GlucCell™ SYSTEM USER'S GUIDE

ver 2.4

Intended Use

The GlucCell™ Cell Culture Glucose Monitoring System (The GlucCell™ System) is designed to quantitatively measure the concentration of glucose during cell culture. It is for use by laboratory researchers or bioreactor professionals to obtain a quantitative measurement of glucose in cell culture.

About the System

The GlucCell™ System uses the latest technology in Cell Culture Glucose monitoring to provide you with easy and reliable testing. The system requires only a 1.5µl of medium sample to complete the testing in only 15 seconds.

The GlucCell™ System consists of 1) the GlucCell™ Glucose Meter; 2) GlucCell™ Glucose Test Strips, and 3) the GlucCell™ check strip. These products

are intended to be used together to get accurate Cell Culture Glucose test results. Do not use other commercial test strips with your GlucCell™ meter.

Important Information

The GlucCell™ System is intended for *in vitro* analysis use with cell culture medium. The system should not be used for diagnosis of diabetes.

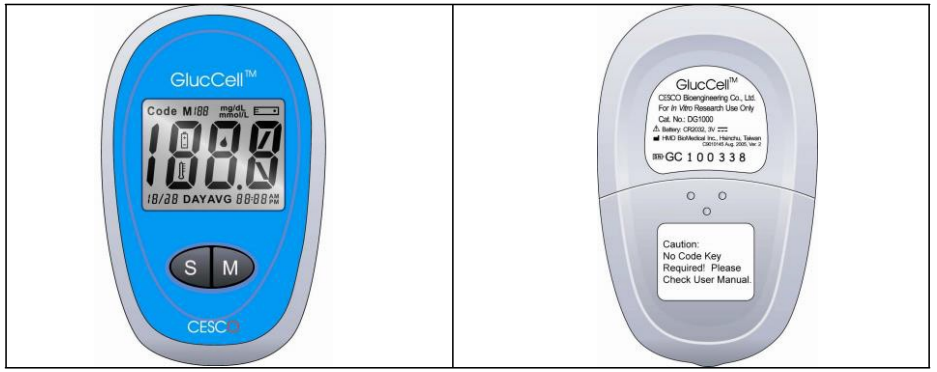
⚠ *Caution*

A sample with large amounts of reducing agent such as ascorbic acid and uric acid may cause result slightly higher than the actual glucose level.
High altitudes above than 2,750 meter (8,800 feet) may affect the test results.

Temperatures outside the range of 10℃ to 40℃ (50℉ to

104℉) may affect the test results.

CELL CULTURE GLUCOSE METER



DISPLAY: The large, easy to read display shows test results, messages, cell culture glucose results stored in memory, time and date.

S BUTTON: Press S button to enter the time setting, and to decrease values in the setting mode.

M BUTTON: Press M button to enter memory mode to recall the information stored in meter's memory and to increase values in the setting mode.

STRIP SLOT : Hold a GlucCell™ Glucose Test Strip in place when you perform Cell Culture Glucose test or perform check test.

DATA PORT : Allow you to transfer the information stored in the meter's memory to a computer to view, analyze and print.

BATTERY COMPARTMENT : Hold one 3v Lithium battery. The battery is not yet installed into meter when new purchasing. Before using the meter, please install the battery first.

TEST RESULT

BATTERY SYMBOL : Appear when battery is weak.

THERMOMETER SYMBOL : Appears when ambient temperature is above or below the acceptable range needed for testing.

DROP SYMBOL : Appear when the test strip is inserted and meter is ready for testing.

STRIP SYMBOL

M188 : Memory capacity is 180 entries. The display shows M188 to ensure that all digits are working properly.

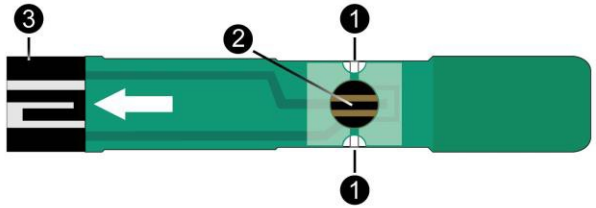
mg/dL mmol/L : The meter has two units of measurement (mg/dL or mmol/L) available to choose from.

