GoodLife™

Blood Glucose Monitoring System (Cloudia)

User Guide

GSM
GLOBAL SYSTEM FOR MOBILE COMMUNICATIONS

Contents

Please read this User Guide before using your GoodLife Blood Glucose Meter (Cloudia). If you have any questions or enquiries, please contact customer support at 1-855-692-3511 for assistance.

About GoodLife™

Intended Use

GoodLife Blood Glucose Monitoring System(Cloudia) is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood sample drawn from the fingertips only. It is intended to be used for single patient and should not be shared. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.

Principle of the Test

The GoodLife 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 GoodLife Blood Glucose Monitoring System (Cloudia) (GoodLife System) is designed to provide blood glucose measurements with easy and comfortable testing. The system requires 0.5µL of blood sample and 5 seconds for the test to complete.

The GoodLife System consists of:
GoodLife Blood Glucose Meter (Cloudia), GoodLife Blood Glucose Test Strips (Cloudia), Check Strip, GoodLife Glucose Control Solution(Level I & II), Safety Lancet (optional for purchase).
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.

NOTE:
Not for use on patients who are dehydrated, hypotensive, in shock, or in a hyperosmolar state.ÿ

Important Information

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

CAUTION

1. The test result does not suggest any medical indication. The user should consult his or her clinician for further diagnostic and treatment.
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. 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).

Substance	Toxic Concertration (mg/dL)	Theraprutic/ Physiological Levels	Highest c oncentration without interference (mg/dL)
Ascorbic acid	N/A	0.40 - 2.00	**2.25**
Triglyserides	N/A	150 - 500	**1000**
Uric acid	N/A	2.52 - 8.00	**15**
Xylose	N/A	57	**50**

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 8,800 feet (2,750 meter) may affect the test results.
7. Temperatures outside the range of 50°F to104°F (10°C to 40°C), 20%-80% RH may affect the test results.
8. Do not use GoodLife system to test on critically ill patient.
9. Not for use on patients who are dehydrated, hypotensive,in shock, or in a hyperosmolar state.

Important Safety Instruction

1. 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.
2. Because all parts of the kit may come in contact with your blood, all parts of the kit are considered biohazardous and can potentially transmit infectious diseases. Please refer to "How to Clean and Disinfect" section to help mitigate biohazard.
3. Users should wash hands thoroughly with soap and water and dry thoroughly after handling the meter, test strips and any lancing device.

For customer support contact at 1-855-692-3511.
(Mon-Fri 9:00 am~4:30 pm Pacific Time)

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 contact customer support at 1-855-692-3511. (Mon~Fri 9:00am~4:30pm Pacific Time)

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/FingerstickDeviceBGM.html

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

STRIP EJECTOR: For easy ejection of the test strip.

Battery Compartment: Holds four AAA batteries. Before using the meter, please install the batteries first.

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

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: A code number should appear before meter is used to test sample.

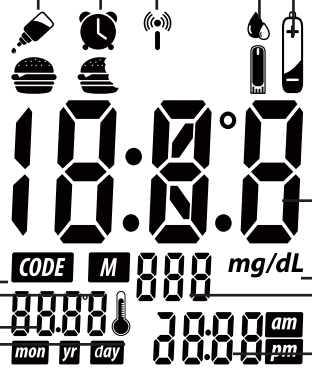
M : Meter is at a Memory mode. Prior analysis results can be read.

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.

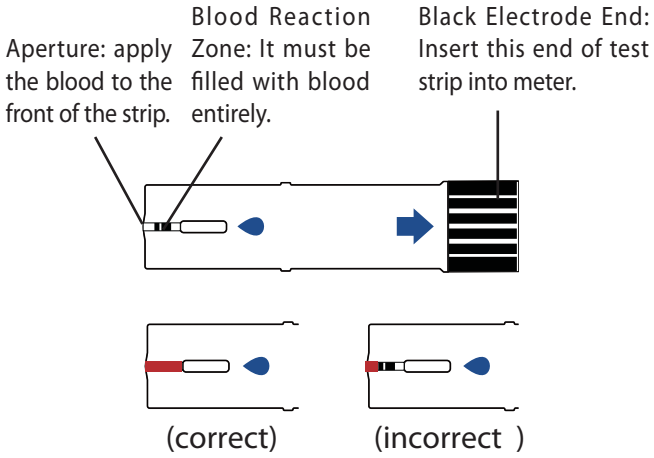
Test Result

mg/dL: The units of measurement in the U.S. are mg/dL.

