



US 20130222760A1

(19) **United States**

(12) **Patent Application Publication**
Pugh et al.

(10) **Pub. No.: US 2013/0222760 A1**

(43) **Pub. Date: Aug. 29, 2013**

(54) **METHODS OF MANUFACTURE AND USE OF ENERGIZED OPHTHALMIC DEVICES HAVING AN ELECTRICAL STORAGE MODE**

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(21) Appl. No.: **13/799,278**

(22) Filed: **Mar. 13, 2013**

Related U.S. Application Data

(63) Continuation-in-part of application No. 13/781,494, filed on Feb. 28, 2013.

(60) Provisional application No. 61/604,206, filed on Feb. 28, 2012.

Publication Classification

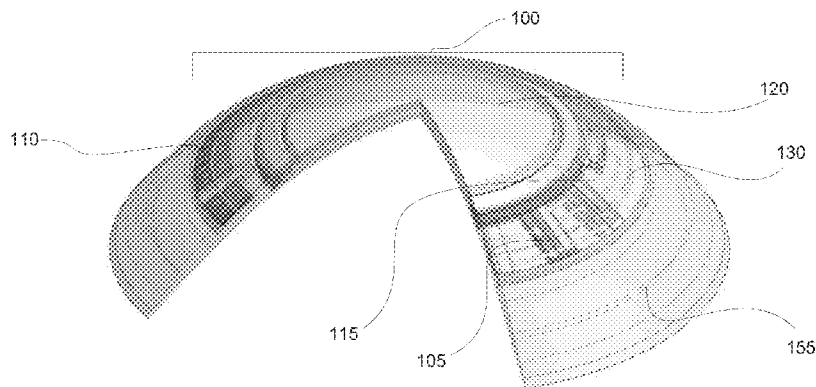
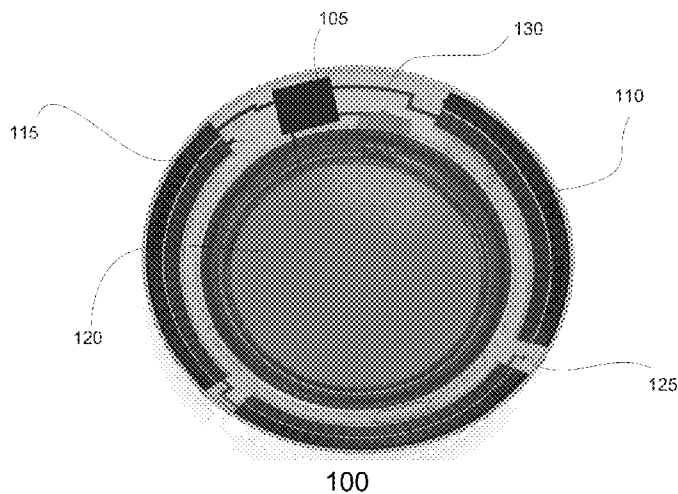
(51) **Int. Cl.**
G02C 7/04 (2006.01)

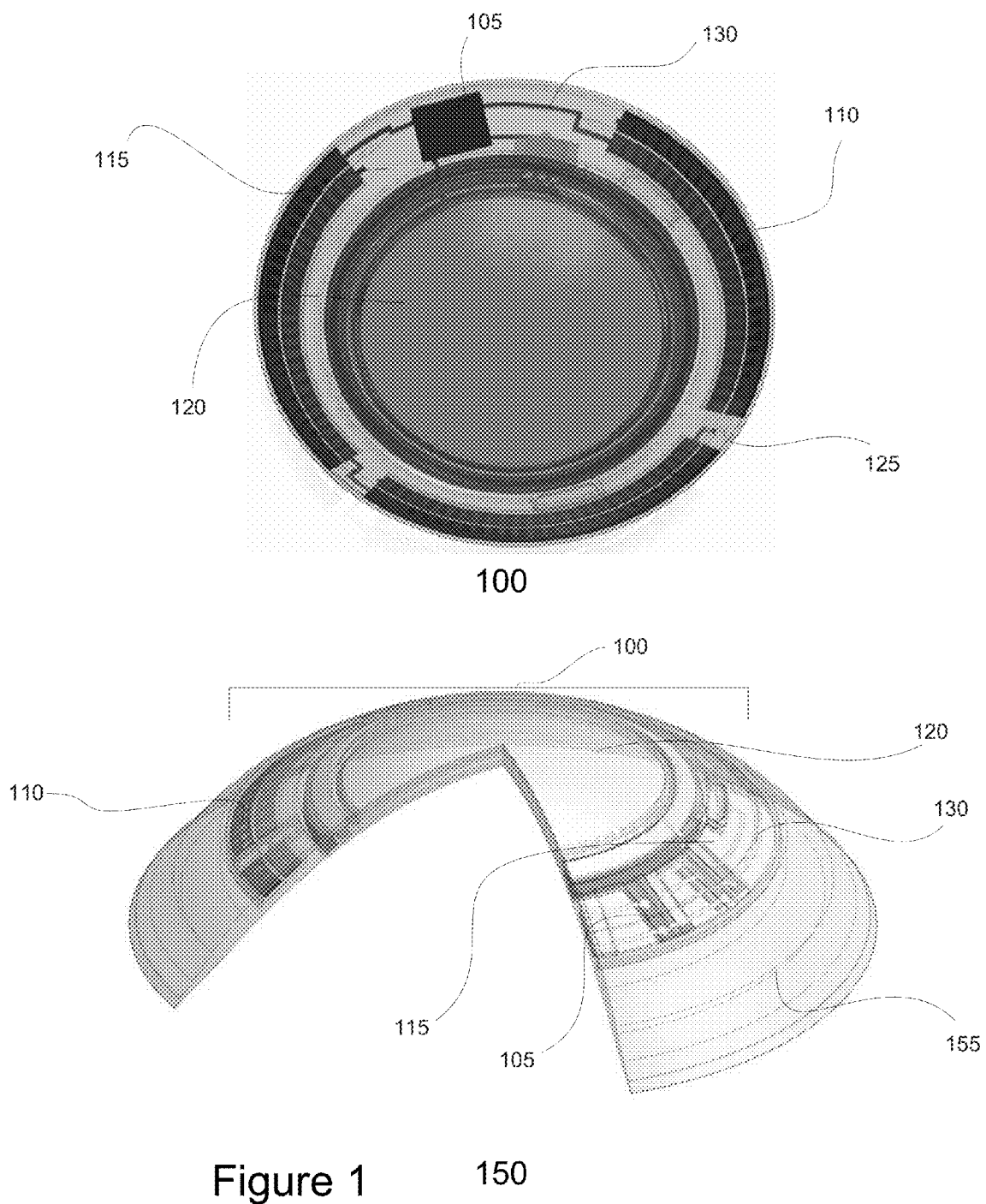
G02C 7/02 (2006.01)

(52) **U.S. Cl.**
CPC . **G02C 7/04** (2013.01); **G02C 7/022** (2013.01)
USPC **351/159.03**; 351/159.73; 351/159.39

ABSTRACT

This invention discloses methods of manufacture and use of an energized Ophthalmic Device with an incorporated Storage Mode for a power source, the method of manufacturing said device, and a method of activation that may restore the power source to an operational mode.





