(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
18 January 2007 (18.01.2007)

PCT

(10) International Publication Number
WO 2007/009049 A2

(51) International Patent Classification:
G01R 31/26 (2006.01)

(21) International Application Number:
PCT/US2006/027274

(22) International Filing Date: 13 July 2006 (13.07.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/698,726 13 July 2005 (13.07.2005) US
11/485,402 12 July 2006 (12.07.2006) US

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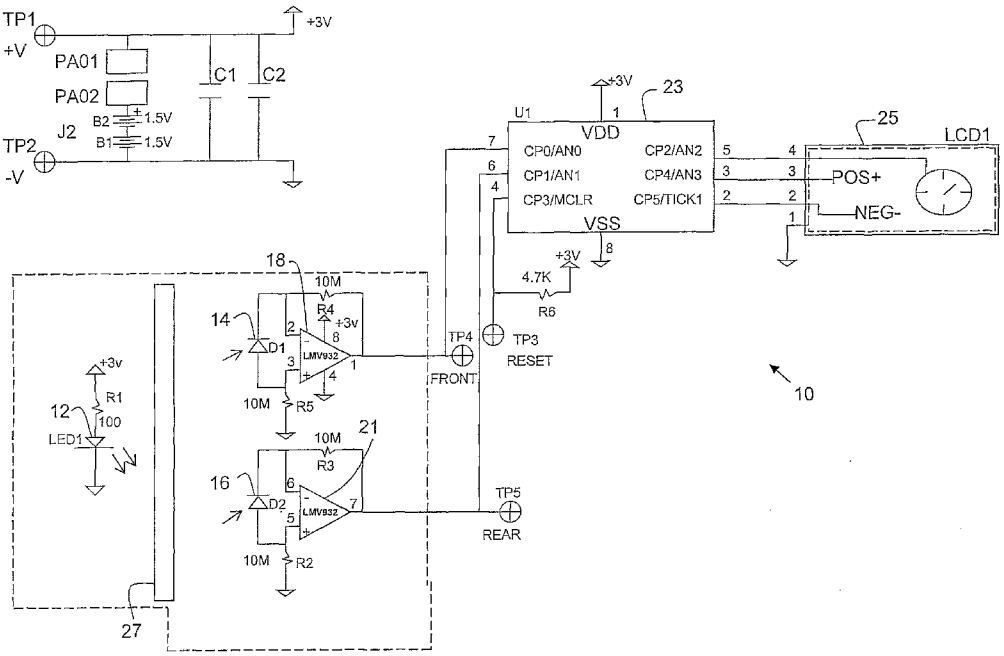
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) **Title:** SYSTEM AND METHOD FOR READING A TEST STRIP



(57) **Abstract:** A system and method is disclosed which relates to reading test strips. The method may include reading and storing initial values of a front photodiode and a rear photodiode, reading current values of the front and rear photodiodes, detecting at least one change between initial and current values in the front or the rear photodiodes, comparing the detected value change of one of the photodiodes with the value of the other photodiode, and determining a condition of the test strip in response to the resulting comparison.

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SYSTEM AND METHOD FOR READING A TEST STRIP

Field of the Invention

The present invention relates in general to a system and method of processing assay test results, and more particularly relates to a method of using it for assay tests such as a test of urine samples for pregnancy, drugs of abuse, tobacco, or other.

Related Application

This application claims priority to U.S. provisional patent application, entitled SYSTEM AND METHOD FOR READING A TEST STRIP, Application No. 60/698,726, filed July 13, 2005.

Background Art

This section describes the background of the disclosed embodiment of the present invention. There is no intention, either express or implied, that the background art discussed in this section legally constitutes prior art.

Assay test strips have employed photo optic sensors to read color changes in liquid test samples. However, the background noise inherent with assay test strip designs may be a problem under certain circumstances when photo optically reading the result of a test strip. Background noise may, for example, be caused by additional dye that remains on the strip in the test area when the result is read. Background noise can sometimes cause the sensor to determine erroneously that the test line is present, when, in fact, it is not present.

The effects of a weakening battery for powering the photo optic sensor also may present a problem when reading the result of a test strip. Once the test kit is energized, the battery may slowly degrade over time. This may be difficult to monitor in certain circumstances. The low voltages may be erroneously interpreted as a wet strip or worse, a test line.

Brief Description of the Drawings

The features of this invention and the manner of attaining them will become apparent, and the invention itself will be best understood by reference to the following description of certain embodiments of the invention taken in conjunction with the accompanying drawings, wherein:

FIG 1. is a schematic circuit diagram of an electronic reader;

FIGS. 2 through 5 are flow chart diagrams of the software or firmware; and

FIG. 6 is a flow chart diagram of a photodiode checker used by the software of FIGS. 2-5.

Certain Embodiments of the Invention

It will be readily understood that the components of the embodiments as generally described and illustrated in the drawings herein, could be arranged and designed in a wide variety of different configurations. Thus, the following more detailed description of the embodiments of the system, components and method of the present invention, as represented in the drawings, is not intended to limit the scope of the invention, as claimed, but is merely representative of certain embodiments of the invention.

According to certain embodiments of the invention, there is provided a method and system of electronically reading a test strip. The method includes reading and storing initial values of a front photodiode and a rear photodiode, reading current values of the front and rear photodiodes, detecting at least one change between initial and current values in the front or the rear photodiodes, comparing the detected value change of one of the photodiodes with the value of the other photodiode, and determining a condition of the test strip in response to the resulting comparison.

