

# **Europäisches Patentamt European Patent Office** Office européen des brevets

EP 1 674 034 A1

(12)

# **EUROPEAN PATENT APPLICATION**

(43) Date of publication:

28.06.2006 Bulletin 2006/26

(51) Int Cl.:

A61B 5/00 (2006.01) G07C 3/00 (2006.01)

(11)

A61B 1/00 (2006.01)

(21) Application number: 06006843.4

(22) Date of filing: 09.02.2001

(84) Designated Contracting States:

AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE TR

(30) Priority: 10.02.2000 US 502032

(62) Document number(s) of the earlier application(s) in accordance with Art. 76 EPC: 01909052.1 / 1 257 190

(71) Applicant: Masimo Corporation Irvine, CA 92614 (US)

(72) Inventor: The designation of the inventor has not yet been filed

(74) Representative: Vossius & Partner Siebertstrasse 4 81675 München (DE)

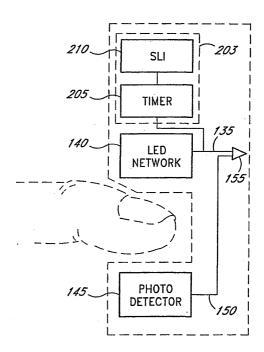
#### Remarks:

This application was filed on 31 - 03 - 2006 as a divisional application to the application mentioned under INID code 62.

#### (54)Sensor life monitor system

A system and a method monitor the useful and safe life of a pulse oximetry sensor. According to one embodiment, the method comprises detecting use of electronics of a noninvasive optical probe, wherein the electronics of the noninvasive optical probe comprise at least one of a plurality of emitters or a light sensitive detector capable of detecting light attenuated by tissue; updating a cumulative measure of an amount of use of the electronics; determining whether the cumulative measure exceeds a predetermined amount of use; and activating an indicator capable of informing a user that the electronics have expired.





EP 1 674 034 A1

1

### Description

#### **Background of the Invention**

### Field of the invention

**[0001]** The present invention in general relates to sensors for measuring oxygen content in the blood, and, in particular, relates to an apparatus and method for monitoring the life of a pulse oximetry sensor.

### **Background**

**[0002]** Early detection of low blood oxygen is critical in a wide variety of medical applications. For example, when a patient receives an insufficient supply of oxygen in critical care and surgical applications, brain damage and death can result in just a matter of minutes. Because of this danger, the medical industry developed pulse oximetry, a noninvasive procedure for measuring the oxygen saturation of the blood. A pulse oximeter interprets signals from a sensor attached to a patient in order to determine that patient's blood oxygen saturation.

[0003] A conventional pulse oximetry sensor has a red emitter, an infrared emitter, and a photodiode detector. The sensor is typically attached to a patient's finger, earlobe, or foot. For a finger, the sensor is configured so that the emitters project light from one side of the finger, through the outer tissue of the finger, and into the blood vessels and capillaries contained inside. The photodiode is positioned at the opposite side of the finger to detect the emitted light as it emerges from the outer tissues of the finger. The photodiode generates a signal based on the emitted light and relays that signal to the pulse oximeter. The pulse oximeter determines blood oxygen saturation by computing the differential absorption by the arterial blood of the two wavelengths (red and infrared) emitted by the sensor.

[0004] The foregoing conventional sensor is typically detachable from the oximeter to allow for periodic replacement. Periodic replacement is advantageous for a wide variety of reasons. For example, the sensor can become soiled, thereby possibly inhibiting sensor sensitivity or causing cross-patient contamination. Furthermore, the electronic circuitry in the sensor can become damaged, thereby causing sensor failure or inaccurate results. Moreover, the securing mechanism for the sensor, such as an adhesive substrate, can begin to fail, thereby improperly positioning the sensor in proximity to a measurement site and providing inaccurate data. Accordingly, periodic replacement of the sensor is an important aspect of maintaining a sterile, highly sensitive, accurate pulse oximetry system.

**[0005]** However, a conventional pulse oximetry sensor is wholly reliant on an operator for timely replacement of soiled, damaged, or otherwise overused sensors. This approach is problematic not only from the standpoint of operator mistake or negligence, but also from the per-

spective of deliberate misuse for cost saving or other purposes.

**[0006]** Based on the foregoing, significant drawbacks exist in the reliance on the operator for the periodic replacement of conventional pulse oximetry sensors. Accordingly, a need exists for a pulse oximetry sensor having the ability to monitor its own usable life.

### **Summary of the Invention**

**[0007]** Accordingly, one aspect of the present invention is to provide an inexpensive, highly accurate sensor life monitoring system for monitoring the useful and safe life of a pulse oximetry sensor. According to one embodiment, the sensor life monitoring system includes a timer and a sensor life indicator. According to another embodiment, the timer includes a divide-by-n counter and a nonvolatile RAM, while the sensor life indicator includes at least one LED or incandescent bulb.

**[0008]** Therefore, one aspect of the present invention is a pulse oximetry sensor comprising a drive connection carrying a drive signal, wherein the drive signal has pulses. The pulse oximetry sensor further comprises a timer connected to the drive connection and configured to generate a timer output signal after a predetermined number of pulses are generated in the drive signal; and a sensor life indicator connected to the timer output signal and configured to provide an indication when the timer output signal is generated. The pulse oximetry sensor further comprises an LED network connected to the drive connection and configured to project light through a measurement site when pulsed by the drive signal; and a photodetector configured to detect the projected light and output a signal representative of constituents or characteristics of the measurement site.

**[0009]** Another aspect of the present invention is a sensor life monitoring system comprising a timer connected to a sensor drive signal; and a sensor life indicator connected to the timer such that the sensor life indicator is configured to indicate the expiration of the useful or safe life of a pulse oximetry sensor.

**[0010]** Another aspect of the present invention is a pulse oximetry system that comprises a pulse oximeter; a sensor connected to the pulse oximeter; and a sensor life monitor connected to the sensor and configured to monitor the useful and safe life of the sensor.

**[0011]** Another aspect of the present invention is a method of manufacturing a sensor. The method comprises connecting a timer to one of a sensor input and a sensor output; and connecting an indicator to the timer such that when the timer expires, the indicator is activated

**[0012]** Another aspect of the present invention is a method for monitoring the life of an oximetry sensor. The method comprises monitoring a parameter responsive to repeated use of a sensor. When the parameter indicates that the sensor has expired, the method generates an expiration indication.