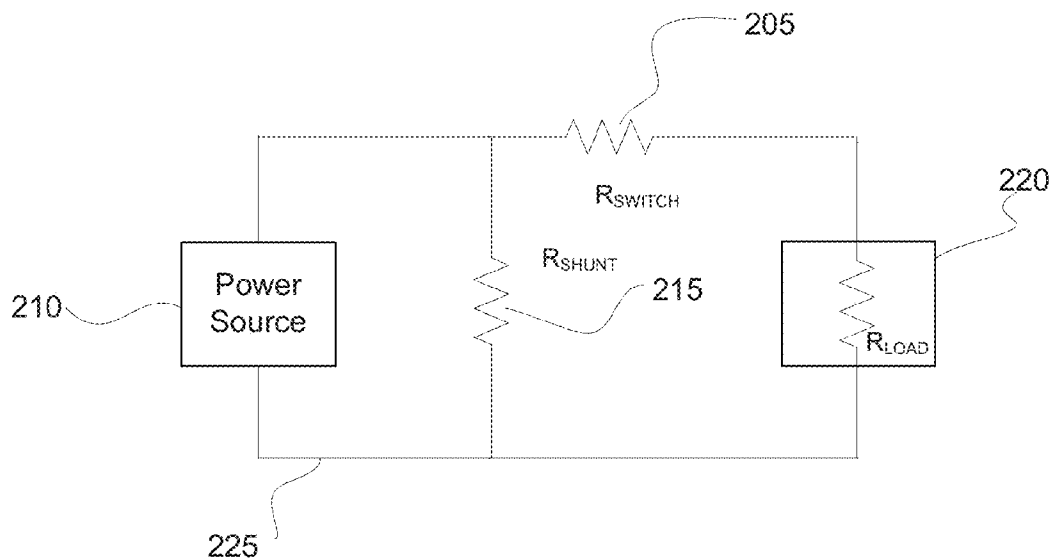


Figure 2

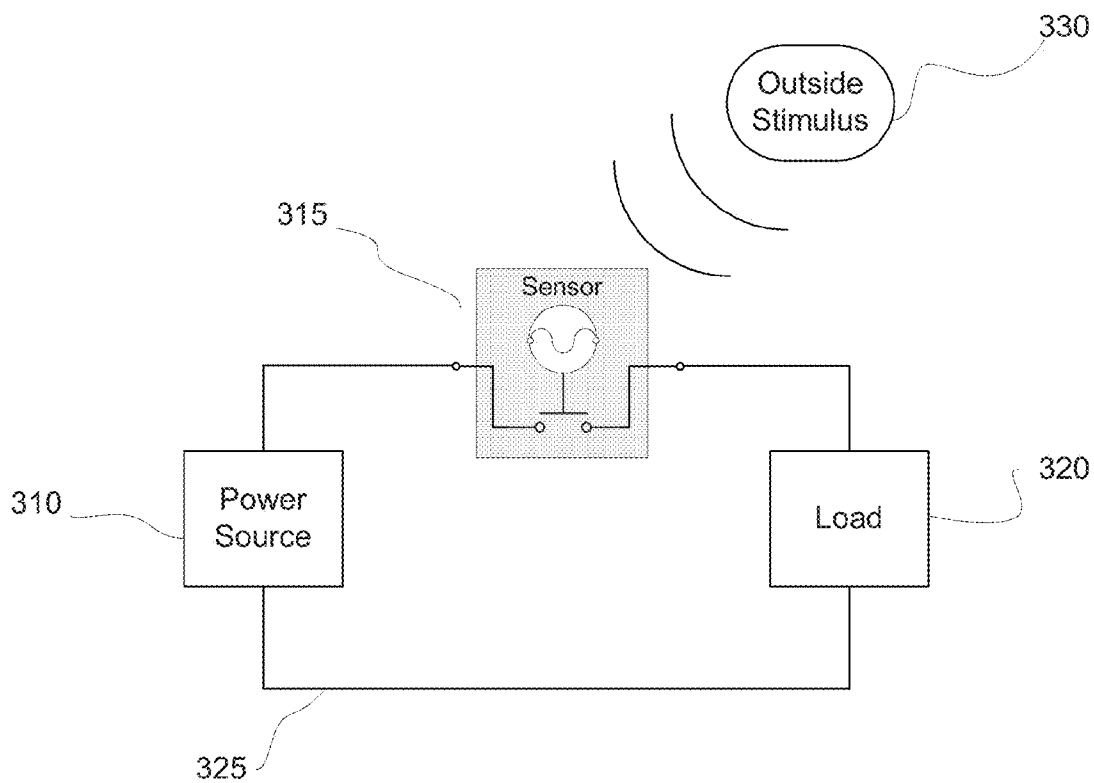


Figure 3

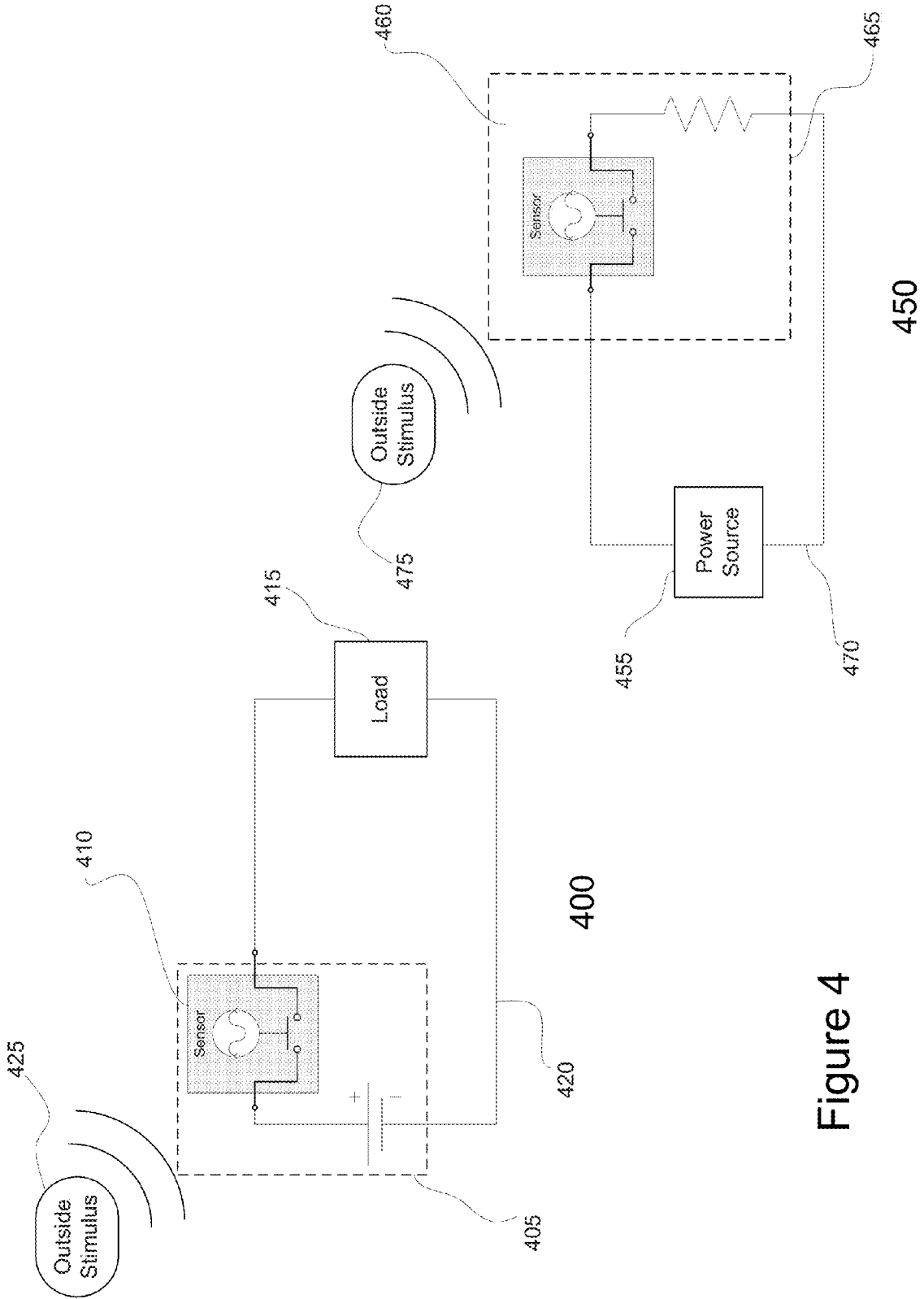


Figure 4

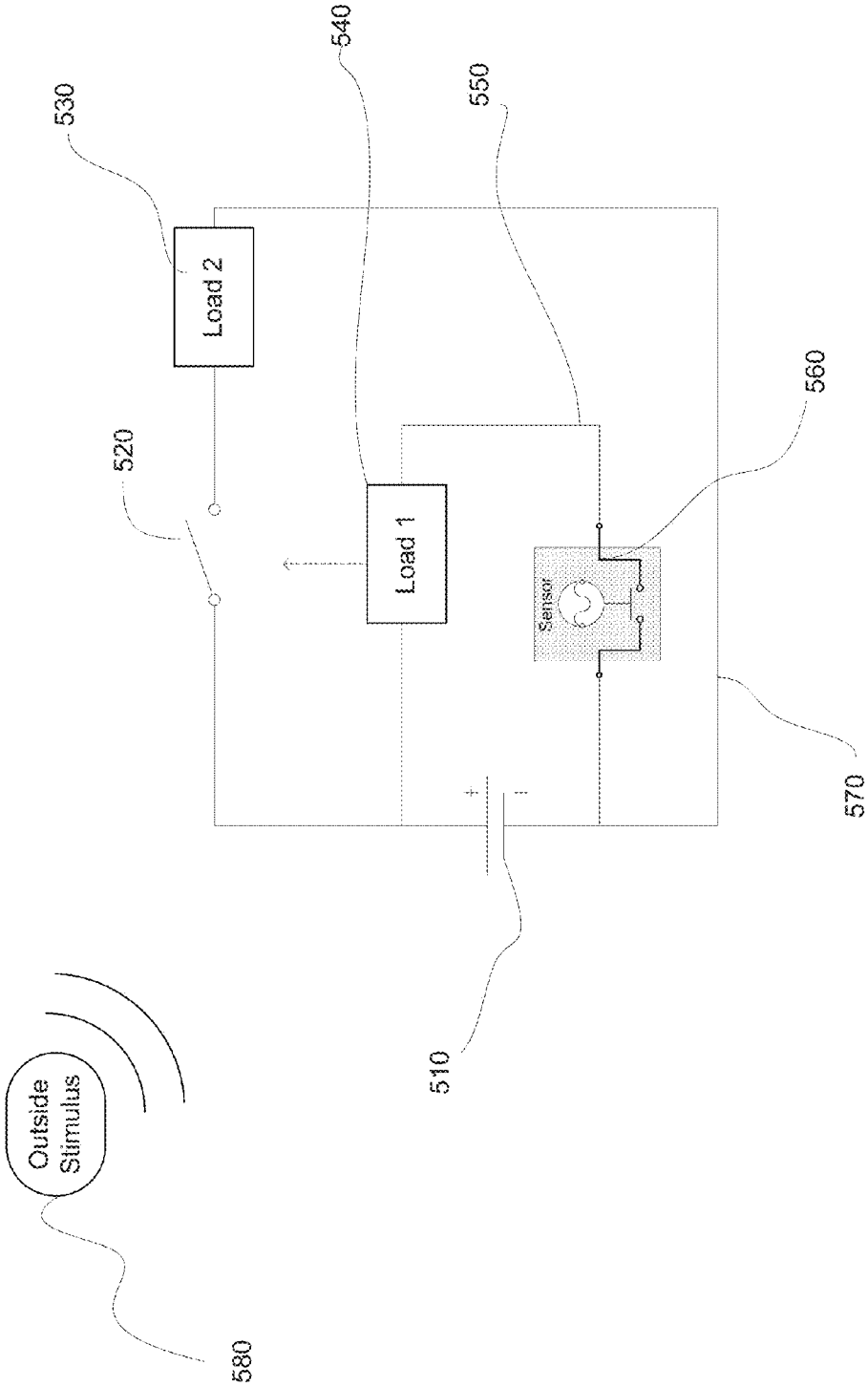


Figure 5

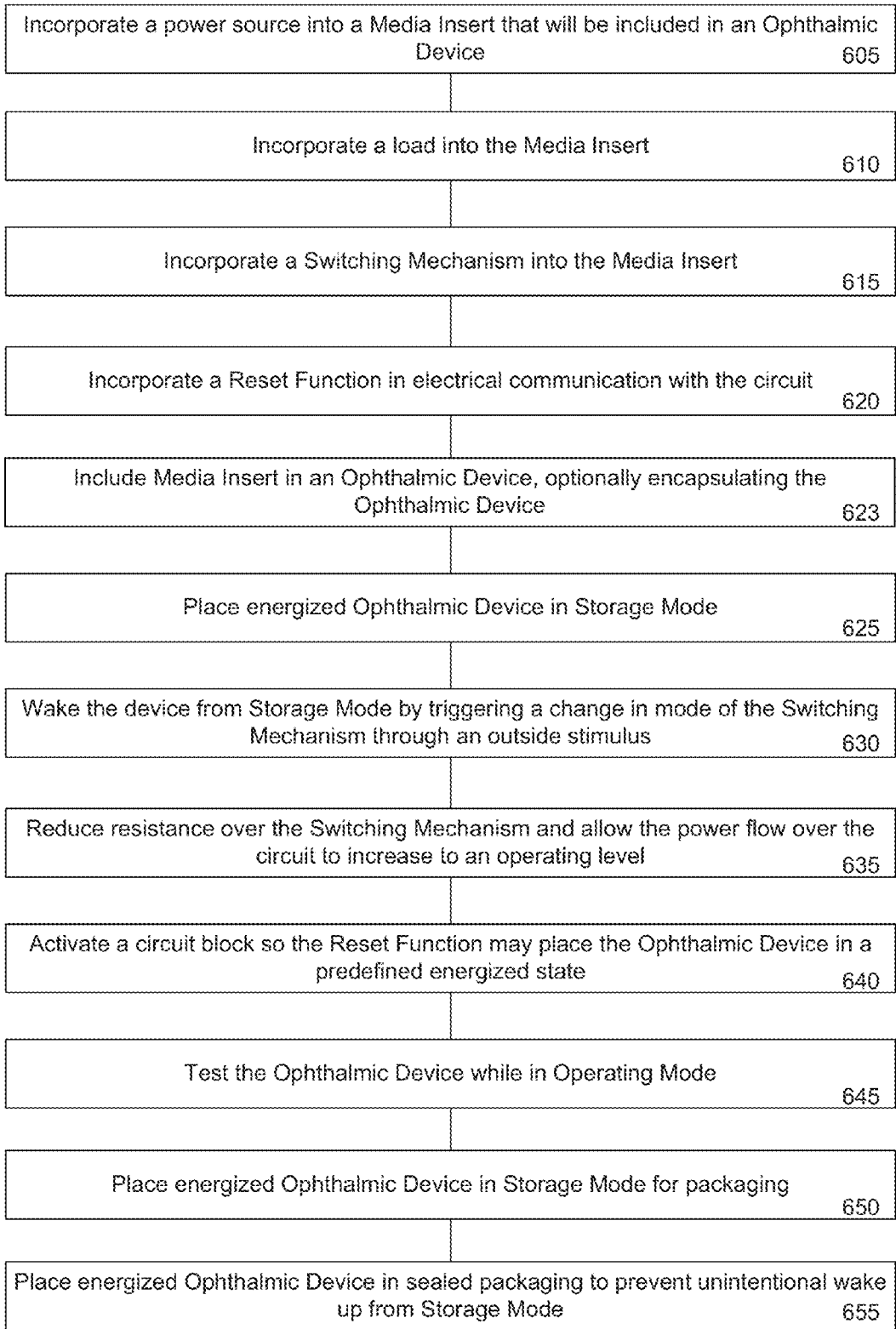


Figure 6

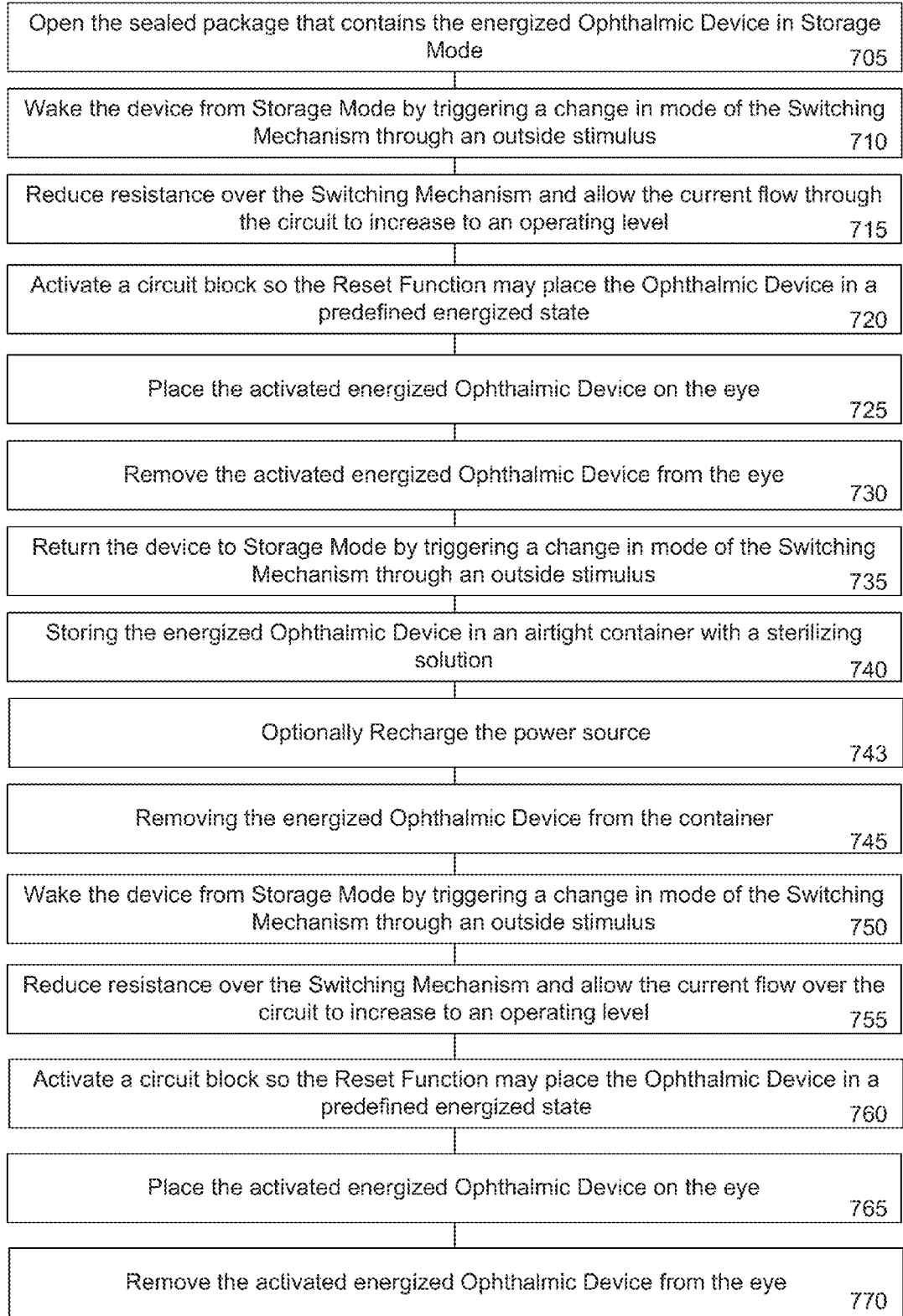


Figure 7

METHODS OF MANUFACTURE AND USE OF ENERGIZED OPHTHALMIC DEVICES HAVING AN ELECTRICAL STORAGE MODE

RELATED APPLICATIONS

[0001] This application claims priority as a Continuation in Part Patent Application to patent application Ser. No. 13/781, 494, filed Feb. 28, 2013, a U.S. Non-Provisional Patent Application entitled Methods And Apparatus To Form Electronic Circuitry on Ophthalmic Devices which claims priority to Provisional Patent Application No. 61/604206, entitled Methods And Apparatus To Form Electronic Circuitry on Ophthalmic Devices on Feb. 28, 2012.

FIELD OF USE

[0002] This invention describes the methods of manufacture and use of an energized Ophthalmic Device with a Media Insert with a Storage Mode, and more specifically, where the Media Insert incorporates a Switching Mechanism that may be placed in a Storage Mode and in an Operating Mode.