According to another embodiment of the invention, there is provided a method of electronically reading a test strip. The method includes providing a power source to an electronic reading circuit, reading and storing initial values of a front photodiode and a rear photodiode, continuing to read current values of the front and rear photodiode, calculating a result using the initial and current values of the front and rear photodiodes, starting a timer for a predetermined period of time when the result indicates adequate liquid has reached the rear photodiode; reading final values of the front and rear photodiodes at the end of the predetermined period of time, and calculating a final result using the final and initial values of the front and rear photodiodes.

Referring now to FIG. 1 of the drawings, there is shown a schematic diagram of an electronic reader circuit 10 that may be used with embodiments of the present invention. The electronic reader circuit 10 may include an illuminator light emitting diode (LED) 12, a front photodiode 14, a rear photodiode 16, resistors R1-R5, a pair of operational amplifiers 18 and 21, a microcontroller 23, and a liquid crystal display (LCD) 25.

In operation the LED 12 illuminates a portion of a test strip 27 and the photodiodes 14 and 16 sense the intensity of the light at two sections of the test strip 27. A signal proportional to the intensity of the light may be generated using one of the photodiodes, a pair of the resistors, and one of the operational amplifiers for both the front and rear photodiodes. The signals may be provided to analog to digital inputs to the microcontroller 23. The microcontroller 23 may calculate the results using these signals and provide an input to the LCD 25 to display the result of the test.

The photodiodes 14 and 16 may assist in determining conditions of the test strip 27. Such conditions of the test strip 27 may include, but are not limited to, the following: 1) adequate fluid on the test strip 27 at the front photodiode 14, 2) adequate fluid on the test strip 27 at the rear photodiode 16, 3) no appearance of a line on the test strip 27 at the rear photodiode, and 4) appearance of a line on the

test strip 27 at the rear photodiode. The appearance of a line on the test strip 27 may indicate the result of the test being accomplished on the test strip 27.

An electronic reader circuit having serially connected and oppositely oriented photodiodes, as described in PCT Patent Application No. _____, entitled TEST STRIP READER SYSTEM AND METHOD, filed on July 7, 2006, and herein incorporated by reference, may also be utilized. This circuit may provide a timing pulse to the microcontroller representing the intensity of the light at the photodiodes.

Referring now to FIGS. 2 through 6 of the drawings, a method of reading a test strip is shown. The main program, generally referenced as 100, is shown in FIGS. 2 through 5 and the check photodiodes routine, generally referenced as 160, is shown in FIG. 6. As indicated at the start, the system waits for the insulator strip to be removed and power provided to the system (step 102). Once power is provide, the microcontroller may blink the symbols on the LCD for approximately five seconds (steps 104 and 106). The photodiodes are then read and the initial readings for both the front and rear photodiodes are stored (steps 108 and 111). The microcontroller may then slowly blink the clock symbol on the LCD to indicate the system is ready for the application of the sample (step 113).

The microcontroller then waits for the application of adequate liquid at the front sensor (step 115). Both photodiodes are read (step 117) and the values checked to be valid in the check photodiode routine (step 119).

In the check photodiode routine 160 of FIG. 6, if the either value is greater than 2.5 volts (step 162) or less than 0.5 volts (166), the microcontroller may blink symbols on the LCD to indicate an invalid result (step 164 or 168, respectively) and end the test. A value greater than 2.5 volts may indicate a faulty reader that may be allowing too much light to be detected by the photodiode. A value less than 0.5 volts may also indicate a faulty reader such that not enough light is detected by the photodiode. If the values are less than 2.5 volts and greater than 0.5 volts, the microcontroller returns to the main program.

A check photodiode routine may also be adapted to utilize the timing pulse of the electronic reader circuit described in the above incorporated PCT application to check the health of the electronic reader circuit. Instead of comparing the photodiodes' values to a desired voltage range, the time periods of the timing pulse generated by the photodiodes may be compared to a desired time period range.

If the photodiode values are valid, a result is calculated (step 122) using the following equation:

$$result = [(R/R_i) - (F/F_i)] * SF$$ where,

F_i = initial reading from front photodiode

F = current reading from front photodiode

R_i = initial reading from rear photodiode

R = current reading from rear photodiode

SF = scaling factor

The scaling factor is a large positive integer and is used to avoid values less than one in the calculations.

While the above equation may be preferred, other calculations may be utilized. The calculation may detect changes between the initial and current readings of the front and rear photodiodes and then compare these changes in the readings of the front and rear photodiodes. The calculation may also include, but is not limited to, finding the difference between the initial and current readings of the photodiodes and/or creating a ratio of the changes in the readings of the photodiodes.

In step 124, if the result from step 122 is less than the value of fluid-check1, the microcontroller continues to wait for adequate fluid at the front photodiode by repeating the above process. If the result is greater than the value of

fluid-check1, the microcontroller moves on to wait for adequate fluid at the rear photodiode (step 126).

When waiting for adequate fluid at the rear photodiode, the microcontroller reads the values of the front and rear photodiodes (step 128). The values may be checked by the check photodiodes routine (step 131). If the values are valid, a result is calculated using the above equation (step 133). In step 135, if the result in step 133 is greater than the value of fluid-check2, the microcontroller continues to wait for adequate fluid at the rear photodiode by repeating the above process. If the result is less than the value of fluid-check2, the microcontroller may fast blink the clock symbol in the LCD (step 137) and may start a delay to allow the test strip to develop (steps 139 and 142).

At the end of the delay, three minutes for example, the microcontroller reads a final (last current) value for both the front and rear photodiodes (step 144). These final values may be checked to be valid by the check photodiodes routine (step 146). If the values are valid, a final result is calculated (step 148) using the following equation:

final result = $[(R_f/R_i) - (F_f/F_i)] * SF$ where,

F_i = initial reading from front photodiode

F_f = final reading from front photodiode

R_i = initial reading from rear photodiode

R_f = final reading from rear photodiode

SF = scaling factor

The scaling factor may be the same value as used in the prior equation.