20

30

40

**[0013]** Another aspect of the present invention is an oximetry sensor life indicator that comprises a non-volatile counter connected to receive a drive signal having a plurality of transitions where the counter changes a count value in response to the transitions. The oximetry sensor life indicator further includes a sensible indicia connected to the counter, where the sensible indicia has a first state, and a second state and the sensible indicia changes from the first state to the second state to indicate the end of life of the oximetry sensor when the count value in the counter reaches a predetermined value.

[0014] Another aspect of the present invention is an oximetry system comprising an oximeter; a sensor attached to the oximeter through a cable; a timer connected to at least one of a sensor drive signal and a sensor return signal; and a sensor life indicator connected to the timer.

[0015] Another aspect of the present invention is an oximetry system comprising a sensor having a timer, wherein the timer produces a sensor expiration signal. An oximeter is connected to the sensor and is configured to receive the sensor expiration signal from the timer.

**[0016]** Another aspect of the present invention is an oximetry system comprising a sensor having a reset indicator. An oximeter is connected to the sensor and is configured to monitor whether the reset indicator has been set.

**[0017]** Another aspect of the present invention is a pulse oximetry system comprising a pulse oximeter and a sensor connected to the pulse oximeter. The sensor is adapted to measure a physiological parameter. The pulse oximetry system also comprises a memory device connected to the sensor and adapted to measure the useful life of the, sensor.

**[0018]** Another aspect of the present invention is a pulse oximetry system comprising a sensor having an emitter, a detector, and a memory device storing a characteristic of the sensor. The pulse oximetry system also comprises a pulse oximeter connected to the sensor and adapted to read the characteristic of the sensor and the output of the detector. The pulse oximetry system also comprises a database connected to the pulse oximeter and adapted to store the characteristic along with a longevity measurement corresponding to the sensor.

**[0019]** For the purposes of summarizing the invention, certain aspects, advantages, and novel features of the invention have been described. Of course, it is to be understood that not necessarily all such advantages may be achieved in accordance with any particular embodiment of the invention. Thus, the invention may be embodied or carried out in a manner that achieves or optimizes one advantage or a group of advantages, as taught herein, without necessarily achieving other advantages as may be taught or suggested herein.

**[0020]** Other aspects and advantages of the invention will be apparent from the detailed description below and the appended claims.

## Brief Description of the Drawings

**[0021]** The present invention is described in more detail below in connection with the attached drawings, which are meant to illustrate and not limit the invention, and in which:

FIGURE 1 illustrates a block diagram of a typical oximetry system;

FIGURE 2 illustrates a block diagram of a sensor life monitoring system according to an embodiment of the invention;

FIGURE 3 illustrates a block diagram of the sensor life monitoring system of FIGURE 2, according to another embodiment of the invention;

FIGURE 4 illustrates a block diagram of an oximetry system having a sensor life monitoring system, according to yet another embodiment of the invention; FIGURE 5 illustrates a block diagram of an oximetry system having a sensor life monitoring system, according to yet another embodiment of the invention; FIGURE 6 illustrates a flow diagram of the operation of a microprocessor of the oximetry system of FIGURE 5;

FIGURE 7 illustrates a block diagram of an oximetry system having a sensor life monitoring system, according to yet another embodiment of the invention; and

FIGURE 8 illustrate a block diagram of an oximetry system having a sensor life monitoring system, according to yet another embodiment of the invention.

### Detailed Description of the Preferred Embodiment

**[0022]** The inventions are described in detail below with reference to the figures, wherein like elements are referenced with like numerals throughout.

[0023] FIGURE 1 illustrates a block diagram of a typical oximetry system 100 used to determine arterial oxygen saturation. The oximetry system 100 includes an oximeter 105 and a sensor 110 connected to the oximeter 105 via a patient cable 115. The oximeter 105 includes a microprocessor (p) 120, a speaker 125 and a display 130. The sensor 110 includes a drive connection 135 connected to at least one LED network 140, a photo detector 145 connected to a return signal connection 150, and a cable connector 155 housing one end of each of the drive connection 135 and the return signal connection 150. As mentioned, the sensor 110 attaches to the oximeter 105 via the patient cable 115. The patient cable 115 includes a sensor connector 160 for electrically mating with the cable connector 155 of the sensor 110.

**[0024]** As previously mentioned, the typical oximetry system 100 produces a drive signal and transmits the drive signal through the patient cable 115 and the drive connection 135 to the LED network 140 such that light energy is transmitted from the LED network 140 through tissue. The photo detector 145 senses the light energy,

which has now been attenuated by the blood in tissue, and sends a representative signal of the light energy back to the oximeter 105 through the return signal connection 150 and the patient cable 115. The oximeter 105 analyzes the representative signal from the photo detector 145 to determine constituence and characteristics of the blood in the tissue.

[0025] The sensor 110 typically includes the foregoing electronic circuitry and an attachment mechanism formed to secure the electronic circuitry to a measurement site. The sensor 110 may be disposable, wherein the attachment mechanism is likely formed from an adhesive structure. Moreover, the sensor 110 may be reusable, wherein the attachment mechanism is likely formed from a clip-on structure. Also, the sensor 110 may be a combination of the disposable and reusable type sensors, wherein a disposable attachment mechanism removably attaches the electronic circuitry such that the electronic circuitry is reusable. Furthermore, the sensor 110 may include an information element electrically connected to the LED network 140. Such an information element advantageously provides quality control, security, and identification functions.

**[0026]** An example of the combination sensor having an information element distributed in the disposable attachment mechanism is described in U.S. Patent Application No. 09/456,666, filed on December 9, 1999, titled, "RESPOSABLE PULSE OXIMETRY SENSOR," assigned to the assignee of the current application, and incorporated by reference herein.

[0027] FIGURE 2 illustrates a block diagram of a pulse oximetry sensor 200, according to an embodiment of the invention. As shown in FIGURE 2, the sensor 200 includes a wholly incorporated sensor life monitoring system 203. The sensor life monitoring system 203 includes a timer 205 and a sensor life indicator (SLI) 210. According to this embodiment, the timer 205 is electrically connected to the drive connection 135 such that the timer 205 also receives the drive signal from the oximeter 105. The timer 205 also connects to the sensor life indicator 210.

