US 20170049395A1

(19) United States
(12) Patent Application Publication
(10) Pub. No.: US 2017/0049395 A1
CAO
(43) Pub. Date: Feb. 23, 2017

(54) **NEURO-VIGILANCE INTEGRATED CONTACT EYE LENS AND SYSTEM**

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(21) Appl. No.: **15/241,941**

(22) Filed: **Aug. 19, 2016**

Related U.S. Application Data

(60) Provisional application No. 62/207,553, filed on Aug. 20, 2015.

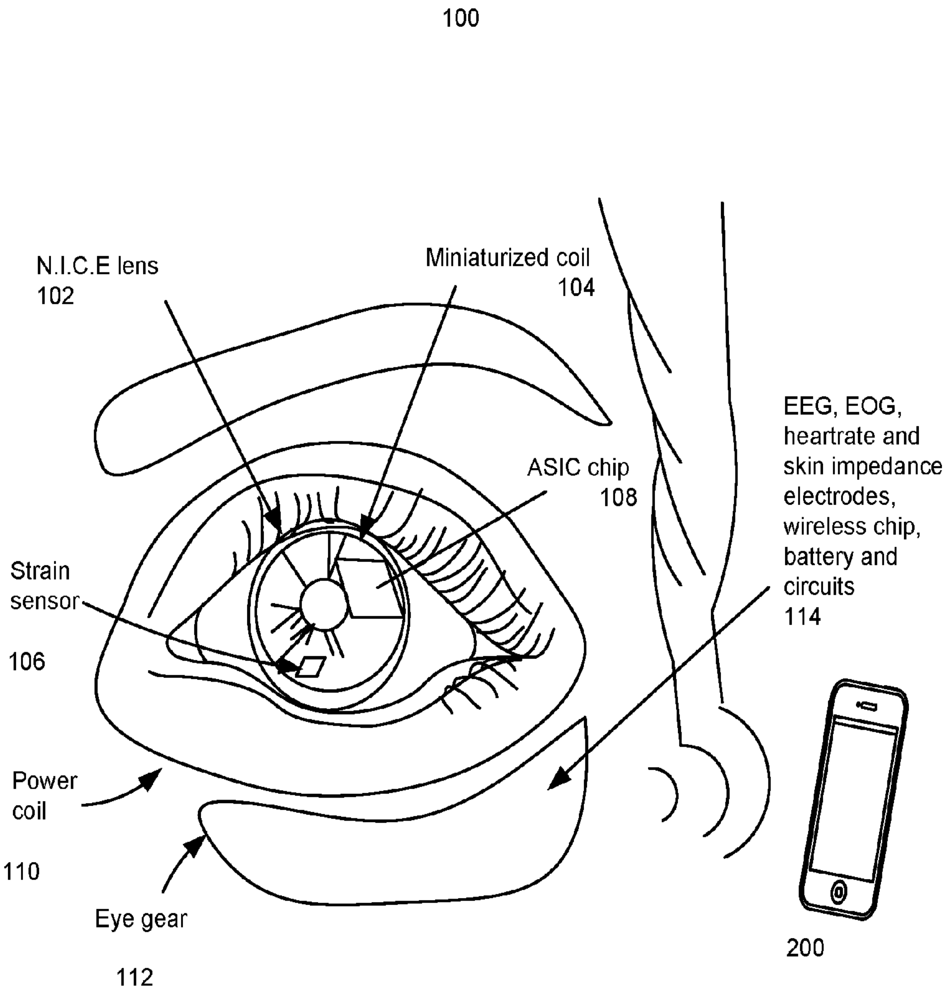
Publication Classification

(51) **Int. Cl.**
A61B 5/00 (2006.01)
A61B 3/113 (2006.01)
A61B 5/0205 (2006.01)
A61B 3/11 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 5/6821*** (2013.01); ***A61B 3/112*** (2013.01); ***A61B 3/113*** (2013.01); ***A61B 5/0205*** (2013.01); *A61B 5/02438* (2013.01)

(57) **ABSTRACT**

A contact lens may comprise at least one sensor. An eye gear package may comprise an interface circuit configured to communicatively couple the eye gear package with the contact lens, a power source configured to power the eye gear package and the contact lens, and a processor configured to process data generated by the at least one sensor.



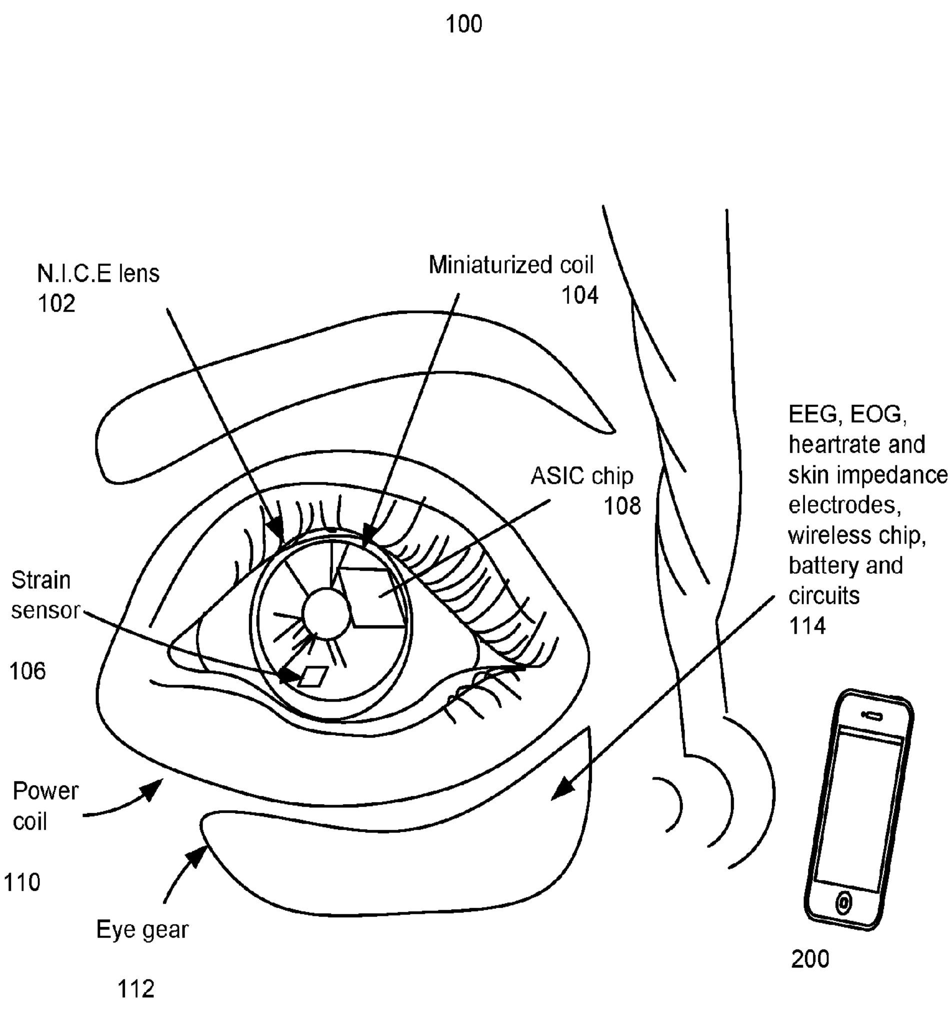

100
N.I.C.E lens
102
Miniaturized coil
104
ASIC chip
108
Strain
sensor
106
EEG, EOG,
heartrate and
skin impedance
electrodes,
wireless chip,
battery and
circuits
114
Power
coil
110
Eye gear
112
200

