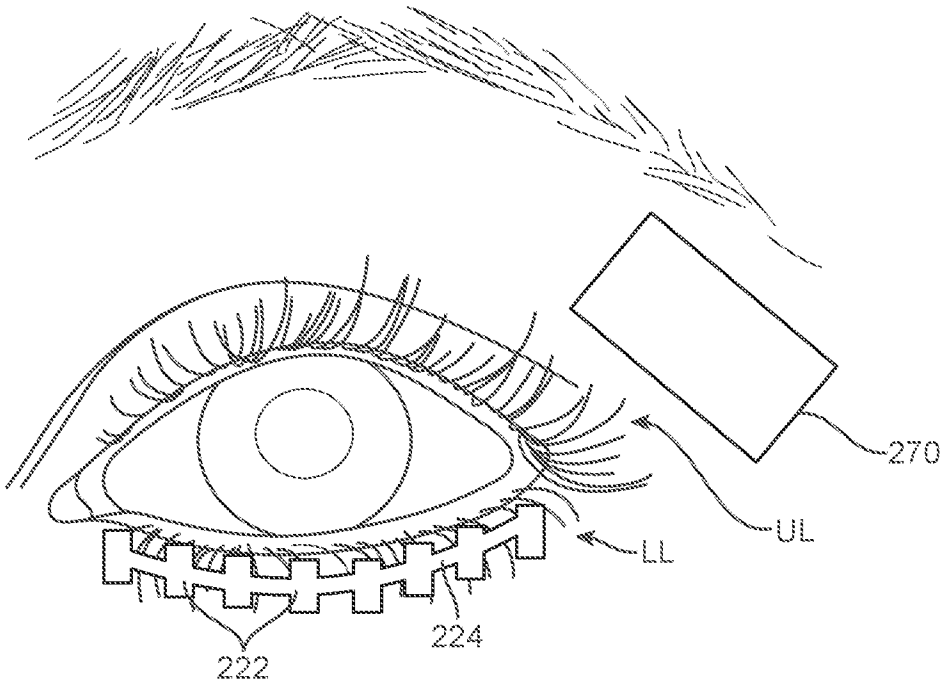


FIG. 31

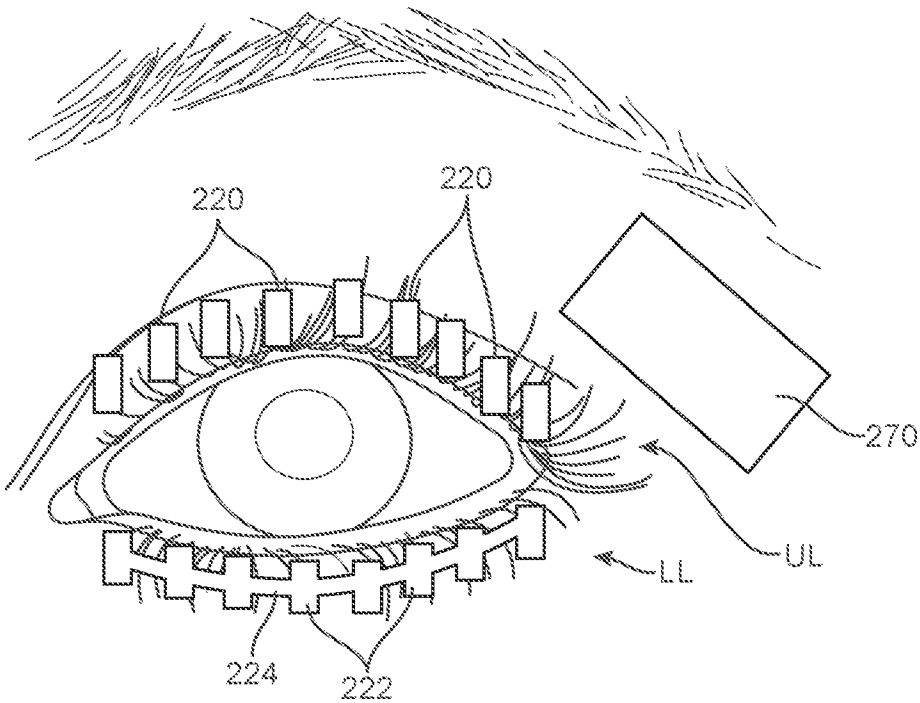


FIG. 32

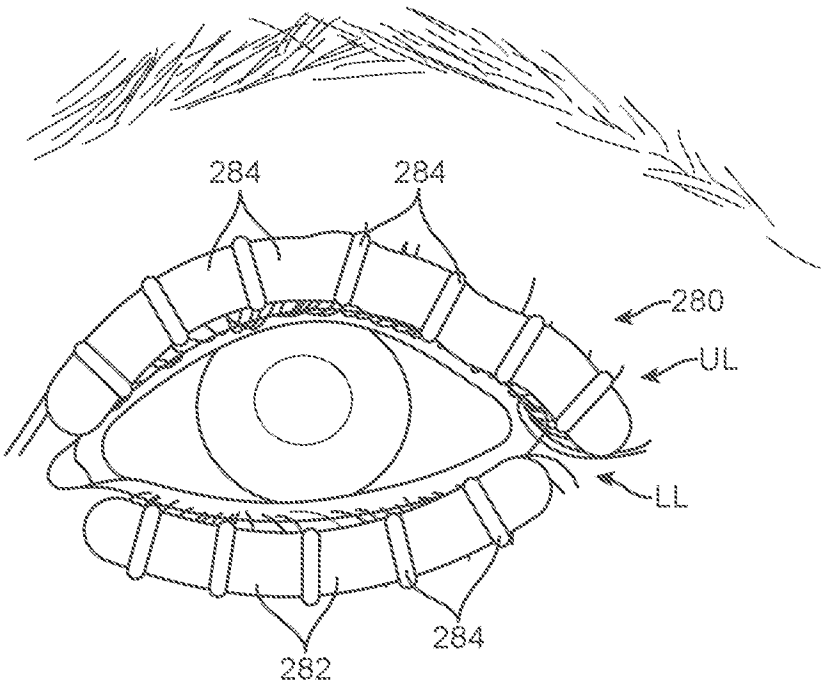


FIG. 33

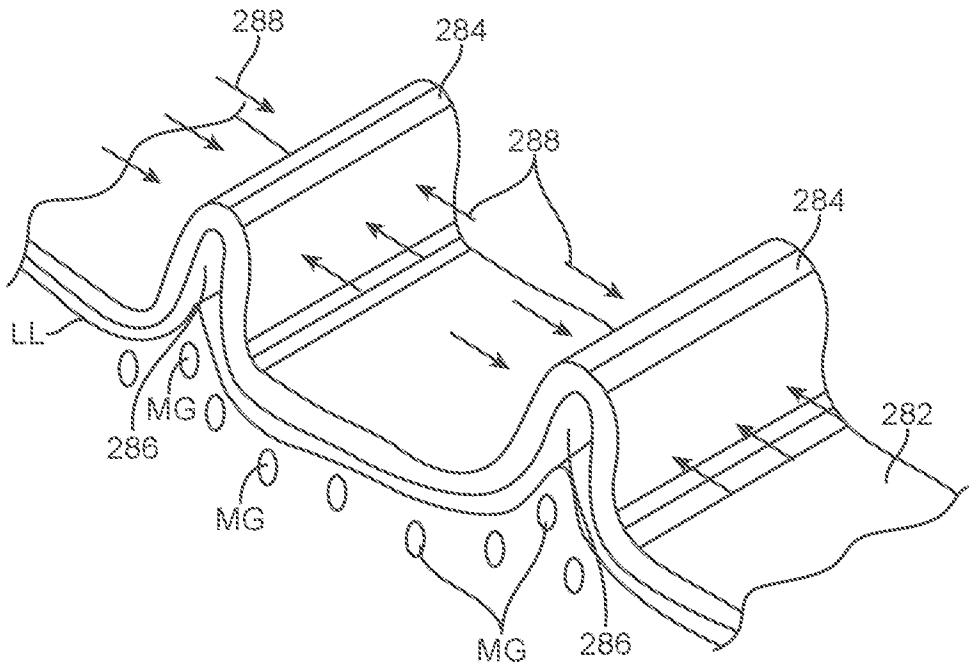


FIG. 34

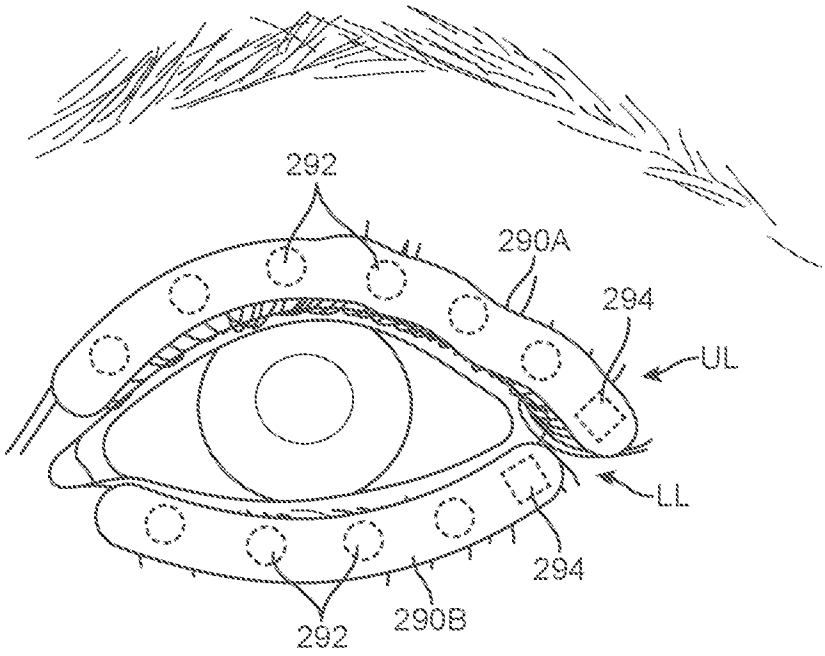


FIG. 35

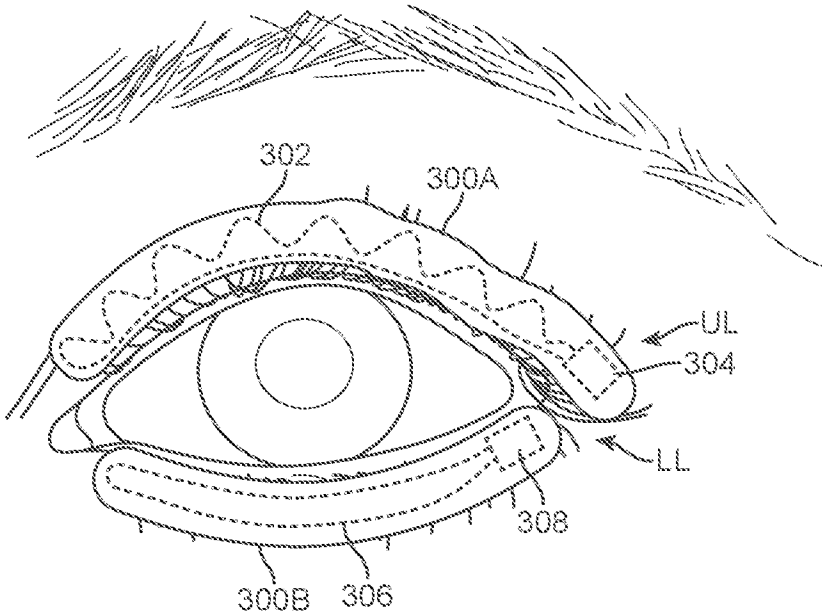


