

GlucCell™ Glucose Monitoring System Operation Manual

ESCO
LIFESCIENCES GROUP

ESCO Bioengineering Co., Ltd.



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EBE warrants that if a product manufactured by EBE shall be free of defects in materials including mechanical parts and electronic parts and other workmanship for one (1) year from the first to occur of (i) the DATE the product is sold by EBE directly or (ii) the DATE the

product is purchased from authorized distributors by EBE (the “Commencement DATE”).

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An authorized distributor of EBE must perform all warranty inspections. In the event of defect covered by EBE’s warranty, EBE shall, as its sole obligation and exclusive remedy, provide free replacement parts to remedy the defective product.

This instrument warranty is not allowed to be transferable. The warranty only applies to the original purchaser of this instrument and will be null and void in the case of resale, and possible re-location.

This warranty shall be invalid due to damage caused by accident, misuse, theft, neglect, natural disaster, use of non-EBE’s authorized spare parts, illegal disassembly, etc., relocation or deterioration caused by application which is not the original purpose to design this product.

Caution

Users, if necessary, have to wear gloves, goggles and suitable protection clothes before operating devices.

This equipment must be operated as described in this manual. If operational guidelines are not followed, equipment damage and personal injury can occur.

Please read the entire User’s Guide before attempting to use this unit.

Do not use this equipment in a hazardous atmosphere or with hazardous materials for which the equipment was not designed.



EBE is not responsible for any damage to this equipment that may result from the use of an accessory not manufactured by EBE.

Return of Material Authorization Policy

EBE Technical Support Team:

info@escobioeng.com, mail@vaccixcell.com

If service is required, please contact our technical support team.

Please do not return any equipment for service without a Return Authorization and Number, which can be obtained from our technical support team.

The return authorization number must appear on the outside of all cartons.

Item	Description
Customer Company Name	
Customer Name	
Customer Phone Number	
Purchase Date	
Machine Serial Number	
Invoice Number	
Reason for Returning Back	

Chapter 1 About the GlucCell™ System

1.1 Intended Use

The GlucCell™ Glucose Monitoring System (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.

1.2 Characteristics

The GlucCell™ System uses the latest technology in Cell Culture Glucose monitoring to provide you with easy and reliable testing. The glucose test strip requires a sample volume of 1.5 uL and takes less than 15 seconds for the result. The glucose meter is a compact hand-held device with a large and easy-to-read display. The meter can store 180 test results with corresponding times and dates.

1.3 Limitations of the System

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

GlucCell™ Glucose Test Strips can be used only with GlucCell™ Glucose Meters. The meter must be coded only with the corresponding code on the glucose test strips bottle that is used - the codes must match.

Use glucose test strips before the expiry date. Test only with cell culture medium or equivalent buffer solution. High concentrations of vitamin C and/or uric acid may affect the test result.

High altitudes may affect the test result. Temperatures outside the range of 10°C to 40°C (50°F to 104°F) may affect the test result.

1.4 Component List

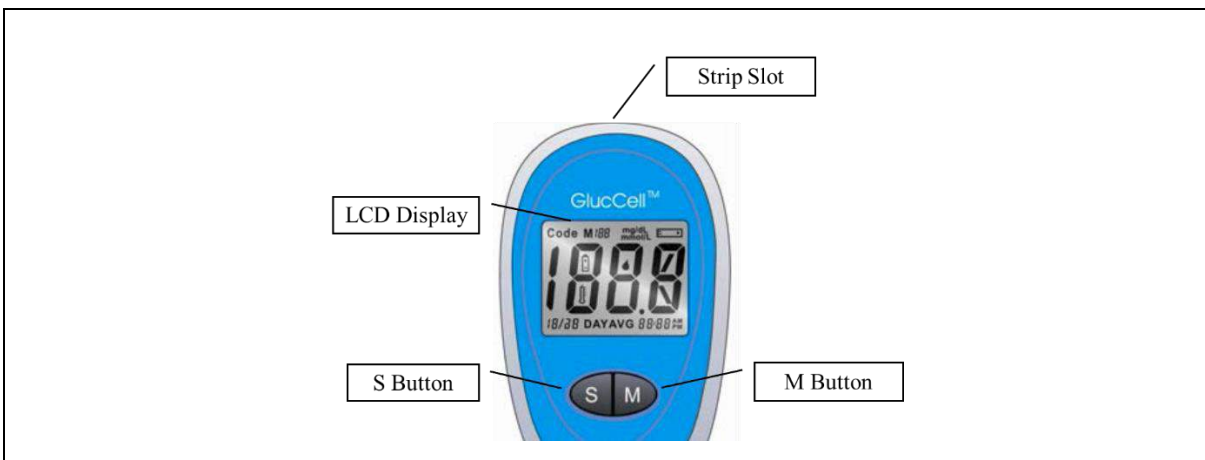
These items are included in your starter kit of GlucCell™ Glucose Monitoring System.



