PRECICHEK
Glucose
Monitoring
System

Cloudia

User Guide

PRECICHEK

Contents

Please read this User Guide before using your PRECICHEK Blood Glucose Meter. If you have any questions or enquiries, please contact us or your local distributor.

About PRECICHEK

Indication for Use

PRECICHEK Cloudia Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood. Testing is done outside the body (In vitro diagnostic use). It is indicated to be used for single patient testing blood glucose, as an aid to monitoring levels in Diabetic Mellitus. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.

Principle of the Test

The PRECICHEK System is an electrochemical biosensor system that measures the amount of electric current produced and displays the result as a blood glucose level.

About the System

The PRECICHEK System are designed to pursuit the accuracy in blood glucose monitoring to provide you with easy and comfortable testing.The system is next generation blood glucose monitoring system due to the new cloud technology. Through the GSM wireless transmission, healthcare professionals and distant family member will be able to access immediate information of the end user. The system requires 0.5μL of blood sample and 5 seconds for the test to complete.

The PRECICHEK System consists of:
PRECICHEK Blood Glucose Meter, PRECICHEK Blood Glucose Test Strips (Model No. : ACH), PRECICHEK Check Strip, GL™ Control Solution, Lancing Device, Lancet (optional)

These products are intended to be used together to get accurate blood glucose test results. Do not use other test strips or control solutions with your meter.

Characteristics

Important Information

IVD The PRECICHEK System is intended for in vitro diagnostic use with capillary whole blood. The system should not be used for diagnosis of diabetes or for testing newborn infant (neonatal testing).

⚠ *CAUTION*

1. The user should not take any medical relevance decision based on test result 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. Severe dehydration or excessive water loss may cause false, high results. Call your doctor right away if you suspect you are suffering from dehydration.
4. For ACH Strip, A sample with large amount of reducing substances such as triglycerides (>1000mg/dL), ascorbic acid (>2.25mg/dL), uric acid (>15mg/dL) and xylose (> 50mg/dL).
5. A red blood cell count (hematocrit) that is either very high (over 55%) or very low (under 30%) can cause false result.
6. High altitudes above than 2,750 meter (8,800 feet) may affect the test results.
7. Temperatures outside the range of 10°C to 40°C (50°F to 104°F) may affect the test results.
8. 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.
9. All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
10. Do not use PRECICHEK system to test on

critically ill patient.

NOTE: PLEASE MAKE SURE THAT ALL PRODUCTS LISTED ON THE “CONTENTS” OF THE BOX ARE CONTAINED IN THE PACKAGE BEFORE USING THIS SYSTEM. IF YOU FIND ANY IMPERFECTION IN OUR PRODUCTS, PLEASE RETURN THE WHOLE SYSTEM TO THE PLACE OF PURCHASE.

Blood Glucose Meter

STRIP SLOT: Holds a Blood Glucose Test Strip or Check Strip in place when you perform blood glucose test or perform check test.

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

Mem BUTTON: Press Mem button to enter memory mode to recall the information stored in meter's memory.

Set BUTTON: Press Set button to enter date and time setting.

button: For data transmission

Meter SN Label: The label shows the meter serial number.

BATTERY COMPARTMENT: Holds four AAA batteries. Batteries are not yet installed into meter when new purchasing. Before using the meter, please install the batteries first.

Meter LCD Window

Symbol:The test can be adjusted and stored into 3 types of test modes - Before Meal Test ( ), After Meal Test( ) and Control Solution Test( ).

CODE: Code appears to indicate code NO. when ready to test.

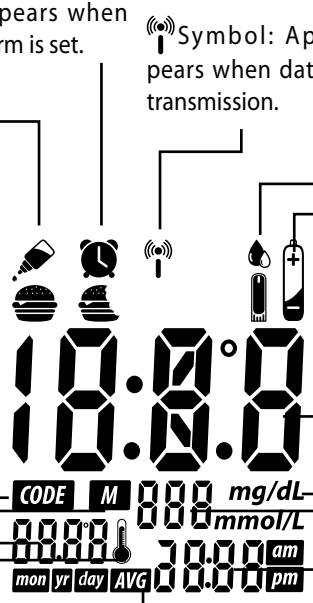
M : appears to indicate memory mode when reading previous results.

DATE: Month/Year/Day and the temperature at the moment of the test.

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

Alarm Symbol: Appears when alarm is set.

Symbol: Appears when data transmission.