Figure 1A

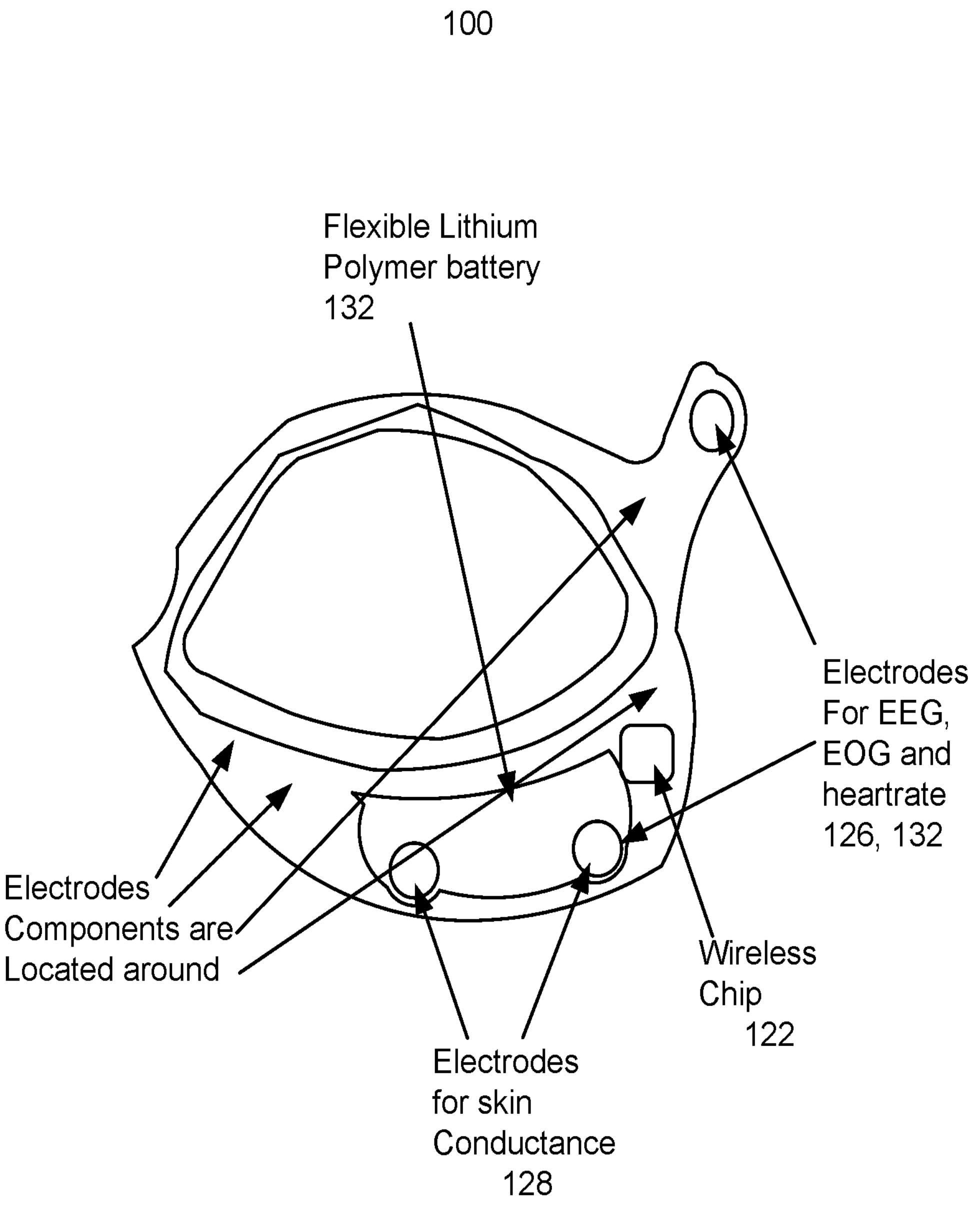

100
Flexible Lithium
Polymer battery
132
Electrodes
For EEG,
EOG and
heartrate
126, 132
Electrodes
Components are
Located around
Wireless
Chip
122
Electrodes
for skin
Conductance
128