Item	Item Name	Quantity
1.	GlucCell™ Glucose Meter	1 set
2.	Check Key	1 pc
3.	Quick Reference Card	1 copy
4.	Case	1 each
5.	GlucCell™ Glucose Test Strip	1 box
5-1	Glucose Test Strip	2 bts/box, 25 strips/bt
5-2	Glucose Test Strip User Instruction	1 copy
5-1 – 5-2 all in GlucCell™ Glucose Test Strip (5)		

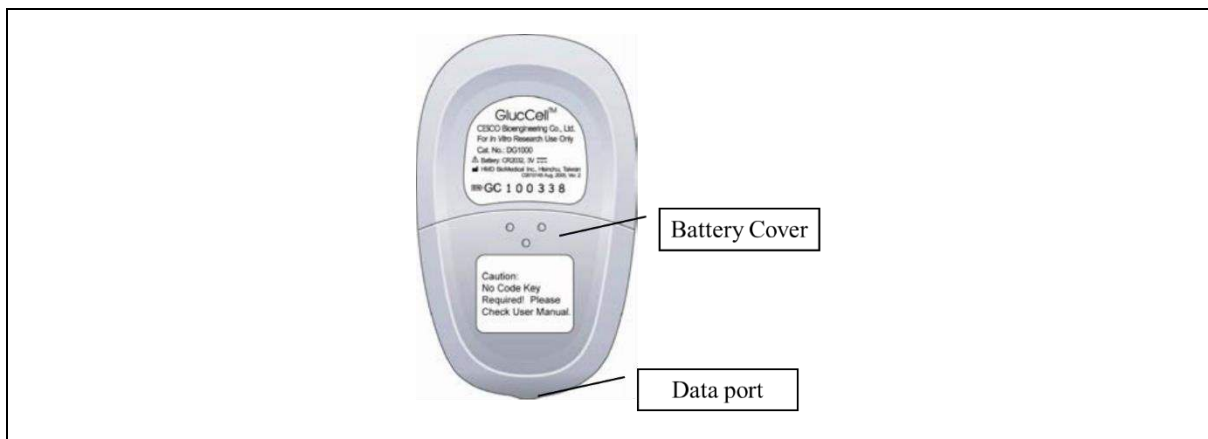
1.5 About the Glucose Meter

- Front Side of the Meter



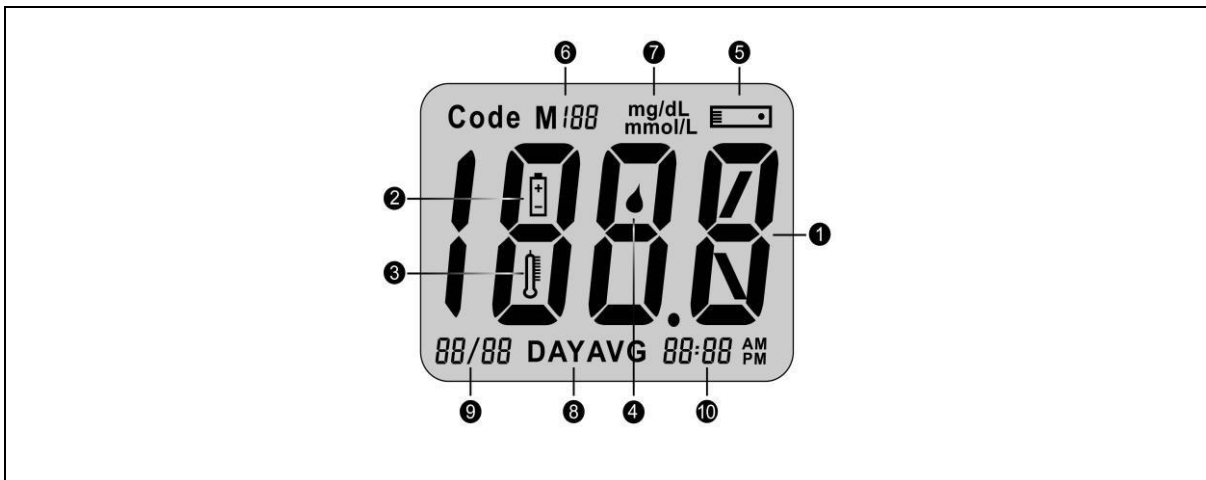
Item	Item Name	Description
1	LCD Display	The large, easy to read display shows test results, messages, cell culture glucose results stored in memory, time and date.
2	S Button	Press S button to enter the time setting, and to decrease values in the setting mode.
3	M Button	Press M button to enter memory mode to recall the information stored in meter's memory and to increase values in the setting mode.
4	Strip Slot	The slot is a connector for GlucCell™ Glucose Test Strips, and Check Key.