While the above equation may be preferred, other calculations may be utilized as described previously.

In step 151, if the final result in step 148 is greater than the threshold value, the microcontroller turns off the blinking clock symbol (step 153) and turns on the "POS +" symbol or other appropriate symbol (step 155). The appearance of a line opposite the rear photodiode may make this final result greater than the threshold value. If the final result is less than the threshold value, the microcontroller turns off the blinking clock symbol (step 157) and turns on the "NEG –" symbol or other appropriate symbol (step 159).

The embodiment described above takes advantage of the concept that the sensor output of the photodiode from a wet test strip may be much lower than the output from a dry strip. Since less light may be reflected off the test strip when it is wet, the output of the photodiode may be lower.

Both photodiodes in the above described embodiments may provide a proportional response and both photodiodes may track in a similar fashion, because both photodiodes may be exposed to the same environmental conditions and both photodiodes may be exposed to a similar light source.

To clarify what is meant by the phrases "proportional response" and "track in a similar fashion", assume both photodiodes are exposed to a light source of a particular wavelength and intensity. Also assume that the spacing between both photodiodes and the light source are similar. The light would cause each photodiode to produce an output response within its particular operating range. One output response could be greater than or less than the other output response. It doesn't matter! Now take the same two photodiodes and expose them to a light source with the same wavelength but with a lower intensity. The output response of each photodiode will be smaller than the previous output response, which means they track in a similar fashion.

If the ratio between the first and second readings for each photodiode is calculated, a comparison of these ratios may show them to be almost equivalent, which means the output responses of the photodiodes may be basically proportional. The proportional response may be a result of the very small intensity

level change of the light source. The response curve of the photodiode may be considered linear over such a small intensity level change.

Using this proportionality of the output responses of the photodiodes, changes in the intensity of the light source may not invalidate the results of the test performed by the test strip reader. Thus a more reliable and efficient method and system of reading test strips may be achieved.

While particular embodiments of the present invention have been disclosed, it is to be understood that various different modifications and combinations are possible and are contemplated within the true spirit and scope of the disclosed embodiments. There is no intention, therefore, of limitations to the exact disclosure herein presented.

WHAT IS CLAIMED IS:

1. A method of electronically reading a test strip, comprising:

reading and storing initial values of a front photodiode and a rear photodiode;

reading current values of the front and rear photodiodes;

detecting at least one change between initial and current values in the front or rear photodiodes;

comparing the detected value change of one of the photodiodes with the value of the other one of the photodiodes; and

determining a condition of the test strip in response to the resulting comparison.

2. The method of claim 1, wherein determining the condition of the test strip includes determining whether adequate fluid has reached the front photodiode.

3. The method of claim 1, wherein determining the condition of the test strip includes determining whether adequate fluid has reached the rear photodiode.

4. The method of claim 3, further comprising:

starting a timer for a predetermined period of time upon the determination that adequate fluid has reached the rear photodiode.

5. The method of claim 4, further comprising:

reading final values of the front and rear photodiodes at the end of the predetermined period of time.

6. The method of claim 1, wherein determining the condition of the test strip includes determining whether a line has appeared at the rear photodiode.

7. The method of claim 1, wherein detecting at least one change includes creating ratios of the current value to initial value of the front and rear photodiodes.

8. The method of claim 7, wherein comparing the changes includes calculating the difference between the ratios of the front and rear photodiodes.

9. The method of claim 8, wherein comparing the changes includes calculating a result by multiplying the difference by a scale factor.

10. The method of claim 9, wherein determining the condition includes comparing the result to a threshold value.

11. The method of claim 1, further comprising:

comparing the values of the front and rear photodiodes with a low threshold and a high threshold to determine validity of the values.

12. A system of electronically reading a test strip, comprising:

means for reading and storing initial values of a front photodiode and a rear photodiode;

means for reading current values of the front and rear photodiodes;

means for detecting at least one change between initial and current values in the front or rear photodiodes;

means for comparing the detected value change of one of the photodiodes with the value of the other one of the photodiodes; and

means for determining a condition of the test strip in response to the resulting comparison.

13. The system of claim 12, wherein means for determining the condition of the test strip includes means for determining whether adequate fluid has reached the front photodiode.

14. The system of claim 12, wherein means for determining the condition of the test strip includes means for determining whether adequate fluid has reached the rear photodiode.

15. The system of claim 14, further comprising:

means for starting a timer for a predetermined period of time upon the determination that adequate fluid has reached the rear photodiode.

16. The system of claim 15, further comprising:

means for reading final values of the front and rear photodiodes at the end of the predetermined period of time.

17. The system of claim 12, wherein means for determining the condition of the test strip includes means for determining whether a line has appeared at the rear photodiode.

18. The system of claim 12, wherein means for detecting at least one change includes means for creating ratios of the current value to initial value of the front and rear photodiodes.

19. The system of claim 18, wherein means for comparing the changes includes means for calculating the difference between the ratios of the front and rear photodiodes.

20. The system of claim 19, wherein means for comparing the changes includes means for calculating a result by multiplying the difference by a scale factor.

21. The system of claim 20, wherein means for determining the condition includes means for comparing the result to a threshold value.

22. The system of claim 12, further comprising:

means for comparing the values of the front and rear photodiodes with a low threshold and a high threshold to determine validity of the values.

23. A method of electronically reading a test strip, comprising:

reading and storing initial values of a front photodiode and a rear photodiode;

reading current values of the front and rear photodiodes;

calculating a result using the initial and current values of the front and rear photodiodes;

starting a timer for a predetermined period of time when the result indicates adequate fluid has reached the rear photodiode;

reading final values of the front and rear photodiodes at the end of the predetermined period of time; and

calculating a final result using the final and initial values of the front and rear photodiodes.