DAY AVG : Appear when the meter is in the memory mode while recalling 1/7/14/21/28 day test averages.

DATE : Month/date.

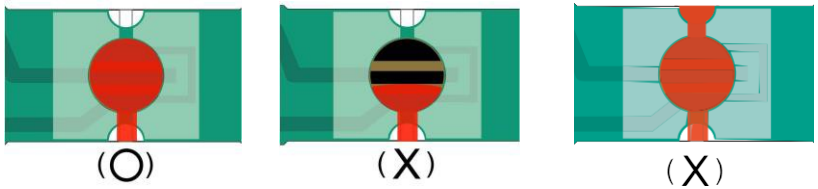
TIME : The meter is programmed for a 12 hour period format.

CELL CULTURE GLUCOSE TEST STRIP



1: Aperture: apply the sample to either side of strip.
2: Test Confirmation Window: make sure the chamber is filled up with test sample to ensure the correct result.

For example:

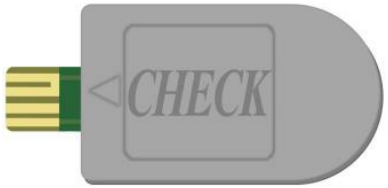


3. Gray Electrode End: insert this end of test strip into meter.

⚠ *IMPORTANT TEST STRIP INFORMATION*

GlucCell™ System measures the amount of glucose in cell culture medium. Sample can be applied both to the right or left side of the test strip's apertures and is automatically drawn to the test confirmation window where the reaction takes place.
GlucCell™ Glucose Test Strips are intended for *in vitro* analysis use with cell culture medium. Results will not be accurate if used with samples containing no electrolyte.
Do not use test strips beyond the expiration date indicated on the strip vial label.
The discard date for test strips is 90 days after first opening the vial. Record the discard date on the vial, when you open a new vial of test strips.
GlucCell™ Glucose Test Strip could be damaged by heat and light. Keep them sealed in the original vial.
Store the vial in a cool, dry place below to 40^0C/104^0F and above 10^0C/50^0F. Do not refrigerate.
Do not use damaged test strips or abnormal test strips.
Use the test strip immediately once after removing it from the vial; replace the vial cap and close it tightly.
Do not transfer test strips to a new vial. Always carry test strips in their original vial.
Do not place test strips in direct heat or sunlight.
Do not carry loose test strips in your carrying case.
Ⓧ Test strips are for single use only.

CHECK STRIP

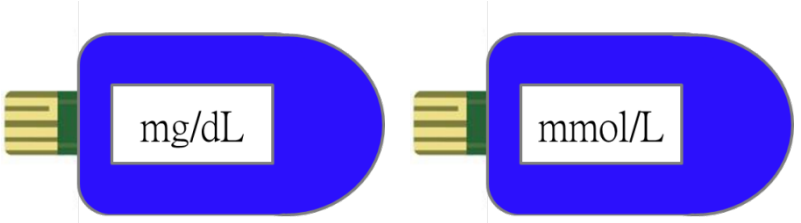


The GlucCell™ Check Strip can be used to check that the meter is operating properly.

1. How to check meter by check strip

Step 1: Insert the check strip into strip slot with label side up as above.
Step 2: You should obtain an acceptable “OK“ reading within 10 seconds, which mean your meter is working properly.
Step 3: Remove the check strip to exit. Meter will automatically off.
NOTE: IF YOU DO NOT GET “OK” READING BUT APPEAR OTHER ERROR MESSAGE, PLEASE FOLLOW BELOW PROCEDURES:
1. TURN OFF THE METER BY PRESSING M BUTTON FOR 3 SECONDS AND REMOVE THE CHECK STRIP FROM THE METER.
2. INSERT CHECK STRIP TO REPEAT TEST. IF THE SECOND RESULT PERSISTS, CONSULT YOUR LOCAL DISTRIBUTOR FOR HELP.