**[0028]** As the oximeter 105 drives the LED network 140, the timer 205 monitors the number of drive pulses produced and keeps a running count. After the oximeter 105 produces a predetermined number of drive signals, the timer 205 provides a signal to the sensor life indicator 210, such that the sensor life indicator 210 produces an indication that the sensor 200 has expired and should be replaced.

**[0029]** FIGURE 3 illustrates a block diagram of an example of the sensor life monitoring system 203 of FIGURE 2, according to one embodiment of the invention. As shown in FIGURE 3, the timer **205** advantageously comprises a non-volatile counter. One embodiment of the non-volatile counter advantageously comprises a counter 300 having an output that connects to an input of a logic gate 302. An output of the logic gate 302 connects to an adder 304. As used herein, an "adder" can

be an arithmetic unit, which may also be implemented as a subtractor or the like. The adder 304 connects to a non-volatile (NV) RAM 305 (A non-volatile RAM does not lose data when the power is turned off or otherwise terminated). An output of the NVRAM-305 reconnects as feedback to the adder 304. Also, an output of the most significant bit (MSB) of the NVRAM 305 connects to both an inverter 307 and the sensor life indicator 210. The inverter 307 connects as feedback to another input of the logic gate 302. Moreover, the output of the logic gate 302 activates or clocks the NVRAM 305.

[0030] According to one embodiment, the counter 300 comprises a divide-by-n counter, producing an incremental output count only after n input pulses, or transitions, of the drive signal. Using a divide-by-n counter advantageously reduces the capacity requirements of the NVRAM 305. Furthermore, according to one embodiment, the logic gate 302 is an AND gate, the adder 304 is a plus-one adder. Thus, each time the adder 304 receives an input, it adds one to the current count stored in the NVRAM 305. According to one embodiment, the NVRAM 305 is a seventeen-bit non-volatile memory that clocks, for example, on the trailing edge of the output of the logic gate 302.

**[0031]** According to an embodiment of the invention, the sensor life indicator 210 comprises a sensible indicia, such as visible light. For example, the sensible indicia may advantageously be an LED 310, or the like. Alternatively, the sensible indicia may be audible, vibrational, a power down of the sensor **200** or the oximeter **105**, or the like.

**[0032]** The operation of the foregoing timer **205** and sensor life indicator **210** will be disclosed with reference to two differing time frames. The first time frame refers to when a new sensor **200** is initially attached to the oximeter 105 and provided with a drive signal. The second time frame refers to when the sensor 200 has previously been used, and a new drive signal is applied.

#### FIRST USE OF THE SENSOR 200

[0033] According to the foregoing embodiment, the sensor life monitoring system 203 initially functions as follows. The oximeter 105 outputs a drive signal at, for example, one kHz. The counter 300 comprises a divideby-1000 counter that advantageously produces, for example, an output only after one thousand cycles of the drive signal, or every one second. Furthermore, assuming the count stored in the NVRAM 305 is initially zero, the output of the MSB of the NVRAM 305 is zero. The inverter 307 inverts the output of the MSB such that the logic gate 302 passes the output of the counter 300 to the adder 304. Thus, according to this example, the adder 304 receives a pulse every second from the counter 300. With each pulse, the adder 304 adds one to count stored in the NVRAM 305. Thus, after one second, the adder 304 places a one in the NVRAM 305. After another second, the adder 304 places a two in the NVRAM 305, and

so forth until the NVRAM 305 fills to capacity, or the oximeter 105 ceases producing the drive signal. Both events are further discussed as follows.

#### SUBSEQUENT USE OF THE SENSOR 200

**[0034]** When the oximeter 105 sends pulses to a previously used sensor 200, the NVRAM 305 will already have a previous count stored therein. The previous count is loaded into the adder 304 such that as the logic gate 302 outputs the foregoing signal every second, the adder 304 adds one to the previous count. For example, if the previous count were one hour, or 3,600 seconds, the first pulse received by the adder 304 from the counter 300 will store 3,601 in the NVRAM 305. Thus, much like an automobile odometer, the NVRAM 305 stores a running count, or times, the used life of the sensor 200.

[0035] When the count stored in the NVRAM 305 reaches capacity (in other words, sets the MSB), the output of the MSB switches. Therefore, the output of the inverter 307 switches such that the logic gate 302 blocks any future signals output from the counter 300 from reaching the adder 304. Moreover, the output of the MSB further activates the LED 310 such that the LED 310 indicates the sensor 200 has expired. This indication by the LED 310 signals the operator to replace the used sensor 200 with a new one. The indication advantageously provides multiple people with the knowledge that the sensor 200 should be changed. For example, doctors, nurses, visitors, and even the patient may perceive the indication that the sensor 200 has expired.

[0036] According to the foregoing embodiment where every second that the oximeter 105 sends drive pulses to the sensor 200, the seventeen-bit NVRAM 305 is incremented, the MSB of the NVRAM 305 will set after 131,072 seconds, or, one day, twelve hours, twenty-four minutes and thirty two-seconds. In other words, according to this embodiment, the useful life of the sensor 200 expires after the sensor 200 has received drive pulses for a combined total of the foregoing time.

[0037] A skilled artisan will understand that a wide number of differing logic mechanisms may be employed in the foregoing embodiment. For example, employing different sized counters 300 or NVRAMs 305 will adjust the predetermined expiration time. Moreover, the counter 300 may advantageously divide by more than one thousand, thereby further reducing the capacity requirements of the NVRAM 305. Also, the timer 205 may advantageously comprise a non-volatile counter that has internal registers that retain their values when the power is turned off. Such non-volatile counters are available, for example, from Dallas Semiconductor Corporation of Dallas, Texas. These non-volatile counters may include, for example, Dallas Semiconductor's DS1602 or DS1603. In the foregoing embodiments employing a non-volatile counter, the adder 304 and the counter 300 may not be

[0038] A skilled artisan will also understand that the

sensor 200 may advantageously employ a wide variety of differing timers 205 and differing sensor life indicators 210. Moreover, the choice may advantageously coincide with particular types of the sensor 200. For example, a purely disposable sensor suggests a less costly solution than that of the reusable sensor because of manufacturing costs and the relatively short life of the disposable sensor. On the other hand, the combination sensor may incorporate a more expensive solution into the reusable portion of the electronic circuitry without dramatic cost changes to the disposable portion.

