

METER USER GUIDE



SYMBOLS DESCRIPTION

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

10-62-6519-0003 V2-JUL15

L-Tac Medicare Pte Ltd
25 Mandai Estate #07-11
Innovation Place Tower 1
Singapore 729930
Tel: +65 6863 8191
Fax: +65 6863 8190
www.medicare-l-tac.com.sg
Customer Service: +65 6334 2273

OK Biotech Co., Ltd.
No. 91, Sec. 2, Gongdao 5th Road,
30070 Hsinchu City, TAIWAN
 MDSS GmbH
Schiffgraben 41, 30175 Hannover, GERMANY

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Before You Begin

PLEASE READ THIS BEFORE USING.

The following basic safety precautions should always be taken.

1. Close supervision is necessary when the device is used by, on, or near children and handicapped persons.
2. The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!
3. All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
4. Use the device only for the intended use described in this manual.
5. Do not use test strips and control solutions which are not supplied by the manufacturer.
6. Do not use the device if it is not working properly, or if it has suffered any damage.
7. Before using any product to test your blood glucose, read all instructions.
8. Thoroughly practice the test. Do all quality control checks as directed and consult with a diabetes healthcare professional.
9. Before starting measurements, please install battery, and download the Smart BGM app program to set correct time and date, measurement unit and/or remove memory.
10. Use only Medicare test strip and control solution with your Medicare LiSmart meter. Using other test strips and control solutions with this meter can produce inaccurate results.
11. Keep this user guide with you.

Intended Use

The system is intended for use outside the body (*in vitro* diagnostic use only). It should be used only for testing blood glucose (blood sugar) and only with fresh capillary whole blood samples. The system is intended for use in the home and in clinical settings. It should not be used for the diagnosis of diabetes or for the testing of newborns.

Principle of Measurement

Blood glucose is measured by an electrical current that is produced when a blood samples mixes with the reagent (special chemicals) of the test strip. The electrical current changes with the amount of glucose in the blood sample.

The meter measures the strength of the electrical current, calculates your blood glucose level and then displays your result in either milligrams of glucose per deciliter (mg/dL) or millimoles of glucose per liter (mmol/L).

Caution

1. The user should not take any decision of medical relevance without first consulting his or her medical practitioner.
2. Call your doctor immediately if you experience symptoms that are not consistent with your blood glucose test results.
3. High altitudes above than 3,402 meter (11,161 ft) may affect the test results.
4. Temperatures outside the range of 10°C to 40°C (50°F to 104°F) may affect the test results. Do not test beyond of temperature range.
5. Do not use this meter near cellular or cordless telephones in a call, walkie-talkies, garage door openers, radio transmitters, or other electrical or electronic equipment that are sources of electromagnetic, radiation, as these may interfere with the proper operation of the meter.

IMPORTANT HEALTH-RELATED INFORMATION

1. Apply only capillary whole blood sample to test your blood glucose. Applying other substances or plasma, serum will cause wrong results.
2. Severe dehydration and excessive water loss may cause false low results. If you believe you are suffering from severe dehydration, consult your healthcare professional immediately.
3. Test results below 60 mg/dL (3.3 mmol/L)*1 indicates low blood glucose(hypoglycemia). Test results greater than 240 mg/dL (13.3 mmol/L)*2 indicates high blood glucose (hyperglycemia).If your results are below 60 mg/dL (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L), repeat the test, and if the results are still below 60 mg/dL (3.3 mmol/L) or above 240 mg/dL (13.3 mmol/L), consult your healthcare professional immediately.
4. Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals

experiencing a hyperglycemic-hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.

5. Abnormal red blood cell counts (hematocrit level below 20% or above 60%) may cause false results. Please consult your healthcare professional if you do not know your hematocrit level.
6. Interference: Reducing substances occurring in the blood naturally (uric acid, bilirubin) or from therapeutic treatments (ascorbic acid, acetaminophen) will not significantly affect Medicare test results. However, elevated concentrations of these substances may affect test results. The compounds listed in the tables were found to have no affect at the concentration indicated.