BACKGROUND

[0003] Traditionally, an Ophthalmic Device, such as a contact lens, an intraocular lens, or a punctal plug, included a biocompatible device with a corrective, cosmetic, or therapeutic quality. A contact lens, for example, may provide one or more of vision correcting functionality, cosmetic enhancement, and therapeutic effects. Each function is provided by a physical characteristic of the lens. A design incorporating a refractive quality into a lens may provide a vision corrective function. A pigment incorporated into the lens may provide a cosmetic enhancement. An active agent incorporated into a lens may provide a therapeutic functionality. Such physical characteristics are accomplished without the lens entering into an energized state. A punctal plug has traditionally been a passive device.

[0004] More recently, active components have been incorporated into a contact lens. Some components may include semiconductor devices. Some examples have shown semiconductor devices incorporated in a contact lens placed upon animal eyes. It has also been described how the active components may be energized and activated in numerous manners within the lens structure itself. The topology and size of the space defined by the lens structure creates a novel and challenging environment for the definition of various functionalities. It is important to provide reliable, compact, and cost effective means to interconnect and attach the components upon form factors consistent with the ophthalmic environment.

[0005] Including energization elements in an Ophthalmic Device adds the issue of loss of energization between the manufacturing date and the date of actual use of the device. One of the more significant causes of loss of energization may be the leakage of electrical current through devices and structures that connect physically and electrically with the energization elements. Many Ophthalmic Devices, such as disposable contact lenses, have typical shelf lives of six years; hence, there is a need to minimize energization losses by ensuring extremely low leakage current. Therefore, it may be important to ensure that included energization elements and the electrical components they connect to have very low leakages and designed modes of operation that minimize the loss of energization during storage periods. Incorporating the

energization elements into the Ophthalmic Device presents the additional issue to current leakage because the solutions to the leakage cannot depend on direct electrical contact.

[0006] Technological embodiments that address such an ophthalmological background need may generate solutions that not only address ophthalmic requirements but also encompass novel embodiments for the more general technology space defining energy conservation for encapsulated energized elements.

SUMMARY

[0007] Accordingly, the present invention includes an encapsulated Media Insert with a Storage Mode that may be included into an energized Ophthalmic Device, and in some embodiments, specifically, a contact lens. Storage Mode reduces leakage within the Media Insert while operating levels of current are not required. In some embodiments, an energized Ophthalmic Device with a Storage Mode is provided.

[0008] The present invention therefore includes disclosure of a Switching Mechanism with a Storage Mode and an Operating Mode, wherein the Switching Mechanism is incorporated into a circuit with at least a load and a power source. For example, the load may control a specific function of the device, such as, for example, optic power adjustment, or administration of an active agent. The circuit may be included in an encapsulated Media Insert that may be included in an energized Ophthalmic Device.

[0009] The Media Insert may be fully encapsulated to protect and contain the energization elements, traces, and electronic components. The Ophthalmic Device, which may be comprised of a polymeric biocompatible material, may include a rigid center, soft skirt design wherein a central rigid optical element comprises the Media Insert.

[0010] In some embodiments, a Storage Mode may be modeled to occur when the Switching Mechanism is modeled to have an increased resistance resulting in a reduced leakage current. This leakage current may meet desired Storage Mode current consumption specifications, and therefore may allow for a substantial shelf life of the energized Ophthalmic Device. Because the Media Insert is fully encapsulated, the Switching Mechanism may be responsive to an outside stimulus that may originate outside the device while not in direct contact with the circuit. Thus, the Switching Mechanism **315** may also be comprised of sensor portions of various kinds. For example, these sensors may be antennas to receive and react to radio frequency emissions as the stimulus, or they may be photocells to react to photon-based outside stimulus.

[0011] To further conserve energy, even when the Ophthalmic Device is not in a Storage Mode, a Sleep Mode may be combined with a Storage Mode function. Whereas a Storage Mode may typically refer to a low energy consumptive state that involves a Switching Mechanism introducing a high resistance into the conductive path of the power source to the load, a Sleep Mode may refer to a low energy consumptive status of electronic circuitry when that circuitry is connected via a low resistance path to the power source.

[0012] In some embodiments, a Reset Function may be triggered during the testing process prior to packaging or during the assembly of components themselves. For example, the Reset Function may establish an optimum resting state of the circuit if the device is put into Storage Mode a specified time later. In some embodiments, a block of electronic cir-

cuitry may be able to perform the Reset Function and place at least a portion of the load in a predefined energized state.

[0013] The methods of including a Media Insert with a Storage Mode in an encapsulated Ophthalmic Device may also be significant. Accordingly, methods of manufacture are described herein. In some embodiments, a load that may operate within an energized Ophthalmic Device may be incorporated in the Media Insert in a circuit with the power source and a Switching Mechanism. In some such embodiments, a reset function may be integrated with the circuit. During the manufacturing process, the energized Media Insert may be placed in a Storage Mode. Some embodiments may include an assembly testing process, wherein the Media Insert may be taken out of Storage Mode to evaluate the operation of the Ophthalmic Device and subsequently returned to Storage Mode. The Ophthalmic Device may be optionally placed in a sealed package that may prevent unintentional activation of the Ophthalmic Device from a Storage Mode prior to user activation. This method of manufacture may be useful in embodiments where the Media Insert is encapsulated in an energized device other than an Ophthalmic Device.

[0014] The methods of using an encapsulated Ophthalmic Device with a Media Insert with a Storage Mode may be significant. Accordingly, methods of use are described herein. In some embodiments, a user may open a sealed package, such as a blister, that contains an energized Ophthalmic Device in a Storage Mode, and an outside stimulus may wake the device from a Storage Mode by triggering the Switching Mechanism. In some specific embodiments, the user may directly trigger the Switching Mechanism, such as, for example, in a mechanical system, the outside stimulus may be pressure on the Switching Mechanism, requiring the user to squeeze or pinch the device. In other embodiments, the removal of the Ophthalmic Device may expose the Switching Mechanism to the appropriate outside stimulus and thereby may not require additional action from the user.

[0015] In embodiments where an Ophthalmic Device may be used multiple times, further steps may be required. In such embodiments, conserving current leakage during storage periods between usages may allow for extended power supply life. Accordingly, a user may be able to return the Ophthalmic Device to a Storage Mode and store the Ophthalmic Device until it is needed for a subsequent use. This method of use may be useful in embodiments where the Media Insert is encapsulated in an energized device other than an Ophthalmic Device.

DESCRIPTION OF THE DRAWINGS

[0016] FIG. 1 illustrates an exemplary embodiment of a Media Insert for an energized

[0017] Ophthalmic Device and an exemplary embodiment of an energized Ophthalmic Device.

[0018] FIG. 2 illustrates a model for the mechanisms of energization loss for devices with energization elements or Power Sources.

[0019] FIG. 3 illustrates an exemplary embodiment of a circuit design for an energized device with an externally activated Storage Mode, which may be useful in Ophthalmic Devices with encapsulated Media Inserts.

[0020] FIG. 4 illustrates alternate embodiments of circuit designs for energized devices with externally activated Storage Modes, which may be useful in Ophthalmic Devices with encapsulated Media Inserts.

[0021] FIG. 5 illustrates an exemplary embodiment of a circuit design for an energized device with a Storage Mode wherein a Switching Mechanism important to the state of the Storage Mode is itself comprised of a separate load and switch, which may be useful in Ophthalmic Devices with encapsulated Media Inserts.

[0022] FIG. 6 illustrates a flowchart for an exemplary process for manufacturing an energized Ophthalmic Device with a Storage Mode.

[0023] FIG. 7 illustrates a flowchart for an exemplary process for using an energized Ophthalmic Device with a Storage Mode.

DETAILED DESCRIPTION OF THE INVENTION

[0024] The present invention relates to an energized Ophthalmic Device having a Storage Mode that may conserve energy by reducing current Leakage when the Ophthalmic Device is not being used, and the invention further includes the methods of manufacture and use. In the following sections detailed descriptions of embodiments of the invention will be given. The description of both preferred and alternative embodiments are exemplary embodiments only, and it is understood that to those skilled in the art that variations, modifications and alterations may be apparent. It is therefore to be understood that said exemplary embodiments do not limit the scope of the underlying invention.

[0025] An incorporated battery may have a low-leakage state or Storage Mode to maintain enough power to be operational upon use of the Ophthalmic Device. The user of the Ophthalmic Device may then be able to activate or wake up the battery and/or load circuit. Power sources with a Storage Mode may already exist in the electronics field to minimize leakage prior to use of the device, but the issues involved with an energized Ophthalmic Device are distinct from those products currently available. For instance, a common technique in toys to preserve power is to package the product with paper used to cover a coin cell battery. Upon pulling a tab, the paper is removed and contact is made between the battery and circuit. Prior to such activation, the system is in a low-leakage state with long shelf life. Such methods cannot be used for an electronic system encapsulated within a contact lens.

[0026] Incorporating the energization elements into the Ophthalmic Device presents additional issues to current leakage because the solutions to the leakage may not depend on direct electrical contact. Therefore, the methods of activation may rely on an outside stimulus whereas the mechanism for switching from storage to active mode could be contained within the energized Ophthalmic Device. This concept is similar to that of a "glow stick" where energy (in the case of a glow stick, a chemical reaction that creates light) is not released until a purposeful event (snapping the slick) activates the device. Unlike a glow stick, an energized Ophthalmic Device with an encapsulated Media Insert may contain complex electronic components and may comprise biocompatible material.