24. The method of claim 23, further comprising:

providing a power source to an electronic reading circuit.

25. The method of claim 24, further comprising:

delaying for a predetermined delay time subsequent providing the power source and prior to reading the initial values.

26. The method of claim 23, further comprising:

comparing the result to a threshold to determine whether adequate fluid has reached the front photodiode.

27. The method of claim 23, further comprising:

comparing the result to a threshold to determine whether adequate fluid has reached the rear photodiode.

28. The method of claim 23, further comprising:

comparing the final result to a threshold to determine a test result of the test strip.

29. The method of claim 23, wherein the result is calculated using the following equation:

result = [(rear photodiode current value/rear photodiode initial value) - (front photodiode current value/front photodiode initial value)] * scaling factor.

30. The method of claim 23, wherein the final result is calculated using the following equation:

final result = [(rear photodiode final value/rear photodiode initial value) - (front photodiode final value/front photodiode initial value)] * scaling factor.

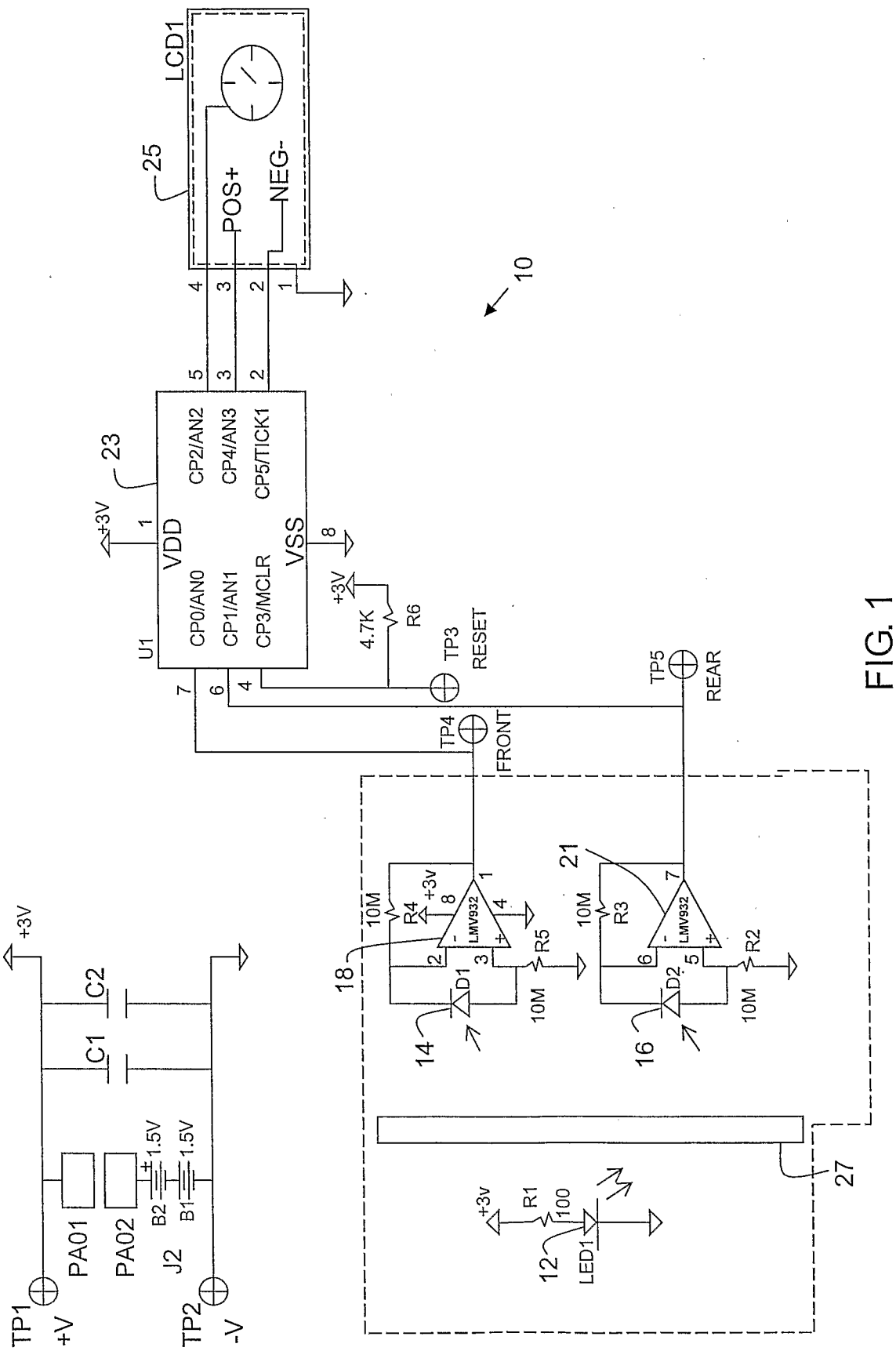

LCD1
25
POS+
NEG-
10
23
U1
VDD
VSS
CP0/AN0
CP1/AN1
CP2/AN2
CP3/MCLR
CP4/AN3
CP5/TICK1
+3V
4.7K
R6
TP3
RESET
TP4
FRONT
TP5
REAR
21
R4
R5
R3
R2
R1
10M
100
LMV932
D1
D2
LED1
14
16
18
12
27
C1
C2
PA01
PA02
J2
B1
B2
1.5V
TP1
+V
TP2
-V