Compounds	Highest concentrations tested at which no interference occurred	Compounds	Highest concentrations tested at which no interference occurred
Acetaminophen	≤ 8.0 mg/dL (0.53 mmol/L)	Hydroxyurea	≤ 3.0 mg/dL (0.39 mmol/L)
Ascorbic Acid	≤ 5.0 mg/dL (0.28 mmol/L)	Ibuprofen	≤ 50 mg/dL (2.42 mmol/L)
Aspirin	≤ 60 mg/dL (3.33 mmol/L)	Icodextrin	≤ 13 mg/dL (0.01 mmol/L)
Bilirubin	≤ 90 mg/dL (1.54 mmol/L)	L-dopa	≤ 10 mg/dL (0.51 mmol/L)
Cholesterol	≤ 500 mg/dL (12.9 mmol/L)	Maltose	≤ 900 mg/dL (26.3 mmol/L)
Creatinine	≤ 5.0 mg/dL (0.44 mmol/L)	Methyldopa	≤ 3.0 mg/dL (0.13 mmol/L)
Dopamine	≤ 2.0 mg/dL (0.11 mmol/L)	Pralidoxime Iodide	≤ 25 mg/dL (0.94 mmol/L)
EDTA	≤ 360 mg/dL (12.3 mmol/L)	Salicylate	≤ 60 mg/dL (4.34 mmol/L)
Galactose	≤ 900 mg/dL (50 mmol/L)	Tolazamide	≤ 100 mg/dL (3.21 mmol/L)
Gentisic Acid	≤ 5.0 mg/dL (0.32 mmol/L)	Tolbutamide	≤ 400 mg/dL (14.8 mmol/L)
Glutathione	≤ 53 mg/dL (1.72 mmol/L)	Triglycerides	≤ 2,000 mg/dL (22.6 mmol/L)
Haemoglobin	≤ 500 mg/dL (0.08 mmol/L)	Uric Acid	≤ 8.0 mg/dL (0.48 mmol/L)
Heparin	≤ 8,000 U/dL	Xylose	≤ 100 mg/dL (6.66 mmol/L)

REFERENCE:

- * 1: Kahn, R. and Weir, G.: Joslinis Diabetes Mellitus, 13thed Philadelphia : Lea and Febiger (1994), 489.
- * 2: Krall, L.P. and Beaser, R. S.: Joslin Diabetes Manual. Philadelphia : Lea and Febiger(1989), 261-263.

2.App Software

1. Your Medicare LiSmart blood glucose meter can be connected to Smart BGM app program. Through this app, the blood glucose curves can be reviewed in the mobile device.
2. The Medicare Smart BGM app supports Andriod and iOS system, please download the APP program to your mobile device before use, and read the APP instruction manual in the app.
3. For Android system user, please go to Google play, download app : Smart BGM.
4. For iOS system user, please go to Apple store, download app: Smart BGM.

QR Code:



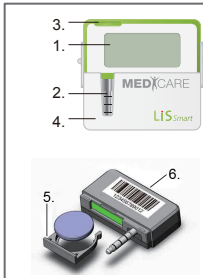
5. To know which mobile device it supports, please see the Smart BGM USER GUIDE- Mobile Compatibility Table for details.

Important:

1. Call your doctor immediately if you experience symptoms that are not consistent with your blood glucose test results.
2. When the app program displays "This mobile device does not support" warning, please stop using and contact your customer service.

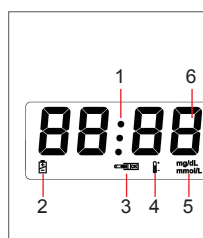
4. Getting To Know Your System

The Medicare LiSmart meter system uses the latest technology to provide you with easy and comfortable testing. The system requires only a 0.3 µL of blood sample to complete the testing in only 6 seconds.



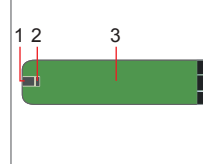
1. Display: Shows test results and messages.
2. Headphone plug: Connect your mobile device to use app.
3. Strip slot: Insert the test strip here. The meter will turn on automatically.
4. Headphone plug Cover: Protect the headphone plug shell.
5. Battery compartment: Holds ONE 3v Lithium battery (battery type CR2032). Please install battery into meter before you start to test.
6. Meter label: Each meter has its meter number on it. Do not alter or tear the label off.

5. Medicare- display



1. Blood drop symbol : Flashes when sample should be applied.
2. Battery symbol : Appears when battery is weak.
3. Strip symbol : Appears when the meter is turned on.
4. Thermometer symbol : Appears when ambient temperature is above or below the acceptable range needed for testing.
5. Unit of measure : Appears with the test result.
6. Number digits: For showing test results and messages.