[0039] Moreover, a skilled artisan will recognize that the timer 205 may advantageously comprise a capacitor that is charged when the sensor 200 is connected to the oximeter 105. In such case, the capacitor has known discharge characteristics such that the voltage across the capacitor can be used to measure the useful life of the sensor 200. Also, rather than using the pulses of the drive signal, the timer 205 may employ an oscillator configured to trigger at the beginning of sensor use.

[0040] Further, the sensor life indicator 210 may include several LEDs of differing colors, such as green and red, to indicate whether the sensor 200 has expired. The sensor life indicator 210 may comprise an incandescent light, an audio or vibrational alarm, a digital or LCD display, or other sensible indicia. Moreover, the sensor life indicator 210 may include a blocking signal for automatically terminating the functionality of the sensor 200. For example, a logic gate may be advantageously added to the drive signal such that the logic gate has the drive signal as an input and has the output of the timer 205 as the another. When the output of the timer 205 is a logic level signaling expiration, the logic gate blocks the drive signal from passing, thus rending the sensor 200 inoperative. The foregoing logic circuit may also be used to block the signal transferred through the return signal connection 150. On the other hand, the blocking signal may also comprise a fuse that once blown, renders the sensor 200 inoperative.

[0041] Accordingly, a skilled artisan may perceive a variety of differing devices to measure the longevity of the sensor 200. Furthermore, the type of the sensor 200 may provide guidance on which of the wide variety of devices to use.

[0042] FIGURE 4 illustrates a block diagram of yet another embodiment of an oximetry system 400 including a sensor life monitoring system 405. According to this embodiment, the sensor life monitoring system 405 employs the timer 205 and a return signal 410 to the oximeter 105. Similar to the foregoing embodiment, the timer 205 connects to the drive connection 135 and uses the pulses of the drive signal to measure the useful and safe life of the sensor 200. In contrast to the foregoing embodiment, the timer 205 then outputs an incremental count of pulses to the oximeter 105 via the return signal 410, the cable connector 155, the sensor connector 160, and the patient cable 115. In this embodiment, the microprocessor 120 of the oximeter 105 receives the incremental count from

35

40

45

the timer 205 and compares the incremental count with a predetermined amount. If the count is greater than the predetermined amount, the microprocessor 120 issues an expiration indication of the sensor 200 through the oximeter 105.

[0043] A skilled artisan will recognize that the oximeter 105 may issue the expiration indication through a wide variety of devices including, but not limited to, those described in relation to the sensor life indicator 210 of FIG-URES 2-3. Moreover, the oximeter 105 may take advantage of the more costly technology already associated therewith. For example, the oximeter 105 may issue the expiration indication by employing an audio alarm through the speaker 125, a visual alarm through the display 130, or a power-down function where the oximeter 105 is inoperable until the sensor 200 is replaced.

**[0044]** FIGURE 5 illustrates a block diagram of yet another embodiment of an oximetry system 500 including a sensor life monitoring system 505. According to this embodiment, the sensor life monitoring system 505 employs a reset indicator 510 and the sensor life indicator 210, as an integral part of the sensor 200. The reset indicator 510 and the sensor life indicator 210 connect to the oximeter 105 through the cable connector 155, the sensor connector 160, and the patient cable 115. Also according to this embodiment, the microprocessor 120 includes a timer 515.

**[0045]** According to this embodiment, the microprocessor 120 measures the useful and safe life of the sensor 200. For example, the microprocessor 120 may track the pulses in the drive signal created by the microprocessor 120, or take advantage of a date/time function to measure actual time. Furthermore, the microprocessor 120 employs the reset indicator 510 on the sensor 200 to indicate whether the sensor 200 is newly attached or has previously expired. For example, the reset indicator 510 may comprise a one-bit memory or a fuse technology, wherein the one-bit memory is set, or the fuse is blown, when the sensor 200 first connects to the oximeter 105 through the mating of the cable and sensor connectors, 155 and 160 respectively.

**[0046]** As shown in FIGURE 5, the sensor life indicator 210 remains an integral part of the sensor 200 and, therefore, may advantageously take any of the forms discussed above with reference to FIGURES 2 and 3. Preferably, the sensor life indicator 210 comprises the LED 310 of FIGURE 3.

[0047] FIGURE 6 illustrates a flow diagram 600 of the steps taken by the microprocessor 120 of the oximetry system 500 of FIGURE 5, according to one embodiment of the invention. As shown in FIGURE 6, the process begins' when the oximeter 105 is activated to a sensing state by, for example, an operator, in a STEP 603. The oximeter 105 first checks the reset indicator 510, in a STEP 605, to determine whether the sensor 200 has been previously used. If the sensor 200 is new, the microprocessor 120 resets the timer 515, in a STEP 610, and sets the reset indicator 510 on the sensor 200, in a

STEP **615**. The microprocessor **120** then proceeds with normal operation, e.g., to output a drive signal to the sensor 200, in a STEP 620.

[0048] On the other hand, if in the STEP 605, the reset indicator 510 indicates that the sensor 200 has been previously used, or when the sensor 200 is in normal operation, in the STEP 620, the microprocessor 120 checks whether the timer 515 indicates the sensor 200 has reached its predetermined longevity, in a STEP 625. For example, the timer 515 may advantageously compare the number of drive pulses to a predetermined number to conclude whether the sensor 200 has expired.

**[0049]** If the sensor 200 has not expired, the microprocessor 120 again proceeds with normal operation, in the STEP 620. On the other hand, if the timer 515 indicates that the sensor 200 has expired, the microprocessor 120 activates the sensor life indicator 210, in a STEP 630, and then the process terminates, in a STEP 635.

[0050] One having ordinary skill in the art will understand that the microprocessor 120 may employ an interrupt driven mechanism for the timer 515. For example, during normal operation, the microprocessor 120 may not continually, or periodically, check the timer 515, as in the STEP 625. Rather, the microprocessor 120 may continually send drive pulses until the timer 515 generates an interrupt that instructs the microprocessor 120 to activate the sensor life indicator 210. A skilled artisan will appreciate that there are a wide number of mechanisms for generating microprocessor interrupts.