Figure 1B

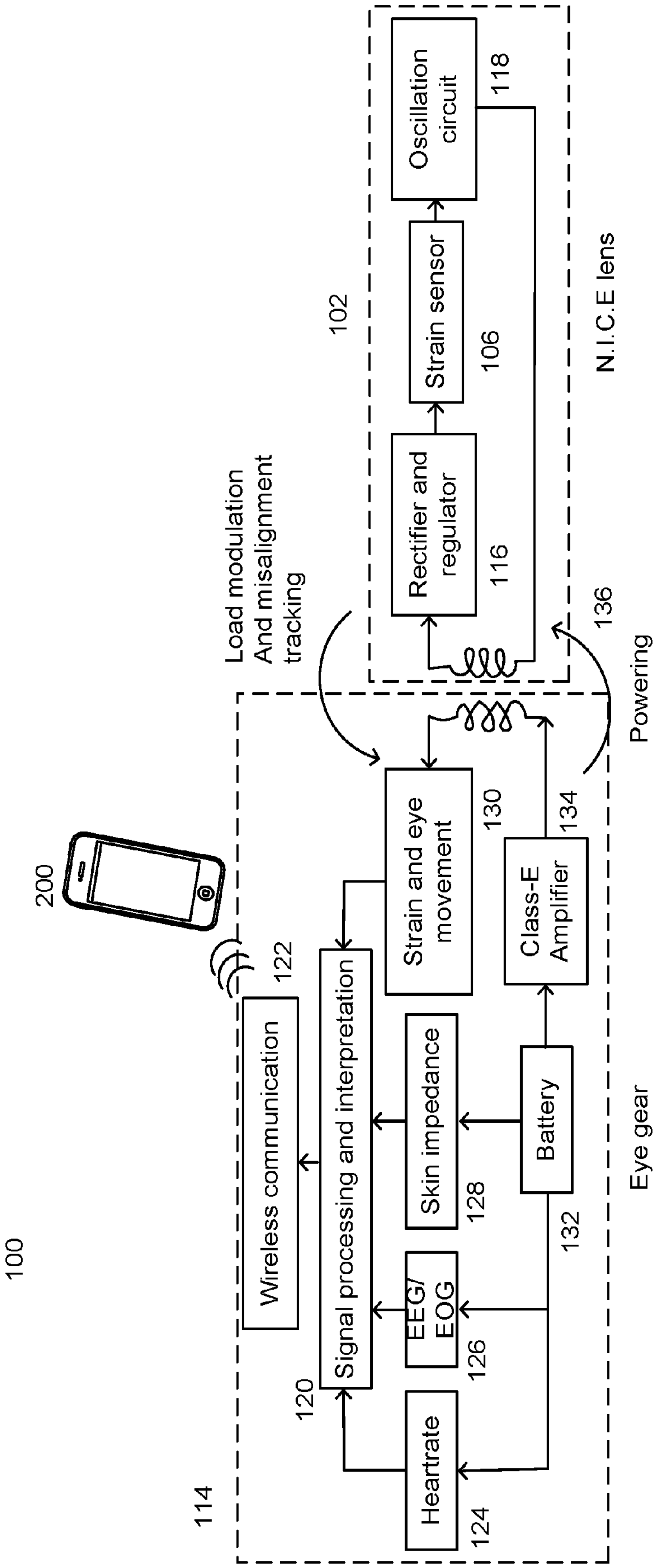

100
114
Eye gear
200
122
Wireless communication
120
Signal processing and interpretation
Heartrate
124
EEG/
EOG
126
Skin impedance
128
Strain and eye
movement
130
Battery
132
Class-E
Amplifier
134
Load modulation
And misalignment
tracking
Powering
136
102
N.I.C.E lens
Rectifier and
regulator
116
Strain sensor
106
Oscillation
circuit
118

Figure 2

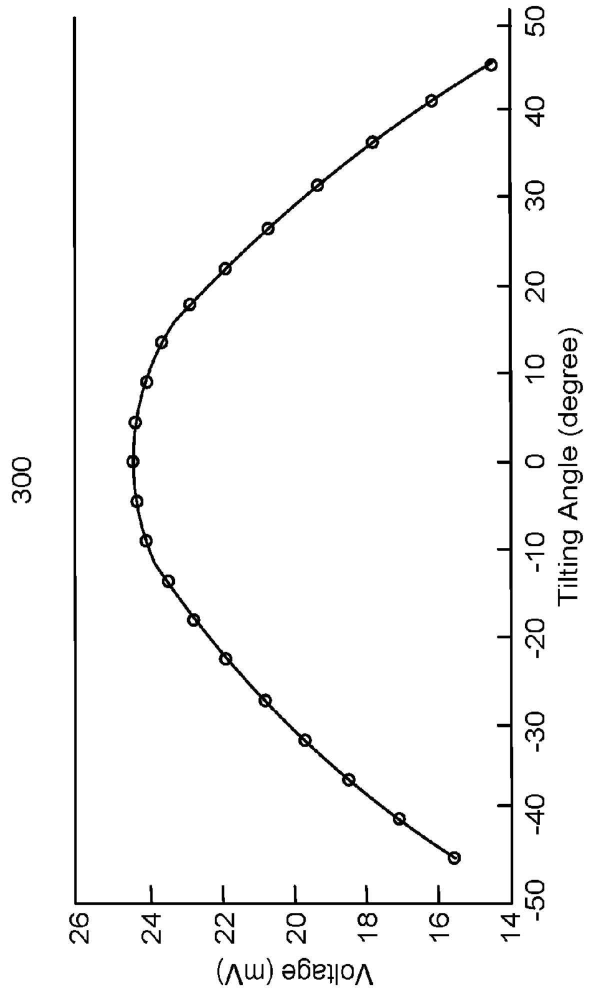


Figure 3

- Receiving
  - 0.3 uH
  - 1.5 cm
  - 28 gauge
  - 3 turns
- Transmitting
  - 20.2 uH
  - 9 cm
  - 24 gauge
  - 10 10 turns
- f=1.36 MHz

