finetest™

Blood Glucose Monitoring System Operation Manual

infopia Co., Ltd.

finetest™

Blood Glucose Monitoring System Operation Manual

$finetest^{TM}$ System Owner

Thank you for choosing the $finetest^{TM}$ Blood Glucose Monitoring System. This booklet has important information you must know about the $finetest^{TM}$ system. Please read it carefully.

We understand that self-testing of blood glucose level provides a way to control your diabetes and may give you peace of mind by testing regularly. As a result $finetest^{TM}$ was developed to provide you with a FAST and Accurate reading with a convenient and simple process. Our goal at $finetest^{TM}$ is to provide the best quality healthcare products coupled with superior customer service. **Always consult with your healthcare professional before making any changes. The $finetest^{TM}$ System is for in vitro diagnostic use only**.

A warranty registration card is included with your system. Please complete the three year warranty card and send it to us. This will ensure that you receive any new information about your $finetest^{TM}$ System. If you have any questions, please contact your local representative.

Quick Reference

This is intended only for quick reference.
Please read the entire manual before you use the $finetest^{TM}$ monitoring system.

1	2	3	4

Insert $finetest^{TM}$ test strip.

Apply blood sample to the test strip.

Apply sample until confirmation window is completely filled before the Meter begins to countdown. If the confirmation window does not fill completely, do not add more blood to the test strip. Immediately discard the test strip and then retest.

Test results in 9 seconds.

Important Information

Before using the *finetest*™ Blood Glucose Monitoring System, read all of the operating instructions in this Operation Manual to practice for safe and accurate testing.

· The *finetest*™ Blood Glucose Monitoring System is intended for use outside the body (in vitro diagnostic use only).

· *finetest*™ was designed only to test blood glucose (sugar) levels and can only be used 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 the *finetest*™ System for any purpose other than for blood glucose testing.

· Consult with your physician or diabetes healthcare professional for the proper use of this meter and daily management of your diabetes.

· Please pay close attention when handling blood. Improper procedures may cause serious hazards to your health.

If you have any questions about the use of the *finetest*™ product, please contact your local representative.

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finetest™ meter

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Lancing Device, Lancets and Check Strip

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One 3V Li-CR2032 battery

Carrying Case

Check your *finetest*™ 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 are not met, please return your system to the place of purchase or contact your nearest Infopia representative.

finetest™ Blood Glucose Meter

Test port

Display

SET button

MEM button

Product Label

Batteries
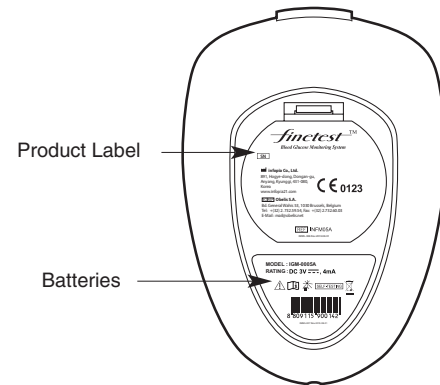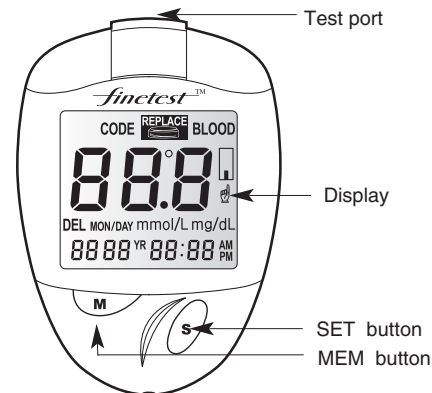
TEST PORT : Insert the *finetest*™ Test Strip here.
DISPLAY : Symbols, simple messages, and test results appear here.
MEM BUTTON : Use for reviewing past records and setting for Time,Date, Month and Year(Refer to pages 12, 13, 20 and 21).
SET BUTTON : Use for recalling past results, and setting Time, Date, Month, Year mode and the code number(Refer to pages 7, 12, 13, 20 and 21).

finetest™ Blood Glucose Meter Display

LCD display segment
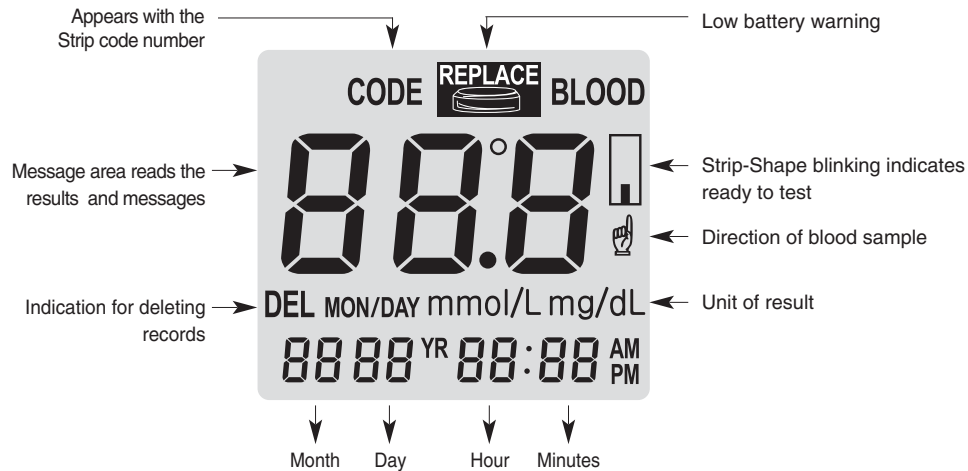
Appears with the Strip code number