[0027] The small space within an ophthalmic Media Insert may add another limitation to a Storage Mode. The area in an ophthalmic Media Insert for all the components of the circuitry including the Switching Mechanism may be 1.5 square millimeters. Size restrictions also limit the possible power supply, and the area used by circuitry may subtract from the area available for the power supply. Accordingly, the range of allowable leakage wherein the energized Ophthalmic Device

may still function for practical use after shelf life is very small. The present invention addresses this issue of energy conservation.

Glossary

[0028] In this description and claims directed to the presented invention, various terms may be used for which the following definitions will apply:

[0029] Encapsulate: as used herein refers to creating a barrier to separate an entity, such as, for example, a Media Insert, from an environment adjacent to the entity.

[0030] Energized: as used herein refers to the state of being able to supply electrical current to or to have electrical energy stored within.

[0031] Energy: as used herein refers to the capacity of a physical system to do work. Many uses within this invention may relate to the said capacity being able to perform electrical actions in doing work.

[0032] Energy Source: as used herein refers to a device or layer that is capable of supplying Energy or placing a logical or electrical device in an Energized state.

[0033] Energy Harvester: as used herein refers to a device capable of extracting energy from the environment and converting it to electrical energy.

[0034] Functionalized: as used herein refers to making a layer or device able to perform a function including for example, energization, activation, or control.

[0035] Leakage: as used herein refers to unwanted loss of energy.

[0036] Lens or Ophthalmic Device: as used herein refers to any device that resides in or on the eye. These devices may provide optical correction, may be cosmetic, or may provide functionality unrelated to the eye. For example, the term lens may refer to a contact lens, intraocular lens, overlay lens, ocular insert, optical insert, or other similar device through which vision is corrected or modified, or through which eye physiology is cosmetically enhanced (e.g. iris color) without impeding vision. Alternatively, the Lens may provide non-optic functions such as, for example, monitoring glucose or administering an active agent. In some embodiments, the preferred lenses of the invention are soft contact lenses are made from silicone elastomers or hydrogels, which include, for example, silicone hydrogels, and fluorohydrogels.

[0037] Lens-forming Mixture or Reactive Mixture or Reactive Monomer Mixture (RMM): as used herein refers to a monomer or prepolymer material that may be cured and cross-linked or cross-linked to form an Ophthalmic Device. Various embodiments may include Lens-forming Mixtures with one or more additives such as, for example, UV blockers, tints, photoinitiators or catalysts, and other additives one might desire in an Ophthalmic Devices such as, contact or intraocular lenses.

[0038] Lens-forming Surface: as used herein refers to a surface that is used to mold a lens. In some embodiments, any such surface can have an optical quality surface finish, which indicates that it is sufficiently smooth and formed so that a lens surface fashioned by the polymerization of a lens forming material in contact with the molding surface is optically acceptable. Further, in some embodiments, the Lens-forming Surface can have a geometry that is necessary to impart to the lens surface the desired optical characteristics, including without limitation, spherical, aspherical and cylinder power, wave front aberration correction, corneal topography correction and the like as well as any combinations thereof.

[0039] Lithium Ion Cell: as used herein refers to an electrochemical cell where Lithium ions move through the cell to generate electrical energy. This electrochemical cell, typically called a battery, may be reenergized or recharged in its typical forms.

[0040] Media Insert: as used herein refers to an encapsulated insert that will be included in an energized Ophthalmic Device. The energization elements and circuitry may be incorporated in the Media Insert. The Media Insert defines the primary purpose of the energized Ophthalmic Device. For example, in embodiments where the energized Ophthalmic Device allows the user to adjust the optic power, the Media Insert may include energization elements that control a liquid meniscus portion in the Optical Zone. Alternatively, a Media Insert may be annular so that the Optical Zone is void of material. In such embodiments, the energized function of the Lens may not be optic quality but may be, for example, monitoring glucose or administering an active agent.

[0041] Mold: as used herein refers to a rigid or semi-rigid object that may be used to form lenses from uncured formulations. Some preferred Molds include two Mold parts forming a front curve Mold part and a back curve Mold part.

[0042] Operating Mode: as used herein refers to a high current draw state where the current over a circuit allows the device to perform its primary energized function.

[0043] Optical Zone: as used herein refers to an area of an Ophthalmic Device through which a wearer of the Ophthalmic Device sees.

[0044] Power: as used herein refers to work done or energy transferred per unit of time.

[0045] Rechargeable or Re-energizable: as used herein refers to a capability of being restored to a state with higher capacity to do work. Many uses within this invention may relate to the capability of being restored with the ability to flow electrical current at a certain rate and for a certain, reestablished time period.

[0046] Reenergize or Recharge: as used herein refers to restoring to a state with higher capacity to do work. Many uses within this invention may relate to restoring a device to the capability to flow electrical current at a certain rate and for a certain, reestablished time period.

[0047] Reference: as use herein refers to a circuit that produces a fixed and stable voltage or current output suitable for use in other circuits. A reference may be derived from a bandgap, may be compensated for temperature, supply, and process variation, and may be tailored specifically to a particular application-specific integrated circuit (ASIC).

[0048] Released from a Mold: as used herein refers to a lens that is either completely separated from the Mold, or is only loosely attached so that it may be removed with mild agitation or pushed off with a swab.

[0049] Reset Function: as used herein refers to a self-triggering algorithmic mechanism to set a circuit to a specific predetermined state, including, for example, logic state or an energization state. A Reset Function may include, for example, a power-on reset circuit, which may work in conjunction with the Switching Mechanism to ensure proper bring-up of the chip, both on initial connection to the power source and on wakeup from Storage Mode.

[0050] Sleep Mode or Standby Mode: as used herein refers to a low current draw state of an energized device after the Switching Mechanism has been closed that allows for energy conservation when Operating Mode is not required.

[0051] Stacked: as used herein means to place at least two component layers in proximity to each other such that at least a portion of one surface of one of the layers contacts a first surface of a second layer. In some embodiments, a film, whether for adhesion or other functions may reside between the two layers that are in contact with each other through said film.

[0052] Stacked Integrated Component Devices or SIC Devices: as used herein refers to the products of packaging technologies that assemble thin layers of substrates that may contain electrical and electromechanical devices into operative-integrated devices by means of stacking at least a portion of each layer upon each other. The layers may comprise component devices of various types, materials, shapes, and sizes. Furthermore, the layers may be made of various device production technologies to fit and assume various contours.

[0053] Storage Mode: as used herein refers to a state of a system comprising electronic components where a power source is supplying or is required to supply a minimal designed load current. This term is not interchangeable with Standby Mode.

[0054] Substrate Insert: as used herein refers to a formable or rigid substrate capable of supporting an Energy Source within an Ophthalmic Device. In some embodiments, the Substrate insert also supports one or more components.

[0055] Switching Mechanism: as used herein refers to a component integrated with the circuit providing various levels of resistance that may be responsive to an outside stimulus, which is independent of the Ophthalmic Device.

Energized Ophthalmic Device

[0056] Proceeding to FIG. 1, an exemplary embodiment of a Media Insert **100** for an energized Ophthalmic Device and a corresponding energized Ophthalmic Device **150** are illustrated. The Media Insert **100** may comprise an Optical Zone **120** that may or may not be functional to provide vision correction. Where the energized function of the Ophthalmic Device is unrelated to vision, the Optical Zone **120** of the Media Insert **100** may be void of material. In some embodiments, the Media Insert **100** may include a portion not in the Optical Zone **120** comprising a substrate **115** incorporated with energization elements **110** and electronic components **105**.

[0057] In some embodiments, a power source **110**, which may be, for example, a battery, and a load **105**, which may be, for example, a semiconductor die, may be attached to the substrate **115**. Conductive traces **125** and **130** may electrically interconnect the electronic components **105** and the energization elements **110**. The Media Insert **100** may be fully encapsulated to protect and contain the energization elements **110**, traces **125** and **130**, and electronic components **105**. In some embodiments, the encapsulating material may be semi-permeable, for example, to prevent specific substances, such as water, from entering the Media Insert **100** and to allow specific substances, such as ambient gasses or the byproducts of reactions within energization elements, to penetrate or escape from the Media Insert **100**.

[0058] In some embodiments, the Media Insert **100** may be included in an Ophthalmic Device **150**, which may comprise a polymeric biocompatible material. The Ophthalmic Device **150** may include a rigid center, soft skirt design wherein a central rigid optical element comprises the Media Insert **100**. In some specific embodiments, the Media Insert **100** may be in direct contact with the atmosphere and the corneal surface

on respective anterior and posterior surfaces, or alternatively, the Media Insert **100** may be encapsulated in the Ophthalmic Device **150**. The periphery **155** of the Ophthalmic Device **150** may be a soft skirt material, including, for example, a hydrogel material.

[0059] Proceeding to FIG. 2, a general model for circuit design aspects important in relation to conserving power in energized devices, which may include energized Ophthalmic Devices, is illustrated. Ideally, when the device is in an Operating Mode, the power source **210** may supply the load **220** with full current and without any loss of current to other paths. In realistic conditions however, there are typically parallel leakage paths that may occur in devices, such as, for example, due to leakage within the power source itself or leakage along the interconnections between the power source **210** and the load components **220**. The paths of these leakage currents may be modeled as a parallel "Shunt resistance" as shown as a shunt resistor **215**. To the extent possible, the leakage paths in the devices are minimized, which would correspond to a model with maximized values of the "Shunt Resistance." Accordingly, preferable embodiments with low leakage may be modeled to have a shunt resistor **225** with very high resistance, such as, for example, 10^9 ohms.