Dynamic REM detection with speeds of eye movement

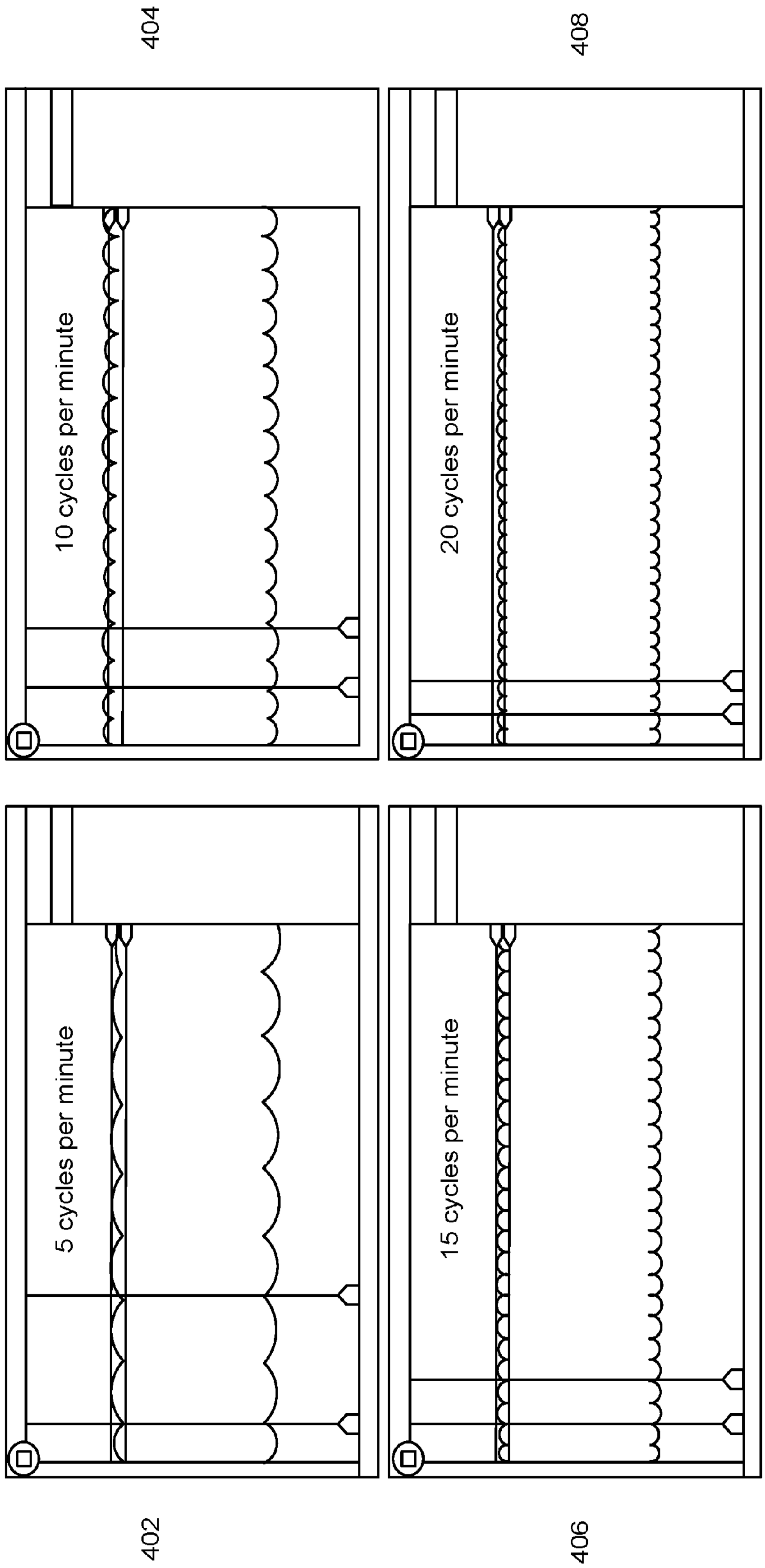


Figure 4

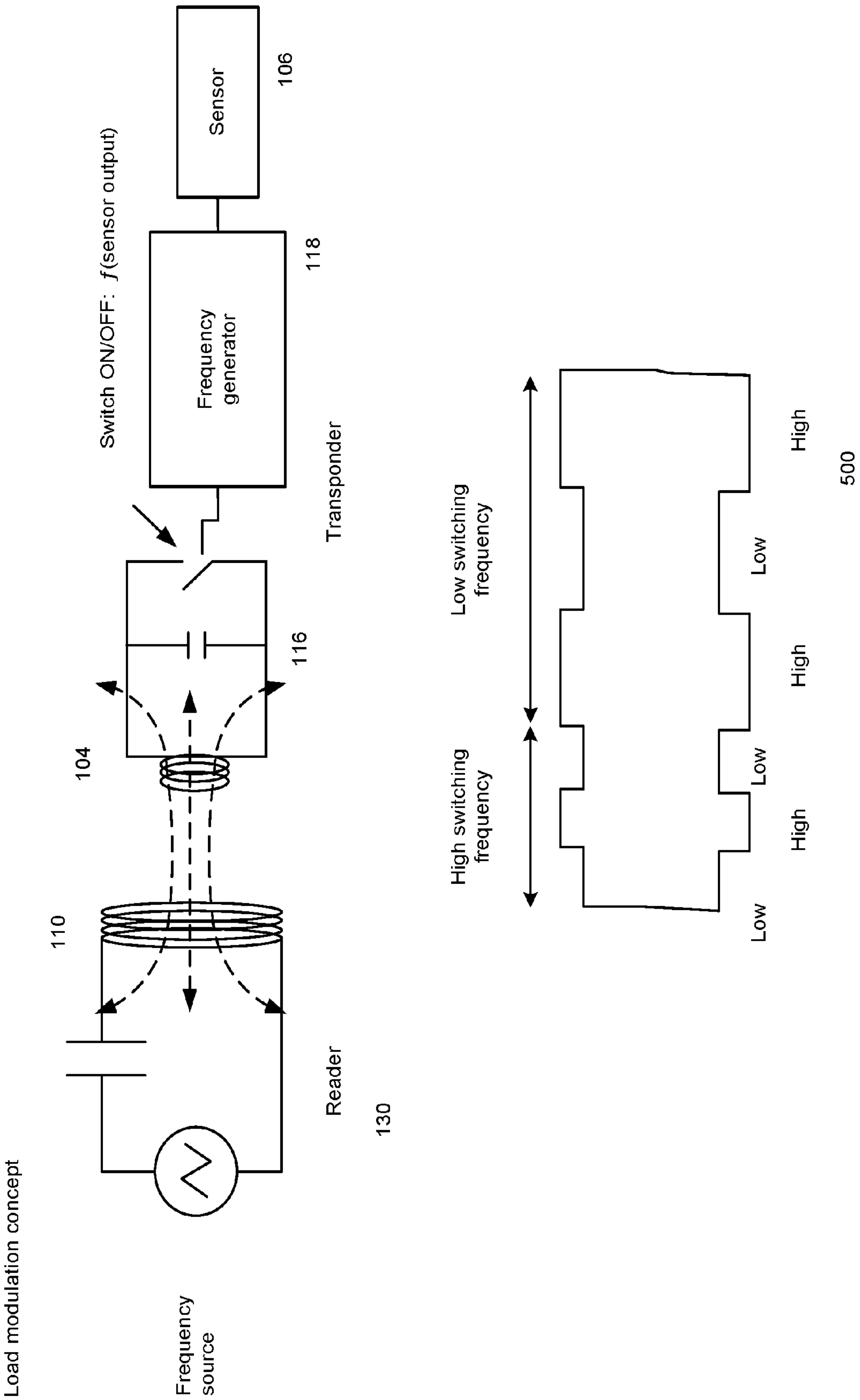

Load modulation concept
Frequency source
Reader
130
110
104
116
Transponder
Switch ON/OFF: *f*(sensor output)
Frequency generator
118
Sensor
106
High switching frequency
Low switching frequency
Low
High
Low
High
Low
High
500