FIG. 36

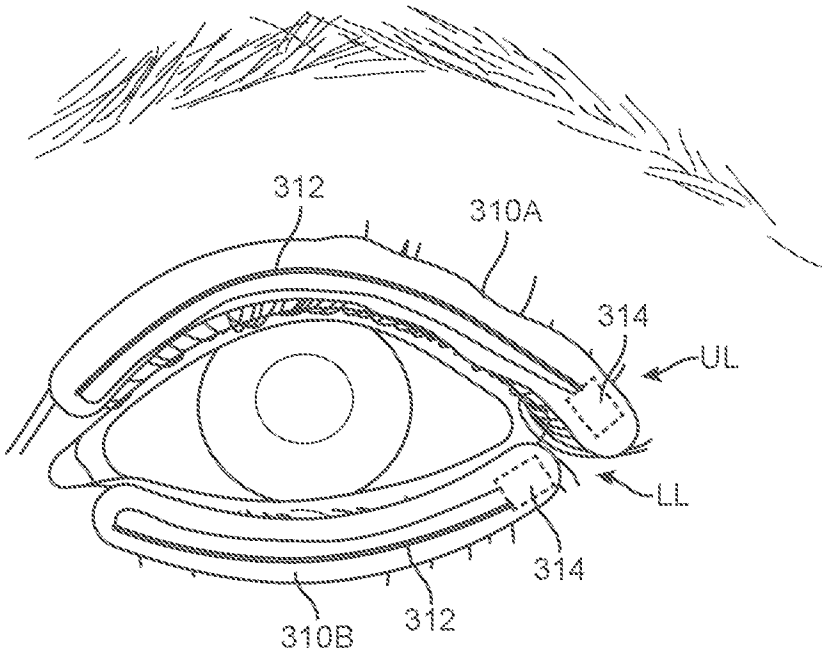


FIG. 37

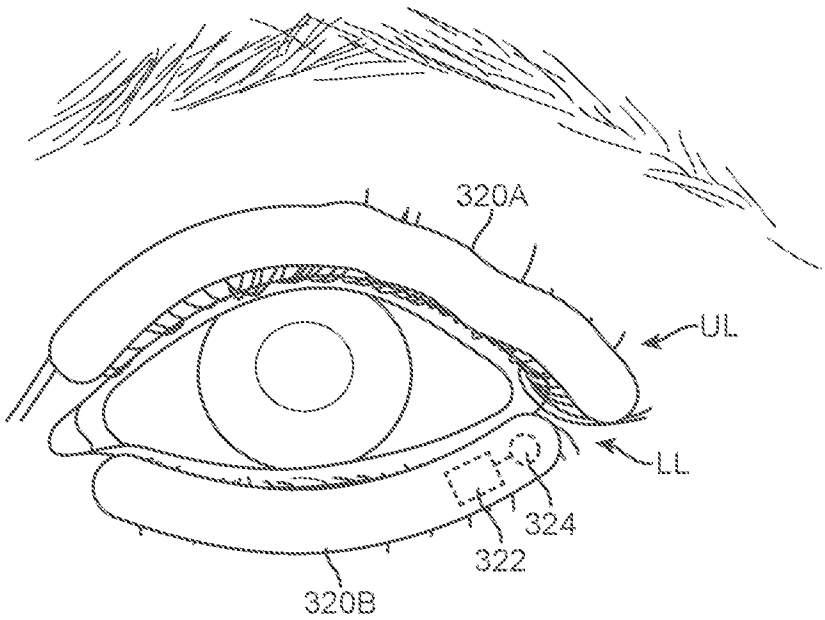


FIG. 38

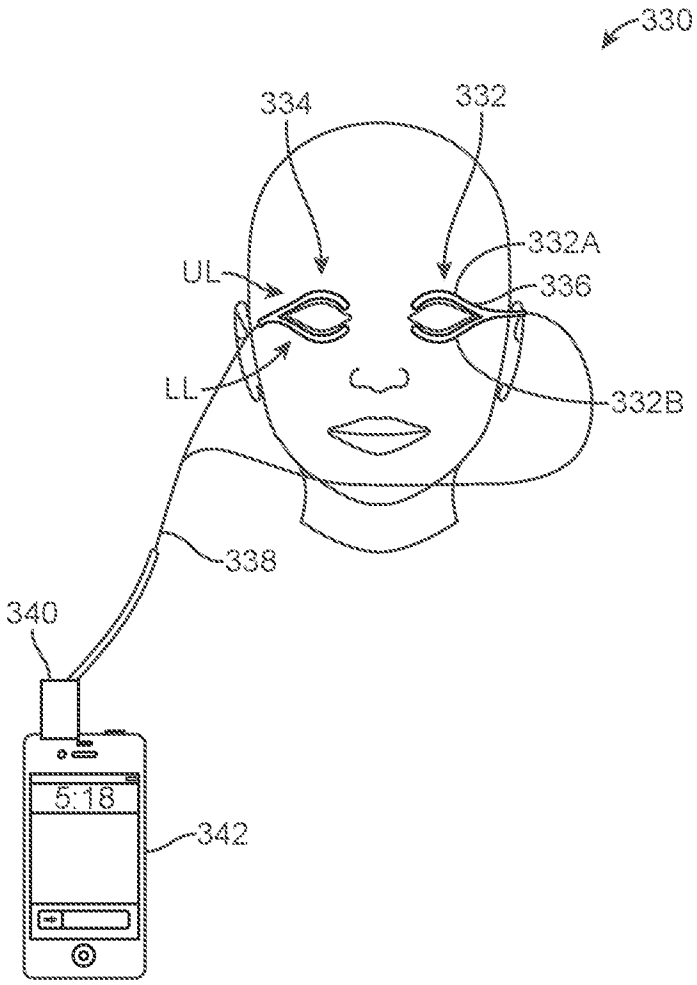


FIG. 39

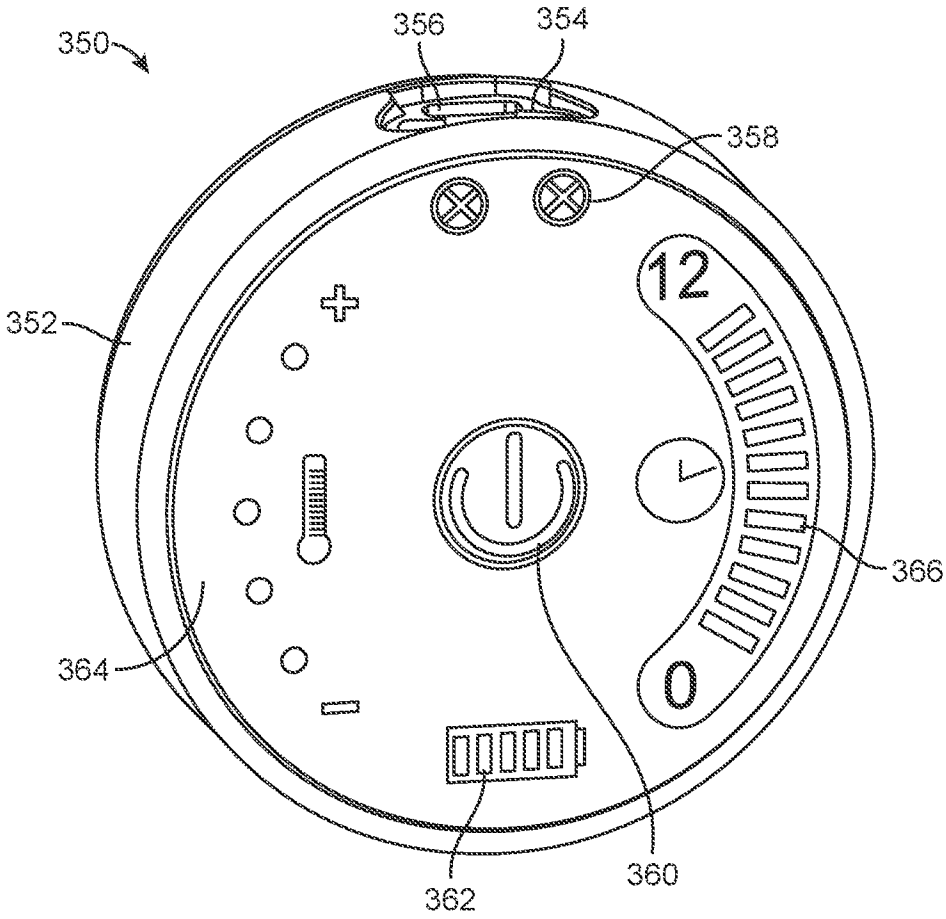


FIG. 40

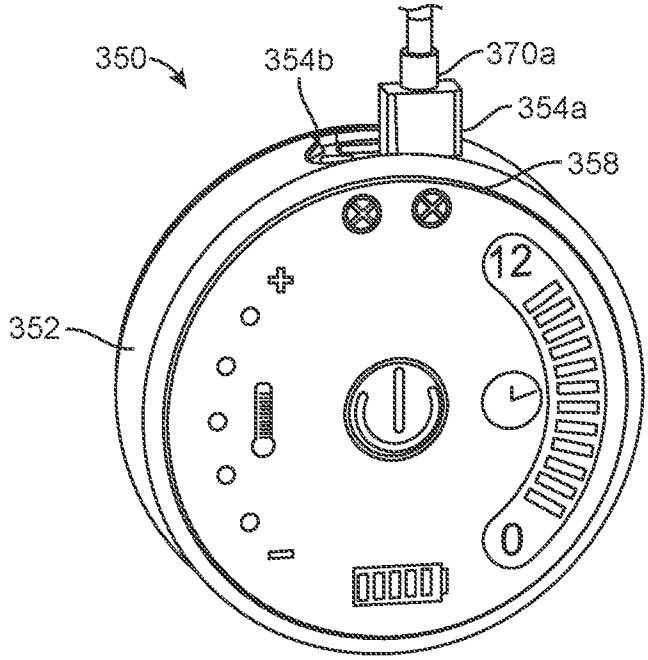


FIG. 41A

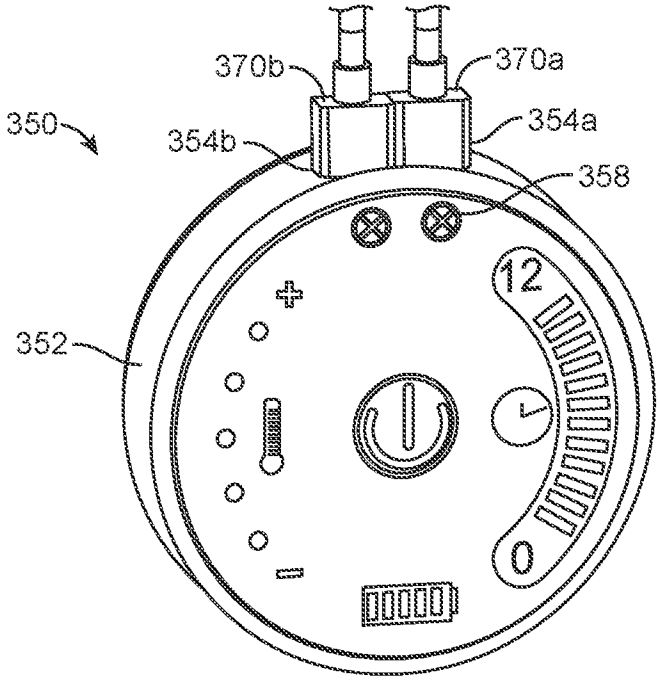