[0060] Even in embodiments where the shunt resistance is very high (and in following discussions assumed to be infinite where the shunt resistor is not included in the circuit illustration), the power source may still have energy drawn from it through the load itself. In some embodiments, a Storage Mode may be modeled to occur when the Switching Mechanism **205** is modeled to have a varying resistance. In ideal cases, the resistance across the Switching Mechanism **205** may be zero when the circuit **225** is in an Operating Mode and infinite when the circuit **225** is in a Storage Mode. In some exemplary embodiments, the Switching Mechanism may add minimal resistance, such as, for example, less than 10 ohms, when the Switching Mechanism **205** is closed, and add very high resistance, such as, for example, 10^9 ohms, when the Switching Mechanism **205** is open. In some embodiments, to meet this specification, the circuit may be inactive in a Storage Mode. For example, some embodiments may include a high-isolation switch that may shut the battery off from the load, where the load may include, for example, a reference, oscillators, a digital logic circuits, or in some embodiments a lens driver circuit.

[0061] In an energized Ophthalmic Device, the load **220** may control a specific function of the device, such as, for example, optic power adjustment, or administration of active agents. In some preferable embodiments, the load resistance may be nominal. The previously described examples for current, power, and resistance may be within the normal operating boundaries that apply in some exemplary embodiments. For example, in some preferable embodiments, the current draw when the energized Ophthalmic Device is in a Storage Mode, which may be classified as the leakage current, may be less than 400 pA.

[0062] This leakage current may meet desired Storage Mode current consumption specifications and therefore may allow for a substantial shelf life of the energized Ophthalmic Device. In some embodiments, for example, the level of leakage while the Ophthalmic Device is in a Storage Mode may be at a targeted level, which may give an added benefit of limiting the wear on the components of the circuit.

[0063] In some preferable embodiments, when the energized Ophthalmic Device is in an operating mode, the current

may be 3 μA or less on average but may contain peaks to 10 milliamps or more. $I_{\text{OPERATING MODE}}$ may be the current after the energized Ophthalmic Device has been woken up from storage, and $I_{\text{STORAGE MODE}}$ may be the non-operating leakage current while the device is in Storage Mode and may directly affect the potential time the device may operate at its $I_{\text{OPERATING MODE}}$.

[0064] In energized Ophthalmic Devices that do not have a Storage Mode, the available power from the energization elements after years of storage might steadily decrease, potentially to a de-energized state of zero available power. By adding a Storage Mode aspect to components or to the device design, the resulting device may be modeled as having a Switching Mechanism **205** with a high $R_{\text{SWITCH OPEN}}$ that may mitigate the current loss over time. The time at which an active circuit may operate at a given $I_{\text{OPERATING MODE}}$ may be directly related to the $R_{\text{SWITCH OPEN}}$ of the model Switching Mechanism **205** in that a higher $R_{\text{SWITCH OPEN}}$ may reduce the leakage draw on the energization element, which may then allow for a longer time that the device may operate at its $I_{\text{OPERATING MODE}}$. In another sense, when the device is operating it may be important that the current flowing through the modeled Switching Mechanism not cause effects within that mechanism itself; therefore, in some embodiments, the Switching Mechanism **205** may be comprised of a material that, when closed, may withstand currents up to and including the $I_{\text{OPERATING MODE}}$ over the expected periods of operation.

[0065] There may be a variety of design parameters that relate to the type, dimension, and quantity of energization cells that are utilized for a particular application. In some embodiments, for example, the power source **210** may be comprised of two battery cells in series each having a cell voltage of between 0.8 to 1.65V thus providing a voltage supply of 1.6 to 3.3V. The desire to configure cells of this type into this voltage range may be related to the technology that is utilized in the electronic circuitry as it may operate in a window around this electrical potential. If different types of battery are used, for example, where the chemistry involved in the anodes and cathodes is varied, the nominal cell voltages may shift.

[0066] Within a certain battery type, the size of the batteries employed may be related to the electrical current phenomena that have been discussed herein. For example, a particular application may have a targeted operating life at a certain operating current. Based on this target value alone, the size requirements of the cells may simply be estimated from the inherent energy density of the cells and the required energy for the operating life. However, as has been described herein, the situation may typically be more complicated since the energy required for the storage life might also factor into the size requirement of the cells as well. The energy required for storage life is a significant function of $I_{\text{STORAGE MODE}}$. Thus, it may be clear why minimization of $I_{\text{STORAGE MODE}}$ is desirable because it either reduces the amount of battery chemicals required for an application, or on the other hand, increases the operating life parameters for a given size of available space for batteries in an application.

[0067] By reducing leakage and limiting the energy flow through the circuit, a Storage Mode may also minimize the byproducts that may result from reactions caused by an energized circuit. This may be particularly significant in embodiments where the Ophthalmic Device is shipped in small, sealed packages, such as, for example, blisters, where even a

small accumulation of byproducts may be damaging to the integrity of the Ophthalmic Device.

[0068] To further conserve energy, even when the Ophthalmic Device is not in a Storage Mode, a Sleep Mode may be combined with a Storage Mode function. Whereas a Storage Mode may typically refer to a low energy consumptive state that involves a Switching Mechanism introducing a high resistance into the conductive path of the power source to the load, a Sleep Mode may refer to a low energy consumptive status of electronic circuitry when that circuitry is connected via a low resistance path to the power source. Such a Sleep Mode may occur when the connected electronic circuitry controls itself to essentially “turn off” most of its circuitry, for example to save energy by waiting to perform sensor sampling at a predetermined rate.

[0069] Proceeding to FIG. 3, an exemplary embodiment of a circuit design for a device with a Storage Mode is illustrated. The circuit **325** may include a power source **310** and a load **320** that may control a specific function of the Ophthalmic Device. As mentioned previously, the parasitic leakages of the power source **310** itself and of the connections between the power source **310** and the load **320** may be designed and manufactured to be very small and thus no “shunt resistance” is depicted for example. In some embodiments, a Switching Mechanism may be placed in series with the power source **310** and the load **320** to facilitate a storage mode.

[0070] The Switching Mechanism **315** may be responsive to an outside stimulus **330** not in direct contact at its origination with the circuit **325**. The Switching Mechanism **315** is depicted generally as a device that is sensitive and reactive to the outside stimulus **330**. Thus, the Switching Mechanism **315** may also be comprised of sensor portions of various kinds. For example, these sensors may be antennas to receive and react to radio frequency emissions as the stimulus, or they may be photocells to react to photon-based outside stimulus. There may be numerous types of sensors inherent to a switch being sensitive to an outside stimulus. In other embodiments, the detection of the outside stimulus may involve a physical change of some kind to an element in the switch. For example, exposure of elements in the switch to a thermal stimulus from outside the lens may physically change the resistivity of a component within the switch and cause a reaction much as the other described sensor elements could. Some embodiments may be sensitive to sound as well.

[0071] In some embodiments, for example, control of the Switching Mechanism **315** may use electronic means, mechanical means, or magnetic means. For example, electronic means may involve transistor circuitry in the switching, mechanical means may involve metallic contacts in the switching, and magnetic means may involve reed relays. There may be numerous switches that will have high resistance when in an off mode and low resistance in an on mode.

[0072] Some embodiments may include a Switching Mechanism **315** that may repeatedly be placed in a Storage Mode and an Operating Mode, which may allow, for example, testing during manufacturing or repeated use of the Ophthalmic Device. In some such embodiments, the load **320** may also control the Switching Mechanism **315**, allowing the load **320** to place the Switching Mechanism **315** back into a Storage Mode. The load **320** may contain additional sensors, such as, for example, an infrared link, which may receive commands from a user or some other passive outside stimulus. Upon reception of a shutdown command, the load **320** may activate the Switching Mechanism.

[0073] In some embodiments, for example, the circuit may be comprised of multiple Switching Mechanisms, not shown, that may independently be activated for a single use, which may allow for a specific number of uses. In such embodiments, after a single use, a component, such as the load, may place one of the Switching Mechanisms into Storage Mode so that the Ophthalmic Device may be activated again with minimal leakage while not in use. Where the circuit comprises multiple single-use Switching Mechanisms, after the first use, the component may trigger a second Switching Mechanism into Storage Mode, allowing that second Switching Mechanism to respond to an outside stimulus. In such embodiments, the uses may be limited by the number of Switching Mechanisms. In some alternative embodiments, such as with single daily use devices, the Switching Mechanism may be placed in a Storage Mode and activated to an Operating Mode one time.

[0074] A Storage Mode may allow for reliable shipping methods because the Ophthalmic Device may be kept in a known off state. In some embodiments, a Storage Mode alone may be sufficient in establishing a stable state for shipping. In other alternative embodiments, a Reset Function may be triggered during the testing process prior to packaging or during the initial assembly of the components into the device. For example, the Reset Function may establish an optimum resting state of the circuit if the device is put into Storage Mode a specified time later. In some embodiments, this specified time may be shorter after testing than after user activation thereby allowing two Reset Functions, one for shipping and one for use. In some embodiments, a block of electronic circuitry may be able to perform the Reset Function and place at least a portion of the load 320 in a predefined energized state. The block of electronic circuitry may be incorporated within the circuit, including, for example, within the load 320.