Strip Symbol: Appears when the strip is inserted and meter is ready for blood testing. Replace vial cap after removing test strips.

Battery Symbol: Appears when battery is low.

Test Result

mg/dL,mmol/L: The units of measurement (mg/dL or mmol/L), mg/dL will be default unit.

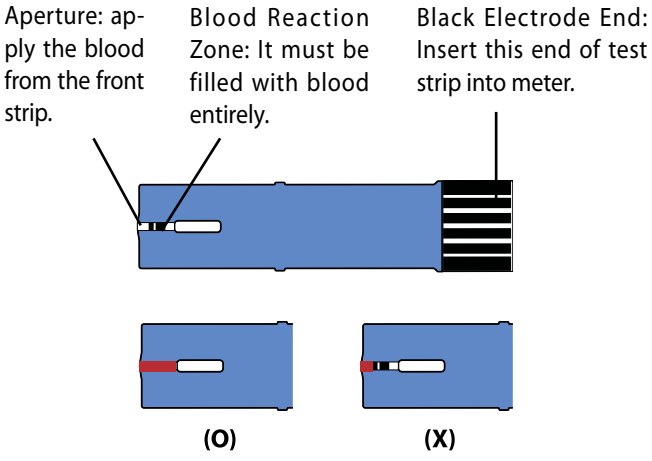
888 : Memory capacity is 999 entries. The display shows to ensure that all digits are working properly.

Time: 12 and 24 hour period format.

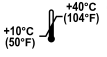
AVG : Appears when the meter is in the memory mode while recalling 7/14/21/28 day test averages.

Blood Glucose Test Strip

ACH



⚠ *IMPORTANT TEST STRIP INFORMATION*

1. PRECICHEK System measures the amount of glucose in capillary whole blood. Blood can be applied to the front of the test strip and is automatically drawn to the test strip through capillary action.
2. PRECICHEK Blood Glucose Test Strips are intended for in vitro diagnostic use with capillary whole blood or GL™ Control Solution. Results will not be accurate if used with plasma or serum samples.
3. Do not use test strips beyond the expiration date indicated on the strip vial label.
4. 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.
5. Blood Glucose Test Strip can be damaged by heat and light. Keep them sealed in the original vial.
6. 

Store the vial in a cool, dry place below to 40°C/104°F and above 10°C/50°F. Do not refrigerate.

7. Do not use damaged test strips in any way. Use test strip immediately after taking it out from the vial or foil packet; replace the vial cap and close it tightly.
8. Do not transfer test strips to a new vial. Always carry test strips in their original vial.
9. Do not place in direct heat or sunlight.
10. Do not carry loose test strips in your carrying case.
11. Test strips are for single use only.

GL™ Control Solution

GL™ Control Solution is used to check if the PRECICHEK Blood Glucose Meter and Test Strip are working correctly as a system.

It can be used in two ways:

1. To practice the test procedure
2. To make sure that the PRECICHEK Blood Glucose Meter and Test Strips are working together properly.

⚠ *IMPORTANT INFORMATION*

1. Do not use control solution beyond the expiration date indicated on the bottle label.
2. The discard date for control solution is 90 days after first opening. Record the discard date on the bottle when you open a new bottle of control solution.
3. +10°C (50°F) – +30°C (86°F) Store the control solution closed at temperatures between 10°C (50°F) and

30°C (86°F).

4. Please carefully read the label before use.

Perform Control Test

1. Insert a new test strip into the strip slot, the meter will activate.
2. The last code number will appear on the screen. Compare the code number shown on the screen against the code number on the test strip vial. If the two numbers match, you may begin test, otherwise consult your local distributor.
3. When shows up, press Set button and choose control solution test.
4. Gently shake the control solution and apply a drop to the aperture of strip. Make sure that the control solution has saturated the test confirmation window.
5. Test result will show up in 5 seconds. The result should correspond to the range printed on the label of strip vial used.

NOTE: REPEAT TEST IF THE RESULT FALLS OUTSIDE THE CONTROL RANGE. IF YOU CONTINUE TO GET THE RESULT FALLING OUTSIDE THE CONTROL RANGE, YOUR METER AND STRIP MAY NOT BE WORKING PROPERLY. DO NOT USE THE SYSTEM TO TEST YOUR BLOOD UNTIL YOU GET A TEST RESULT FALLS WITHIN THE CONTROL RANGE. CONSULT YOUR LOCAL DISTRIBUTOR FOR HELP.