6. Test Strip



1. Absorbent channel : Apply a drop of blood here.
2. Confirmation window : This is where we confirm if enough blood is applied for has been drawn into strip.
3. Test strip handle : Hold this part to insert the test strip into the meter slot.
4. Contact bars : Insert this end into strip slot.

3. About Alternative Site Testing (AST)

Important

There are important limitations for doing AST. Please consult your healthcare professional before you perform AST.

What is AST?

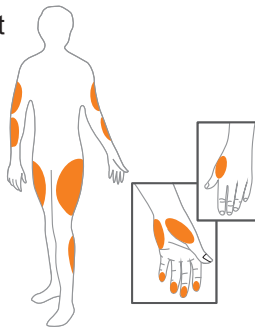
Alternative Site Testing (AST) means you can use parts of the body other than your fingertips to check your blood glucose levels. The system allows you to test from the palm, forearm, upper arm, calf or thigh, with equivalent results to fingertip testing.

What is the advantage?

Fingertips feel pain more readily because they are full of nerve endings (receptors). At other body sites, nerve endings are not so numerous and you will not feel as much pain as you will experience at the fingertip.

When to use AST?

Food, medication, illness, stress and exercise can affect blood glucose levels. Capillary blood at fingertip reflects these changes faster than capillary blood at other sites. Therefore, if you are testing blood glucose level during or immediately after meal, physical exercise or stressful event, take the blood sample from your fingertip only.



Use AST only :

1. In a pre-meal or fasting state (more than 2 hours since the last meal).
2. Two hours or more after taking insulin.
3. Two hours or more after exercise.
4. During steady state blood glucose conditions.

Do NOT use AST if :

1. You have reason to believe you have hypoglycemia or hyperglycemia.
2. Your routine glucose results are often fluctuating.
3. You are pregnant.

How to increase the accuracy ?

Stimulating blood perfusion by rubbing the puncture site prior to blood extraction has a significant influence on the glucose value obtained. Blood from the site without rubbing exhibits a measurably different glucose concentration than blood from the fingertip. When the puncture site was rubbed prior to blood extraction, the difference was significantly reduced.

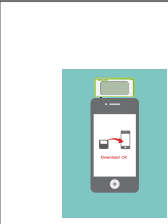
IMPORTANT :

To increase the accuracy when using AST, rub the puncture site more than 20 seconds before extracting blood.

8. Memory Download

The Medicare meter can store 100 test results with time and date. When the memory is full, the oldest memory value will be overwritten. The memory can only be reviewed under the Medicare APP program. If you test blood glucose without connecting mobile device, you have to download the meter data to your mobile device followed by below procedure:

Recall the Memory



1. Call up Medicare APP on your mobile device, and connect your meter to mobile device.
2. After connect, tap the screen icon " " to enter setting function. Then touching the Screen "Config", to enter meter settings.
3. Touching the screen "download meter records", the meter will start to download. Wait till you see the display shows "download OK" message.

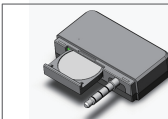
Important:

1. Please do not disconnect or remove meter from mobile device during download.
2. Please refer to your Medicare Mobile APP instruction manual for details about download, delete and reviewing your meter memory.

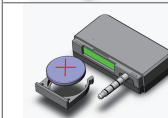
9. Replacing The Battery

The Medicare meter comes with ONE Lithium battery (battery type CR2032). Battery life will vary depending on usage, so always keep a spare battery on hand. The battery should last about 1000 tests or 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 and Eb shows up in the meter display, the meter will no longer give results and you must replace the battery immediately. Please always have one spare battery with you to ensure that you can replace the battery anytime.

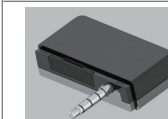
How to replace the battery



1. Make sure the meter is turned off. Let the front of the meter rest in the palm of your hand. Slide battery cover open.



2. Insert new battery (battery type CR2032), being sure to align the plus (+) side up.

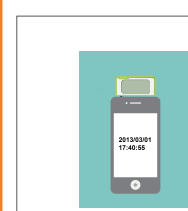


3. Close battery cover.

7. Setting Meter

Setting time and date : The time and date of Medicare meter can only be setting through Medicare APP program.