FIG. 41B

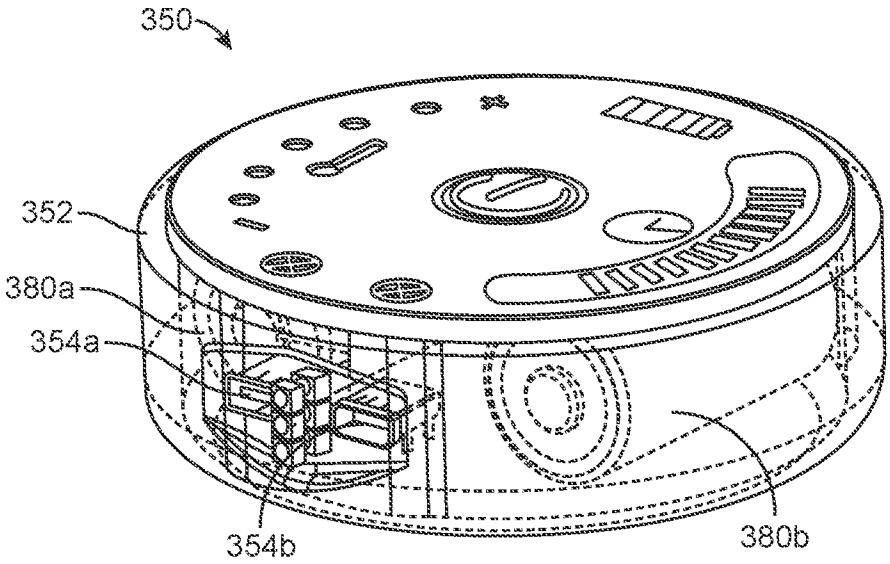


FIG. 42A

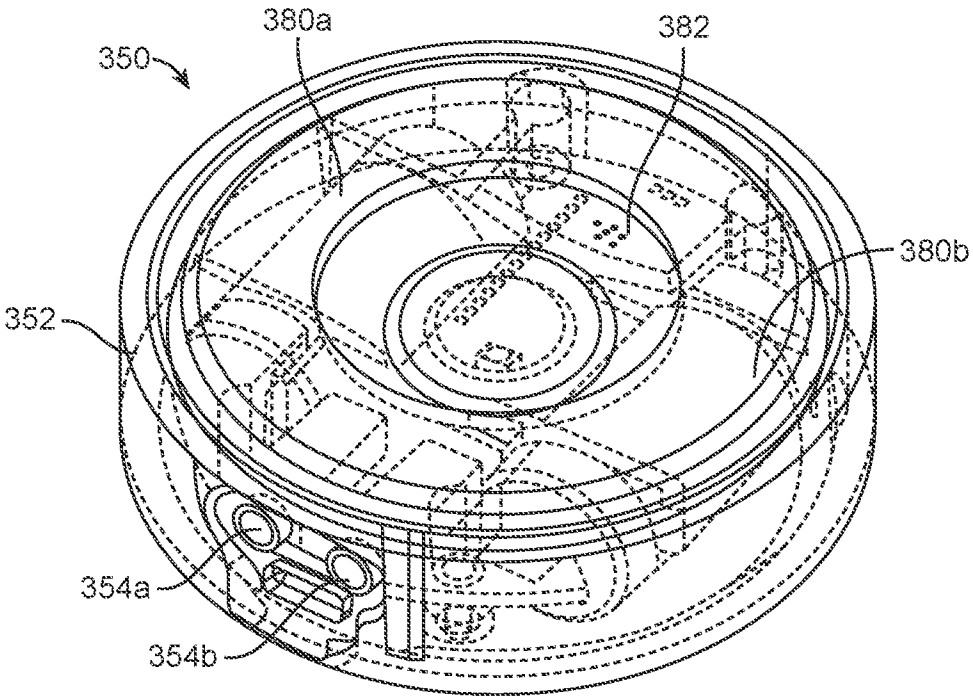


FIG. 42B

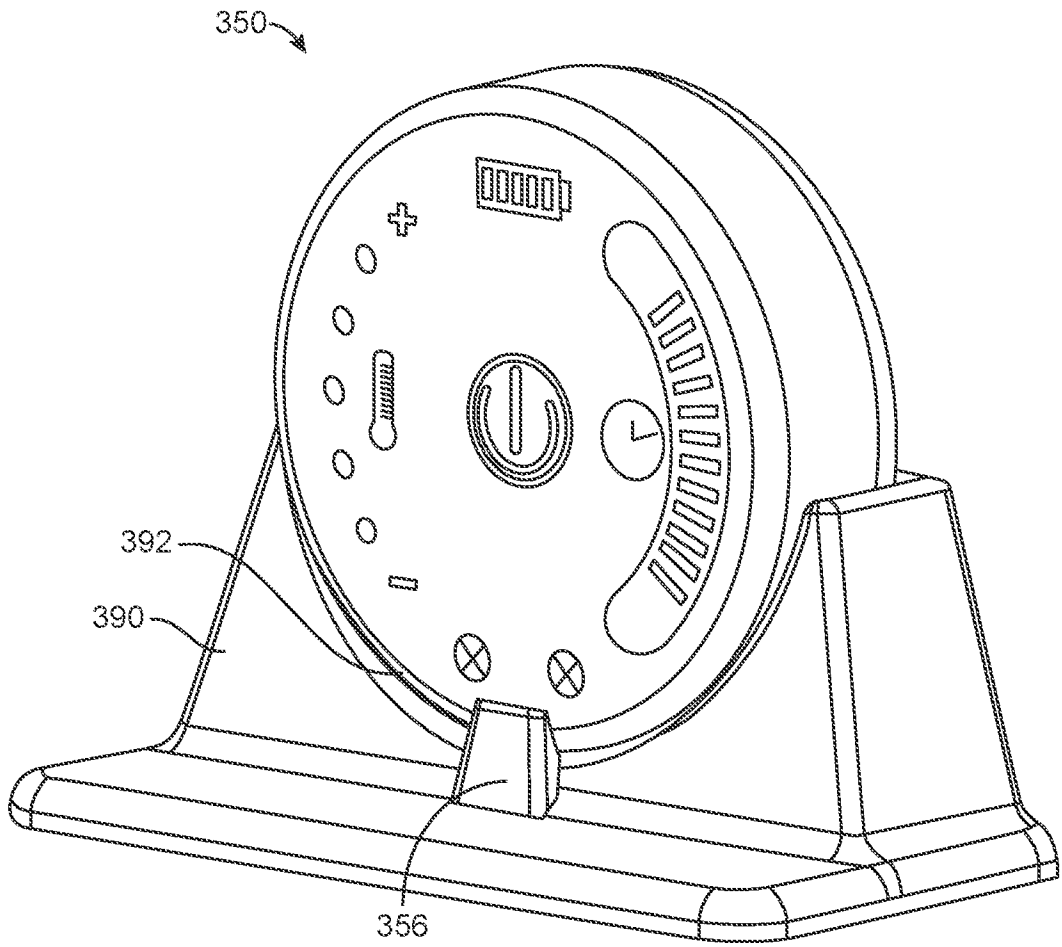


FIG. 43

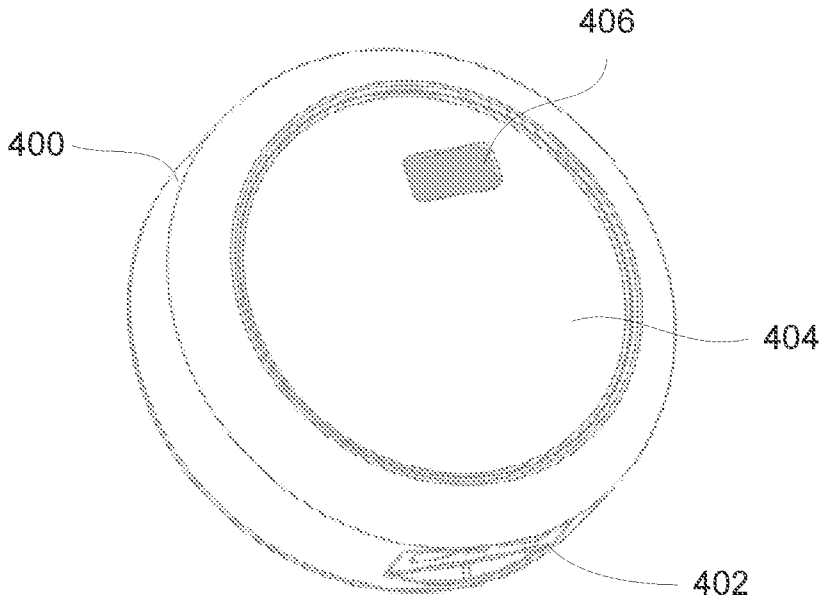


FIG. 44A

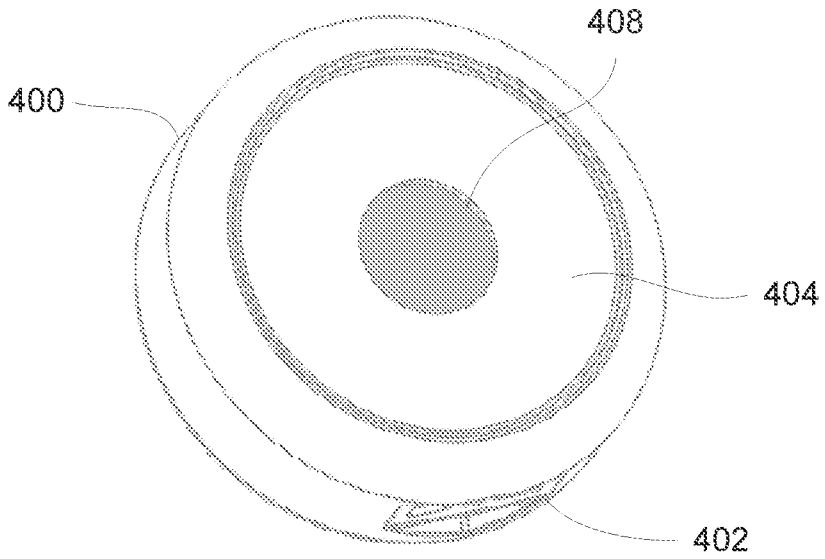


FIG. 44B

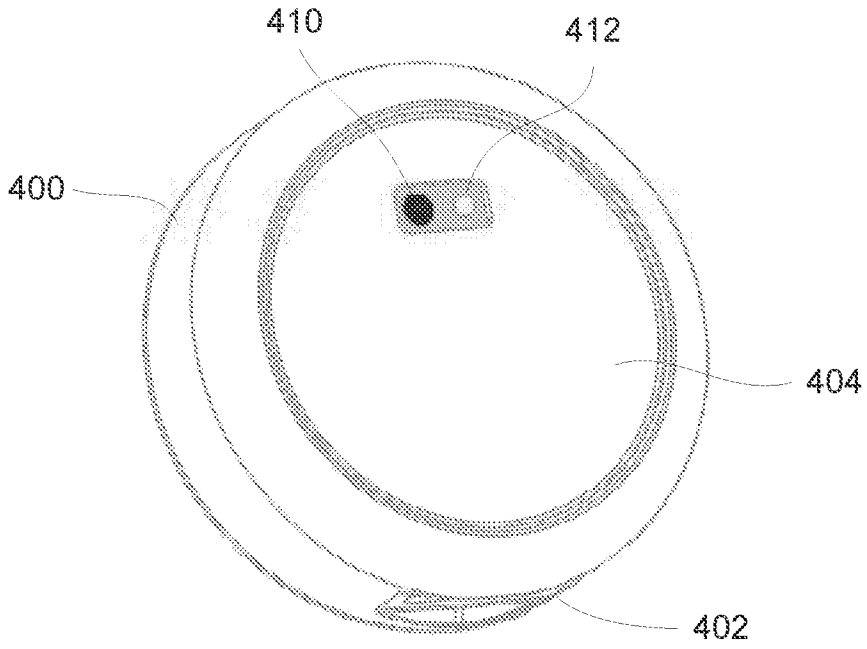


