



myglucohealth™

Blood Glucose Monitoring System

Operation Manual



Entra Health Systems, Ltd
www.myglucohealth.co.uk

myglucohealth™

Blood Glucose Monitoring System



www.myglucohealth.co.uk

Quick Reference

1



1. Insert **myglucohealth™** Strip. The code number is automatically entered.

2



2. Select activities related to the test result by press ▲ button or ▼ button. When it is selected, press the Ⓚ button.

3



3. Apply sample until confirmation window is completely filled before the meter begins to count-down.

4



4. Test results in 3 seconds.

Important Information

The **myglucohealth™** system provides a quick and easy way to measure the blood glucose level. **myglucohealth™** is used for self-monitoring of blood glucose level by diabetes patients.

It should be used only for testing blood glucose (sugar) and only with fresh capillary whole blood samples. It should not be used for the diagnosis of diabetes or for the testing of newborns (neonates).

Do not use **myglucohealth™** system for any purpose other than blood glucose test. The **myglucohealth™** system is for in vitro diagnostic use only.

Warning

Before using **myglucohealth™** meter, read all instructions in this manual and the additional information given in instructions for use of the test strips. Practice for accurate and safe test. You should have commentary and recommendation from your diabetes care professional for the proper use of this meter and daily management of your diabetes.

Do not change your therapy due to blood glucose results of the **myglucohealth™** system without prior consulting your physician.

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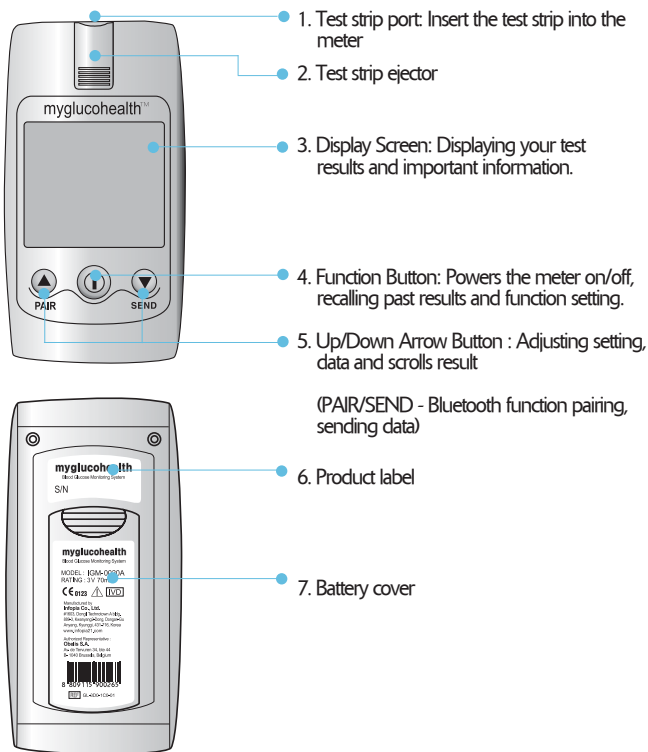
myglucohealth™ Blood Glucose Monitoring System KIT Contents

- | | |
|-------------------------|---|
| 1. myglucohealth™ meter | 2. myglucohealth™ test strips |
| 3. Landing Device | 4. Lancets |
| 5. Operation Manual | 6. Warranty Registration Card |
| 7. Patient Logbook | 8. Two 1.5V Alkaline battery (AAA Size) |
| 9. Carrying Case | |

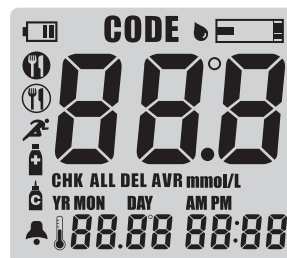
Check your myglucohealth™ system to make sure that it is unopened prior to use and that it contains all of the complete parts shown above.