Check Strip

The Check Strip can be used in 2 ways:

1. To test only the function of the meter and not complete BGM test system. Please check the complete test system with Contrl Solution
2. To delete all test memories.

How to check meter by check strip

1. Insert the check strip into strip slot with label side up as above.
2. You should obtain an “OK“ reading within 10 seconds, which means your meter is working properly.
3. Remove the check strip to exit. Meter will automatically turn off.

NOTE: IF YOU DO NOT GET “OK” READING BUT APPEAR OTHER ERROR MESSAGE, TURN OFF THE METER BY REMOVE CHECK STRIP FROM THE METER. THEN CHECK THE BATTERY AND REPEAT THE TEST. IF THE SECOND RESULT PERSISTS, CONSULT YOUR LOCAL DISTRIBUTOR FOR HELP.

How to delete memory

1. Insert check strip into strip slot with label side up.
2. After “OK” displayed, press and hold the Set button until flashing “dEL” shows up with a beep sound.
3. Press and hold the Mem button until you hear a beep sound, Meter will display “OK” before turning off and all the memory has been deleted successfully.
4. Remove the check strip from the meter.

Setting Meter Parameters

Setting Time & Date

When you first time installing the battery into the meter or when replacing a battery, the meter will connect with GSM system. If it succeeds to connect, the time and date will be updated automatically. If the connection is failed, the “Err“ message will show up. Please refer to chapter “Display Messages and Problem-Solving Guide “

1. Press Mem button, the meter will enter to the setting of “year”. Press Set button to select the desired year.
2. Press Mem button to confirm and shift to the next setting.
3. Repeat above steps to set the month, day, hour and minute by Set and Mem buttons.
4. After minute is set, the meter will display “OK” before turning off.

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

Setting Temperature Unit/ 12h,24h period/ Alarm

Celsius and Fahrenheit can be set according to your preference.

1. Press Set and Mem buttons at same time for 2 seconds to turn on the meter.
2. Then Press Set button to choose between “C” (for Celsius) and “F” (for Fahrenheit).
3. When Temperature Unit preference is set, press Mem button to enter the 12h/24h period setting.
4. Press Set button to choose your preference of 12h/24h period.
5. The PRECICHEK has 5 alarms to keep your blood glucose monitoring on time. Press Set button to turn on or turn off the alarm.
   - When “ON“ is choosen, press Mem button to configure the alarm hour. Press Set button to change hour. When alarm hour is set, Press Mem button to configure the alarm minutes. Press Set button to change minutes

and press Mem button to enter next setting.

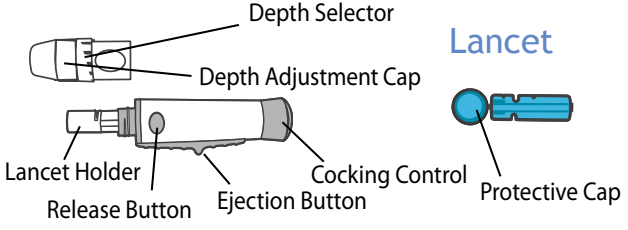
- When “OFF“ is chosen, press Mem button to enter next setting.

6. To configure the other 4 alarms, please repeat step 5.
7. After setting, press and hold Mem button until the meter turning off.

Setting Auto GSM Transmission

1. Press Set button for 2 seconds to turn on the meter. When “ON“ show up, it means auto transmission..
2. Press Set button to choose between “ON“ (auto) and “OFF“ (manual). When the preference is set, press Mem button, meter will display “OK“ before turning off.

Adjustable Lancing Device

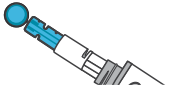


⚠ *IMPORTANT TEST STRIP INFORMATION*

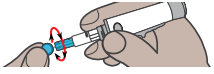
1. ⊗ Lancet is for single use only.
2. Be cautious when removing the used lancet from the device and when disposing the used lancet.
3. The lancing device and lancets are in conformity with MDD 93/42/EEC. Refer to product labels for contact information of manufacturer and CE marking.

Set Lancing Device

1. Remove the depth adjustment cap. Insert a lancet into the lancet holder and push down until it is fully seated.

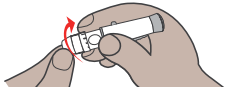


2. Twist off the protective cap until it separates from the lancet.

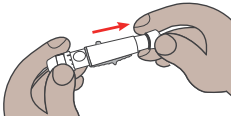


3. Replace the depth adjustment cap and set the puncture depth to the desired number.

   NOTE: THE SHORTER THE SCALE THE SHALLOWER THE PUNCTURE.