- Backside of the meter



Item	Item Name	Description
1	Data Port	Allow you to transfer the information stored in the meter's memory to a computer to view, analyze and print.
2	Battery Cover	Slides down for battery access

- LCD Display



Item	Item Name	Description
1	Numerical Display	Data display
2	Battery symbol	Low battery indication
3	Thermometer symbol	Out-of-range temperature indication
4	Droplet symbol	Ready for test indication
5	Strip symbol	Ready for strip insertion indication
6	M188	Memory capacity is 180 entries. The display shows M188 to ensure that all digits are working properly.
7	mg/dL; mmol/L	Selected unit display
8	DAYAVG	Number of days average display
9	Date	Month/day display
10	Time	The meter is programmed for a 12 hour period format.

1.6 Glucose Test Strip

Item	Item Name	Description
1	Aperture	Apply the sample to either side of strip.
2	Test Confirmation Window	<p>Make sure the chamber is filled up with test sample to ensure the correct result.</p> <p>For example:</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> (O) </div> <div style="text-align: center;"> (X) </div> <div style="text-align: center;"> (X) </div> </div>
3	Gray Electrode End	Insert this end of test strip into meter.

Important 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.

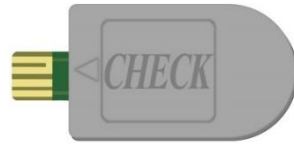
- Store the vial in a cool, dry place between 10°C to 40°C (50°F to 104°F). Do not refrigerate.
- Do not use damaged test strips or abnormal test strips.
- Use the test strip immediately once after removing it from the vial; replace the vial cap and close it tightly.
- Do not transfer test strips to 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.**

1.7 Test Strip Vial



Item	Item Name
1	Code Number
2	Expiry Date
3	Discard Date: 90 days from first opening of bottle

1.8 Check Key



The GlucCell™ Check Key can be used to check that the meter is operating properly. Use when performing quality control check on your meter.

Chapter 2 Installation and Replacement Battery

2.1 How to install/replace the battery

2.1.1 Push the battery cover with two thumbs and slides down to open.



2.1.2 Replace with a 3.0 volt lithium battery (CR 2032) into the battery compartment with the positive (+) side up.



2.1.3 Slide the Battery Cover up (until it snaps into place) to close.



Notes:

Test results that are stored in memory will not be erased after the battery is changed within 30 minutes.

Warning

Discard the used battery according to your local environmental regulations.

Chapter 3 Set the Glucose Meter

3.1 How to enter into Set Mode

3.1.1 When replacing a battery or first time install the battery into the meter

3.1.1.1 The meter will automatically enter the setting mode. Please set the correct time and date before you begin testing.

3.1.2 Press “S button” to turn on the meter when battery was installed

3.1.2.1 Press “S button” for 3 seconds to turn on the meter. The meter will enter to the setting mode automatically.

3.2 Set the Year



a. The Year field flashes.

- b. Press the “S or M button” to change the Year.
- c. Wait the new setting flash 3 times to confirm and shifts to the next setting. (i.e., month).

3.3 Set the Month



- a. The Month field flashes.
- b. Press the “S or M button” to change the Month.
- c. Wait the new setting flash 3 times to confirm and shifts to the next setting. (i.e., Day).

3.4 Set the Day



- a. The Day field flashes.
- b. Press the “S or M button” to change the Day.
- c. Wait the new setting flash 3 times to confirm and shifts to the next setting. (i.e., Hour).

3.5 Set the Hour



- a. The Hour field flashes.
- b. Press the “S or M button” to change the Hour.

- c. Wait the new setting flash 3 times to confirm and shifts to the next setting. (i.e., Minutes).

3.6 Set the Minutes



- a. The Minutes field flashes.
- b. Press the “S or M button” to change the Minutes.
- c. Wait the new setting flash 3 times to confirm and shifts to the next setting. (i.e., Unit of Measurement).