UNIT CHANGE STRIP



The GlucCell™ Unit Change Strip can be used to change measuring unit. The meter has two measuring units to choose from, mg/dL and mmol/L. The default unit is mg/dL.

2. How to change measuring unit

Step 1: Remove battery.
Step 2: Insert unit change strip into strip slot with label side up.
Step 3: Insert battery and meter will display unit, which is depend on the unit change strips.
Step 4: Remove the unit change strip to exit. Meter will automatically off.

SETTING METER PARAMETERS

SETTING TIME & DATE

When you first time install the battery into the meter or every time when replace a battery, the meter will automatically enter to the setting mode. Please set correct time and date before you begin testing.

How to set time and date

Press S BUTTON for 3 seconds to turn on the meter. The meter will enter to the setting mode automatically.
At the beep sound, the year will flash - for example for the year of 2009, number ” 09 “will appear.
Press S or M button to obtain the desired year.
Wait the new setting flash 3 times to confirm and shifts to the next setting.
Repeat to set the month, day, hour and minute. After minute is set, the meter will display “OK” before turn off.

NOTE: WHILE SETTING THE TIME AND DATE, YOU CAN EXIT THE SETTING MODE ANYTIME BY PRESS M BUTTON FOR 3 SECONDS.

CODING YOUR METER

Before you use your meter for the first time and every time you open a new box of test strips, you need to set the meter to “match” the strips. This is called coding. Insert the test strip into the strip slot (FIG 1), the meter will activate. The last code number will appear on the screen. Compare the code number shown on the meter display against the code number on the test strip vial (FIG 2). If the two numbers match, you may begin testing. Otherwise continue to the next step.

Press S button until you hear the sound of buzzer and the code value flashes, press S or M button to obtain the code number indicated on the new test strip vial. (FIG 3)

Upon obtaining the right code number, wait the new setting to flash 3 times to validate the change. (FIG 4)

After screen shows the proper code and a blinking drop symbol shows up, your meter is ready to perform a test. (FIG 5)

NOTE: THE NEW CODE NUMBER IS DISPLAYED ON THE SCREEN TOO.(FIG 4)

FIG 1

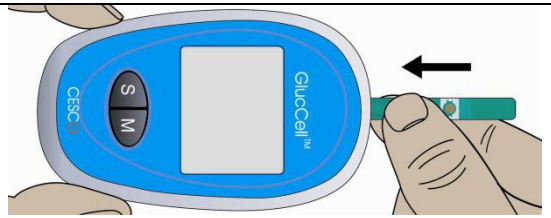


FIG 2

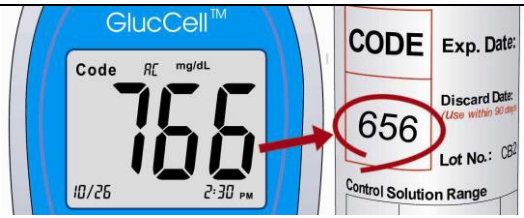


FIG 3

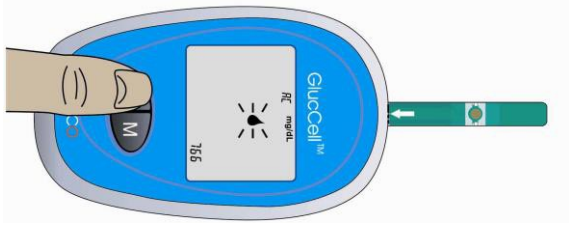


FIG 4

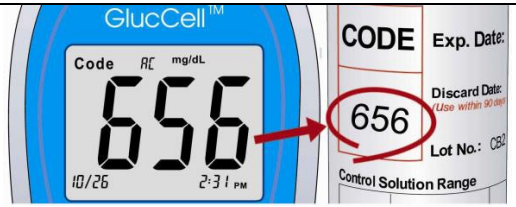
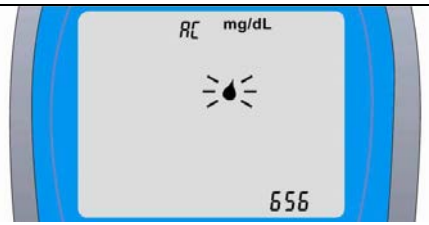