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

Time: 12 and 24 hour period format.

Blood Glucose Test Strip



1. GoodLife 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. GoodLife Blood Glucose Test Strips (Cloudia) are intend ed for in vitro diagnostic use with capillary whole blood or GoodLife Glucose Control Solution.
   Results will not be accurate if used with plasma or
3. serum samples.
   Do not use test strips beyond the expiration date
4. 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
5. vial when you open a new vial of test strips.
   Blood Glucose Test Strip can be damaged by heat
6. and light. Keep them sealed in the original vial.
   Store the vial in a cool, dry place between
7. 104°F(40°C) and 50°F (10°C). Do not refrigerate.
   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.

Glucose Control Solution

GoodLife Glucose Control Solution is used to check if the GoodLife Blood Glucose Monitoring System(Cloudia) and Test Strip are working correctly as a system.

Users should perform a control solution test when:

1. a new vial of test strip is opened.
2. a meter is dropped
3. whenever results are not consistent with patient's symptoms.

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. Store the control solution closed at temperatures between 50°F (10°C) and 86°F (30°C).
4. Please carefully read the label before use.
5. For purchase of control solution, please contact your local distributor or customer support at 1-855-692-3511 for more information.

Perform Control Test

1. Insert a new test strip into the strip slot, the meter will activate.
2. The 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 contact customer support at 1-855-692-3511 or your healthcare provider for help.
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 blood reaction zone.

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, the potential causes are
1. the test strip is damaged or get moist
2. the test strip is expired.
3. the 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.
Contact customer support at 1-855-692-3511 or your healthcare provider 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 Control 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.
   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, contact customer support at 1-855-692-3511 or your healthcare provider.

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 begin to use the meter or replace a new battery, please follow the steps below to set the date and time manually.

1. Press the Mem button, the meter will enter to the setting of "year". Press Set button to select the desired year.
2. Press the Mem button to confirm and shift to the next setting.
   Repeat above steps to set the month, day, hour and minute by Set and Mem buttons.
   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 the Set and Mem buttons at same time for 2 seconds to turn on the meter.
2. Then press the Set button to choose between "C" (for Celsius) and "F" (for Fahrenheit).
3. When Temperature Unit preference is set, press the Mem button to enter the 12h/24h period set ting.
4. Press the Set button to choose your preference of 12h/24h period.
5. When 12h/24h period is set, press the Mem button to enter the alarm setting.
6. Press the Set button to turn on or turn off the alarm. The GoodLife has 5 alarms to keep your blood glucose monitoring on time.
   - When "ON" is choosen, press the Mem button to configure the alarm hour. Press the Set button to change hour. When alarm hour is set, Press the Mem button to configure the alarm minutes. Press the Set button to change minutes and press the Mem button to enter next setting.
   - When "OFF" is chosen, press the Mem button to enter next setting.

7. To configure the other 4 alarms, please repeat step 6.
8. After setting, the meter will display “OK“ before turning off.

Setting Auto Data Transmission

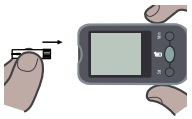
1. Press and hold the Set button for 2 seconds to turn on the meter when “ON“ show up, it means
2. auto transmission.
   Press the Set button to choose between “ON“(auto) and “OFF“ (manual).

When the preference is set, press the Mem button, the meter will display “OK“ before turning off.

Performing Blood Test

1. Wash your hands in warm, soap water. Rinse and dry completely.

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 customer support at 1-855-692-3511 for help.

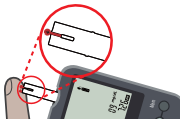
4. When the symbol flashes, you are ready to perform a test.

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

6. Use safety lancet or lancing device to obtain the required blood volume. To perform the test, you need 0.5 uL of blood sample.

Caution: To avoid the blood borne pathogen transmission, the lancing device is for single patient use. Do not share with anyone else including other family members. Do not use on multiple patients.
NOTE: Please refer to safety lancet or lancing device user manual for further instructions on use and handling.

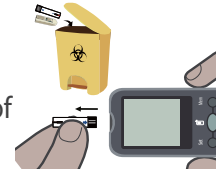
7. Apply the blood sample to the front aperture of test strip in a way that comfortab.e for you. Make sure that the blood drop has saturated the blood reaction zone.



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 MEALS TEST, or AFTER MEALS TEST, or a CONTROL SOLUTION TEST.

10. After setting complete, remove the strip from meter. Please follow the healthcare provider's recommendations for disposal of used lancets and strips.