If either of these conditions is not met, please do not use it. Contact the place of purchase to receive a new one.

myglucohealth™ Blood Glucose Meter



LCD Display



Low battery warning

CODE Strip code

Blood drop for test

Alarm

Before having a meal

After having a meal

After sports activity

After taking drugs

Control solution test

Temperature / Date

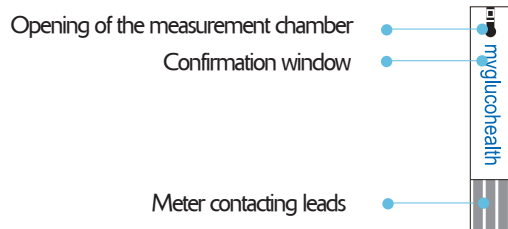
mmol/L Test result unit

AM PM 88:88 Time

DEL Delete

myglucohealth™ Test Strip

myglucohealth™ test strips are only to be used with myglucohealth™ meter.



[Storage and Handling Caution]

1. Keep out of direct sunlight.
2. Store the myglucohealth™ Test Strip vials in a cool, dry place between 35.6-86°F (2-30°C). Do not refrigerate or freeze.
3. Make a notation of the discard date on the vial label when you first open it. Discard remaining myglucohealth™ strips 3 months after first opening the vial.
4. Close the vial cap tightly immediately after removing the myglucohealth™ test strip.
5. Do not use test strips after the expiration date printed on the package or vial since it may cause inaccurate results.
6. Avoid getting dirt, food or water on the test strip. Do not bend, cut, or alter the myglucohealth™ strip.
7. myglucohealth™ test strips are for single use only.
8. Keep the test strip bottle away from children.
9. Please refer to the user's manual for myglucohealth™ blood glucose test strip for additional information.

Automatic code recognition



1. myglucohealth™ has automatic code recognition function.



2. It recognizes automatically the code number and set it. It is a user friendly function, since there is no need for the user to set the code number on the meter, everytime when a new strip vial is opened.

< Caution >

1. Do not bend the test strip to prevent the automatic code recognition failure.
2. If the code recognition label is damaged, code recognition failure may occur. Please check the code number on the LCD display window and on the test strip vial.

Checking the system with the myglucohealth™ Control Solution

Note : The myglucohealth™ Control Solutions are sold separately. The low, normal, high level control solution can be obtained through your local distributor. Refer to the myglucohealth™ Control Solution package for additional information.

The myglucohealth™ Control Solution is used to check that the Meter and the Test strips are working together as a system and that you are performing the test correctly. It is very important that the control solution is used routinely to make sure that you receive accurate results.

The myglucohealth™ Control Solution contains a measured amount of glucose that reacts with the myglucohealth™ Control Solution Test Strips. Compare your control solution test results with the expected range printed on the strip vial label.

The myglucohealth™ Control Solution should be used to:

- Practice the test procedure.
- Make sure your meter and test strips are working together properly.
- Ensure you are performing the test correctly.

Before you use the myglucohealth™ Meter to test your blood for the first time, practice the procedure using the control solution. When you can do three tests in a row that are within the expected range, you are ready to test your blood.

When to do a control solution test:

- When a new vial of test strips is opened.
- Any suspicion that the meter or the strip is not working properly.
- When your blood glucose test results are not consistent with your symptoms, or if you think they are not accurate.
- If you drop the meter
- Use routinely to obtain accurate results.

The control solution test is similar to a blood test except that you use the myglucohealth™ Control Solution instead of a drop of blood

Checking the system with the myglucohealth™ Control Solution

Important Control Solution Test information

- Use only the myglucohealth™ Control Solution.
- Check the expiration date on Control Solution vial. DO NOT USE if expired.
- myglucohealth™ Control Solution should be stored at room temperature below 30 °C. Do not refrigerate.
- It is recommended that meter, control solution, and test strips come to room temperature 23 ~ 25 °C before testing.
- Shake the Control Solution, and wipe off the vial tip and reseal tightly after each use.
- Use only for three months after first opening. Record the discard date on the Control Solution vial.
- Discard after three months.