Low battery warning

Message area reads the results and messages

Strip-Shape blinking indicates ready to test

Direction of blood sample

Indication for deleting records

Unit of result

CODE **REPLACE** BLOOD

88.8

DEL MON/DAY mmol/L mg/dL

8888 YR 88:88 AM PM

Month   Day   Hour   Minutes

[3]   *finetest*™

finetest™ Blood Glucose Test Strip

The *finetest*™ System measures the amount of glucose in your blood.

Blood is applied to the Top Edge of the *finetest*™ Test Strip and is automatically drawn into the channel where the reaction takes place

Apply blood here

Check here to confirm if enough blood have been applied

CONTACT BAR

Insert this end into the Meter.
Push it all the way in until it will go no further.

front

back

[4]
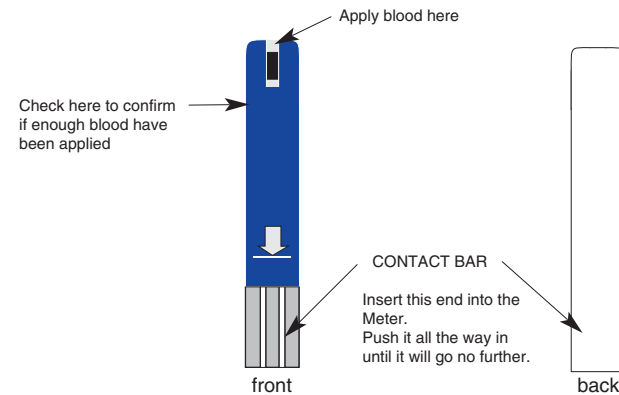
Important *finetest*™ Test Strip Information

· Store the *finetest*™ Test Strip vials in a cool, dry place between 39 - 86˚F (4 - 30˚C). Keep out of direct sunlight. Do not freeze.
· Store test strips in it's original vials only. Do not mix the test strips in new vials or in any other container.
· Immediately replace the vial cap and close tightly after removing an *finetest*™ Test Strip.
· Use test strip immediately after removing it from the vial.
· Make a notation of the discard date on the vial label when you first open it. Discard remaining *finetest*™ Test Strips 3 months after first opening the vial.
· Avoid getting dirt, food, and water on the test strip. Do not handle test strips with wet hands.
· Do not use test strips after the expiration date printed on the package or vial since it may cause inaccurate results.
· Do not bend, cut, or alter an *finetest*™ Test Strip.
· *finetest*™ Test Strips are for single use only. Do NOT re-use.
· Refer to additional information in the *finetest*™ Test Strip package.

Checking the Meter with the Check Strip

The "Check Strip" is to make sure that the Meter functions properly.
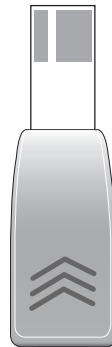
· The Check Strip automatically checks the Meter when inserted into the Test Port.
· Please Insert the Check Strip with "<<<" facing up into the test port of the Meter. If the value displayed is ranged between 107-127, the Meter is good to use.
 If the value displayed does not meet the proper range, reinsert the calibration key 2 or 3 more times. If it's still does not meet the proper range, please contact your local representative.
· Please note that the Check Strip does not check the POWER-ON status of the Meter.

Coding The Meter

Code numbers are used to calibrate the *finetest*™ Meter with the *finetest*™ Test Strips for accurate results. You must code the meter before using it. Confirm the code number for the first time and then every time you change to another vial of test strips.

STEP 1

Insert the *finetest*™ Test Strip to turn on the Meter. Push it all the way in until it will go no further. Avoid bending the test strip. The code number will appear on the LCD window for 3 seconds. Compare the code number (example: C20) on the Meter's LCD window with the code number on the test strip vial. If these two code number matches, you can start testing. If any error messages appear any time, refer to the Troubleshooting section of the booklet for more information, see page 24.

STEP 2

If the two code numbers do NOT match, you must code the meter according to the test strip vial code number before the LCD display ends. Press the SET button to select the correct code. The number increases by one digit every time you press the SET button. To move more quickly, press and hold the SET button.
After selecting the correct code number, it will appear solid for a second.
Then the Strip-Shape symbol on the LCD will starts blinking, indicating that the *finetest*™ System is ready for testing.