Figure 5

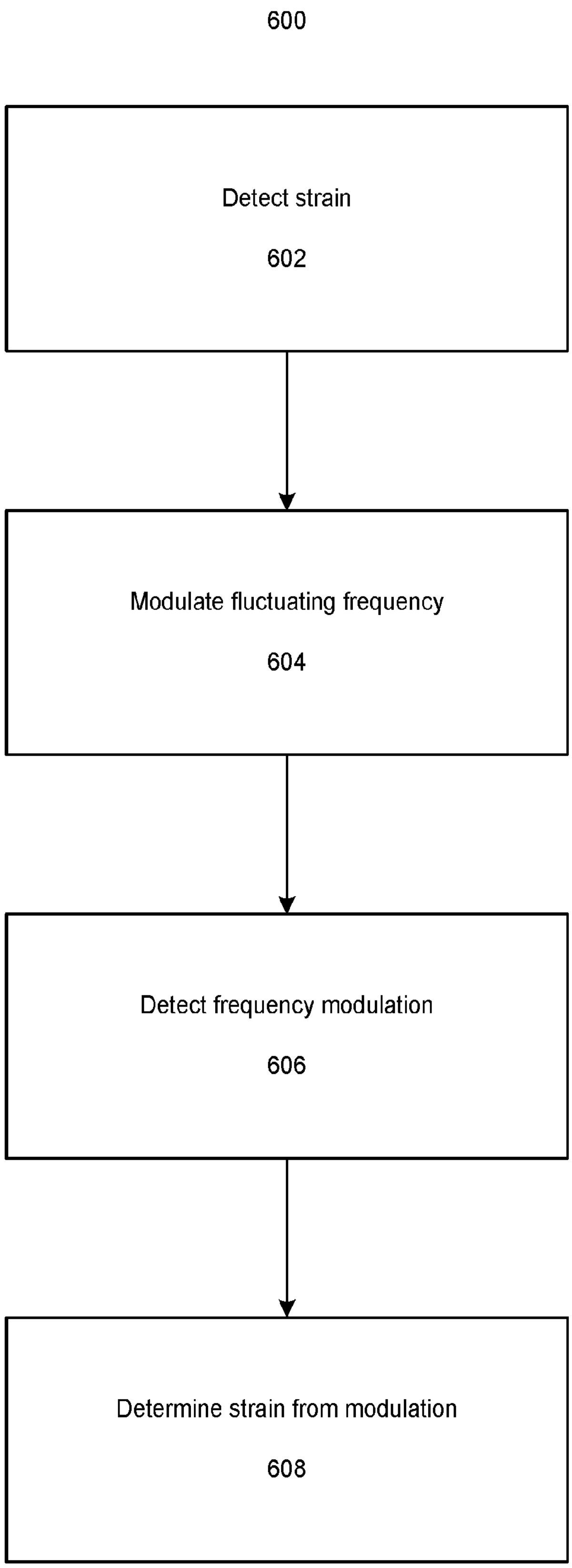

600
Detect strain
602
Modulate fluctuating frequency
604
Detect frequency modulation
606
Determine strain from modulation
608