< caution >

The Control Solution range printed on the Test Strip vial is for the myglucohealth™ Control Solution only.

It is used to test the meter and test strip performance. It is not a recommended range for your blood glucose level.

How to do the myglucohealth™ Control Solution test

1



STEP 1: Insert Test Strip

Insert a Test Strip, with the arrow into the test port of the Meter firmly. The meter will automatically turn on and display the code number.

2



STEP2: Select activities related to the test result

Select activities related to the test result by press ▲ button or ▼ button.

Before having a meal, after having a meal, after taking drugs, after sports activity, using control solution (the value which you don't want to average in the memory)

When it is selected, press the power Ⓚ button. Once completed, "Strip-Shape" symbol will appear on the LCD.

3



STET 3: Apply Control Solution

Shake the control solution vial well. Remove the cap. Invert the bottle and discard the first drop of the control solution. If large bubbles are present at the tip of the vial, wipe the bubbles off with a clean tissue before applying the drop of control solution to the test spot. Do not drop bubbles on the test strip. Apply an entire drop of the control solution onto the test spot at once by gently squeezing the vial to form a small drop. Take the meter with test strip inserted and touch the end of the test strip to the hanging drop. Be sure to hold the test strip to the drop until you hear a "beep" sound.

4



STEP 4: Result appears in 3 Seconds

Once you hear the "beep", it indicates that the test strip is filled and the meter will begin to count down from "3" seconds to "1" second and the Control Solution test result will be displayed. Compare the result with the range printed on the test strip vial. The result should fall within that range.

Comparing Control solution Results

If the Control Solution test results fall outside the range, repeat the test.

Out of range results may be caused by one or more of the following reasons:

- Error in performing the test.
- Failure to shake the control solution vial well enough (must shake vigorously).
- Failure to discard the first drop of control solution.
- Expired or contaminated control solution.
- Meter malfunction.
- Control solution that is too warm or cool.

Set the Meter

The myglucohealth™ has a variety of excellent functional modes:

Beep sound to alert when function is set, date, time, test unit of results, and the ability to designate three unique data averages.

power on

- ➔ **power on**
Press \odot button for 3 seconds at least

Year

- ➔ **year**
Press and release either \blacktriangle or \blacktriangledown buttons to set the year. Enter \odot button.

date, time

- ➔ **date, time**
Press and release either \blacktriangle or \blacktriangledown buttons to set the date and time. Enter \odot button.

Set the Meter

Average date

- ➔ **Average date**
Press and release either \blacktriangle or \blacktriangledown buttons to set the average of testing day. Enter \odot button.

Alarm

- ➔ **Alarm**
Press and release either \blacktriangle or \blacktriangledown buttons to set the alarm. Enter \odot button.

Alarm time

- ➔ **Alarm time**
Press and release either \blacktriangle or \blacktriangledown buttons to set the alarm time. Enter \odot button.

Collecting a Drop of Blood

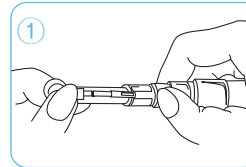


Alarm
INPUT the number of desired ALARMS.
Enter \odot button.

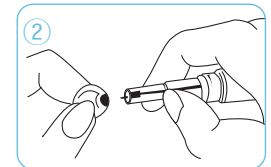
Available to set Max 5 alarm function and new 3 average dates.

<Caution>

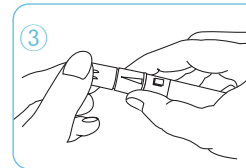
1. Without setting the date properly, the average glucose level and the results in memory will not show proper values. It is recommended to set the meter before use and when new batteries are installed.
2. You can't test your blood glucose while in the setting mode.
3. You will be unable to test while setting up your meter.
Year Mode : From 2006 to 2099



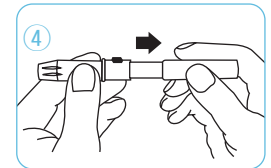
1. Unscrew the lancet device tip and insert a lancet firmly into the carrier.