Setting Time and Date



1. Call up Medicare Smart BGM App on your mobile device, and connect your meter to mobile device.
2. After connect, your meter will automatically calibrate its time and date according to your mobile device's time and date.
3. Please refer to your Medicare Smart BGM USER GUIDE for details of setting.

Set the Unit of Measurement (mg/dL or mmol/L)

Setting the Unit of Measurement : Medicare LiSmart meter can display test result in milligram per deciliter (mg/dL) or millimoles per liter (mmol/L). Your meter has been preset at the factory with the standard unit measurement used where you live. The measurement unit of Medicare meter can only be setting through Medicare APP program. When you turn off the meter or replace the battery, the unit will not be changed. Use of the wrong unit of measure may cause you to misinterpret your blood glucose level, and may lead to incorrect treatment. Please always consult with your healthcare professionals first if you want to reset the unit of measure.



1. Call up Medicare Smart BGM on your mobile device, and connect your meter to mobile device.
2. After connect, tap the screen icon " ", you will enter the setting function.
3. Touching the Screen "Config", will enter to meter settings. Select the unit of mg/dL or mmol/L and wait until it complete setting.
4. Please refer to your Medicare Mobile APP instruction manual for details of setting.

NOTE:

1. Replacing the battery does not affect the test result stored in memory. However the time and date may need to re-set by app.(Read the Smart BGM User Guide.)
2. As with all small objects, the battery should be kept away from small children as a safety precaution. If the battery is swallowed, seek medical assistance immediately.
3. Batteries might leak chemicals if not used for a long time. Remove the batteries if you are not going to use the device for a long period of time (i.e., 3 months or more).
4. Please discard the used or dead batteries properly according to the regulations of your country.

10. Prepare For Blood Sampling

Adjustable Lancing Device
Your lancing device and lancets are used for obtaining capillary blood samples from the puncture site.

Lancet

⚠ Important Lancing Device and Lancets Information

1. ⓧLancet is for single use only.
2. Keep lancing device and lancets clean.
3. Use caution when removing the used lancet from the device and when disposing the used lancet.

IMPORTANT :
The meter and lancing device are for single patient use.
Do NOT share them with anyone including other family members !
Do NOT use on multiple patients !

Setting your Lancing Device

1. Screw off the cap of lancing device. Insert a lancet into the lancet holder and push down until it is fully seated

2. Twist off the protective cap until it separates from the lancet.

3. Replace the lancing device cap and set the puncture depth to the desired number.
NOTE:
The depth selector offers 5 levels of skin
1-2 : for soft or thin skin
3 : for average skin
4-5 : for thick or calloused skin

4. Pull back the cocking control until it makes a click, and then release. If it does not click, the device may have been cocked when the lancet was inserted.

11.Prerforming Blood Test

1. Wash Your Hands and the Puncture Site : Wash your hands in warm, soapy water. Rinse and dry completely. Warm your fingers to increase blood flow.

2. Insert Test Strip : Remove a 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. The meter turns on automatically. When the blood symbol is blinking, you are ready to perform a test.

3. Select and Lance a Puncture Site
*For Fingertip
Hold the prepared lancing device firmly against the side of your fingertip. Press release button.
*For AST
Please refer to the "About Alternative Site Testing (AST)" Section. Please consult your healthcare professional before obtaining blood from site other than your fingertip.

4. Obtain a Blood Sample : Gently massage your finger or puncture site to obtain the required blood volume. To perform the test, you need only 0.3 µL of blood sample. Do not smear the blood sample. To obtain best accurate result, wipe off the first drop of blood and gently squeeze another drop of blood.

5. Apply Blood Sample : Apply the blood sample to the opening of absorbent channel of test strip until the confirmation window is fully covered with blood. Then the meter begins to count down and displays the test result in 6 seconds.

6. Read Your Result : The result is displayed in 6 sec. For any medical action or drug prescription, please consult with your healthcare professional.