11. After removing the strip, the result will be transmitted to database through GSM system automatically. It will diaplay "OK" if the transmission succeeds.
Press the "Mem" button to turn the meter off. If "Err" appears, please refer to "Display Messages and Problem-Solving Guide.

WARNING: Inaccurate results may occur in severely hypotensive individuals or patients in shock, inaccurate low results may occur in individuals experiencing a hyperglycemic/hyperosmolar state, with or without ketosis, and critically ill patients should not be tested with the meter.

Important Safety Information

* The meter is for single patient use. Do not share them with anyone including other family member.

* All parts of the kit are considered biohazardous and canpotentially transmit infectious disease. Please refer to "How to Clean and Disinfect" section to help mitigate biohazards.
* Safety Lancet is for single use only.

Understanding Your Test Result

Expected range for people without diabetes :

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

Source: American Diabetes, Association Position Statement, Diabetes Care Vol.37 (Suppl.1) p.s16 (2014).

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 Glucose 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.

Data Transmission

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

1. When the meter is set as “auto transmission” (refer to the section “Setting Auto Data Transmission”), the test result will be transmitted to the database through GSM system after every time you test.
2. When the meter is set as “manual transmission”, press es and holds the  button for 2 seconds to turn the meter on.
   - If there is no record in the meter, it will display “M0”, and then “OK“ before turning off.
   - If there are records in the meter that haven’t been transmitted, it will display “OnL“ and transmit the data. After that, it will display “OK“. Press the Mem button to turn off or allow the system to auto turn off after 3 minutes of inactivity.
3. When the meter displays “Err”, please refer to the section “Display Messages and Problem-Solving Guide“.

NOTE:

1. It is recommended to transmit in good reception areas.

For example:

- Pacemaker (Keep a safe distance more than 15cm),
- Medical telemetry or telemetry equipment (Telemetry),
- Physiological signal sensing or monitoring device (such as ECG, EMG, EEG, ERG, ENG, MEG, Holter, asphyxia monitors, etc.),
- NMR diagnosis photography devices,
- Electronic microscope,
- Life-sustaining devices with micro-processor control (such as infusion pumps, hemodialysis machines, breathing assistor, anesthesia machines, infant incubators, etc.)

3. The test records in the meter will not be removed after transmission. Please refer to the section "Check Strip" for removing records.

Memory Recall

The GoodLife Blood Glucose Meter automatically store a maximum of 999 test results including the result done before a meal or after a meal, or for a control solution test.
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 12 th recorded of the overall results on this meter.

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

3. Press and hold the Mem button for 2 seconds to turn the system off or allow the system to auto turn off after 30 seconds of inactivity.

Replacing the battery

The GoodLife Blood Glucose Meter comes with four AAA batteries. Please install your batteries before starting.
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. Place the meter face down on a flat surface.	
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 the batteries are replaced, the meter will turn on. Please follow the section "Setting Meter Parameters" to set the time and date.

How to Clean and Disinfect

To mitigate the risk of bloodborne pathogen transmission (eg. viral hepatitis), the meter must be properly cleaned and disinfected.
The life of the meter is 5 years for 18,250 cleaning and disinfection cycles. The meter, for single patient home use, should be cleaned and disinfected at least once per week as recommended.

The following disinfactant product with sodium hypochlorite 0.55% as the active ingredient have been shown to be safe for use with GoodLife meter, but any disinfectant product with the EPA registration number of 67619-12 may be used on this device. It should be cleaned and disinfected once per week. The Clorox Germicidal Wipes can be purchased on

1. www.cloroxprofessional.com
2. www.amazon.com
3. or call the Clorox service number at 1-800-234-7700

Differences between Cleaning and Disinfection

- Clean: to remove visible signs of dirt or pollution.
- Disinfect: to free from infection especially by destroying harmful microorganisms.

NOTE: If the meter is operated by the care giver rather than the primary user, the meter should be disinfected by the meter operator rather than by the user.

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 until visibly clean.

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

CAUTION

1. The meter should always be cleaned before it is disinfected.

2. All parts of the meter should be considered to be biohazardous. Make sure that you clean and disinfect the entire meter.

Disinfection Steps

1. Prepare wipes and meter.

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

3. Slowly wipe the meter back and forth for at least 3 times. Repeat the same wiping procedure to all meter outer surfaces.