Figure 6

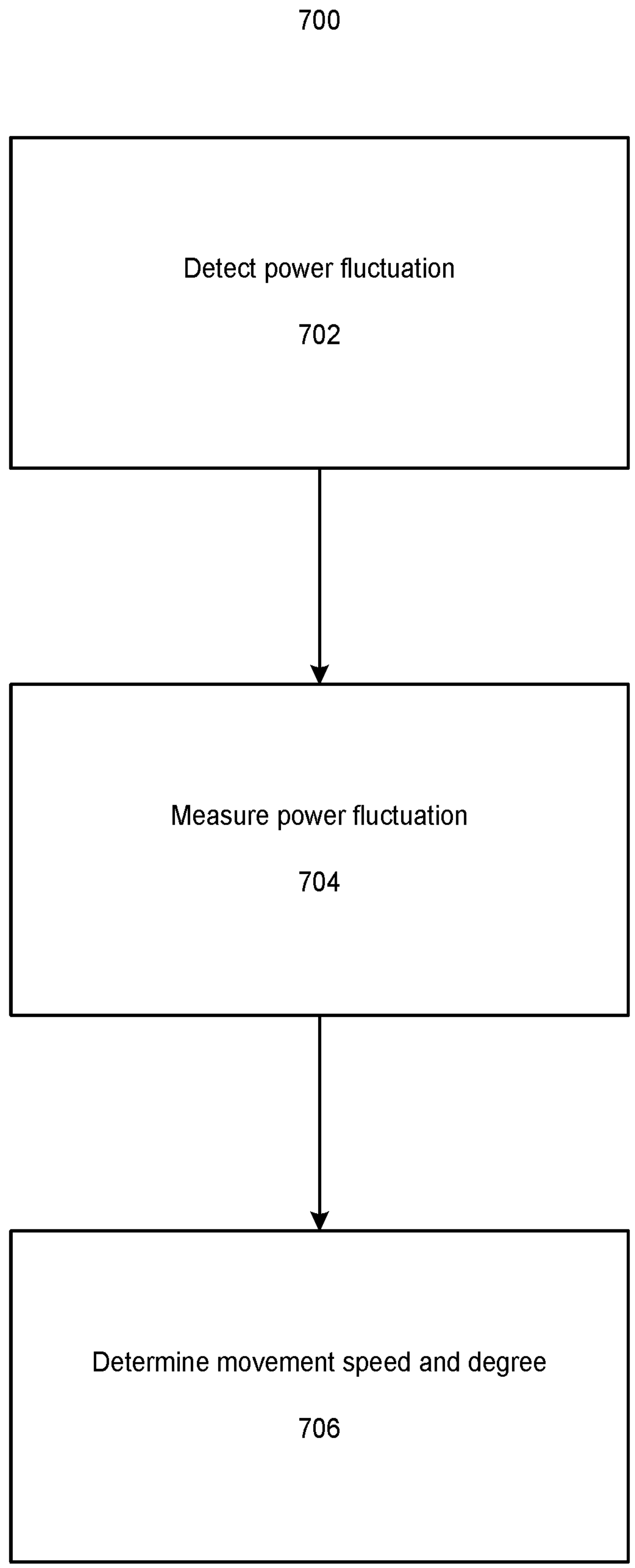

700
Detect power fluctuation
702
Measure power fluctuation
704
Determine movement speed and degree
706

Figure 7

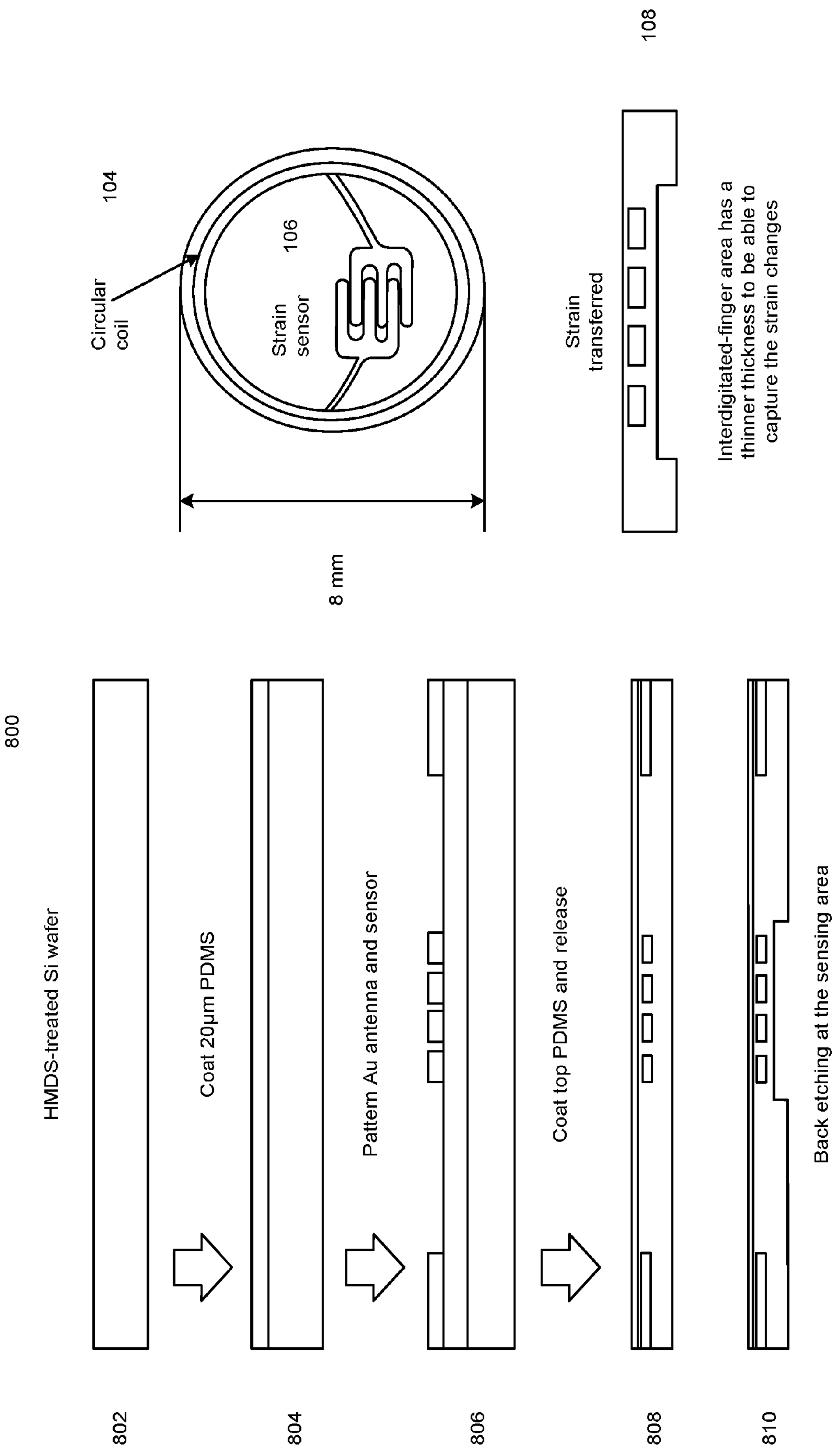

800
802
HMDS-treated Si wafer
804
Coat 20µm PDMS
806
Pattern Au antenna and sensor
808
Coat top PDMS and release
810
Back etching at the sensing area
8 mm
Circular coil
104
Strain sensor
106
Strain transferred
108
Interdigitated-finger area has a thinner thickness to be able to capture the strain changes

Figure 8

NEURO-VIGILANCE INTEGRATED CONTACT EYE LENS AND SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority from U.S. Provisional Application No. 62/207,553, filed Aug. 20, 2015, the entirety of which is incorporated by reference herein.

BACKGROUND

[0002] A person's Sympathetic Nervous System (SNS) can be indirectly assessed with either immobile, wired devices or wrist devices capturing skin conductance, motion, and heart rate—yet these are not validated for SNS activities. Many of these existing tools are battery powered and limited by the battery's operation (e.g., about 6-10 hours).

SUMMARY

[0003] Pupilometry is a physiological representation of neurological function (e.g. after stroke), physiological stresses, emotional reactions, and attention processes (e.g. that change with development or aging). Pupil diameter is under the control of the sympathetic nervous system (SNS). Systems and methods described herein may provide a non-invasive system capable of measuring high-fidelity SNS activity for the long term, low stress monitoring of animals in research facilities and in studies of animals that model human diseases, in addition to humans. An indirect, but accurate, real-time, SNS activity measurement system may include a portable, non-invasive system comprising a wearable device capable of detecting electroencephalography and a wirelessly-coupled smart contact lens capable of providing simultaneous detection of pupil diameter, light levels, and eye movements.

[0004] Embodiments disclosed herein may provide a Neuro-vigilance Integrated Contact Eye (N.I.C.E.) lens and system to measure pupil diameter and eye movement of the person wearing the lens and system.

[0005] Embodiments disclosed herein may provide a Neuro-vigilance Integrated Contact Eye (N.I.C.E.) lens in communication with an eye gear, which together may form a system for measuring, processing, and communicating, among other things, pupil diameter and eye movement of the person wearing the lens and eye gear.

[0006] Embodiments disclosed herein may also detect, monitor, process and/or communicate electroencephalogram (EEG), electrooculogram (EOG), heart rate, and skin impedance data.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] FIGS. **1**A and **1**B show a N.I.C.E. system according to an embodiment of the invention.

[0008] FIG. **2** shows a N.I.C.E. system block diagram according to an embodiment of the invention.

[0009] FIG. **3** shows a tilting angle detection according to an embodiment of the invention.

[0010] FIG. **4** shows examples of eye movement speed detections according to an embodiment of the invention.

[0011] FIG. **5** shows a load modulation arrangement according to an embodiment of the invention.

[0012] FIG. **6** shows a strain detection process according to an embodiment of the invention.

[0013] FIG. **7** shows a movement detection process according to an embodiment of the invention.

[0014] FIG. **8** shows a manufacturing process according to an embodiment of the invention.

DETAILED DESCRIPTION OF SEVERAL EMBODIMENTS

[0015] Systems and methods described herein may provide contact lens technology that may perform simultaneous detection of pupil diameter and eye movement. A N.I.C.E. (Neuro-vigilance Integrated Contact Eye) lens may measure pupil diameter and eye movement in a single contact lens. The disclosed lens may allow science and technology to move away from invasive measurements of the Sympathetic Nervous System (SNS), and instead use the N.I.C.E. lens as a non-invasive tool for SNS-related (e.g., sleep) investigations and applications. Together with a comfortable polymer-based "eye gear" providing a power supply, communications, and the detection of electroencephalogram (EEG), electrooculogram (EOG), heart rate and skin impedance data, the disclosed N.I.C.E. lens and its system may allow for more definitive detection of rapid eye movement (REM) sleep and studies of theta power changes during sleep after trauma that track post-traumatic stress disorder (PTSD) in susceptible patients, for example.

[0016] FIGS. **1**A and **1**B show a N.I.C.E. system **100** according to an embodiment of the invention. The system **100** may be designed based on micro-electromechanical systems (MEMS) technology developed on a thin film of contact-lens material forming the lens **102**, such as polydimethylsiloxane (PDMS). In some embodiments, the system's powering mechanism may be inductive coupling between two antennas in the eye gear (power coil **110**) and the N.I.C.E lens (miniaturized coil **104**), respectively. The operating frequency may be chosen at the near field communication (NFC) frequency of 13.56 MHz, for example. A miniaturized coil **104** may harvest the energy sent from the power source in the eye gear **112** via inductive coupling to operate the circuit components within the lens **102**, which may provide efficiency and biocompatibility. The sensory data, including pupil dilation and eye movement, may be sent from the coil **104** to the power coil **110** in the eye gear **112** via backscattered load modulation. A fabricated coil **104** can be used, and the film thickness may be increased by electroplating it to enhance its quality factor. Since the distance between the coils may be almost zero, sufficient power may be delivered. A smart MEMS-based carbon strain microsensor **106** or other strain sensor may be integrated into the lens **102**. Circuit elements of the lens **102**, such as those described in FIG. **2**, may be arranged in an application-specific integrated circuit (ASIC) chip **108** or other circuit element. The ASIC chip **108** may be back-side etched in a reactive ion etching (RIE) chamber to obtain a thickness of 30 μm or similar to be flexible before integration, as described below. The eye gear **112** may be fabricated on a parylene C substrate, containing thin-film goal electrodes, power coil **110**, and circuit routings to assemble electronics (circuitry **114**). Data, such as EEG, EOG, heart-rate, and skin impedance, may be gathered (e.g., through electrode and/or communication with the lens **102** as described below) and sent to a smartphone connected to the cloud integrated with a diagnostic system **200** for distanced care. The wireless communication between the eye gear **114** and a smartphone may be done via low-power Bluetooth or other suitable wireless communications, and a Lithium-polymer battery **132** may be used to keep the entire eye gear **112** flexible. The N.I.C.E. lens **102** may be capable of measuring pupil diameters indirectly via the strain sensor **106** and eye movement via the misalignment between the coils **104** in the lens and the eye gear **110**, respectively, as described below.