FIG 5



PERFORMING TEST

Remove new test strip from vial. Be sure to tightly replace vial cap after removing test strips. Insert test strip immediately into strip slot as illustrated (FIG 1). The meter turns on automatically.

Check that the code number in the meter matches the code on the vial (FIG 2). If the two numbers match you may begin testing. Otherwise refer to above section to code your meter first.

When the drop symbol flashes (FIG 3), you are ready to perform a test. To perform the test, you need only 1.5µL of test sample. Use a pipette tip to withdraw around 1.5µL test sample (FIG 4).

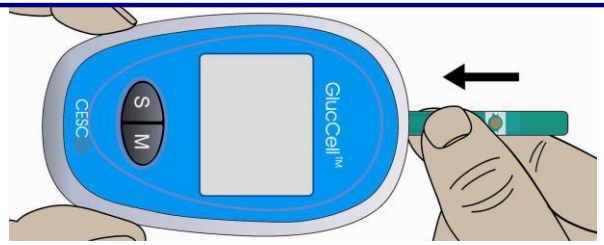


FIG 1

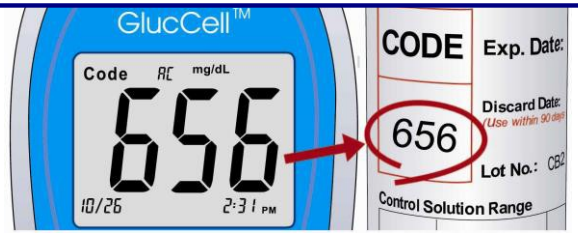


FIG 2

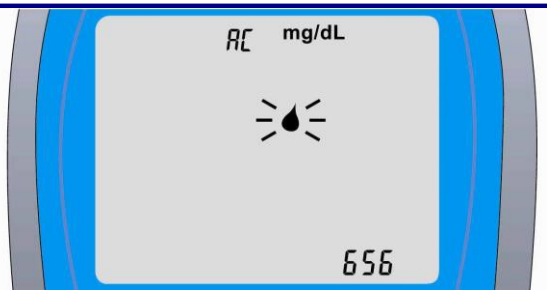


FIG 3

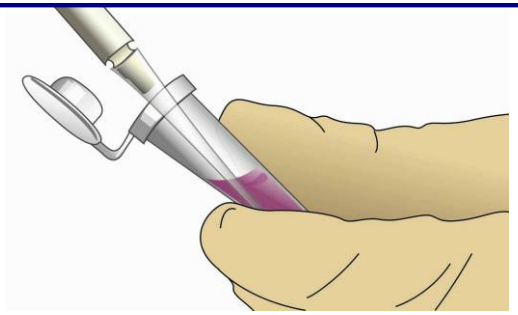


FIG 4

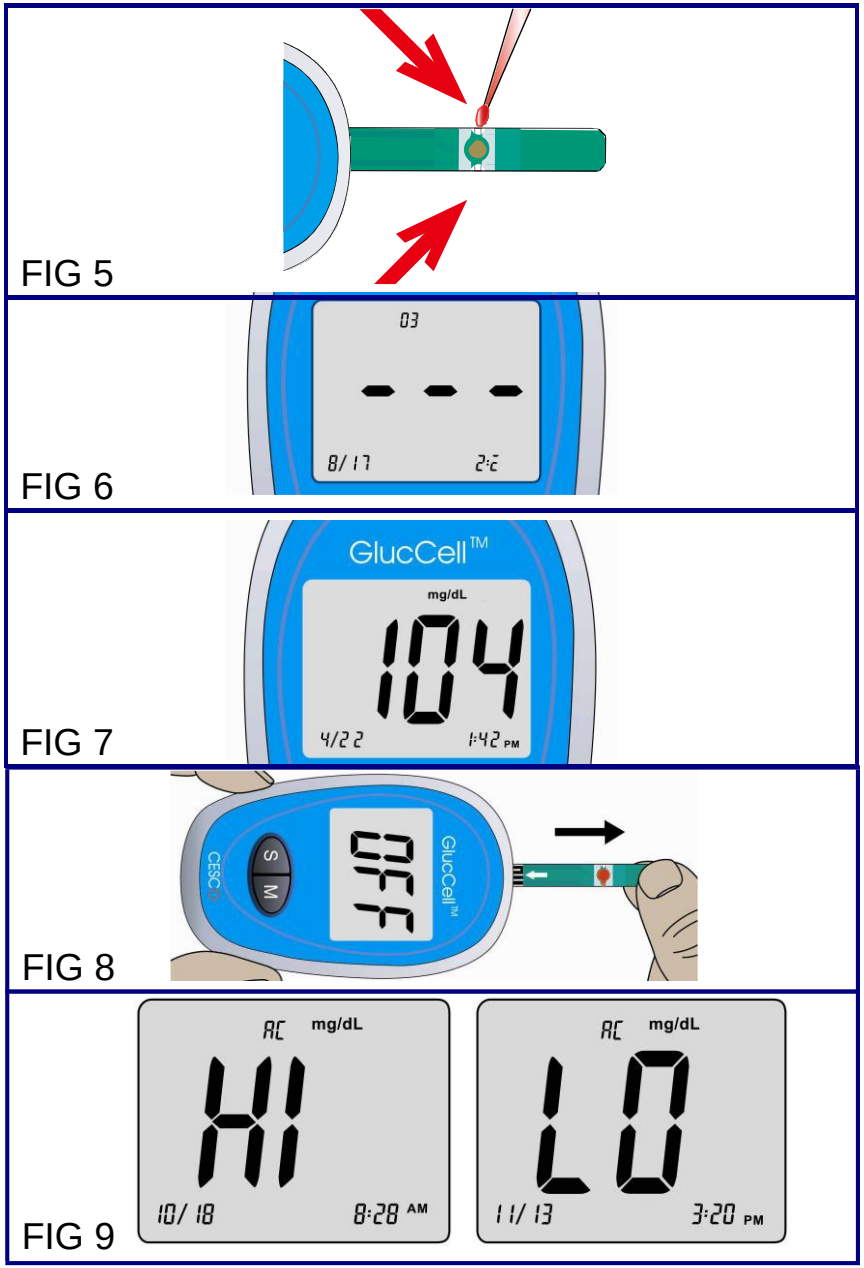
Carefully depress to form a 1.5μL droplet on the pipette tip. Bring the droplet underneath the right or left aperture of the testing strip and touch gently to the strip, allowing the entire droplet to be wicked into the strip. (FIG 5).

Please allow the sample to be absorbed naturally to fill up the confirmation window Make sure that the sample has saturated the test confirmation window. Never push test sample over the aperture and cause overloading of the sample. When sample is applied to the strip, a line moves on the screen until measurement is completed (FIG 6).

Test result will show up in 15 seconds (FIG 7).

After test complete, remove the strip from meter (FIG 8), and discard the used strip safely.

The measuring range of the meter is from 20 to 600 mg/dL (1.1 to 33.3 mmol/L). However, the accurate testing range of the meter is from 30 to 500 mg/dL(1.67 to 27.78 mmol/L). If **HI** is displayed, your Cell Culture Glucose result may be higher than 33.3 mmol/L or 600 mg/dL. If **LO** is displayed, your Cell Culture Glucose result may be lower than 1.1 mmol/L or 20 mg/dL (FIG 9).When the measurement is higher than 500 mg/dL, please dilute the sample. If the measurements is between 20~30mg/dL, the deviation may larger than ±15%.