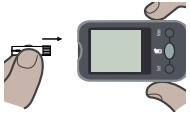


4. Pull back the cocking control until it makes a click, press release button for penetration. If it does not click, the device may have been cocked when the lancet was inserted. Please contact local distributor.



1. Wash your hands in warm, soap water. Rinse and dry completely. Warm your fingers to increase blood flow.

2. 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. The meter turns on automatically.



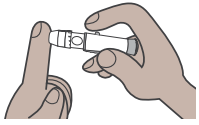
3. Check if the code number on the meter matches the code on the vial. If the 2 numbers match, you may begin blood testing. Otherwise insert another new one. If the code number still doesn't match, please contact your local distributor.

4. When the symbol flashes, you are ready to perform a test.

5. If the test is done within 2 hours of meal, press Set button to change the setting from to . If the test is a control solution test, press Set button again to change the setting from PC to .

NOTE: IF A TEST IS SET FOR "", THE RESULT WILL NOT BE CALCULATED INTO AVERAGES.

6. Hold the prepared lancing device firmly against the side of your finger. Press the release button. Gently massage your finger to obtain the required blood volume. To perform the test, you need only 0.5uL of blood sample resting on your finger.



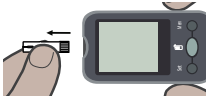
NOTE: FOR LANCING DEVICE SETTING, PLEASE REFER TO SECTION "SET LANCING DEVICE".

7. Apply the blood sample to the front aperture of test strip in a way that is comfortable for you. Make sure that the blood drop has saturated the blood reaction zone.

8. Test result will show up in 5 seconds.

9. Before removing the strip from the meter, you can press Set button to set the test as BEFORE MEAL TEST, or AFTER MEAL TEST, or a CONTROL SOLUTION TEST. If not set, the default of the meter is BEFORE MEAL TEST .

10. After setting complete, remove the strip from meter and discard the used strip and lancet safely in a puncture resistant container.



11. After removing the strip, the result will be transmitted to database through GSM automatically. If OK appears on screen, the transmission succeeds. If Err appears, please see Display Messages and problem solving guide to eliminate error.

12. The testing range of the meter is from 20 to 600 mg/dL (1.1 to 0 33.3 mmol/L). If HI is displayed, your blood glucose result may be higher than 33.3 mmol/L or 600 mg/dL. If LO is displayed, your blood glucose result may be lower than 1.1 mmol/L or 20 mg/dL.

Understanding Your Test Result

Normal Blood Glucose Range

According to ADA current information, glucose values are listed for an healthy adult.

Time of Day	Expected Range, Non-Diabetes
Before Meals	Less than 100 mg/dL
After Meals	Less than 140 mg/dL

Reference: American Diabetes Association Standards of Medical Care in Diabetes.

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 results, check the following:

1. Does the code number on the test strip vial match the code number on the meter?
2. Was the blood sample applied to the test strip immediately after the strip was removed from the vial?
3. Was the size of the blood sample sufficient?
4. Was the test strip vial cap tightly sealed?
5. Was the test strip used before the expiration date?
6. Were the test strips stored away from extreme temperatures or from areas of high humidity?

Then run a quality control check with your GL™ Control Solution and a new test strip. 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, contact your doctor immediately for help.

Memory Recall

The PRECICHEK Blood Glucose Meter can automatically store up to 999 results and auto-calculate your average results of 7-, 14-, 21-, 28- days on both before and after meal.

When recalling the results, each single result appears from the latest to the earliest with time and date.

To recall Results Stored in Memory

1. Turn meter on by pressing Mem button till you hear a beep sound. The first result displayed on the screen is your latest test result. M 12 represents the 12th recorded of the overall results on this meter.

2. By pressing Mem button, you will see your test record from the latest to the oldest.

3. Press the Set button to view the average results. “19” represents within the past 7 days there were 19 -test results. Press the Set button continuously to view the average results sequentially for 14, 21 and 28 days.

4. Please press the Mem button for 2 seconds to EXIT or put it aside for 3 minutes for auto shutdown.

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

Data Transmission

The test result could be transmitted to database for further management.