4. Make sure the meter stays wet for 1 min. Please do not get disinfectant liquid into the test strip slot.

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

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 canister before starting cleaning and disinfection.
4. Please don't use the wipes on any human part.
5. Store disinfectants out of the reach of children.
6. If any signs of deterioration are noted as below: Cloudy Display, material cracking, brittle, softening or meter buttons malfunction,

performance of meter has changed (i.e. control fails). Stop using the meter and please contact customer support at 1-855-692-3511.

NOTE

1. The Clorox Germicidal Wipes can be purchased on www. cloroxprofessional.com, www.amazon.com or call the Clorox 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 customer support 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

Storage and Handling

1. Keep your meter free of dust or water. Protect it from extreme temperature and humidity.
2. Store the meter and test strips between 50°F (10°C) and 104°F (40°C)

CAUTION

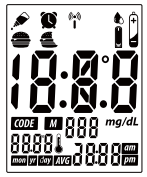
If the meter will not be used for over 1 week, it is recommended to remove the battery from the meter. This will prevent the potential meter damage due to leaking battery.
Please follow all the instructions on the User Guide while operating GoodLife Blood Glucose Meter. HMD BioMedical Inc. will not be responsible for any impairment occurred from NOT following the instructions.

Display Messages and Problem-Solving Guide

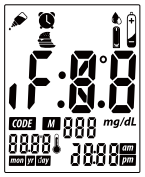
Display check

Every time when meter is turned on, the meter will display as illustrated.

Normal:

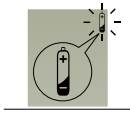


Abnormal:
(for example)



If some parts of the display are not working, contact customer support at 1-855-692-3511 for help.
When any of the following messages appears, there is a problem with your GoodLife Blood Glucose Meter or perform wrong steps during a test. There messages will help you to identify certain problems.
If error messages appear that are not listed on the

following messages, contact customer support at 1-855-692-3511 for help.

Display	Description	Action to Take
	Blood glu - cose result may be higher than 600 mg/dL.	Review proper testing procedure and perform a quality check with control solution. Re - peat blood test, if "HI" still appears, call your doctor immediately.
	Blood glu - cose result may be lower than 20 mg/dL.	Review proper testing procedure and perform a quality check with control solution. Repeat test, if "LO" still ap - pears, call your doctor immediately.
	Tempera - ture 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 50°F - 104°F (10°C to 40°C). Do not artificially heat or cool the meter.
	Battery is low.	Change battery imme - diately.
	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 re-sponses 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 customer support at 1-855-692-3511 for help.
No re-sponses when blood sample is applied to the strip.	Maybe: 1. Blood sample is not suf-ficient. 2. Meter is defective.	You have to: 1. Repeat test with suf-ficient sample. 2. Perform Meter Check by inserting check strip.

	Error message: Err1. Data communi-cation module is malfunction Err2. Failure to con-nect to Base Station Err5. Failure to con-nect to the Sever Err6. TCP/IP data transmission failure Err1. The meter might be damaged. Contact custom-er support at 1-855-692-3511 for help. Err2. Antenna or SIM Card might be damaged. Con-tact customer support at 1-855-692-3511 for help. Err5, 6. Move to an area of better reception and 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
6. Acceptable Hematocrit Range: 30%-55%
7. Operating Temp. Range: 50°F-104°F(10°C-40°C)
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. Power Supply: AAA Alkaline Batteries x 4
12. Battery Life: Approximately 1000 tests
13. Automatic shut-off: In 3 minutes
14. Meter Dimension: 108.9mm (L) x 59.9mm (W) x 16.5mm (H)
15. Weight: Approximate 100g (with batteries)

Performance Evaluations

Precision

Tests were conducted 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.

Within-run

Level	No. of test	Mean (mg/dL)	Within-Run C.V. (%)
40.6	100	41.5	4.5
93.3	100	99.5	4.2
120	100	124.0	3.1
213	100	216.4	3.8
336	100	340.7	3.5
532	100	531.7	3.3

Between-run

Level	No. of test	Mean (mg/dL)	Within-Run C.V. (%)
50	100	61.5	4.7
100	100	123.9	4.2
300	100	346.8	3.9

Accuracy

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

Glucose concentration < 75 mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL	
6/13 (46%)	11/13 (85%)	13/13 (100%)	
Glucose concentration ≥ 75 mg/dL			
Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
35/87 (40%)	67/87 (77%)	78/87 (90%)	85/87 (98%)

iglucose Diabets Management

Introduction of the system

The system is an optional software for use with the iglucose system with data management capacities. t is designed to connect to glucose meters (Cloudia) and automatically transmit blood glucose readings or control solution test results to a secure database.