[0075] Proceeding to FIG. 4, alternative embodiments of a circuit design for an energized device with a Storage Mode are illustrated, and such circuits may be incorporated into Ophthalmic Devices. In some embodiments of the circuit design 400, the Switching Mechanism 410 may be integrated within the power source 405, which then may be placed in the circuit 420 in series with the load 415. In some alternative embodiments of a circuit design 450, the Switching Mechanism 460 may be integrated within the load 465. The load 465 may be placed in the circuit 470 in series with the power source 455. In these embodiments 400 and 450, the Switching Mechanism 410 may be responsive to an outside stimulus 425 and 475.

[0076] Proceeding to FIG. 5, an embodiment where the primary Switching Mechanism 550 is a discrete circuit is illustrated. The primary Switching Mechanism 550 may be comprised of a load 540 separate from the controlling load 530 that may operate the energized Ophthalmic Device. In some embodiments, the primary Switching Mechanism 550 may operate at a very low power to constantly sample for the outside stimulus 580. By utilizing power from the source 510, the primary Switching Mechanism 550 may provide benefits over a passive Switching Mechanism, for exemplifying having greater sensitivity or selectivity to external stimulus.

[0077] Upon activation by an outside stimulus 580, the switching load 540 may control a switch 520 that may be in the main circuit 570 in series with the controlling load 530 and the power source 510. In some embodiments, when the main switch 520 is activated, the main circuit 570 may operate at a high power, such as, for example, 3 uA average and 10

mA peak. In some embodiments, the main switch 520 may further be controlled by the load 540, which may place the switch 520 back in a Storage Mode.

[0078] The primary Switching Mechanism 550, in some embodiments, may include an additional Switching Mechanism 560. This additional Switching Mechanism 560 may provide many functions, such as, for example, further reducing current leakage and protecting the power components. In some embodiments, the additional Switching Mechanism 560 may only be activated once the Media Insert is incorporated in the energized Ophthalmic Device and the device is ready to be packaged. This may protect the circuitry from damage that may be caused by subsequent manufacturing procedures, including, for example, curing lights used to set the hydrogel. In some embodiments, the additional Switching Mechanism 560 and the primary Switching Mechanism 550 may also be responsive to different types of outside stimulus 580.

[0079] For example, in some embodiments, the additional Switching Mechanism 560 may be responsive to temperature, and the primary Switching Mechanism 550 may be responsive to ambient light. Such embodiments may allow the energized Ophthalmic Device to be stored in a cool or cold temperature while in the most conservative stage of a Storage Mode. Once the energized Ophthalmic Device is exposed to warmer temperatures, the additional Switching Mechanism 560 may trigger the primary Switching Mechanism 550 to begin sampling in low power for ambient light, while still keeping the main circuit 570 in a Storage Mode. Upon exposure to ambient light, the primary Switching Mechanism 550 may close the main switch 520 and trigger an Operating Mode.

[0080] This combination of temperature and light is for exemplary purposes only, and it may be apparent to those ordinarily skilled in the art that other combinations of switching systems may be practical. The combination of the primary Switching Mechanism and additional Switching Mechanism may include, for example, electrical, mechanical, or magnetic systems and may depend on stimuli such as, for example, electromagnetic emissions, sound, temperature, or light.

Processes

[0081] Proceeding to FIG. 6, a flowchart illustrates exemplary steps that may be used to manufacture an energized Ophthalmic Device with a Storage Mode. At 605, a power source may be incorporated in a Media Insert that will be included in an Ophthalmic Device. At 610, a load that may operate within an energized Ophthalmic Device may be incorporated in the Media Insert in a circuit with the power source. At 615, a Switching Mechanism may be integrated with the circuit incorporated on the Media Insert. In some embodiments, at 620, a reset function may optionally be integrated with the circuit.

[0082] In embodiments where a load may be incorporated in the Media Insert prior to battery assembly, the reset design may be different from where the battery is completed prior to die attachment. For example, where the battery is completed prior to die attachment, the reset function may need to handle a “noisy” connection to the battery, such as, for example, one with conductive epoxy where the resistance may change during curing.

[0083] The order of steps 605-620 is for exemplary purposes only, and other orders and combinations are well within the art described herein. For example, in embodiments where

the Switching Mechanism is integrated with the power source, as illustrated in the embodiment 400 in FIG. 4, steps 605 and 615 may be combined. In some embodiments, the circuit components may be incorporated in the Media Insert simultaneously.

[0084] At 623, the Media Insert with the incorporated circuitry may be included in the Ophthalmic Device. Optionally, the Media Insert or the Ophthalmic Device may be encapsulated. In some embodiments, step 623 may occur prior to the steps 605-620, wherein the circuit components may be injected onto the Media Insert after the insert has been encapsulated in the Ophthalmic Device.

[0085] At 625, the energized Media Insert may be placed in a Storage Mode. The order of the steps may depend on the overall manufacturing process for a particular embodiment. For example, in some embodiments, placing the circuit in a Storage Mode prior to subsequent steps may protect the circuitry from damage that may be caused by subsequent manufacturing procedures, including, for example, curing lights used to set the hydrogel. In said embodiments, for example, step 625 may occur prior to step 623.

[0086] At 630 to 645, some embodiments may optionally include an assembly testing process. The assembly test mode may allow testing of the electronic circuitry and energized Ophthalmic Device following assembly of the insert and of the Ophthalmic Device. At 630, the energized Ophthalmic Device may be woken from a Storage Mode by an outside stimulus. This outside stimulus may be the same or different from the outside stimulus that may put the Ophthalmic Device in an operating mode for the user. In some embodiments, to allow for exiting a Storage Mode and entering an Operating Mode while still meeting the Storage Mode current requirements for use, energy may need to enter the circuitry to trigger the Storage Mode exit.

[0087] For example, some embodiments may utilize a photovoltaic device wherein a bright light may be incident on the photodetector, for example from a flash light or infrared fiber optic bundle. Sufficient potential may result from the exposure to light to close the Switching Mechanism. With the Switching Mechanism closed, at 635, the resistance in series with the load may diminish allowing the Ophthalmic Device to enter an Operating Mode. In embodiments that include a reset function, at 640, exiting a Storage Mode may trigger a power-on reset, as an example, that may place the Ophthalmic Device in a known energized state.

[0088] At 645, in some embodiments, after a specified startup period to initialize the digital block and settle the band-gap, regulators, and oscillator, the system may begin sampling the system. Depending on the system of activation in the specific embodiment, this sampling may, for example, build a history of ambient light levels, detect blinks, or detect the presence of infrared control fiber optic bundles. At 650, the Ophthalmic Device may be returned to a Storage Mode until later activation by a user. In some embodiments, the assembly test mode may be the normal Operating Mode with the ability to end the test mode and exit to a Storage Mode. Depending on the embodiment of the device and the specific method of manufacture, the Ophthalmic Device may be returned to a Storage Mode, for example, through the original means, reversal of the external stimulus, or by a new means.

[0089] At 655, the Ophthalmic Device may be placed in a sealed package that may prevent unintentional activation of the Ophthalmic Device from a Storage Mode prior to user activation. In some embodiments, such as where a Storage

Mode may be sensitive to ambient light, the common blister packaging design may need to be modified to include physical attributes that may prevent the outside stimulus from waking the Ophthalmic Device from a Storage Mode before the user opens the package. For example, where a Storage Mode may be sensitive to ambient light, the packaging may be impermeable to triggering light. Alternatively, if a Storage Mode depends on the device being held within a specific temperature range, the blister may be comprised of a material that better retains cold temperature. These blister modifications are for exemplary purposes only, and it may be obvious to one skilled in the art that other modifications to packaging may be practical and is well within the art described herein.

[0090] Proceeding to FIG. 7, a flowchart illustrates exemplary steps for using an energized Ophthalmic Device with a Storage Mode. In some embodiments, at 705, a user may open a sealed package, such as a blister, that contains an energized Ophthalmic Device in a Storage Mode. At 710, an outside stimulus may wake the device from a Storage Mode by triggering the Switching Mechanism. In some specific embodiments, the user may directly trigger the Switching Mechanism, such as, for example, in a mechanical system, the outside stimulus may be pressure on the Switching Mechanism, requiring the user to squeeze or pinch the device. Alternatively, opening the sealed packaging may trigger the Switching Mechanism without requiring additional action by the user. For example, the outside stimulus may be ambient light.

[0091] In some embodiments, such as in FIG. 5, where the Switching Mechanism 550 may have an additional switch 560, the energized Ophthalmic Device may have multiple levels of Storage Modes. In such embodiments, the user may trigger multiple levels of activation or, in alternate embodiments, may trigger the final activation step that places the energized Ophthalmic Device in an Operating Mode. Where the user triggers multiple levels of activation, the process of FIG. 7 may include steps prior to step 705, such as, for example, removing the sealed package from refrigeration, where the additional switch 560 may be responsive to temperature as the outside stimulus.

[0092] In some embodiments, at 715, waking the energized Ophthalmic Device from a Storage Mode may minimize the resistance of the Switching Mechanism, allowing the current flow through the circuit to increase to an operating level. An Operating Mode may be reached after a specified startup period to initialize the digital block and settle a reference, regulators, and oscillator. In embodiments with a reset function, at 720, an Operating Mode may prompt the reset function, which may place the energized Ophthalmic Device in a known energized state. At 725, the user may place the activated energized Ophthalmic Device on the eye.