FIG. 1

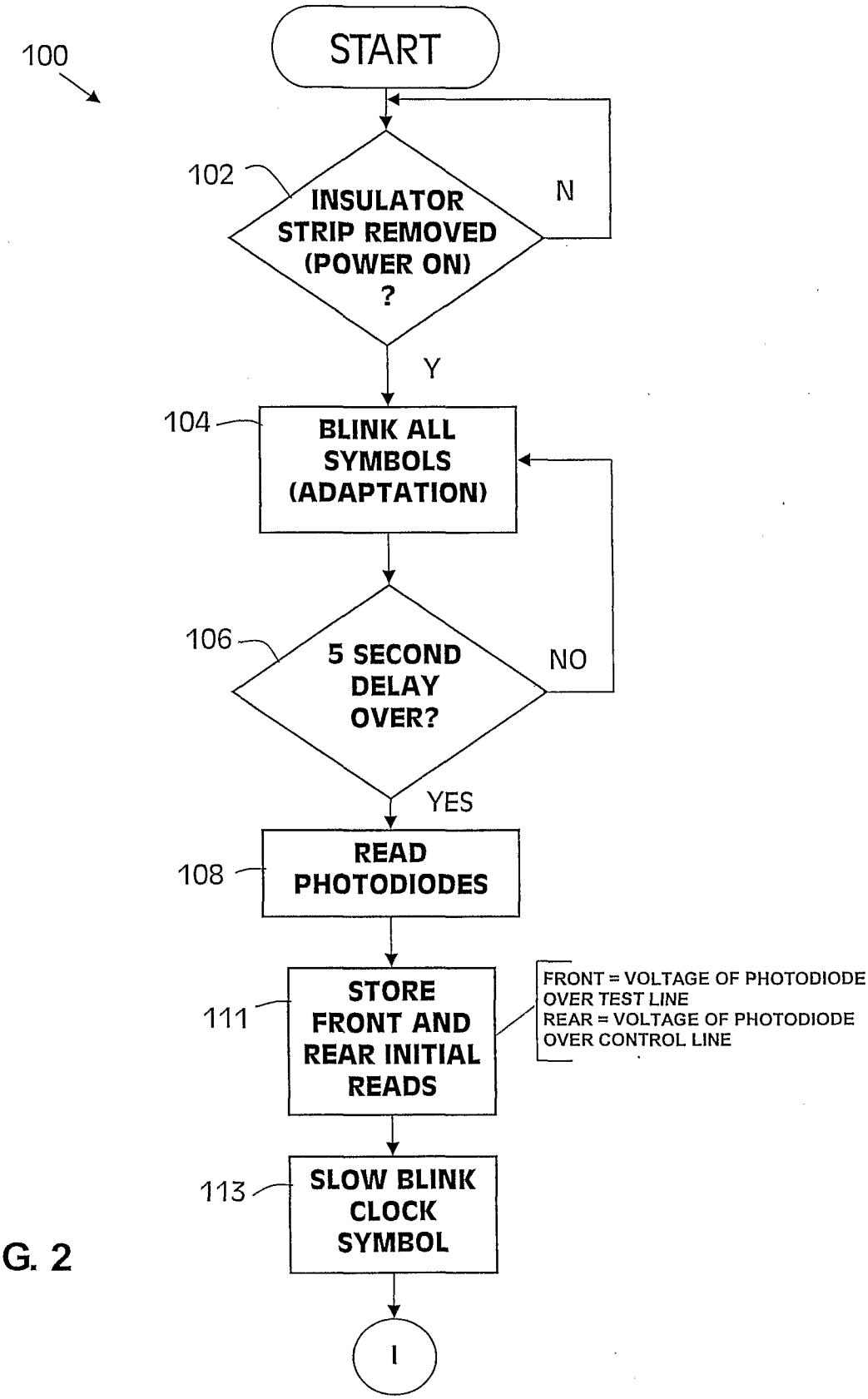

100
START
102
INSULATOR STRIP REMOVED (POWER ON) ?
N
Y
104
BLINK ALL SYMBOLS (ADAPTATION)
106
5 SECOND DELAY OVER?
NO
YES
108
READ PHOTODIODES
111
STORE FRONT AND REAR INITIAL READS
FRONT = VOLTAGE OF PHOTODIODE OVER TEST LINE
REAR = VOLTAGE OF PHOTODIODE OVER CONTROL LINE
113
SLOW BLINK CLOCK SYMBOL
I