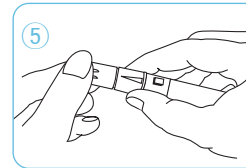
2. Pinch the lancet and twist off the protective cover. Do not discard the cover.



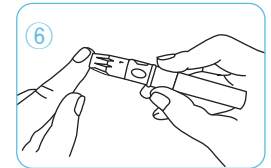
3. The tip of the lancet device offers 5 different levels of skin penetration, to select the best depth: Use 1-2 for soft or thin skin, 3 for average skin, 4-5 for thick or calloused skin.



4. Hold the tip in one hand and pull on the sliding barrel with the other hand. Pull the end apart and you will feel a click. This indicates that the lancet device is in a locked position ready for lancing.



5. Release the sleeve. It will automatically contract and move back to its original position near the trigger hub.



6. Place the lancet device against the tip of the finger. Press the trigger button. Your blood sample should now be ready to be applied on the test strip. Lift the lancet device out and away.

Testing Your Blood

Before testing, be sure to read carefully this section and test strip instruction for use found in the test strip box carefully. Make sure you have all the necessary items to begin your test



1. myglucohealth™ Meter
2. myglucohealth™ Test Strip
3. Lancing device
4. Sterile lancets

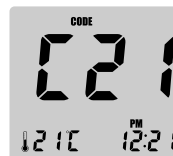
Practice using the lancing device and become accustomed with its use. Wash your hands with warm, clean water and soap. Dry your hands completely before testing.

< Caution >

The Lancing Device and Sterile Lancets should NOT be shared with others to reduce the chance of infection. It is only for your own personal use.

1. Always use a new, sterile lancet. Lancets are for single use only
2. Avoid getting hand lotion, oils, dirt, or debris in on the lancets and the lancing device.

Testing Your Blood



Step 1.

Firmly insert the myglucohealth™ test strip into myglucohealth™ Meter test port. Insert the strip with the myglucohealth™ logo up firmly. Please do not insert the test strip upside down. When you insert the test strip into the meter, the power automatically turns on with the code and temperature. After 3 seconds, the code number and testing temperature will disappear.

Note : Inserting the test strip in the wrong direction will turn the meter in but the test will not be done.

< Caution >

1. If you did not confirm the code in 3 seconds, pull the test strip out of the port and re-start the procedure from the beginning.
2. If the code on the LCD display window and on the test vial does not match, try another new strip. If the mismatch persists, please contact your local representative for help.
3. If the meter does not power on, pull the test strip out of the port, and reinsert the test strip.
4. Avoid testing under direct sunlight, for a more accurate test result.
5. If you apply your blood sample too early, error message will appear on LCD (refer to p35)

Testing Your Blood



Step 2: Select activities related to the test result

Select the activity based features, press ▲ or ▼ button to select the activity that correlates with your result, then press ⓘ button.

Before having a meal, After having a meal, After taking medications, After sports activity, Using control solution (the value which you don't want to average in the memory)

Once completed, "Strip-Shape" symbol will appear on the LCD.

When the test sign blinks, apply your blood to the test port.

Testing Your Blood

- Correct



Completely filled

- Incorrect



Poorly filled

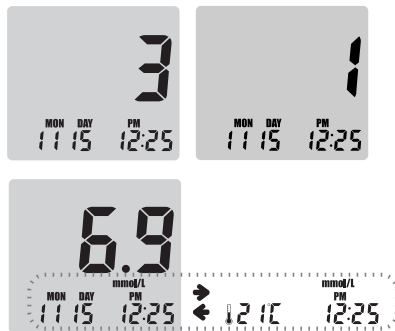
Step 3.