MEMORY RECALL

The GlucCell™ cell culture glucose Meter automatically stores 180 test results, letting you review them in order from the most recent to the oldest. If the memory is full and a new result is added, the meter deletes the oldest result.
The meter also calculates and displays the previous 1-, 7-, 14-, 21-, and 28-day averages.

To recall Results Stored in Memory

Turn meter on by press M button till you hear a beep sound. The first result displayed on the screen is your latest test result.
By pressing M button, you will see your test record from the most recent to the oldest.
By pressing S button you will obtain the averages of the last 1-, 7-, 14-, 21- and 28-days.

NOTE: ANYTIME IN MEMORY MODE, YOU CAN PRESS M BUTTON UNTIL YOU HEAR THE BEEP TO EXIT AND TURN OFF THE METER.

To Delete Memory

While in the memory mode, select the test result you wish to delete and display it on the screen.
Press S button until you hear a beep sound. The blink “dEL” symbol will appear on the meter.
Press M button until the “OK” symbol appears which confirms that the selected test result has been deleted successfully.
The meter will return to memory mode and display next result after deleting.

SYSTEM SPECIFICATIONS

1	Assay Method	Electrochemical biosensor
2	Test Sample	Animal cell culture medium or buffer solution
3	Test Result	Glucose concentration in mg/dL or mmol/L
4	Sample Size	1.5 µL
5	Measuring Time	Less than 15 seconds
6	Measuring Range	20 – 600 mg/dL (1.1 – 33.3 mmol/L). Alarm HI when over 600 mg/dL, LO when over 20 mg/dL
7	Accurate Testing Range	30 – 500 mg/dL (1.67 – 27.78 mmol/L)
8	Operating Temp. Range	10℃~40℃(50℉~104℉)
9	Operating Relative Humidity	20% - 80% RH
10	Memory Capacity	180 test results with time and date
11	Power Supply	One 3-volt Lithium Battery
12	Battery Life	Approximately 1000 tests
13	Automatic shut-off	In 3 minutes

TAKING CARE OF YOUR METER

REPLACING THE BATTERY

The GlucCell™ Glucose Meter comes with a battery (not yet be installed when new purchasing). Please install your battery before started.
Battery life will vary depending on usage, so always keep a spare on hand.
The battery should last about 12 months when testing 3 times a day.
When the battery symbol appears on the meter display, battery is getting low. You will still be able to test with low battery, but you should replace it as soon as possible.
When battery symbol appears flashing on the display, the meter will no longer give results and you must replace the battery immediately.

TO REPLACE THE BATTERY

Make sure the meter is turned off.
Let the front of meter rest in the palm of your hand.
Slide battery compartment door open.
Remove the old battery and insert the new 3 volt Lithium battery into the metallic hood of the battery holder with the plus(+) side up.
Slide battery compartment door closed. Check to see that your meter is working. If it fails to turn on, the battery may have been inserted incorrectly. Remove the battery and reinsert it as illustrated.
NOTE: EVERY TIME WHEN YOU REPLACE THE BATTERY, THE METER WILL TURN ON AUTOMATICALLY AND ENTER TO THE TIME/DATE SETTING. PLEASE SET CORRECT TIME AND DATE BEFORE TESTING.

CLEANING

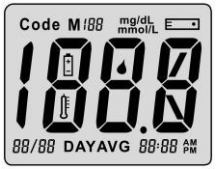
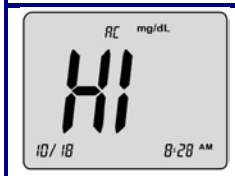
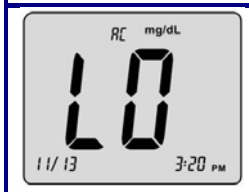
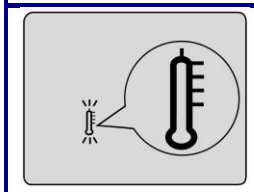
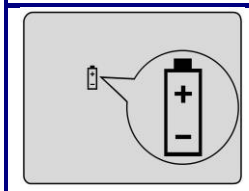
Clean the outside of the meter with a soft cloth, slightly dampened with water. Do not get moisture into the strip slot and data port.