FIG. 45A

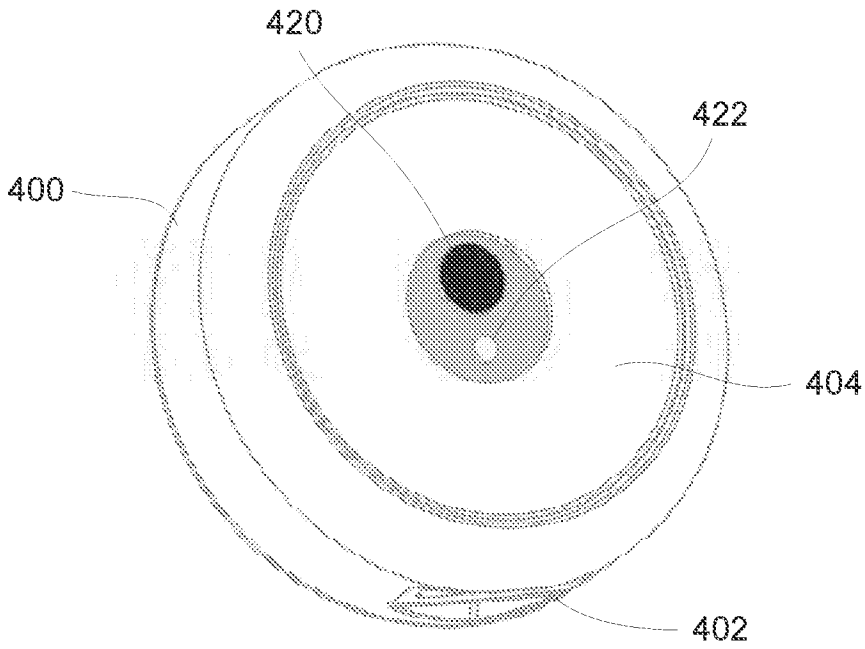


FIG. 45B

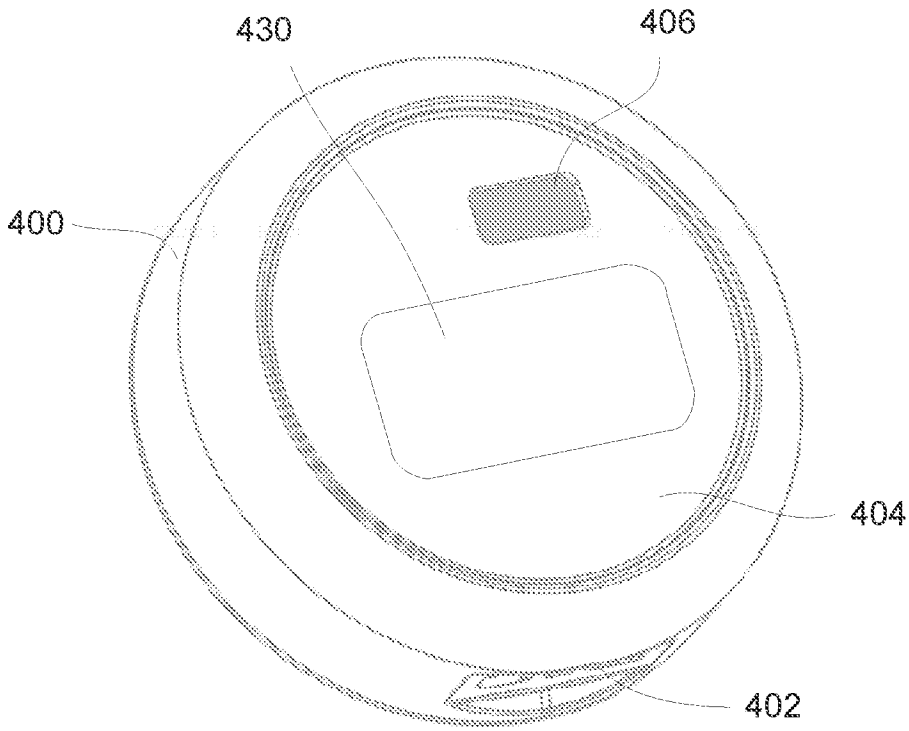


FIG. 46

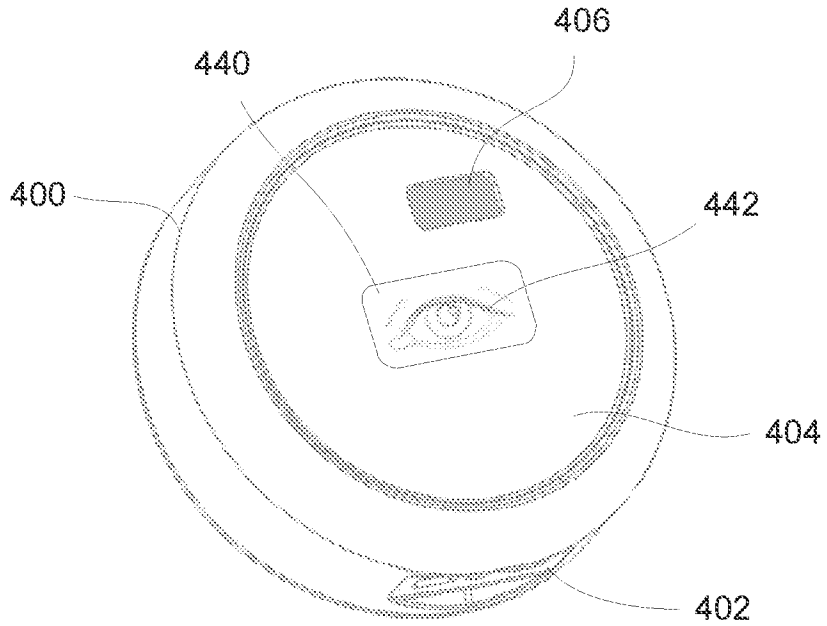


FIG. 47

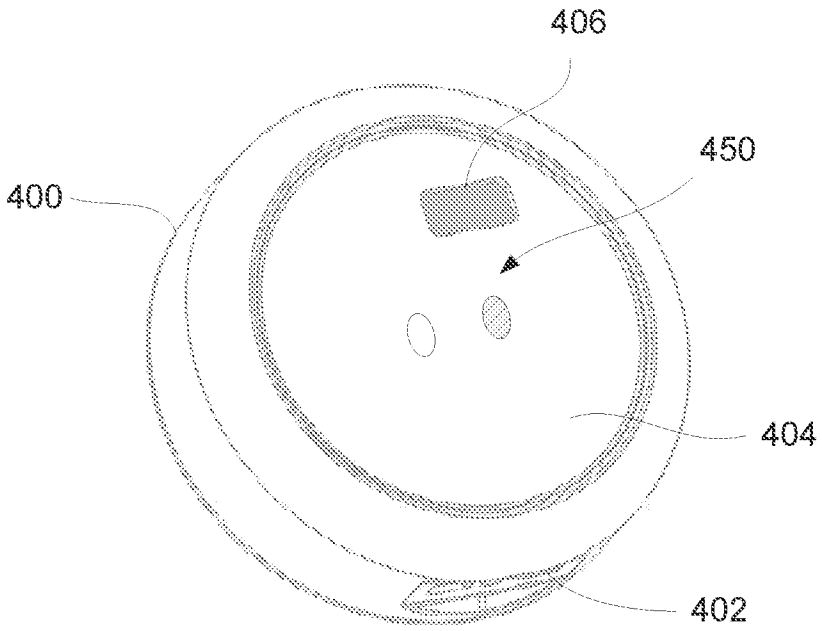


FIG. 48

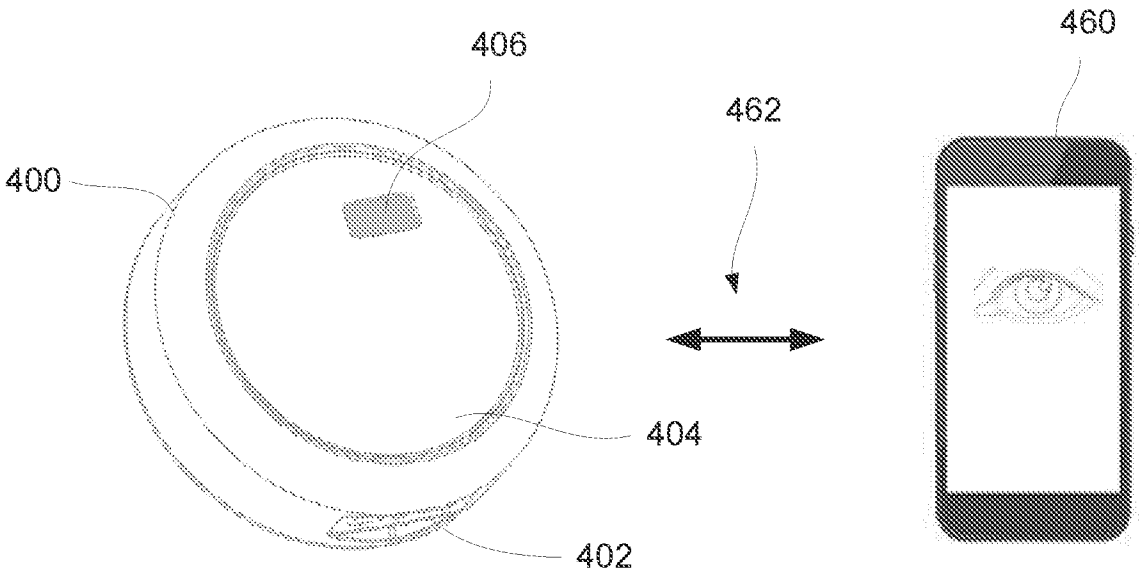


FIG. 49