1. When the meter is set “auto transmission” (refer to section “Setting auto GSM Transmission”), the test result will be transmitted to database throught GSM system after every time you test.
2. When the meter is set “manual transmission”, press “” button for 2 seconds to turn on the meter.
   - If the meter without the test record, it will display “ M 0”, and then “OK“ before turning off.
   - During transmission, it will display “OnL“. After finishing, it will display “OK“. Press Mem button to turn off or put it aside for 3 minutes for auto shut down.
3. When the meter display “Err”, press Mem button to turn off or see the display message and problem solving guide section.

Taking Care of Your Meter

Replacing the battery

The PRECICHEK Blood Glucose Meter comes with 4 AAA battery (not yet be installed when new purchasing). Please install your batteries before starting.

Battery life will vary depending on usage, so always keep a spare on hand.

The batteries should last about 24 months when testing 3 times a day.

When the battery symbol appears on the meter display, batteries level is getting low. You will still be able to test with low battery, but you should replace them as soon as possible. When battery symbol appears flashing on the display, the meter will no longer give results and you must replace the batteries immediately.

To Replace the Batteries

1. Make sure the meter is turned off.
2. Let the front of meter rest in the palm of your

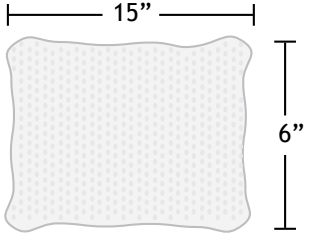
hand.

3. Slide battery compartment door open.
4. Remove the old batteries and insert 4 new AAA batteries into the battery compartment. Be sure to align the plus (+) and minus (-) signs correctly.
5. Close the battery compartment door. Check to see that your meter is working. If it fails to turn on, the batteries may have been inserted incorrectly. Remove the batteries and reinsert them correctly.

NOTE: EVERY TIME WHEN YOU REPLACE THE BATTERIES, THE METER WILL TURN ON AUTOMATICALLY AND ENTER TO THE TIME/DATE SETTING. PLEASE SET CORRECT TIME AND DATE BEFORE TESTING.

How to Clean and Disinfect

The following disinfactant product have been shown to be safe for use with Cloudia meter, but any disinfectant product with the EPA registration number of 67619-12 may be used on this device.



Differences between Cleaning and Disinfection

According to the Merriam-Webster Medical dictionary, the definitions of both terms are below:

- Clean - to free from the dirt, or pollution to free from disease or infectious agents.
- Disinfect - to free from infection especially by destroying harmful microorganisms.

Cleaning Procedures

1. Place device and wipes on a smooth surface. Be sure there is enough light.

2. Wash hand with soap and water then pat dry.

3. Take a piece of premoistened wipe out of canister. Remember to recap the canister.

4. Wipe entire device and lancing device until visibly clean.

5. Throw away the used wipe. Please do not reuse the wipe.

⚠ ***CAUTION***

1. Always clean before disinfect
2. All parts of devices are considered biohazard. Disinfect the whole parts thoroughly.

Disinfect Procedures

1. Prepare wipes and meter.

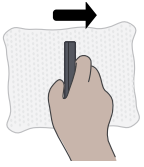
2. Take a piece of pre moistened wipe out of canister. Remember to recap the canister.

3. Put the moistened wipe on a smooth surface.

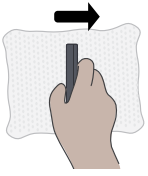
4. LCD side up, wipe the device from left to right 3 times slowly.

5. Repeat step 4 for Front surface.

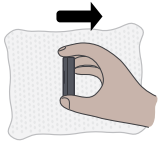
6. Repeat step 4 for left sides surface.



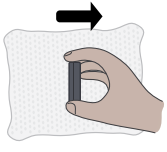
7. Repeat step 4 for right sides surface.



8. Repeat step 4 for Bottom surface.



9. Repeat step 4 for Top surface.



10. Make sure the meter stays moisted for 1 min.

11. Discard the used wipes.

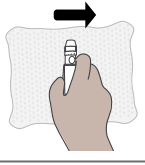
Warning

1. Please use disinfectant with caution.
2. For your own safety, please do not mix disinfectant with other liquid.
3. Please read the instructions carefully on the cainesiter before Starting cleaning and disinfection.
4. Please don't use the wipes on any human part.
5. All parts of the glucose monitoring system should consider potentially infectious and are capable of transmitting blood-born pathogens even after cleaning and disinfection.
6. Please do not cloud up LCD by over-moist the meter.
7. Please call us if a tear or a crack appeared on the meter.