7. Remove Strip to Turn Meter Off : Your blood glucose result is automatically stored in the meter memory. Turn the meter off by removing the test strip. Discard the used strip and lancet safely in a puncture resistant container

12. Understanding Your Test Result

The normal blood glucose range is below 100 mg/dL (5.6 mmol/L) for a fasting, non-diabetic adult, but less than 140 mg/dL (7.8 mmol/L) two hours after meals. Consult your healthcare professional to find out your target blood glucose value. If your blood glucose result seems unusually high or low, or inconsistent with your previous result, check the following :

1. Was the blood sample applied immediately to the test strip after removing it from the vial?
2. Was the volume of the blood sample sufficient?
3. Was the test strip vial cap tightly sealed?
4. Was the test strip used before the expiration date?
5. Were the test strips stored away from extreme temperatures in very cold or hot weather or from areas of high humidity?

The run a control test with Medicare control solution. if the control test result is within the acceptable range. review testing procedure and repeat your blood glucose test with a new test strip, if your blood glucose value is still inconsistent with your previous results, glucose trend, or how you feel, contact your doctor immediately for help.

REFERENCE:
*American Diabetes Association Website (<http://www.diabetes.org>)

14. Caring For Your Meter And Test Strip

To avoid the meter and test strips getting dirt, dust or other contaminants, please wash and dry your hands thoroughly before use.

Cleaning
Your meter does not require special maintenance. As long as no blood or control solution comes in direct contact with the meter, there is no special cleaning required.
To clean the meter exterior, wipe with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft and dry cloth. Do not flush with water.
Do not use organic solvents to clean the meter. Your meter is a precision instrument. Please handle it with care.

Storage

1. Meter Storage
* Storage condition: -20°C~50°C (-4°F~122°F), below 90% relative humidity.
* Avoid dropping and strong impact.
* Avoid direct sunlight and humidity.
2. Strip Storage
* Storage condition: 4°C~40°C (39°F~104°F), and 10~85% relative humidity. Do not freeze.
* Store your test strips in their original vial only. Do not transfer to other container.
* Store test strip packages in a cool and dry place. Keep away from direct sunlight and heat.
* After removing a test strip from the vial, immediately replace the vial cap and close it tightly.
* You may touch the test strip anywhere with clean, dry hands when removing it from the vial or inserting it into the meter.
* Use each test strip immediately after removing it from the vial.
* Do not bend, cut, or alter a test strip in any way.
* Keep the strip vial away from children since the cap and the test strip can be a potential choking hazard. If swallowed, please seek medical assistance immediately.
3. Control solution storage
* Storage condition: Store the control solution tightly closed at temperatures between 4°C (39°F) and 30°C (86°F). Do not freeze.

13.Control Solution Testing

Medicare control solution contains a known amount of glucose that reacts with Medicare test strips. By testing your control solution and comparing the test results with the expected range printed on the test strip vial label, you can make sure that the meter and the test strips are working properly together as a system and that you are performing the test correctly. It is very important that you do this simple check routinely to make sure you get accurate results.

Why perform a control solution test ?

1. To ensure that your meter and test strip are working properly together.
2. To allow you to practice testing without using your own blood.

When should the control solution test be performed ?

1. When you first get your Medicare LiS Smart meter. Before use this system to test your blood, you can practice the procedure by using control solution. When you can do three tests in a row that are within the expected range, you are ready to test your blood.
2. Once a week (to make sure that you continue to get accurate results)
3. When you begin using a new vial of test strips.
4. Whenever you suspect that the meter or test strips are not working properly.
5. When your blood glucose test results are not consistent with how you feel, or when you think your results are not accurate.
6. When test strips are exposed to extreme environmental conditions.
7. If you drop the meter.
8. when replace the battery

Important Control Solution Information

1. Check the expiration date on the control solution bottle. Do not use if expired.
2. Control solution, meter, and test strips should come to room temperature (68-77°F/20-25°C) before testing.
3. Shake the bottle before use, discard the first drop of control solution after squeezing, wipe off the dispenser tip to avoid contaminations. These steps ensure you will get a good sample and an accurate result.
4. Record the discard date on the bottle when you open a new bottle of control solution.

How to Perform a Control Test

1. Call up Medicare Smart BGM App on your mobile device, and connect your meter to mobile device.

2. After connecting the meter and mobile device, insert test strip to strip slot, the meter will activate.

3. Squeeze a drop of Control Solution : Shake control solution bottle well. Remove the cap. Squeeze bottle, discard the first drop and wipe off the dispenser tip with a clean tissue paper or cotton swab. Squeeze a drop on a clean non-absorbent surface.

4. Apply Control Solution : Apply the drop to the opening of the strip absorbent channel until the confirmation window is filled. The meter begins to count down.