FIG. 2

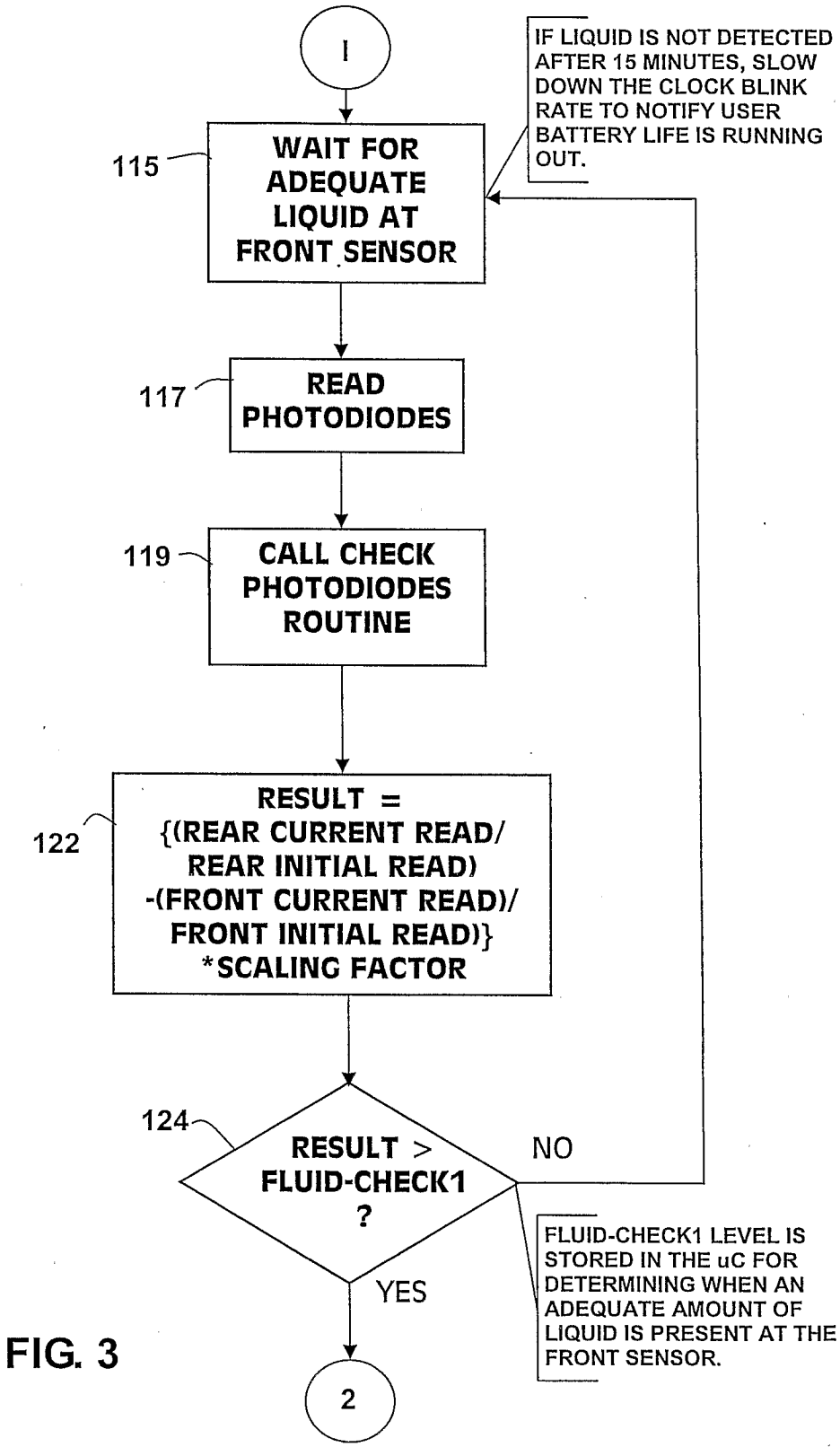

1
115
WAIT FOR ADEQUATE LIQUID AT FRONT SENSOR
IF LIQUID IS NOT DETECTED AFTER 15 MINUTES, SLOW DOWN THE CLOCK BLINK RATE TO NOTIFY USER BATTERY LIFE IS RUNNING OUT.
117
READ PHOTODIODES
119
CALL CHECK PHOTODIODES ROUTINE
122
RESULT = {(REAR CURRENT READ/ REAR INITIAL READ) -(FRONT CURRENT READ)/ FRONT INITIAL READ)} *SCALING FACTOR
124
RESULT > FLUID-CHECK1 ?
NO
YES
FLUID-CHECK1 LEVEL IS STORED IN THE uC FOR DETERMINING WHEN AN ADEQUATE AMOUNT OF LIQUID IS PRESENT AT THE FRONT SENSOR.
2