[0017] FIG. **2** shows a N.I.C.E. system **100** block diagram according to an embodiment of the invention. The eye gear **112** circuitry may include signal processing and interpretation circuitry **120**, wireless communication circuitry **122** which may be used to communicate data with the cloud or cloud-based network or diagnostic system **200**, heartrate sensor **124**, EEG sensor **126**, skin impedance sensor **128**, strain and eye movement sensor **130**, battery or other power source **132**, and/or an amplifier (e.g., class-E amplifier **134**). The N.I.C.E. lens **102** may include a strain sensor **106** as mentioned above, an oscillation circuit **118**, a rectifier and regulator **116**. The amplifier **134** may provide power to the N.I.C.E. lens **102** electronics through the energy harvest via inductive coupling between coils **104** and **110**, which may be rectified by the rectifier **116**. The N.I.C.E. lens **102** electronics may provide feedback for load modulation and misalignment tracking to the circuitry **114** through the inductive coupling link.

[0018] In some embodiments, both the N.I.C.E. lens **102** and the eye gear **114** may be based on flexible polymer with embedded components and sensors. The circuit routings, inductor antenna, and electrodes in the eye gear **114** may be made of 0.5-um thick gold sputtered film, for example. The strain sensor may be developed by sputtering carbon onto a 10-um thick parylene C film and etched to define a final size of 0.5 mm×1 mm. Circuits in the N.I.C.E lens **102** may be integrated into an application-specific integrated circuit (ASIC) chip. The ASIC chip, at 3 mm×3 mm, may be back-side etched to obtained a thickness of 30 μm so that it becomes flexible. The thinned ASIC chip and the strain sensor may be integrated and encapsulated in the N.I.C.E lens **102** with connection to the coil **104** for powering and operation.

[0019] FIG. **8** shows an example process **800** for creating ASICs for both the N.I.C.E lens **102** and the eye gear **114**. An hexamethyldisilazane-treated (HMDS) silicon wafer may be processed **802**. First, 20 μm parylene C may be spin coated onto the wafer **804**. Next, a double layer of Au (0.2 μm) on Ti (0.02 μm) may be deposited and patterned **806**, followed by another deposition of 10-μm thick parylene to encapsulate the entire device **808**. The device may be back-etched at the location of the carbon strain sensor to ensure the strain information from the iris muscle is effectively transferred to the sensing area **810** and then released in water. For the N.I.C.E lens **102**, the entire system may be then encapsulated inside the lens material PDMS. For the eye gear **114**, a gecko-inspired texture may be formed on the surface to secure it on the skin while bringing comfort to user.

[0020] FIG. **7** shows a movement detection process **700** according to an embodiment of the invention. As noted above, the system **100** may detect eye movement and speed. As the eye ball moves, the coil **104** may become misaligned with respect to the coil **110**, thus the received power will be fluctuated. in The power fluctuations may be detected **702** by strain and eye movement sensor **130** and measured **704** by signal processor **120**, and based on the measured fluctuations, the speed of the movement as well as the degree of the movement may be tracked **706** by signal processor **120** and reported by wireless communication system **122**. FIG. **3** shows a tilting angle detection example **300**. As shown by the graph, changes in voltage represent changes in tilting angle of the eye. Furthermore, a slope of the curve represents the speed of the movement of the eye. FIG. **4** shows additional examples of REM detection made by the process **400** of FIG. **7**. For example, graph **402** shows 5 cycle per minute eye movement, graph **404** shows 10 cycle per minute eye movement, graph **406** shows 15 cycle per minute eye movement, and graph **408** shows 20 cycle per minute eye movement. As shown, faster eye movement results in steeper curves on the graph.

[0021] FIG. **5** shows a load modulation arrangement using elements of the circuit of FIG. **2**, and FIG. **6** shows a strain detection process **600** according to an embodiment of the invention. As the iris muscle contracts, the strain of the muscle contraction will be partially sent to the cornea, where it may be detected **602** by the resistive strain sensor **106**. The resistance of the sensor may modulate a fluctuating frequency **604** produced by frequency generator **118** which may be detected **606** by strain and eye movement sensor **130** in the coil **110** of the eye gear via the back-scattering signal. Based on this detected signal, the strain may be determined **608** by signal processor **120** and reported by wireless communication system **122**. For example, the signal **500** of FIG. **5** is varied between a high switching frequency and a low switching frequency, with one of the frequency modes (e.g., either high or low depending on embodiment) indicating the presence of a muscle contraction strain.

[0022] It should be appreciated that in accordance with the principles disclosed herein, processing can be done at the lens level or cloud level. For example, some embodiments may include an embedded algorithm (e.g., within signal processing and interpretation circuitry **120**) that may monitor for an anomaly to look for/diagnose e.g., wrong dilations during REM sleep and then send a signal using wireless communication circuitry **122** to the user's cell phone (e.g., remote system **200**) to wake the user because he/she is going to enter the wrong stage of sleep (e.g., for users with PTSD). The disclosed lens system may include wireless communication circuitry **122** (Bluetooth, WiFi, Zigbee, cellular) that sends the lens data to a cloud-based network or system phone (e.g., remote system **200**) where it can be processed and analyzed for anomalies, etc.

[0023] The data sent to the cloud based network or system could be used by a physician/nurse who can diagnose an anomaly and call the patient if there is bad pupil dilation. In addition, or alternatively, the cloud based network or system could send an action to the user's home which e.g., triggers a light switch (via the "Internet of Things"—IoTs) to wake up the user and to avoid bad REM sleep. These are just some example uses of the lens and system data disclosed herein.

[0024] The N.I.C.E. lens and system can be used in both animal studies and human subject studies. For example, an animal study may include simultaneously measuring multiple peripheral sympathetic nervous system (SNS) activity metrics and central norephinephrine (NE) activity. This could be an exploratory study to see which peripheral metrics best correlate with central NE activity in the locus coeruleus (LC). Moreover, the disclosed lens and system can be used to determine, among other things, (1) which peripheral metrics best correlate with central NE activity in the locus coeruleus (LC), (2) which peripheral measures best correlate with central NE activity in the LC, (3) which peripheral activation metrics best correlate with the hyperarousal and intrusive symptoms in those with PTSD, (4) which behavioral and medical (e.g. drug) interventions best lower SNS activity in those with prolonged SNS hyperactivity after trauma, (5) if SNS-lowering interventions are put in place or sleep is prevented until SNS hyperactivity is reversed, does that protect against developing the symptoms of PTSD, and (6) if sleep is allowed, but only REM sleep and TR sleep is prevented when the SNS is too high (e.g. the storms of SNS activity during sleep are exaggerated) is that enough to prevent PTSD from developing.