Place your fingertip to the top edge of **myglucohealth**™ Test Strip. The blood on your finger will automatically draw into the applying channel of the test strip. Allow your finger to remain until you hear a “beep” sound from the **myglucohealth**™ Meter. A sample volume of 0.3 ul is required.

< Caution >

If you do not conduct the test within 3 minutes, the meter will automatically power off to save battery life. In this case the test procedure should start again from the beginning.

Testing Your Blood



Step 4.

After beeping sound, the test will begin automatically and your results will appear in 3 seconds. It should begin counting down from 3 to 1 second on the LCD display window. The LCD window will display the result of your blood glucose level, temperature and time.

Record the result value in your logbook. When you pull out the test strip, the meter will turn off automatically.

< Caution >

1. If the test result is out of the test range, error message will be shown on the LCD. (refer to p35~37)
2. Safely discard used test strips and lancets.

Test strip ejector function



1. After checking your test result, slide the ejector button forward to remove the test strip from the meter.
2. Discard the used strip and lancet to a proper place.

< Caution >

1. If you push the ejector button forward too much, it may be part of the failure.
2. Do not give strong impact to meter.

Reviewing your results

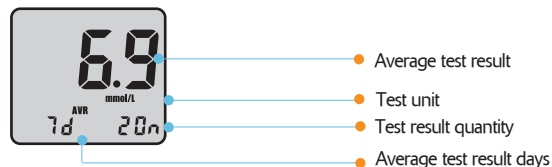
The myglucohealth™ saves up to 250 test results in its built-in memory and records the average glucose level for the number of days which you had pre-set to be calculated and saved. These values can be recalled in the LCD date display at any time. The newest result will replace the oldest beyond the 250 data stored.

Press \odot button shortly

* The newest data appears during setup.(refer to p21)

You can check your individual data of the latest 3 days and previously set up 3 different types of average days(7d, 14d, 21d) through pressing $\blacktriangle/\blacktriangledown$ button.

Ex>



Press \blacktriangle button: displaying the previous result

Press \blacktriangledown button: displaying the 7d \rightarrow 14d \rightarrow 21d average test result

Deleting Test Results

myglucohealth™ has the delete function.



Deleting individual test result

To delete any individual test result in the memory press \blacktriangle or \blacktriangledown button for 3 seconds.



Deleting all test results

To delete all test results press \blacktriangle and \blacktriangledown at the same time for 3 seconds.

< Caution >

1. Only selected Individual test results are deleted when you recall test results
2. The deleted test results can't be recovered. Please make sure that the data is the one you want to delete

Transfer Test Results

Transfer Test Results - myglucohealth™ Bluetooth function

- * You need a Bluetooth mobile phone which has SPP a,b Profiles function. (SPP -Serial Port Profile, a- Initiator, b-Acceptor)
- * JAVA application is built in the mobile phone and provides UI according to the kind of phone. Please refer to the mobile phone manual.



- * You can transfer test results from myglucohealth™ meter to a mobile phone. First, please check communication connection between myglucohealth™ meter and mobile phone. (pairing)
- * Please conduct pairing process from step 1 to step 3. If you finish pairing process, you can use communication service from step 4.



Step 1. Pairing

Pressing Pair button(▲ button). The LCD window will display "bt" and "st:1". This shows that myglucohealth™ meter is in the process of pairing work with the mobile phone. Within minutes, LCD window will display "st:3" when myglucohealth meter is pairing with mobile phone. And then, It should begin counting as displayed on the lower left side of the LCD window. The operating time is counted in one second unit.

Step 2. Input the pin number

Input the fixed pin number into mobile phone to conduct pairing process with myglucohealth™ meter.
(Input initial result "0000" into mobile phone if pin number is not fixed.)

Step 3. Standby Mode

Within minutes, LCD window will display "st:3" when myglucohealth meter is pairing with mobile phone. And then, If you press ① button, meter goes into standby status and LCD window will turn off.