For Lancing Device

1. For the lancing device take another new piece of pre moistened wipe out.

2. Repeat the same steps as meter.



3. Cover the device in the wipes to keep it disinfected for 1 min.

4. Discard the used wipe according to the local regulation.

NOTE

1. The Clorox Germicidal Wipes can be purchased on www. cloroxprofessional.com or call the service number at 1-800-234-7700.
2. If you have any question about the cleaning and disinfection or need more information, please contact your distributor or HMD costumer service at 1-855-692-3511.

References

1. "FDA Public Health Notification: Use of Fingerstick Devices on More than one Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010)

   http://www.fda.gov/MedicalDevice/Safety/AlertsandNotices/ucm224025.htm

2. "CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010)

   http://www.cdc.gov/injectionsafety/Fingerstick-DeviceBGM.html

3. "Letter to Manufacturers of Blood Glucose Monitoring Systems Listed With the FDA" (2010)

   http://www.fad.gov/MedicalDevice/ProductsandMedical Procedures/InVitroDiagnostic/

4. "ISO 15197 In Vitro Diagnostic Test System- Requirements for Blood- Glucose Monitoring Systems for Self-Testing in Managing Diabetes Mellitus"

Storage and Handling

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

⚠ ***CAUTION***

If the product is not used for longer periods of time, please remove the inserted battery in order to prevent damage caused by leaking battery.
Please follow all the instructions on the User Guide while operating PRECICHEK Blood Glucose Meter. HMD BioMedical Inc. will not be responsible for any impairment occurred from NOT following the instructions.

Warranty

HMD BioMedical Inc. warrants to the original purchaser that this instrument will be free of defects in material and workmanship for 5 years from the date of original purchase. During the stated 5-year period, HMD shall, at no charge, replace a unit found to be defective with an equivalent or current version of the owner's model.

This warranty is limited to replacement due to defects in parts or workmanship. HMD shall not be required to replace any units which malfunction or are damaged due to abuse, accidents, alteration, misuse, neglect, maintenance by other than HMD, or failure to operate the instrument according to instructions.

POST- SALE SERVICE

Questions?
Please call toll free number
at 1-855-692-3511
Mon-Fri 9:00am-4:30pm (Pacific Time)

Display Messages and Problem-Solving Guide

When any of the following messages appears, there is a problem with your PRECICHEK Blood Glucose Meter or perform wrong steps during 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.
	Blood glucose result may be higher than 600 mg/dL or 33.3 mmol/L.	Review proper testing procedure and perform a quality check with control solution. Repeat blood test, if “HI” still appears, call your doctor immediately.
	Blood glucose result may be lower than 20 mg/dL or 1.1 mmol/L.	Review proper testing procedure and perform a quality check with control solution. Repeat test, if “LO” still appears, call your doctor immediately.
	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 immediately.

	Test strip unknown or 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 was 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 blood sample is applied to the strip.	Maybe: 1. Blood sample is not sufficient. 2. Meter is defective.	You have to: 1. Repeat test with sufficient sample. 2. Perform Meter Check by inserting check strip.
	Communication between meter and GSM Module-failure.	Please return the device to distributor if err code 1 appears.
	Device can not be recognized by base.	Please return the device to distributor if err code 2 appears.

	Device can not be synchronous with local date/time.	Please switch to manual transmission and change location then try again.
	Device can not connect to the server.	Please switch to manual transmission and change location then try again.
	Database fail to return signal.	Please switch to manual transmission and change location then try again.

System Specification

1. Assay Method: Electrochemical biosensor
2. Test Sample: Fresh Capillary Whole Blood
3. Sample Size: 0.5 µL
4. Measuring Time: 5 seconds
5. Measuring Range: 20 – 600 mg/dL (1.1 – 33.3 mmol/L)
6. Acceptable Hematocrit Range: 30%-55%
7. Operating Temp. Range: 10°C~40°C (50°F~104°F)
8. Operating Relative Humidity: 20% - 80% RH
9. Memory Capacity: 999 test results with time and date
10. Result Setting: Before meal, After meal and Control solution test setting
11. Average Display: 7, 14, 21, 28-days AC/PC average
12. Power Supply: AAA Alkaline Batteries x 4
13. Battery Life: Approximately 1000 tests
14. Automatic shut-off: In 3 minutes
15. Meter Dimension: 108.9mm (L) x 59.9mm (W) x 16.5mm (H)
16. Weight: Approximate 100g (with batteries)

Performance Evaluations

Precision

Tests were carried by trained technicians in the laboratory setting. The venous whole blood from one subject was adjusted to 6 different levels. Strips out of a single lot were tested. The results are shown in the following table.