Users can then utilize the iglucose Diabets management portal (web-based application) to view their blood glucose readings at home through their PC or other Internet capable devices.

The system provides an integrated table including test results of blood glucose measurements and quality controls.

The system does not recommend any medical treatment or dosing recommendations.

Hardware and Software requirement

1. Hardware requirement:
   PC, NB, iPad or Cellular-Internet phone

2. Software requirement:
   Microsoft IE 8.0 , Mozilla FireFox 3.6,
   Google Chrome v-12, Apple Safari 5

3. Minimum requirements:
   Pentium processor, 64mb ram, 1 gb disc space

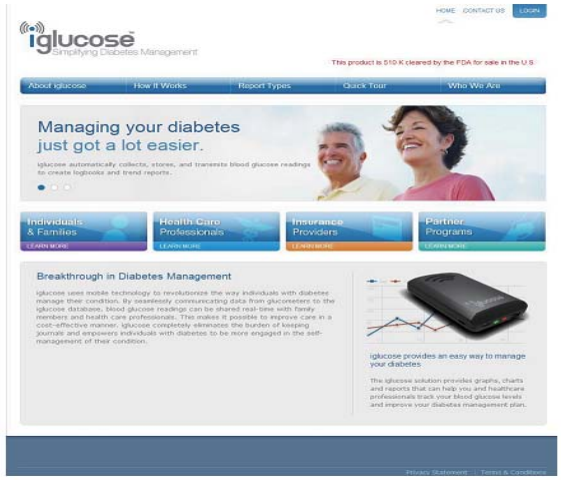
How to use

1. Start the PC or other compatible-Internet connected device. Connect to the chosen Web Browser to the Internet.(e.g. Microsoft IE, Google Chrome or Apple Safari)

2. Enter the Website address www.iglucose.net, the user could view the record table of the blood glucose or control solution measurement.The user could view the test result according to his/her Meter ID.

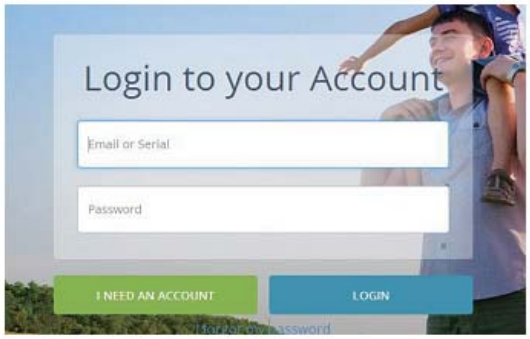
How to view transmitted reading

1. Open a web browser window on your computer and go to www.iglucose.net



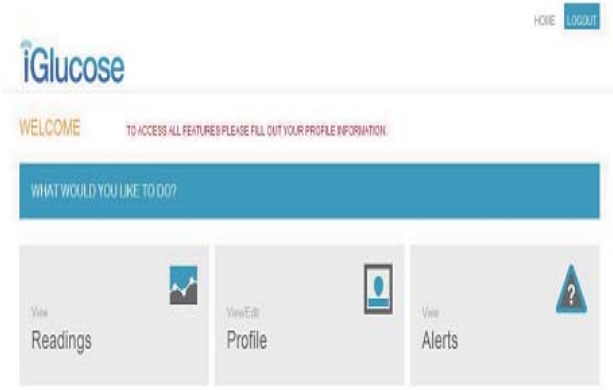
2. Click on the “login” button from the iglucose homepage.

3. Enter the meter serial number in "Email or Serial" and "Password" and click the "login" button

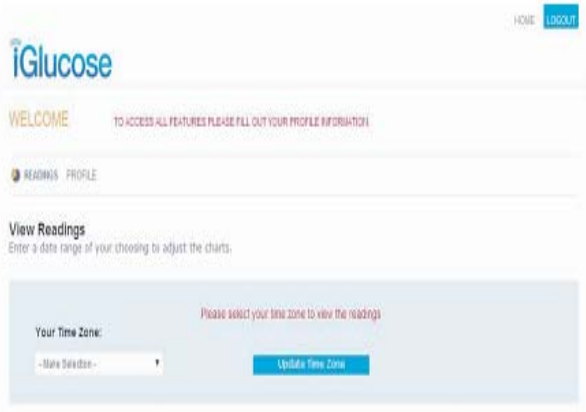


If you have no any account, please you apply a new account.