Transfer Test Results



Step 4. Testing your Blood

Step 5. Sending glucose data

Pressing send button while display blood glucose test result on LCD window. LCD window will display "bt" and st:2". Within minutes, LCD window will display "st:3" when myglucohealth™ meter is connected to mobile phone and stored blood glucose test result is transferred to mobile phone. It should begin counting down and you can see the time lower left of LCD window. At this time, the operating time will count on by one second unit.

* How to read memory the meter by Bluetooth function

It is available to read the reserved glucose data by using Bluetooth function

myglucohealth™ Blood Glucose Program

Step1. Read Memory data

Pressing PAIR button (▲ button) in a state of standby LCD off. LCD window will display "bt" and st:1". Within minutes, LCD window will display "st:3" when myglucohealth™ meter is connected to mobile phone or PC. At this time, the operating time will count on by one second unit.

Step2. Read the following data according to the built in UI.

(Get the number of records, Read data on the memory, etc.)

*JAVA application is built in mobile phone and provides UI according to a kind of phone.

Please refer to a mobile phone manual.

Step3. Done

Pressing Ⓚ button after data transmission and LCD window will be turned off




Taking care of your glucose meter

Cleaning your meter and maintenance

For safe, accurate and long-lasting use of the **myglucohealth™** Meter, the meter must be maintained with proper care.

1. The meter should be cared for after testing and cleaned if necessary with a soft cloth or tissue. If necessary, rubbing alcohol can be used to wipe away dirt on the outer surface of the meter. Do not use chemical solutions such as benzol or acetone since both of these solutions can harm and damage the meter surface. When cleaning the meter with rubbing alcohol, **DO NOT** pour directly onto the meter, but use a cloth soaked with a small amount of alcohol. After cleaning the meter, dry completely at a cool place avoiding the sun rays.
2. Do not soak the meter and test strip into water or liquid. Use as properly as you can. Strong electromagnetic fields (e.g. mobile phones, microwave ovens) could disturb the meter function. Do not put the meter and strip near fire or microwave ovens.
3. After testing, place the **myglucohealth™** Meter in the carrying case to prevent loss or damage. Make sure it is placed in a cool and dry area and out of the reach of children. Do not refrigerate. Avoid exposure to sun.
4. Close the vial cap tightly immediately after removing the Prime 4G strip. Please refer to your **myglucohealth™** strip instruction if you want to get more information.

- 
5. The lancing device should be cleaned if blood or stain remains after the test, to prevent infectious diseases.
 6. When you need to purchase lancing device, lancets and/or test strips, please visit your local pharmacy or contact your local representative.
 7. Discharge used materials according to the local regulations for contaminated materials.
 8. The blood glucose measuring meter could be sent back to the manufacturer for recycling or proper disposal after their useful lives. Alternatively the meter shall be disposed in accordance with national laws after their useful lives.

Battery installation

The battery shortage mark will appear in the upper left corner of the LCD screen to alert you when the battery power is running low, indicating a new battery is needed. The **myglucohealth™** meter will not power on when the battery power is exhausted.



Your **myglucohealth™** meter uses only Two 1.5V Alkaline battery (AAA Size). The battery is included in the set box. When replacing the battery, or equivalent alkaline battery can only be used.





Before replacing the battery, make sure your meter is in the 'OFF' position for meter safety. When changing your battery, match the polarity symbols (+ or -) printed on the battery deck of the meter to the symbols on the face of the battery.


Troubleshooting

The following chart may help you identify certain problems, but may not solve all problems that can occur. Contact your authorized representative or customer support if the problem persists.