[0025] An example beneficiary from the disclosed N.I.C.E. lens system will be warfighters and veterans facing PTSD or TBI. The disclosed principles can measure pupil diameter and eye movement to help resolve SNS activity, especially during REM sleep. The disclosed system can provide a "green light" to users whose sympathetic readouts indicate that they are ready for adaptive sleep. However, if they are not yet ready, yet are driven to sleep, the disclosed sensor could provide an alarm-type awakening signal when it senses that the user is going into REM sleep and it would do this for the purpose of preventing maladaptive REM. Another impact is that patients who are not yet in the sleep safe zone can indicate SNS calming task that uses the disclosed metrics to indicate when they have succeeded in calming their SNS. The EEG signal helps detect REM and possible hemisphere asymmetries.

[0026] Moreover, the disclosed system provides a way to detect REM sleep and study theta power changes during sleep after trauma that track PTSD in susceptible people and help explore EEG frequency cross-coupling differences in those exposed to trauma. Another outcome from the disclosed N.I.C.E. lens system is that the military warfighter can use the tool as a device to determine mission readiness. The disclosed N.I.C.E. lens system can advance the field of sleep medicine by offering the first device to measure REM sleep and circadian rhythms. Furthermore, the disclosed lens will remove the need for many obtrusive, wired sensors used in sleep studies. Psychologists can better assess patients and their emotions with the N.I.C.E. lens system.

[0027] While various embodiments have been described above, it should be understood that they have been presented by way of example and not limitation. It will be apparent to persons skilled in the relevant art(s) that various changes in form and detail can be made therein without departing from the spirit and scope. In fact, after reading the above description, it will be apparent to one skilled in the relevant art(s) how to implement alternative embodiments.

[0028] In addition, it should be understood that any figures which highlight the functionality and advantages are presented for example purposes only. The disclosed methodology and system are each sufficiently flexible and configurable such that they may be utilized in ways other than that shown.

[0029] Although the term "at least one" may often be used in the specification, claims and drawings, the terms "a", "an", "the", "said", etc. also signify "at least one" or "the at least one" in the specification, claims and drawings.

[0030] Finally, it is the applicant's intent that only claims that include the express language "means for" or "step for" be interpreted under 35 U.S.C. 112(f). Claims that do not expressly include the phrase "means for" or "step for" are not to be interpreted under 35 U.S.C. 112(f).

What is claimed is:

1. A system comprising:

a contact lens comprising at least one sensor; and

an eye gear package comprising:

an interface circuit configured to communicatively couple the eye gear package with the contact lens;

a power source configured to power the eye gear package and the contact lens; and

a processor configured to process data generated by the at least one sensor.

2. The system of claim **1**, wherein the at least one sensor comprises a strain sensor.

3. The system of claim **2**, wherein:

the contact lens further comprises an oscillation circuit;

the strain sensor is configured to modulate an output of the oscillation circuit based on detected strain;

the eye gear package further comprises strain detection circuitry configured to detect the modulated output of the oscillation circuit; and

the processor is configured to determine eye strain based on an output of the strain detection circuitry.

4. The system of claim **1**, wherein the at least one sensor comprises a first coil.

5. The system of claim **4**, wherein the interface circuit comprises a second coil.

6. The system of claim **5**, wherein:

the eye gear package further comprises eye movement detection circuitry configured to detect a power fluctuation in power sent to the contact lens by the interface circuit caused by a change in alignment between the first coil and the second coil; and

the processor is configured to determine eye movement based on an output of the eye movement detection circuitry.

7. The system of claim **1**, wherein the contact lens comprises a flexible application-specific integrated circuit comprising the at least one sensor.

8. The system of claim **1**, wherein the eye gear package comprises a flexible application-specific integrated circuit comprising the interface circuit, the power source, and the processor.

9. The system of claim **1**, wherein the eye gear package comprises at least one eye gear sensor.

10. The system of claim **9**, wherein the at least one eye gear sensor comprises a heart rate sensor, an electroencephalogram sensor, an electrooculogram sensor, a skin impedance sensor, or a combination thereof.

11. The system of claim **1**, wherein the eye gear package comprises a wireless communication system coupled to the processor and configured to transmit an output of the processor.

12. A method comprising:

powering, with a power source of an eye gear package, a contact lens comprising at least one sensor;

detecting, with the at least one sensor, an eye condition;

receiving, with an interface circuit of the eye gear package, data associated with the eye condition from the contact lens; and

processing, with a processor, the data associated with the eye condition.

13. The method of claim **12**, wherein:

the at least one sensor comprises a strain sensor;

detecting the eye condition comprises modulating, with the strain sensor, an output of an oscillation circuit of the contact lens based on detected strain;

the method further comprises detecting, with strain detection circuitry of the eye gear package, the modulated output of the oscillation circuit; and

the processing by the processor comprises determining eye strain based on an output of the strain detection circuitry.

14. The method of claim **12**, wherein:

the at least one sensor comprises a first coil;

the interface circuit comprises a second coil;

the method further comprises detecting, with eye movement detection circuitry of the eye gear package, a power fluctuation in power sent to the contact lens by the interface circuit caused by a change in alignment between the first coil and the second coil; and

the processing by the processor comprises determining eye movement based on an output of the eye movement detection circuitry.

15. The method of claim **12**, further comprising sensing data with at least one eye gear sensor of the eye gear package.

16. The method of claim **15**, wherein the data detected with the at least one eye gear sensor comprises heart rate data, electroencephalogram data, electrooculogram data, skin impedance data, or a combination thereof.

17. The method of claim **12**, further comprising transmitting, with a wireless communication system coupled to the processor, an output of the processor.

* * * * *

专利名称(译)	神经警戒集成接触式眼睛晶状体和系统		
公开(公告)号	US20170049395A1	公开(公告)日	2017-02-23
申请号	US15/241941	申请日	2016-08-19
[标]申请(专利权)人(译)	赞索斯有限责任公司		
申请(专利权)人(译)	ZANSORS LLC		
当前申请(专利权)人(译)	ZANSORS LLC		
[标]发明人	CAO HUNG		
发明人	CAO, HUNG		
IPC分类号	A61B5/00 A61B3/113 A61B5/0205 A61B3/11		
CPC分类号	A61B5/6821 A61B3/112 A61B3/113 A61B5/0531 A61B5/02438 A61B5/0476 A61B5/0496 A61B5/0205 A61B5/4035		
优先权	62/207553 2015-08-20 US		
外部链接	Espacenet USPTO		

摘要(译)

隐形眼镜可包括至少一个传感器。眼齿轮组件可以包括：接口电路，被配置为通信地耦合眼齿轮组与接触透镜;电源，被配置为为眼齿轮组和接触透镜提供动力;以及处理器，被配置为处理由至少一个传感器。