FIG. 3

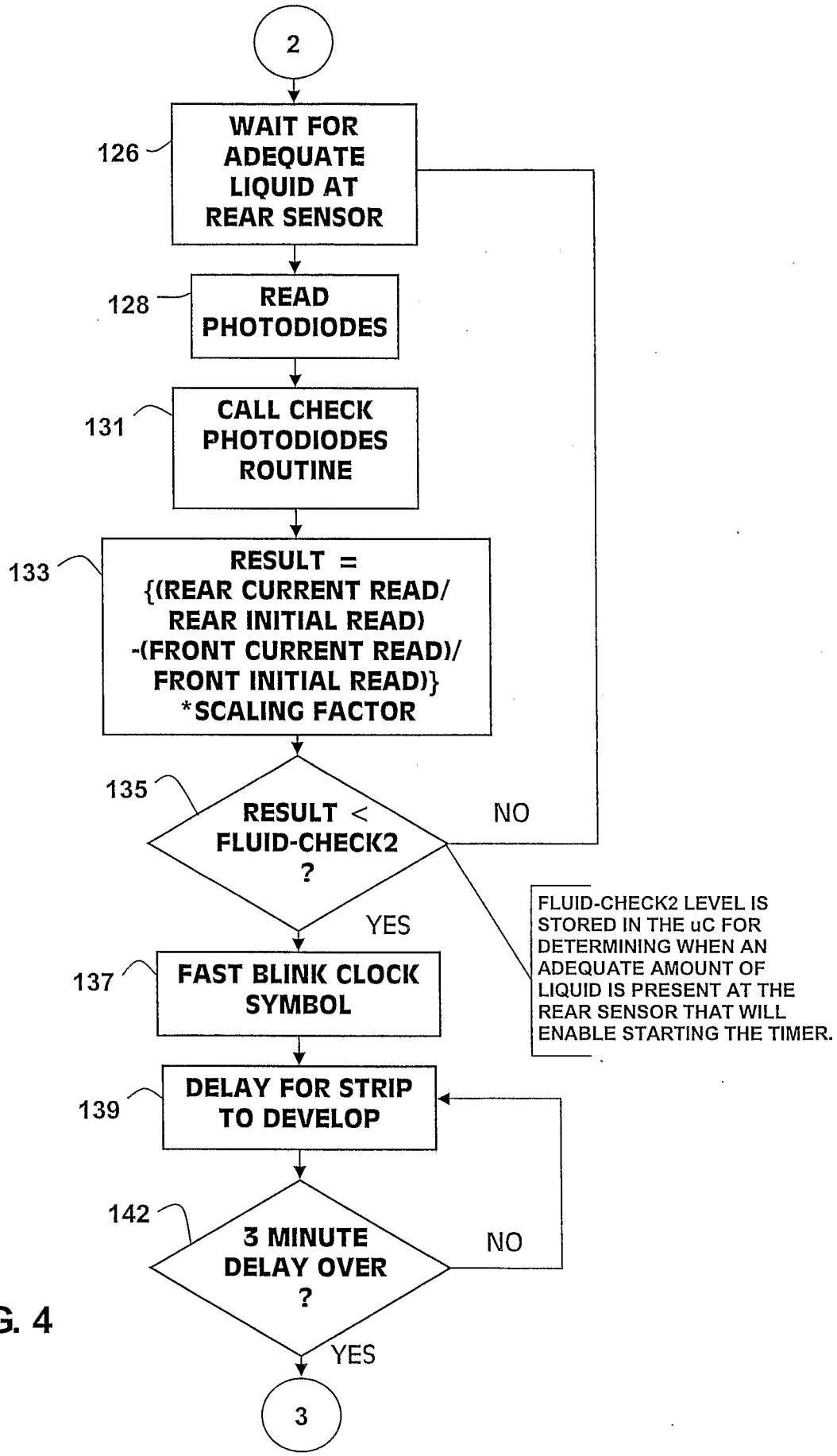

2
126
WAIT FOR ADEQUATE LIQUID AT REAR SENSOR
128
READ PHOTODIODES
131
CALL CHECK PHOTODIODES ROUTINE
133
RESULT = {(REAR CURRENT READ/ REAR INITIAL READ) -(FRONT CURRENT READ)/ FRONT INITIAL READ)} *SCALING FACTOR
135
RESULT < FLUID-CHECK2 ?
NO
YES
FLUID-CHECK2 LEVEL IS STORED IN THE uC FOR DETERMINING WHEN AN ADEQUATE AMOUNT OF LIQUID IS PRESENT AT THE REAR SENSOR THAT WILL ENABLE STARTING THE TIMER.
137
FAST BLINK CLOCK SYMBOL
139
DELAY FOR STRIP TO DEVELOP
142
3 MINUTE DELAY OVER ?
NO
YES
3