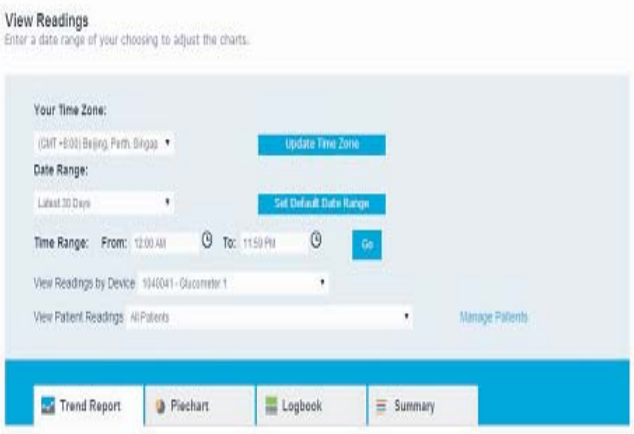
4. The "welcome" page will appear.
   Click on the "View Readings" button.



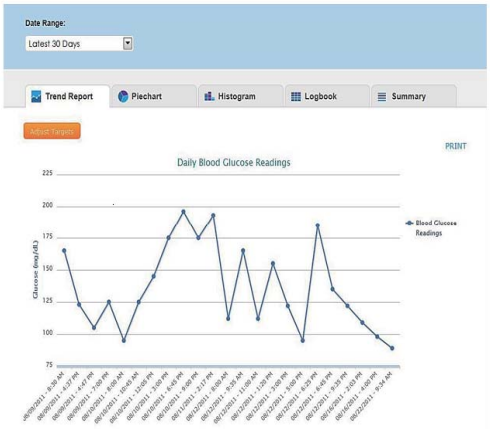
5. "Your Time zone" page will appear, choose your time zone and click on "Update Time zone" button.



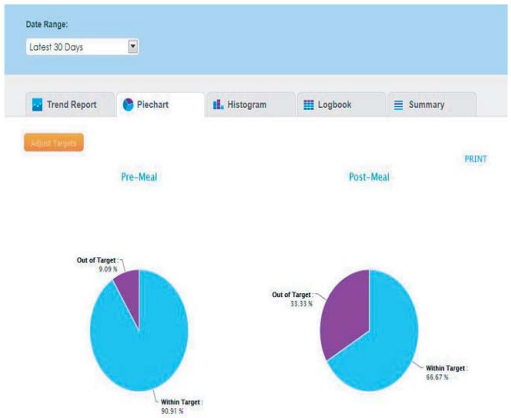
6. Select any of the following tabular or graphic report formats to view your reading: Trend Report, Pie Chart, logbooks or Summary.



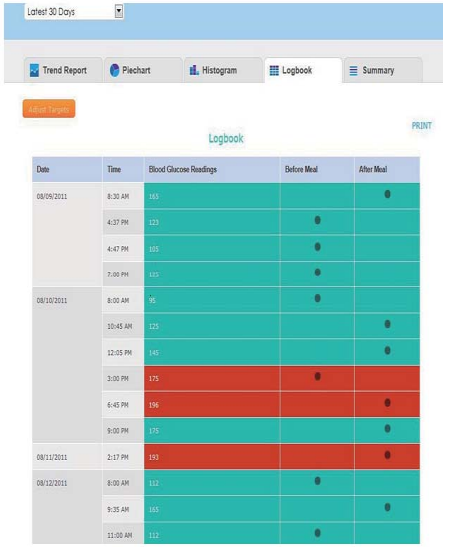
Trend Report:Displays high and low glucose readings within a customized date and time range.



Pie Chart: Displays percentage of pre-meal and post- meal glucose readings that fall in and out of target ranges.



logbooks: Displays daily and historical glucose readings with date and time stamp. Glucose readings are also displayed before and after meals with pre-determined out-of-target ranges.



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 pro vide 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 er levels so as to use only the poser required to reach thestation 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 SAR Value) and 3.26 W/kg(Extremity-worn SAR Value). (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 FCCRF 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: AYY0000002.

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 applicable FCC KDB guidance.
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 hand set a minimum of 1.0cm from the body. Use of other accessories may not ensure compliance with FCC RF exposure guidelines.
Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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

Manufacturer:
HMD BioMedical Inc.
Hsinchu,Taiwan
Questions?
Please call toll free number
at 1-855-692-3511
Mon-Fri 9:00am-4:30pm(Pacific Standard Time)
Please contact a healthcare provider for assistance at all other times.
E-mail: service@hmdbio.com