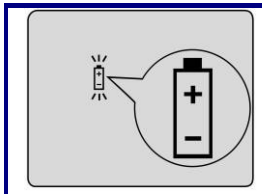
STORAGE AND HANDLING

Keep your meter free of dust. Protect it from extreme temperature and humidity.

DISPLAY MESSAGES AND PROBLEM-SOLVING GUIDE

When any of the following messages appear, there is a problem with your GlucCell™ Cell Culture Glucose Meter or the way in which you are performing a test. These messages will help you to identify certain problems. If error messages appear that are not listed on the following pages, contact with your local distributor for help.

DISPLAY	DESCRIPTION	ACTION TO TAKE
	Display check	If some parts of the display are not working. Contact your local distributor for help
	Cell Culture Glucose result is higher than 600 mg/dL or 33.3 mmol/L.	If this not confirmed by the way you feel, review proper testing procedure and perform a quality check with control solution. Repeat test, if “HI” still appears, contact your local distributor for help
	Cell Culture Glucose result is lower than 20 mg/dL or 1.1 mmol/L.	If this not confirmed the way you feel, review proper testing procedure and perform a quality check with control solution. Repeat test, if “LO” still appears, contact your local distributor for help
	Temperature is above or below the operating range of test strips.	The result you have obtained may not be accurate. Move to an area with temperature between 10℃ to 40℃ (50℉ - 104℉). Do not artificially heat or cool the meter.
	Battery is low	Change battery soon.

	Battery is dead.	Change battery now.
	Test strip may be damaged.	Perform the test with new test strip.
	Test strip is used or test was not performed correctly.	Perform the test with a new test strip and follow the test procedure correctly.
No responses when strip is inserted into the meter	Maybe: 1. Battery is dead 2. Wrong strip be inserted 3. Meter is defective	You have to: 1. Replace battery 2. Insert the test strip correctly 3. Contact us for help
No responses when sample is applied to the strip	Maybe: Sample is not sufficient Meter is defective	You have to: 1. Repeat test with sufficient sample 2. Perform Meter Check by inserting check strip.

NOTE : If there is any error message displayed but not listed here, or your meter shut down for no reason, you can reset the meter by following two ways:

1. Replace the battery.

2. Open the battery door and use a needle to prink the “reset” hole (with a reset mark beside) the battery component.

PERFORMANCE EVALUATIONS

PRECISION

Tests were carried by trained technicians in the laboratory setting. The sample from one subject was adjusted to 3 different levels. Strips out of a single lot were tested. The results are shown in the following table.

Level	No. of tests	Mean (mg/dL)	Within-Run C.V. (%)
Low	20	43.3	4.7
Normal	20	96.2	3.4
High	20	381.0	2.4

ACCURACY

Tests were carried by trained technicians in the laboratory setting. Samples from the subjects were tested with both GlucCell™ Meter and YSI Model 2300 Glucose Analyzer as reference. The results are shown in the following table.

Slope	1.07
y-intercept	-5.9 mg/dL; -0.3 mmol/L
Correlation Coefficient (R)	0.99
Number of tests	120
Range tested	54-490 mg/dL 3.0–27.2 mmol/L

SYMBOL

			Do not reuse
LOT	Lot number		Please consult instructions for use
	Use by /Expiry date		Caution, consult accompanying document
	Temperature limitation / Store at		Manufacturer
CE 0537	This product fulfills the requirements of Directive 98/79/EC in vitro diagnostic medical device.	EC REP	EU representative

CONTACT INFORMATION

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