3.7 Set the Unit of Measurement

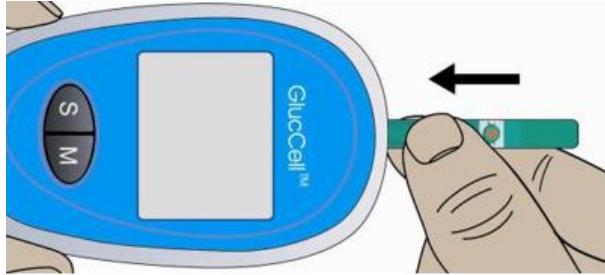
GlucCell™ meter has two measuring units to choose from, e.g. mg/dL and mmol/L. The default unit is mg/dL. The switch of measuring units requires a Unit Switch Key (USK). However, the USK is not included in GlucCell™ product. If users require to switch units to mmol/L, please contact your local dealers or EBE, and we will send you the USK. Once you receive the USK, please follow the instructions below to switch the measuring unit.

- a. Remove battery.
- b. Insert Unit Switch Key (USK) into strip slot with label side up.
- c. Insert battery and meter will display unit, which is depend on the unit switch key.
- d. Remove the unit switch key to exit. Meter will automatically be off.

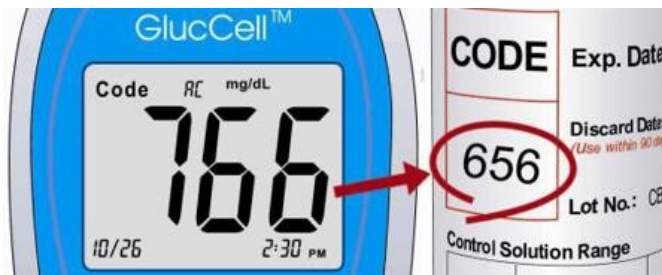
Chapter 4 Perform a Glucose Test

4.1 Insert the glucose test strip firmly into the strip slot; the meter turns on automatically.

Recap the strip bottle immediately after taking out the glucose test strip.



4.2 Ensure the code number displays onto the screen matches the code number on the strip bottle that is using. If the two numbers match, you may begin testing by referring step 4.4. Otherwise continue to the next step.

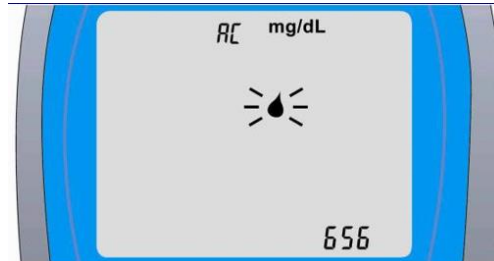


4.3 Press S button until you hear the sound of buzzer and the code value flashes, press S or M button to obtain the code number indicated on the new test strip vial. Upon obtaining the right code number, wait the new setting to flash 3 times to validate the change. The new code number is displayed on the screen.



4.4 The meter is ready for testing when the flashing droplet symbol appears.

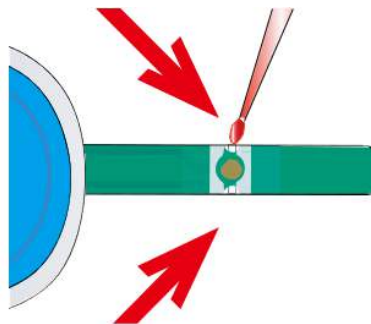
Note: perform the test within three minutes; or the meter makes a long beep and turns off automatically.



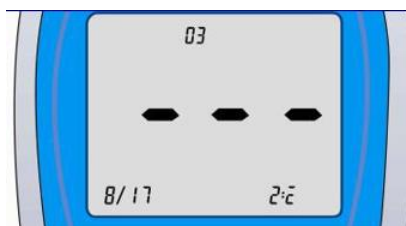
- 4.5 Pipet around 1.5 μ l of culture medium and produce a small droplet in the tip of pipette.



- 4.6 Touch the droplet culture medium to the sample chamber of the test strip until the chamber is fully filled. The meter beeps indicating that the test has started.



- 4.7 The Measuring Symbol is displayed to indicate the test is in progressing.



- 4.8 The test result displays within 15 seconds, and pauses for 3 minutes or until the

glucose test strip is pulled out.



4.9 Record the test results in your logbook



4.10 Remove the test strip to turn off the meter. The test result has been stored.



Chapter 5 Test Results

5.1 What your results mean

Test results are displayed in either mg/dL or mmol/L depending on the unit setting (refer to Section 3.7 for how to set the meter). The mmol/L results will always include a decimal point; mg/dL results do not include a decimal point.