Message	Casued by	What to do
	Problem with the meter	Place the battery again, and set the meter. If the problem persists, please contact your authorized representative or customer support
	Using polluted test strip and/or used test strip	Test with a new test strip
	Problem with the test strip	Retest with a new test strip re-test with a new test strip. If Er3 message persists, please contact your authorized representative or customer support If blink with "Sun", Avoid to the direct sunlight and retest
	Problem with test strip	Test with a new test strip

Troubleshooting

Message	Casued by	What to do
	The blood sample was applied before the test symbol (blood insertion picture) appeared on the display	Repeat the test with new test strip. Apply blood only after the test symbol (blood insertion picture) appears on the display.
	The ambient temperature is too low	Place the meter within the operating temperature range for more than 10 minutes and retest.
	The ambient temperature is too high	Place the meter within the operating temperature range for more than 10 minutes and retest.
	The test result is lower than 0.6 mmol/L	When “Lo” message persists, please consult a doctor for assistance.

Message	Casued by	What to do
	The test result is higher than 33.3 mmol/L	When “Hi” message persists, please consult a doctor for assistance.
The meter does not power on	Batteries are dead or flat. It is a problem with the meter	Change the battery and if the problem persist, contact your local representative
Test does not start after applying blood sample	Poor amount of sample	Apply a sufficient amount of the blood sample to a new test strip and re-test
The result is doubtful	There may be a problem with the test strip The code of meter failure	Re-test with a new strip Match code of the meter and of the test strip vial

Specifications

Sample type	Capillary whole blood
Sample volume	0.3ul
Test Range	0.6~33.3 mmol/L
Reading time	3 seconds
Calibration	Plasma - Equivalent
Altitude	≤3048 m
Operating Temperature	10-40℃
Operating Humidity	10-90%
Strip storage temperature	2℃ - 30℃
Display Type	LCD
Dimension	52.2 X 98.5 X 23.4 (mm)
Weight	74.5g (battery include)
Power rating	3 V (Alkaline Battery, 1.5V AAA Size X 2)
Battery Life	Running 2,000 times
PC communications port	<p>Communication is available to connect computer with USB cable</p> <p>Communication is available to connect mobile phone or computer with bluetooth function</p>

Symbol

Description



consult operating instructions



Used By



This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices



Caution, consult accompanying documents



In-Vitro-Diagnosticum



Batch code



Reference number



Store at



Do not re-use



Use within 3 months after first opening



Manufacturing date

Test principle

The glucose enzyme oxidase on the test strip reacts specifically with the blood glucose. The current generated is converted and displayed as blood glucose level.

The myglucohealth™ system is plasma-calibrated to allow easy comparison of results with laboratory methods.

Blood glucose meter which are calibrated against a whole blood method may have different results in comparison to myglucohealth™. The laboratory system used for calibration of the myglucohealth™ system is YSI 2300 STAT plus which is equipped with a glucose oxidase system.

mmol/L	0.55	1.0	1.5	2.0	2.2	2.5	2.8	3.0
mg/dL	10	18	27	36	40	45	50	54
mmol/L	6.7	7.0	7.2	7.5	7.8	8.0	8.3	8.9
mg/dL	120	126	130	135	140	145	150	160
mmol/L	14.4	15.0	16.0	16.6	17.0	18.0	19.0	20.0
mg/dL	260	270	288	300	306	325	342	360
mmol/L	3.3	3.9	4.0	4.4	4.7	5.0	5.5	6.0
mg/dL	60	70	72	80	85	90	100	108
mmol/L	9.0	9.4	10.0	10.5	11.0	11.1	12.0	12.5
mg/dL	162	170	180	190	196	200	216	225
mmol/L	20.8	22.2	23.0	24.0	25.0	26.4	27.7	30.0
mg/dL	375	400	414	432	450	475	500	540

EC Declaration of Conformity


FCC

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. This device and its antenna must not be co-located or operating in conjunction with any other antenna or transmitter.

CAUTION: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

EC-R&TTE

EC-R&TTECE Marking	 0678
Indication of the intended use of the equipment	Blood Glucose Monitoring System with built in Bluetooth function (For self testing only)
Declaration of Conformity (DoC)	Hereby, infopia Co.,Ltd, declares that this Myglucohealth™(Blood Glucose Monitoring System) is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC. The declaration of conformity may be consulted at www.infopia21.com/Doc.pdf



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