FIG. 4

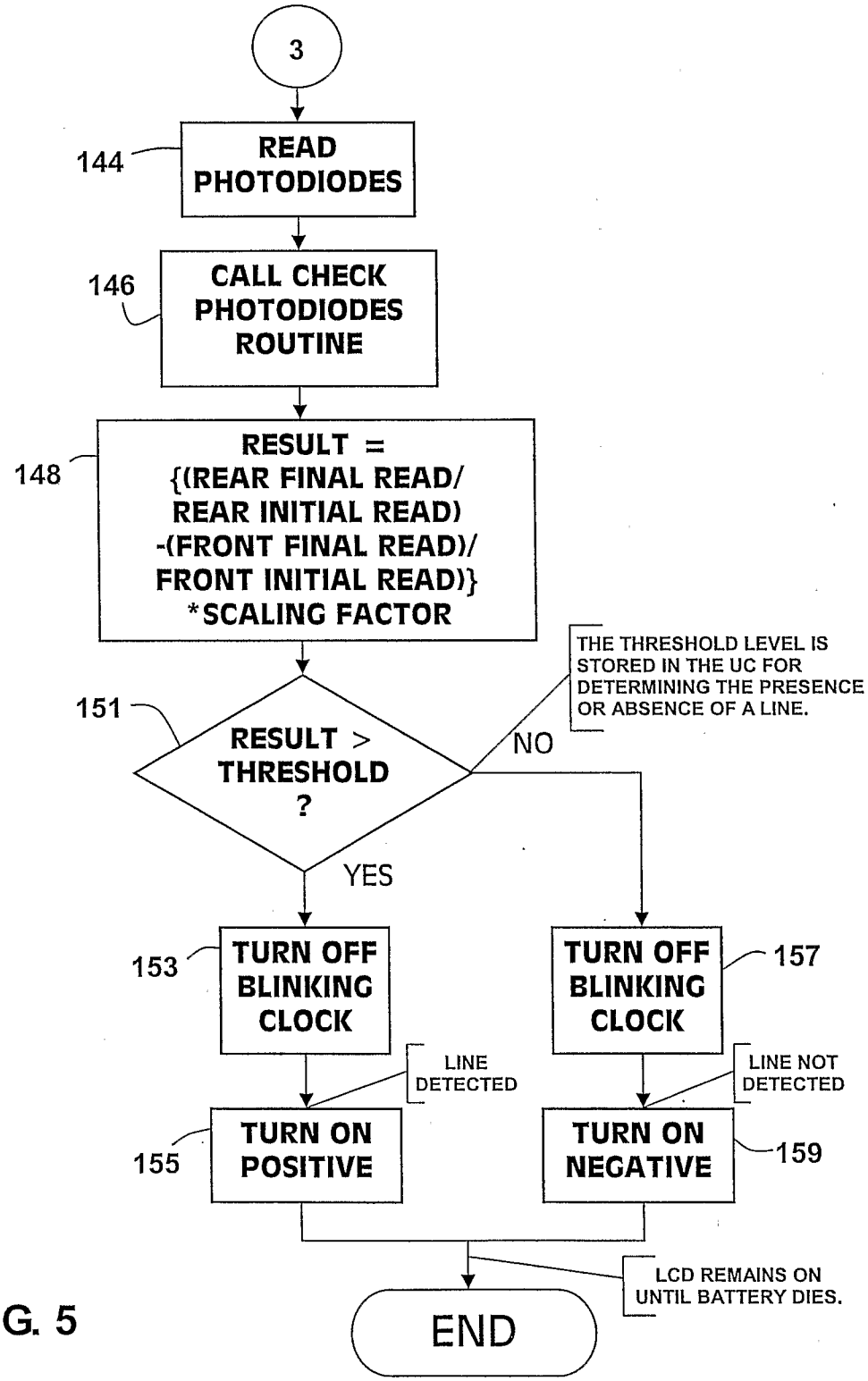

3
144
READ PHOTODIODES
146
CALL CHECK PHOTODIODES ROUTINE
148
RESULT = {(REAR FINAL READ/ REAR INITIAL READ) -(FRONT FINAL READ)/ FRONT INITIAL READ)} *SCALING FACTOR
151
RESULT > THRESHOLD ?
THE THRESHOLD LEVEL IS STORED IN THE UC FOR DETERMINING THE PRESENCE OR ABSENCE OF A LINE.
NO
YES
153
TURN OFF BLINKING CLOCK
157
TURN OFF BLINKING CLOCK
LINE DETECTED
LINE NOT DETECTED
155
TURN ON POSITIVE
TURN ON NEGATIVE
159
LCD REMAINS ON UNTIL BATTERY DIES.
END

FIG. 5

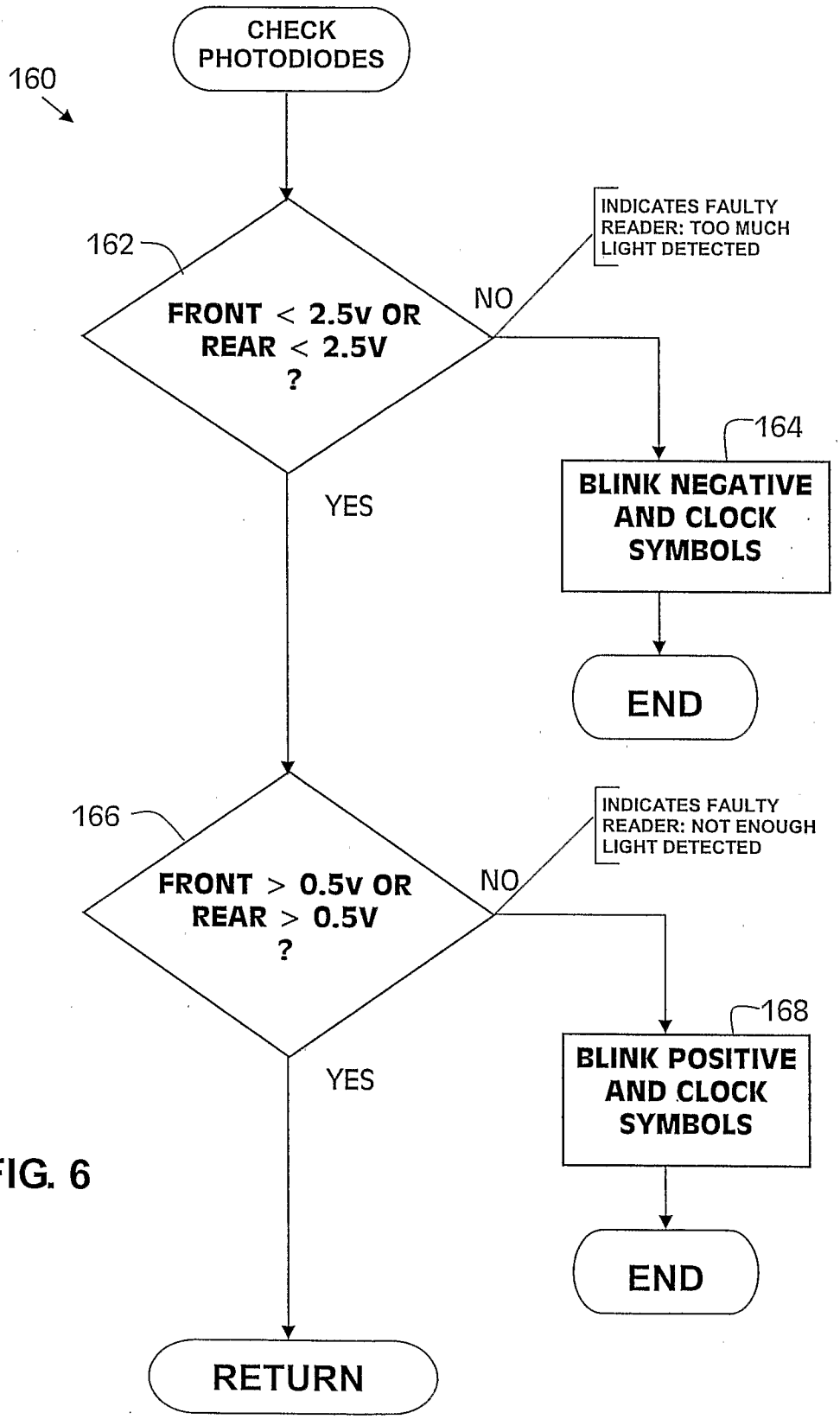

CHECK PHOTODIODES
160
162
FRONT < 2.5v OR REAR < 2.5V ?
NO
INDICATES FAULTY READER: TOO MUCH LIGHT DETECTED
164
BLINK NEGATIVE AND CLOCK SYMBOLS
END
YES
166
FRONT > 0.5v OR REAR > 0.5V ?
NO
INDICATES FAULTY READER: NOT ENOUGH LIGHT DETECTED
168
BLINK POSITIVE AND CLOCK SYMBOLS
END
YES
RETURN

FIG. 6