ACH

Level	No. of test	Mean (mg/dL)	Within-Run C.V. (%)
I	100	41.6	4.6
II	100	100.1	4.1
III	100	124.8	2.5
IV	100	215.8	3.6
V	100	340.0	3.5
VI	100	537.4	2.6

Accuracy

Tests were performed at hospital by healthcare professionals and diabetic patients. Fresh capillary finger whole blood samples were tested with the PRECICHEK System; plasma samples from the subjects were tested with YSI Model 2300 Glucose Analyzer as reference. The results are shown in the following table.

Slope	0.94
Y-Intercept	13.9 mg/dL
Correlation Coefficient	0.99
Number of test	118
Range Tested	25-580 mg/dL

Reference

1. American Diabetes Association Position Statement, Diabetes Care Vol. 34 (Suppl.1), p. S13 (2011)
2. American Diabetes Association Position Statement, Diabetes Care Vol. 34 (Suppl.1), p.S21 (2011).

NOTE: THE PRODUCT IS TESTIFIED BY A THIRD PARTY THAT IT DOESN'T INTERFACE WITH OTHER POSSIBLE ELECTROMAGNETIC WAVE.

LOT	Batch code		Please consult instructions for use
	Temperature limitation/ Store at	IVD	In vitro diagnostic medical device
	Caution		Use by /Expiry date
	Do not reuse	SN	Serial number
	Keep away from sunlight	CE 0537	This product fulfills the requirement of directive 98/79/EC in vitro diagnostic medical device
	Biological risks		Manufacturer

EC REP Authorised representative in the European community

The symbol indicating seperate collectionfor electrical and electronic equipment consists of the crossed-out wheeled bin. When the end-user wishes to discard this product, it must be sent to seperate collection facilities for recovery and recycling. By separating this product from other household-type waste, the volume of waste sent to incinerators or land-fills will be reduced and natural resources will thus be conserved.

The content of this user guide pass the Flesch-kincaid grade level at 8th grade.

FCC Regulations:

15.19(a)(3):

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

15.105(b):

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

—Reorient or relocate the receiving antenna.

—Increase the separation between the equipment and receiver.

—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

—Consult the dealer or an experienced radio/ TV technician for help.

RF Exposure Information (SAR)

This device meets the government's requirements for exposure to radio waves.

This device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government.

The exposure standard for wireless mobile devices employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6W/kg. *Tests for SAR are conducted using standard operating positions accepted by the FCC with the device transmitting at its highest certified power level in all tested frequency bands. Although the

SAR is determined at the highest certified power level, the actual SAR level of the device while operating can be well below the maximum value. This is because the device is designed to operate at multiple power levels so as to use only the poser required to reach the network. In general, the closer you are to a wireless base station antenna, the lower the power output.

The highest SAR value for the device as reported to the FCC when tested for use when worn on the body, as described in this user guide, is 1.26 W/kg. (Body-worn measurements differ among device models, depending upon available accessories and FCC requirements.)

While there may be differences between the SAR levels of various devices and at various positions, they all meet the government requirement.

The FCC has granted an Equipment Authorization for this device with all reported SAR levels evaluated as in compliance with the FCC RF exposure guidelines. SAR information on this device is on file with the FCC and can be found under the Display Grant section of www.fcc.gov/oet/ea/fccid/ after searching on FCC ID: AYY0000001.

This device is compliance with SAR for general population /uncontrolled exposure limits in ANSI/IEEE C95.1-1999 and had been tested in accordance with the measurement methods and procedures specified in OET Bulletin 65 Supplement C.

For body worn operation, this device has been tested and meets the FCC RF exposure guidelines for use with an accessory that contains no metal and the positions the handset a minimum of 1.0 cm from the body. Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

EC REP Zengqing Jian
Maire-Baum-Str.3,
D-76137 Karlsruhe, Germany

HMD BioMedical Inc.

Questions?
Please call toll free number
at 1-855-692-3511
Mon-Fri 9:00am-4:30pm (Pacific Time)

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