[0051] FIGURE 7 illustrates a block diagram of yet another embodiment of an oximetry system 700 including a sensor life monitoring system 705. According to this embodiment, the oximetry system 700 is similar to that described in reference to FIGURE 5. Like FIGURE 5, the microprocessor 120 of the oximeter 105 includes the timer 515, or timer-like functions. Also, the sensor life monitoring system 705 advantageously employs the reset indicator 510 to ensure replacement of new sensors when the sensor 200 expires. Moreover, like FIGURE 4, the oximetry system 700 employs the oximeter 105 to provide an expiration indication once the sensor 200 expires. [0052] Thus, according to one embodiment, the microprocessor 120 of the oximeter 105 checks the reset indicator 510 to ensure the sensor 200 has not previously been used. Then, the microprocessor 120 drives the LED network 140 and tracks the timing functions. When the predetermined number of drive pulses is reached, the microprocessor 120 employs various mechanisms on the oximeter 105 to generate the expiration indication. For example, the microprocessor 120 may use the speaker 125 or the display 130, even power down the oximeter 105, or the like, to create the expiration indication.

[0053] FIGURE 8 illustrates a block diagram of yet another embodiment of an oximetry system 800. According to this embodiment, the oximetery system 800 includes a sensor life monitoring system 805 having a memory device 810. The memory device 810 is preferably a single wire memory device having a unique identifier, such as

35

40

45

50

memory devices commercially available from companies such as Dallas Semiconductor Corporation. For example, Dallas Semiconductor's DS2401 includes a unique, 64-bit identification number. In this way, the memory device 810 can uniquely identify the sensor 200 from all other sensors.

[0054] The oximetry system 800 further includes the microprocessor 120 of the oximeter 105 connected to a memory, such as a database 815. According to the preferred embodiment; the database 815 is stored locally in the memory of the oximeter 105. The oximeter 105 reads the unique identifier from the memory device 810 on the sensor 200 and, if necessary, creates a record in the database 815 corresponding to the unique identifier. Then, as the sensor 200 is used, the oximeter 105 accesses the record corresponding to the unique identifier so as to update the information relating to the longevity of the sensor 200. This information may advantageously include timing information, such as a decremented or incremented chronological count. The information may also, or alternatively, include the number of times the sensor 200 has been used, the number of drive signals the sensor 200 has received, or other similar methods of determining the amount of use for the particular sensor 200 having the particular unique identifier.

[0055] According to this embodiment, when the information stored in the database 815 reaches a predetermined threshold for a particular unique identifier, the oximeter 105 advantageously produces the expiration indication in a similar manner to that described in reference to FIGURE 4. For example, the oximeter 105 may issue the expiration indication by employing an audio alarm through the speaker 125, a visual alarm through the display 130, or a power-down function that renders the oximeter 105 inoperable. These expiration indications may advantageously continue until the sensor 200 having the unique identifier is replaced with one having a different unique identifier.

[0056] Although the database 815 is described as being stored in memory associated with the oximeter 105, the invention is not meant to be limited thereby. Rather, a skilled artisan would recognize that the database 815 may advantageously be stored in a central location, such a remote server connected through a wide number of known technologies, such as a local or wide area network, the internet, or other communications connection. In this way, a monitoring authority, ranging from a pair of pulse oximeters, to one or a number of hospitals, to a particular sensor manufacturer, and the like, can monitor the useful life of sensors identified through their unique identifier stored in the memory device 810.

**[0057]** As an alternative to, or in addition to, the foregoing embodiment where the memory device 810 includes a unique identifier, the memory device 810 may include the ability to store data. Again, such memory devices are commercially available from, for example, Dallas Semiconductor Corporation, and typically allow for read/write access over a single wire. For example, Dallas

Semiconductor's DS2502 has the ability to accept new data for non-volatile storage.

[0058] According to this embodiment, the oximeter 105 reads data stored in the memory device 810 relating to longevity, and updates that data according to use. For example, the oximeter 105 may read the memory device 810 of sensor 200 and determine that the sensor 200 has been in use for one increment of time, such as one minute. After the sensor 200 has been used for another increment of time, such as another minute as measured by the oximeter 105, the oximeter may write to the memory device 810 such that the memory device 810 now reflects that the sensor 200 has been used for two minutes. This periodic read and write to the memory device 810 continues until the memory device 810 reflects a longevity measurement greater than a predetermined threshold. At that time, the oximeter 105 may advantageously issue the foregoing expiration indication.

[0059] A skilled artisan would recognize that a wide variety of timing schemes may be implemented using the foregoing read/write technique. For example, the oximeter 105 may advantageously decrement from a predetermined threshold stored in the memory device 810. On the other hand, the memory device may store the number of times the sensor 200 has been used, the number of drive signals the sensor 200 has received, or other similar methods of determining the amount of use for the particular sensor 200.

**[0060]** Moreover, a skilled artisan would recognize that the foregoing embodiments may advantageously be combined such that the memory device 810 includes both the unique identifier and the ability to store other data. This other data may advantageously include the foregoing read/write timing data, manufacturing data such as sensor type, manufacturing source indication, tolerance levels, operating characteristics, and the like.

[0061] Although the foregoing invention has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art. For example, a skilled artisan will recognize the distinction in the foregoing embodiments between those components described as being integral with the sensor 200, or on-sensor components, and those components described as not being integral with the sensor 200, or off-sensor components. The on-sensor components may advantageously be housed in the disposable, reusable, or combination sensors. With respect to the combination sensors, the on-sensor components may be advantageously housed in the disposable portion, the reusable portion, or both portions, of the combination sensor.

[0062] Further, the off-sensor components may be housed in any of the longer lasting components associated with the oximeter 105. For example, the off-sensor components may be advantageously located on the sensor connector 160 or on the patient cable 115 where they are readily seen, heard, or felt by the operator or patient. [0063] Moreover, the foregoing embodiments incorpo-

rating the memory device 810 of FIGURE 8 may advantageously be combined with those embodiments describing the sensor life indicator 210 housed on the sensor 200. In such embodiment, the oximeter 105 may advantageously provide the expiration indication to the sensor life indicator 210 when the oximeter 105 determines that the sensor 200 had expired.

[0064] Additionally, other combinations, omissions, substitutions and modifications will be apparent to the skilled artisan in view of the disclosure herein. Accordingly, the present invention is not intended to be limited by the reaction of the preferred embodiments, but is to be defined by reference to the appended claims.