[0093] In embodiments where the Media Insert is not encapsulated into the Ophthalmic Device, the user may not be able to place the Ophthalmic Device directly on the eye. In such embodiments, an additional step, not shown, may be required to use the Ophthalmic Device on the eye. For example, in some embodiments, the user may place a soft lens, such as a hydrogel lens, on the eye and then place the energized Ophthalmic Device on the soft lens. Alternatively, the user may combine the Ophthalmic Device and the soft lens prior to placement on the eye.

[0094] In some embodiments, this step at 725 may occur after a specified time after waking the device from a Storage Mode to ensure the device is in a known state, which may be

configured for comfort and safety, as examples. Once in an Operating mode, in some embodiments, a reference, regulators, core oscillator, and some digital circuitry may be continuously active. For example, in some embodiments, a photodetector system, including an amplifier and additional digital circuitry, may be active in repetitive, bursted operation to limit average current consumption. The lens driver may be activated depending on system inputs.

[0095] After use, at **730**, the user may remove the energized Ophthalmic Device from the eye. In some embodiments, such as with a daily-use lens, the process may end with removal of the energized Ophthalmic Device from the eye. In other embodiments where an Ophthalmic Device may be used multiple times, further steps may be required. In such embodiments, conserving current leakage during storage periods between usages may allow for extended power supply life. At **725**, a user may return the Ophthalmic Device to a Storage Mode. As with the assembly test mode in FIG. 6, a Storage Mode may be reinitiated through various outside stimuli, including, for example, reversal of the activating stimulus or an independent outside stimulus specific to triggering a Storage Mode.

[0096] At **740**, the user may store the Ophthalmic Device in an airtight container with a sterilizing solution. During storage, at **743**, the Ophthalmic Device may optionally be recharged. The order of steps **735-743** are for exemplary purposes only and other orders may be practical. For example, in some embodiments, steps **735** and **740** may be combined wherein placement of the device in the container may initiate a Storage Mode. In a further embodiment, steps **735-743** may be combined so that placement of the device in the container initiates a Storage Mode and recharges the device. Depending on the specific embodiment, the sterilizing solution may also operate as the outside stimulus, a recharging fluid, or both. In some embodiments, the container may provide the outside stimulus, may recharge the power source, or both.

[0097] In embodiments that allow for repeated use, at **745**, the user may remove the Ophthalmic Device from the storage container. At **750**, an outside stimulus may wake the device from a Storage Mode, and, at **755**, the resistance over the Switching Mechanism may decrease to allow current flow over the circuit to increase to an Operating Mode. In some embodiments, at **760**, an Operating Mode may trigger a reset function that may place the device in a known energized state. At **765**, the user may then place the energized Ophthalmic Device on the eye. After use, at **770**, the user may remove the device from the eye. In some embodiments, steps **745-765** may be repetitions of the initial steps **705-725**, while in other embodiments, the initial steps **705-725** may be distinct from the steps **745-765** required for reactivation.

[0098] The description of both preferred and alternative embodiments are for exemplary purposes on, and it understood that to those skilled in the art that variation, modification, and alteration may be apparent. It is therefore to be understood that the exemplary embodiments are not limiting the broadness of the aspects of the underlying invention define by the claims.

1. A method of manufacturing an energized Ophthalmic Device having an electrical Storage Mode, the method comprising the steps of:

incorporating a Media Insert within the energized Ophthalmic Device, wherein the Media Insert comprises an electrical circuit, wherein the electrical circuit com-

prises an electrical power source, an electrical load, and a first Switching Mechanism, and wherein the first Switching Mechanism comprises a plurality of modes including a first Storage Mode that places the Ophthalmic Device in a predefined low energy consuming state, wherein the first Switching Mechanism adds resistance to restrict current flow through the electrical load while in the first Storage Mode, and an Operating Mode, wherein the first Switching Mechanism allows increased current flow through the electrical load while in the Operating Mode; and

placing the first Switching Mechanism in the first Storage Mode.

2. The method of claim **1** further comprising the steps of: encapsulating the Ophthalmic Device and the Media Insert.

3. The method of claim **1**, wherein the first Switching Mechanism is sensitive to a first stimulus originating external to the energized Ophthalmic Device.

4. The method of claim **1** further comprising the steps of: testing the operation of the electrical circuit included in the Media Insert before the first Switching Mechanism is placed in the first Storage Mode.

5. The method of claim **3** further comprising: triggering a first change in mode of the first Switching Mechanism by a first stimulus originating external to the Ophthalmic Device, wherein the first change places the first Switching Mechanism in the Operating Mode; stabilizing current flow at an operating level; testing the operation of the electrical circuit included in the Media Insert while the first Switching Mechanism is in the Operating Mode; returning the first Switching Mechanism to the first Storage Mode.

6. The method of claim **5** wherein the returning of the first Switching Mechanism to the first Storage Mode is controlled by a first component of the electrical circuit.

7. The method of claim **1**, wherein the electrical circuit further comprises a first block of electronic circuitry able to perform a first Reset Function upon a first portion of the electrical load, wherein the first block is comprised within the electrical circuit and, when activated, places the portion of the electrical load in a first predefined energized state.

8. The method of claim **5** further comprising the steps of activating the first Reset Function when the current flow increases to the operating level, wherein the electrical circuit further comprises the first block of electronic circuitry able to perform the first Reset Function upon the portion of the electrical load, wherein the block is comprised within the electrical circuit and, when activated, places the first portion of the electrical load in the first predefined energized state.

9. The method of claim **1**, wherein the placement of the first Switching Mechanism in the first Storage Mode occurs prior to incorporating the Media Insert within the energized Ophthalmic Device to protect components within the electrical circuit.

10. The method of claim **1** further comprising: packaging said energized Ophthalmic Device in a sealed container.

11. The method of claim **9**, wherein the sealed container comprises a physical attribute to maintain the first Storage Mode.

12. A method of using the energized Ophthalmic Device having the first Storage Mode, the method comprising the steps of:

opening the sealed container, wherein the sealed container holds at least the energized Ophthalmic Device with the first Storage Mode; and

triggering a second change in mode of the first Switching Mechanism through the second stimulus originating external to the Ophthalmic Device, wherein the second change in mode reduces resistance of the first Switching Mechanism.

13. The method of claim **12**, further comprising the steps of:

placing the energized Ophthalmic Device on an eye.

14. The method of claim **12** further comprising the steps of: activating a second block of circuitry to perform a second Reset Function when the current flow through the electrical circuit rises to a specified level above the Storage Mode level, wherein the second Reset Function results in placement of the Ophthalmic Device in a second predefined energized state.

15. The method of claim **14**, wherein the second predefined energized state is optimized for initial use of the Ophthalmic Device and placement upon the eye.

16. The method of claim **13** further comprising the steps of: removing the energized Ophthalmic Device from the eye; triggering a third change in mode of the first Switching Mechanism, wherein the third change in mode returns the Ophthalmic Device to the first Storage Mode by increasing resistance of the first Switching Mechanism; storing said energized Ophthalmic Device in a sealable container with at least a sterilizing means; removing the energized Ophthalmic Device from the sealable container;

triggering a third change in mode of the first Switching Mechanism through a third stimulus originating outside of the Ophthalmic Device, wherein the third change in mode reduces resistance of the first Switching Mechanism; and

placing the energized Ophthalmic Device on the eye.

17. The method of claim **16**, wherein the returning of the first Switching Mechanism to the Storage Mode is controlled by a second component of the electrical circuit.

18. The method of claim **17**, wherein the second component further comprises a sensor sensitive to a fourth stimulus originating external to the energized Ophthalmic Device.

19. The method of claim **13**, wherein the first Switching Mechanism is a first single-use Switching Mechanism, and the method further comprises the steps of:

removing the energized Ophthalmic Device from the eye; triggering a first change in mode of a second single-use Switching Mechanism, wherein the first change in mode of the second single-use Switching Mechanism returns the Ophthalmic Device to the first Storage Mode by increasing resistance of the second single-use Switching Mechanism;

storing said energized Ophthalmic Device in the sealable container with at least the sterilizing means;

removing the energized Ophthalmic Device from the sealable container;

triggering a second change in mode of the second single-use Switching Mechanism through a fourth stimulus originating external to the Ophthalmic Device, wherein the second change in mode of the second single-use Switching Mechanism reduces resistance of the second single-use Switching Mechanism; and

placing the energized Ophthalmic Device on the eye.

20. The method of claim **12**, wherein the electrical circuit further comprises a second Switching Mechanism, and wherein the method further comprises the steps of:

exposing the sealed container to a fifth stimulus originating external to the Ophthalmic Device, wherein the exposure triggers a change in mode of the second Switching Mechanism and places the Ophthalmic Device in a second Storage Mode.

21. The method of claim **20**, wherein the second Storage Mode is a low energy consumption state and allows the first Switching Mechanism to begin sampling for the second stimulus.

22. A method of using the energized Ophthalmic Device having the first Storage Mode, the method comprising the steps of:

opening the sealed container, wherein the sealed container holds at least the energized Ophthalmic Device with the first Storage Mode;

triggering the second change in mode of the first Switching Mechanism through the second stimulus originating external to the Ophthalmic Device, wherein the second change in mode reduces resistance of the first Switching Mechanism;

placing a soft ophthalmic lens on the eye; and

placing the energized Ophthalmic Device adjacent to the soft ophthalmic lens.

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