5. Check if the test result is in range: After the meter counts down from 6 to 1, the test result shows up. Compare the test result with the range printed on the test strip vial. The result should fall within the printed range.

6. Tap the control solution icon, the reading will become "0" as figure which means your control solution reading has been deleted.

7. Remove the used strips from meter.

Important:

1. When you do the control solution test with meter alone (NOT connected with your mobile device under APP program), the control test result will be stored in the meter. We recommend you do the control solution ONLY under APP program and delete the control solution reading every time when you finish test.
2. Please refer to your Medicare Mobile APP instruction manual for details about control solution setting.

3. Repeat test if test result falls outside the control range stated on the test strip label. If subsequent test remains to produce unacceptable result, the meter or test strip may be faulty. DO NOT use the system. Contact us or your local distributor for help.

16. System Specifications

Model Name	LiS Smart
Assay Method	Electrochemical biosensor
Test Sample	Capillary Whole Blood
Test Result	Referenced to plasma glucose value
Alternative Site Testing	YES (palm, forearm, upper arm, calf, or thigh)
Sample Size	0.3 µL
Measuring Time	6 seconds
Measuring Range	20~600 mg/dL (1.1~33.3 mmol/L)
Acceptable Hematocrit Range	20~60%
Operating Condition	10°C~40°C (50°F~104°F), 10~85% R. H.
Storage/Transportation Condition	4°C~40°C (39°F~104°F), 10~85% R. H
Memory Capacity	100 test results with time and date
Power Supply	One 3-volt Lithium Battery (battery type CR2032)
Battery Life	Approximately 1,000 tests
Automatic shut-off	In 3 minutes
Dimensions	48 x 47 x 13 mm
Weight	20g

15. Performance Characteristics

ACCURACY:
95 % of the measured glucose values shall fall within either ± 15 mg/dL (± 0.83 mmol/L) of the average measured values of the reference measurement procedure at glucose concentrations <100 mg/dL (< 5.55 mmol/L) or within ± 15 % at glucose concentrations ≥ 100 mg/dL (≥ 5.55 mmol/L).

PRECISION:
CVs (%) of intermediate precision and repeatability were less than 5%.

17. Display Messages And Problem-Solving Guide

The following is a summary of some display messages and symbols. These messages help to identify certain problems but do not appear in all cases when a problem has occurred. Improper use may cause an inaccurate result without producing an error message. In the event of a problem, refer to information under "action to take".

DISPLAY	DESCRIPTION	ACTION TO TAKE
	Display check	If some parts of the display are not working. Contact your local distributor for help
	Blinking Blood	The meter is ready for blood applying into test strip.
	Test result	Display result
	Test result is higher than 600 mg/dL (33.3 mmol/L).	High or low blood glucose levels can indicate a possibly serious medical condition. If you get a "Hi" result, repeat the test with a new strip. If the result is still "Hi" contact your healthcare provider immediately. If you get a "Lo" result, contact your healthcare provider immediately.
	Test result is lower than 20 mg/dL (1.1 mmol/L).	
	Battery is dead.	Replace battery now.
	Temperature is below the operating range.	The meter is not working. Move to an area with temperature between 10°C to 40°C (50°F - 104°F) and wait at least 30 minutes. Do not artificially heat or cool the meter.
	Temperature is above the operating range.	
	Maybe: 1.Used strip or moistened strip 2.Defective meter.	You have to: 1.Repeat test with a new test strip. 2.Contact your local distributor for help.
	When the jack of meter insert mobile device.	The meter is connected to mobile devices. The meter is waiting for app.
	Meter linking app	Wait until the linking process is done.
	Meter in app mode	Operate the meter with the app.
	Meter OFF mode	Meter is shutting off.
	Date and time are not set or calibrated	Launch the app, and connect the meter to the mobile device to automatically set the date time.
No responses when the test strip is inserted into the meter	Maybe: 1. Battery is dead. 2. Wrong test strip is inserted. 3. Meter is defective.	You have to: 1. Replace battery. 2. Insert the test strip correctly. 3. Contact your local distributor for help.
No responses when blood sample is applied to the test strip.	Maybe: 1. Blood sample is not sufficient. 2. Meter is defective.	You have to: 1. Repeat test with sufficient sample. 2. Contact your local distributor for help.

18. Trademark

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