#### Claims

1. A method of tracking an amount of use of electronics of a noninvasive optical probe to alert a user when the electronics have expired, the method comprising:

> detecting use of electronics of a noninvasive optical probe, wherein the electronics of the noninvasive optical probe comprise at least one of a plurality of emitters or a light sensitive detector capable of detecting light attenuated by tissue; updating a cumulative measure of an amount of use of the electronics:

> determining whether the cumulative measure exceeds a predetermined amount of use; and activating an indicator capable of informing a user that the electronics have expired

- 2. The method of claim 1, wherein the expiration is associated with overuse of the electronics.
- 3. The method of claim 1, wherein the noninvasive optical probe comprises a combination of disposable and reusable components and wherein reusable components include at least some of the electronics.
- 4. The method of claim 1, wherein the activating the indicator comprises activating at least one of an audio or visual alarm.
- 5. A method of determining an amount of use of an optical probe, the method comprising:

communicating with one or more emission devices of a noninvasive optical probe over at least one conductor to drive the one or more emission

communicating with a timer of the noninvasive optical probe over the at least one conductor used to drive the one or more emission devices; incrementing the timer during use of the noninvasive optical probe; and

when the timer is proximate to a predetermined amount, activating an indicator configured to illustrate that the use of the noninvasive optical probe is proximate the predetermined amount.

6. The method of claim 5, further comprising:

determining whether the noninvasive optical probe is new; and

when the noninvasive optical probe is new, resetting the timer.

- 7. The method of claim 6, wherein the determining comprises accessing a memory identifying whether the noninvasive optical probe has been used.
- 8. The method of claim 6, wherein the determining comprises accessing a memory identifying the noninvasive optical probe.
- 9. A noninvasive optical probe comprising a reusable portion and a disposable portion, wherein the reusable portion includes at least one of emitters capable of emitting light or a detector capable of detecting light attenuated by tissue, the noninvasive optical probe being capable tracking an amount of use of the reusable portion, wherein the noninvasive optical probe comprises:

a reusable portion comprising at least one of one or more emitters capable of emitting light or a detector capable of detecting the light after the light has been attenuated by tissue, wherein attenuated light is indicative of one or more parameters of the tissue;

a device capable of determining a cumulative amount of use of the reusable portion; and a disposable portion capable of removably securing the reusable portion to the body tissue.

- **10.** The noninvasive optical probe of claim 9, wherein the device is capable of determining whether the cumulative amount of use exceeds a predetermined value.
- 11. The noninvasive optical probe of claim 9, wherein the reusable portion further comprises an indicator capable of informing a user that the reusable portion has expired and should be replaced.
- 12. A method for monitoring the life of an oximetry sensor, the method comprising:

monitoring a parameter responsive to repeated use of a sensor; and

when the parameter indicates that the sensor has expired, generating an expiration indication.

8

15

20

25

45

40

**13.** A method of indicating that a sensor has been used beyond a predetermined amount, the method comprising:

monitoring one of a drive signal and a return signal of sensor, wherein the drive signal and the return signal comprises transitions; and when a predetermined amount of transitions are reached, activating an indicator to indicate that the predetermined amount of transitions has occurred on the one of the drive signal and the return signal.

d d

10

**14.** The method of claim 13, wherein the monitoring comprises monitoring the drive signal.

15

**15.** The method of claim 13, wherein the activating of the indicator comprises changing an attribute of the indicator, wherein the attribute preferably comprises a color.

20

**16.** The method of claim 13, wherein the monitoring comprises storing a count of the transitions, wherein each count preferably comprises a predetermined number of transitions.

25

**17.** The method of claim 13, wherein the indicator indicates the expiration of a milestone in the life of the sensor, wherein the milestone preferably comprises the expiration of the useful life of the sensor.

30

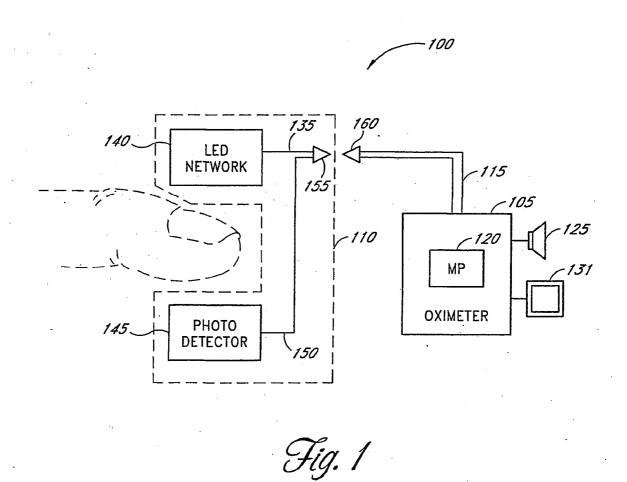
**18.** The method of claim 13, wherein the sensor comprises a pulse oximetry sensor.