5.2 Low Glucose Value

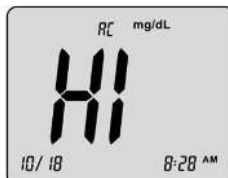
The LO Symbol appears when your glucose test result is less than 20 mg/dL (1.1 mmol/L).



5.3 High Glucose Value

The HI symbol appears when your glucose test result is higher than 600 mg/dL (33.3 mmol/L).

Note: In the situation, please dilute the sample with PBS to proper concentration for next test.



Chapter 6 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.

6.1 To recall Results Stored in Memory

6.1.1 Turn on the meter by press M button till you hear a beep sound. The first result displayed on the screen is your latest test result.

6.1.2 By pressing M button, you will see your test record from the most recent to the oldest.

6.1.3 By pressing S button you will obtain the averages of the last 1-, 7-, 14-, 21- and 28-days.

6.2 To Delete Memory

6.2.1 While in the memory mode, select the test result you wish to delete and display it on the screen.

6.2.2 Press S button until you hear a beep sound. The blink “DEL” symbol will appear on the meter.

6.2.3 Press M button until the “OK” symbol appears which confirms that the selected test result has been deleted successfully.

6.2.4 The meter will return to memory mode and display next result after deleting.

Chapter 7 Quality Control Test

7.1 How to check meter by check key

7.1.1 Insert the check strip into strip slot with label side up as above.

7.1.2 You should obtain an acceptable “OK“ reading within 10 seconds, which means your meter is working properly.


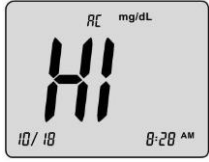
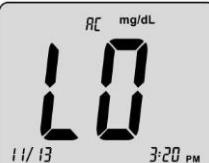
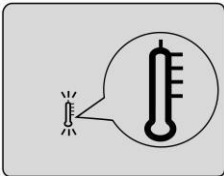
7.1.3 Remove the check key to exit. The meter will automatically be off.

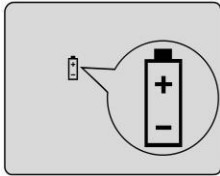


Note:

If you do not get an “OK” reading but another error message appears, please follow the procedures below:

- 1. Turn off the meter by pressing the M button for 3 seconds and remove the Check Key from the meter.**
- 2. Insert the check Key to repeat the test. If the second result persists, consult your local distributor for help.**

Chapter 8 Display Messages and Solution

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 did not confirm 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°C to 40°C (50°F - 104°F). Do

		not artificially heat or cool the meter.
	Battery is low	Change battery soon.
	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 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 key.

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.

If the error message repeats, please contact your local dealer for help

Chapter 9 Taking Care of your Glucose Meter

9.1 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.

9.1.1 To replace the battery

9.1.1.1 Make sure the meter is turned off.

9.1.1.2 Let the front of meter rest in the palm of your hand. Slide battery compartment door open.

9.1.1.3 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.

9.1.1.4 Slide battery compartment door closed.

9.1.1.5 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: You replace the battery every time, the meter will turn on automatically and

enter the time/date setting. Please set the correct time and date before testing.

9.2 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.

9.3 Storage and handling

- Keep the meter, test strips and code key away from extremely high or low temperatures.
- Free from dust and dirt.
- Keep the meter away from water or any forms of liquids.
- Do not drop the meter.
- Store the meter in the case.
- Keep the meter away from UV.

9.4 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.

Chapter 10 System Specifications

Assay Method	Electrochemical biosensor
Test Sample	Cell culture medium or equivalent solution
Test Result	glucose (mg/dL or mmol/L)
Sample Size	1.5 μ L (0.0015 c.c.)
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
Accurate Testing Range	30 – 500 mg/dL (1.67 – 27.78 mmol/L)
Measuring Time	Less than 15 seconds
Memory Capacity	Last 180 test results
Battery Type	CR2032 3V-Lithium battery
Battery Life	Approximately 1000 tests
Operating Temperature Range	10°C~40°C (50°F~104°F)
Operating Relative Humidity	20%~80%RH
Dimensions of the meter	96 mm *60 mm * 18.5 mm
Weight of the meter	70 g included battery
Auto Shut-off	In 3 minutes

Chapter 11 Performance Evaluations

11.1 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

11.2 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

11.3 Symbol

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

Chapter 12 Related Products

Item	Product Name	Item Code
1	GlucCell™ Glucose Monitoring System	1400009
2	GlucCell™ Glucose Test Strip (2 bottles (25 strips/bottle))	1400010



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