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2020/044886

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 3/00; A61B 3/02; A61B 3/10; A61B 3/14; A61B 5/00; G06T 7/00 (2020.01)
CPC - A61B 3/0025; A61B 3/0008; A61B 3/0058; A61B 3/101; A61B 3/14; G06T 2207/30041 (2020.08)

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 2017/0087009 A1 (SIGHT SCIENCES INC) 30 March 2017 (30.03.2017) entire document	1-6, 8, 11-15, 18, 19, 21-28
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Y		7, 9, 10, 16, 17, 20
Y	US 2010/0172567 A1 (PROKOSKI) 08 July 2010 (08.07.2010) entire document	7, 16
Y	US 2014/0330129 A1 (TEARSCIENCE INC) 06 November 2014 (06.11.2014) entire document	9, 10, 17, 20
A	WO 1994/011739 A1 (CYMBUS BIOSCIENCE LIMITED et al) 26 May 1994 (26.05.1994) entire document	1-28
A	US 2017/0188805 A1 (PRADEEP) 06 July 2017 (06.07.2017) entire document	1-28
A	US 2002/0180929 A1 (TSENG et al) 05 December 2002 (05.12.2002) entire document	1-28

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
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"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
06 October 2020	20 OCT 2020
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver Telephone No. PCT Helpdesk: 571-272-4300