35

40

45

50



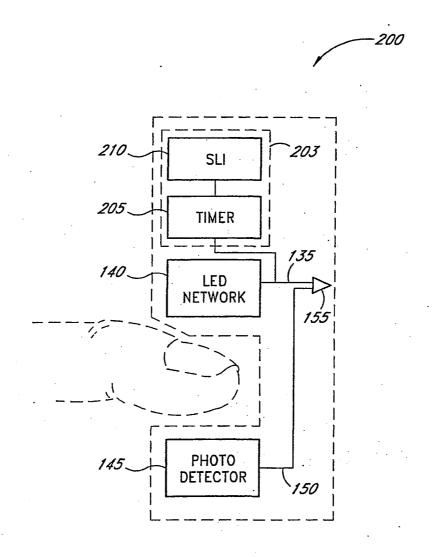
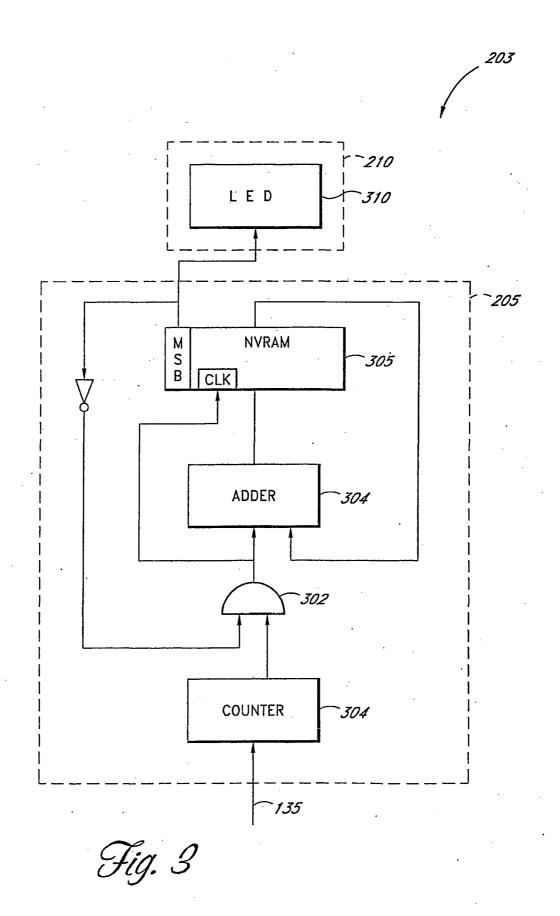
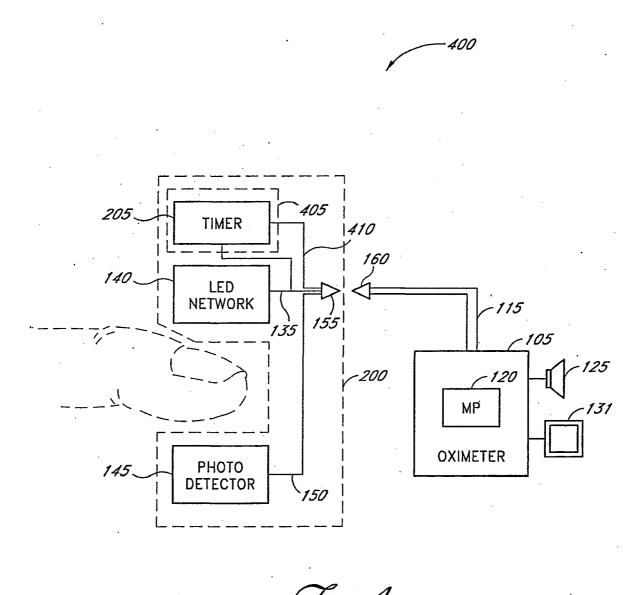


Fig. 2





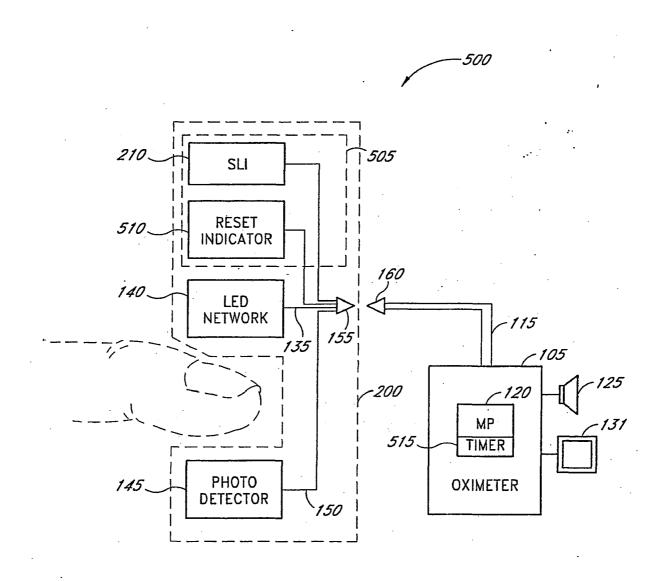
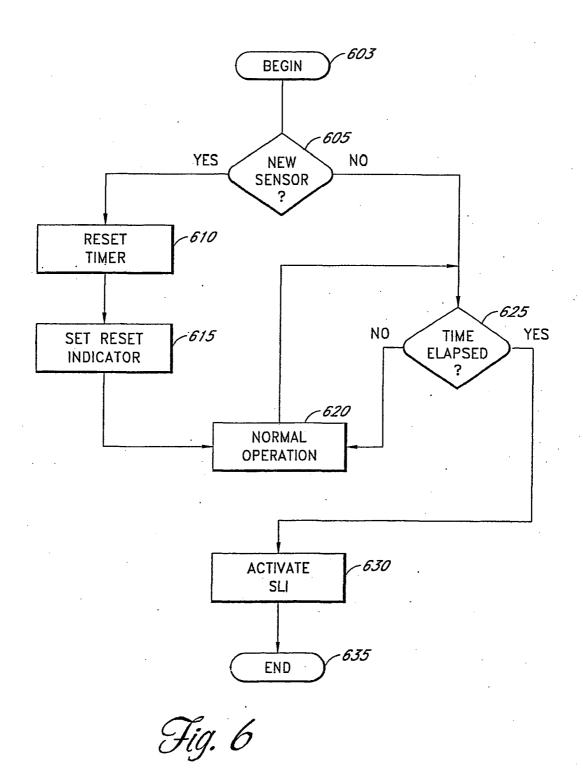
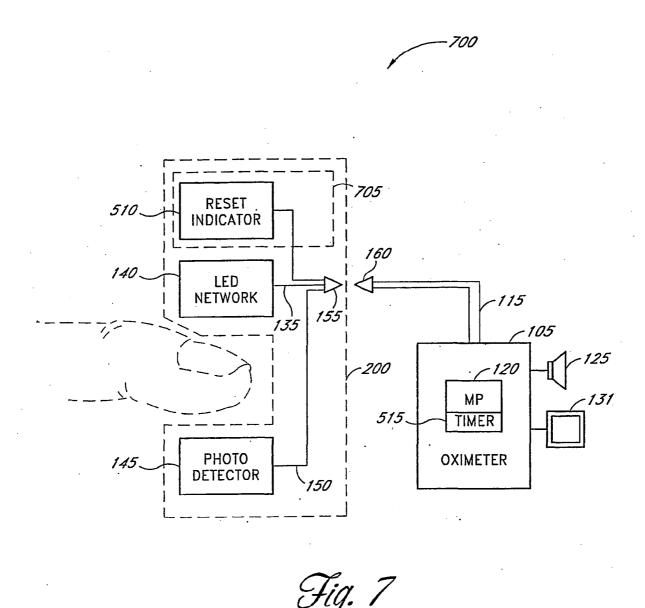
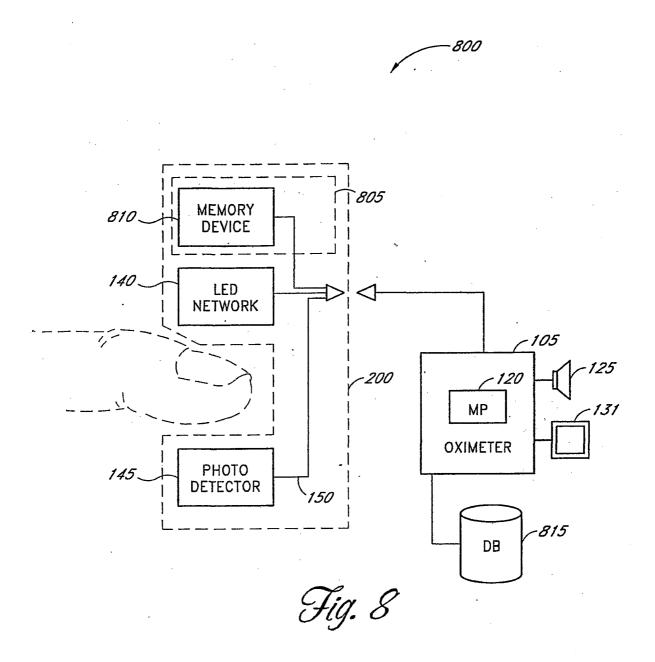


Fig. 5









# **EUROPEAN SEARCH REPORT**

Application Number EP 06 00 6843

	DOCUMENTS CONSID	ERED TO BE RELEVANT			
Category	Citation of document with ir of relevant passa	dication, where appropriate, ges	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)	
Υ	US 5 987 343 A (KIN 16 November 1999 (1 * column 3, line 29 claim 1; figure 2 *	999-11-16) - column 4, line 31;	1,2,4,5, 7,9-13, 18		
Υ	US 4 996 975 A (NAK 5 March 1991 (1991-	1,2,4,5, 7,9-13, 18			
	* column 3, lines 2 31-36; claim 1 *				
Υ	US 5 991 355 A (DAH 23 November 1999 (1	1,2,4,5, 7,9-13, 18			
	* column 2, lines 6				
A	PATENT ABSTRACTS OF vol. 014, no. 160 ( 28 March 1990 (1990	1-18			
	& JP 02 017462`A (H 22 January 1990 (19 * abstract *	ITACHI LTD),		TECHNICAL FIELDS SEARCHED (IPC)	
A	EP 1 424 036 A (OLY 2 June 2004 (2004-0 * paragraph [0016];	6-02)	1-18		
А	WO 97/29678 A (BIOSENSE INC; OSADCHY, DANIEL; FRIED, SHLOMO; BEN-HAIM, SHLOMO; FENSTE) 21 August 1997 (1997-08-21) * page 20, lines 15-22; claim 1 *		1-18		
A	US 5 939 609 A (KNA 17 August 1999 (199 * the whole documen	1-18			
	The present search report has I	peen drawn up for all claims			
Place of search Munich		Date of completion of the search 16 May 2006	Cha	Examiner Chopinaud, M	
X : part Y : part docu A : tech O : non	ATEGORY OF CITED DOCUMENTS icularly relevant if taken alone icularly relevant if combined with another icularly relevant if combined with another icularly relevant if combined with another icularly relevant icu	T : theory or princi E : earlier patent c after the filing d principle in the comment of the com	ple underlying the in locument, but publis ate d in the application	nvention shed on, or	

# ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO.

EP 06 00 6843

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

16-05-2006

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
US 5987343	Α	16-11-1999	NONE	<u> </u>		
US 4996975	Α	05-03-1991	JР	3004831	Α	10-01-19
US 5991355	А	23-11-1999	DE JP	19825754 11099131		14-01-19 13-04-19
JP 02017462	Α	22-01-1990	NONE			
EP 1424036	A	02-06-2004	JP US	2004174008 2004107113		24-06-20 03-06-20
WO 9729678	А	21-08-1997	AU CA DE DE EP ES I L JP	720597 1731497 2246340 69732362 69732362 0932362 2236791 125755 2000506027	A A1 D1 T2 A2 T3 A	08-06-20 02-09-19 21-08-19 03-03-20 23-03-20 04-08-19 16-07-20 29-05-20 23-05-20
US 5939609	Α	17-08-1999	WO	9949313	A1	30-09-19

FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82



专利名称(译)	传感器寿命监控系统					
公开(公告)号	EP1674034A1	公开(公告)日	2006-06-28			
申请号	EP2006006843	申请日	2001-02-09			
[标]申请(专利权)人(译)	梅西莫股份有限公司					
申请(专利权)人(译)	Masimo公司					
当前申请(专利权)人(译)	Masimo公司					
[标]发明人	THE DESIGNATION OF THE INVENTOR HAS NOT YET BEEN FILED					
发明人	THE DESIGNATION OF THE INVENTOR HAS NOT YET BEEN FILED					
IPC分类号	A61B5/00 A61B1/00 G07C3/00 G01N21/27 A61B5/024 A61B5/145 A61B5/1455					
CPC分类号	G07C3/00 A61B5/02427 A61B5/145 A61B5/14552 A61B5/6826 A61B5/6838 A61B2560/0276 A61B2560/028 A61B2562/08					
代理机构(译)	法思博事务所					
优先权	09/502032 2000-02-10 US					
其他公开文献	EP1674034B1					
外部链接	Espacenet					

# 摘要(译)

系统和方法监测脉搏血氧饱和度传感器的有效和安全寿命。根据一个实施例,该方法包括检测非侵入式光学探针的电子器件的使用,其中非侵入性光学探针的电子器件包括多个发射器或能够检测由组织衰减的光的光敏检测器中的至少一个;更新电子设备使用量的累积量度;确定累积量度是否超过预定的使用量;并激活能够通知用户电子设备已经过期的指示器。

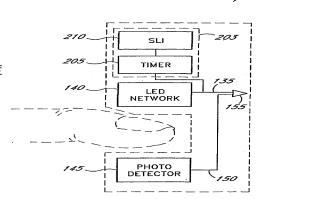


Fig. 2