> **CAUTION :** If you do not adjust and match the code numbers, you may receive inaccurate test results.

Important: Each time you test, be sure to check that the code number on the meter display matches the code number on the Test Strip vial.

Checking the System with the *finetest*™ Control Solution

Note: The *finetest*™ Control Solution is sold separately. Both, the low and high level control solution can be obtained through Infopia Co., Ltd.
Refer to the *finetest*™ Control Solution package for additional information.

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

The *finetest*™ 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 *finetest*™ 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.

Do a control solution test:

· When a new vial of test strips are opened.
· Any suspicion that the meter or test strips are 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 *finetest*™ Control Solution instead of a drop of blood.

Checking the System with the *finetest*™ Control Solution

Important Control Solution Test Information

· Use only the *finetest*™ Control Solution.
· Check the expiration date on the control solution vial. DO NOT USE if expired.
· The *finetest*™ Normal Control Solution should be stored at room temperature below 86˚F (30˚C).
  Do not refrigerate.
· It is recommended that the 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 *finetest*™ 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.

Checking the System with the *finetest*™ Control Solution

How to do the *finetest*™ Control Solution test

STEP 1: Insert Test Strip
Insert a Test Strip, with the arrow side "⬇" facing up and in the direction of the arrow, insert it into the test port of the Meter firmly. The meter will automatically turn on and display the code number. Make sure the code number on display matches the code number on the test strip vial (picture1). If the code number does not match, code the meter correctly. Once completed, "Strip-Shape" symbol will appear on the LCD.
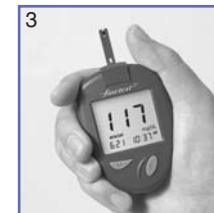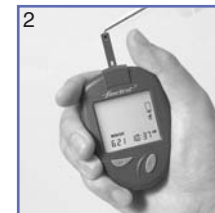
STEP 2: Apply Control Solution
Shake the control solution vial well. Remove the cap. Invert the bottle and discard the first drop of the control solution. If large bubbles are present at the tip of the vial, wipe the bubbles off with a clean tissue before applying the drop of control solution to the 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 the test strip inserted and touch the end of the test strip to the hanging drop (picture 2). Be sure to hold the test strip to the drop until you hear a "beep" sound.

Checking the System with the *finetest*™ Control Solution

STEP 3: Result appears in 9 seconds

Once you hear the "beep", it indicates that the test strip is filled and the meter will begin to count down from "9" seconds to "1" second and the control solution test result will be displayed (picture 3). 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:

· 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.
· Test Strip deterioration.
· Meter malfunction (Use the Check Strip in your *finetest*™ kit to check the meter).
· Control solution that is too warm or cool.

Setting The Meter

The *finetest*™ Meter has three functional modes as settings: 1) Average period, 2) Unit, 3) Date & Time.
If you need to change the time, or if you remove the battery, you may need to enter the setting mode and reset.

Turn on the meter by pressing the SET button for 3 seconds. This will initiate the "Set the Meter" mode.

How to Calculate Your Average Blood Glucose Level

Enter set mode   Change the status   Move to next

The setting mode begins with setting the number of days of which you would like to receive an average calculation of your glucose level. The LCD window will be flashing the most recent number of days that was selected.   The number of days can range from 7 days to 90 days. To increase the number of days, press the SET button; holding the SET button down will increase the value at a quicker rate. With the correct number of days displayed, press the MEM button. This will set the number of days that you would like to receive your average blood glucose calculation. (By pressing the MEM button it saves your settings as well as moves you to your next item to set).

Setting The Meter

Set Unit of Measurement

You should now be at the Unit of Measurement selection. Select the proper unit of measurement (mg/dL or mmol/L) for your blood glucose result by pressing the SET button. Once the unit of measurement is selected, press the MEM button. This will save the unit of measurement that you have selected for your blood glucose result. Note: The past results in memory will appear automatically in proper values according to the unit selection.

Set the Year and Date

Press and release the SET button to select year. You can select the year from 2000 to year 2099 with SET key (Year does not display on the LCD in normal operation). After setting the year, press MEM button to select month. With the correct month selected on the display, press the MEM button and the day setting will starts flashing. Press the SET button to advance one day. To move faster, hold the SET button down.

Set the Time

Press and release the SET button to select the proper hour. With the correct hour on display, press the MEM button and the minutes setting will start flashing. Press the SET button to advance one minute. To move faster, hold the SET button down. With the correct minute on display, press the MEM button.

CAUTION : Without setting the date properly, the average glucose level and the results in memory will not show proper values but instead an error message will be displayed. It is highly recommended to set the meter before use and when new batteries are installed. You cannot test your blood glucose while in the setting mode.
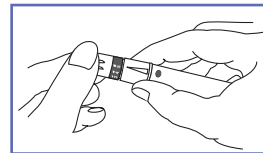
Collecting a Drop of Blood
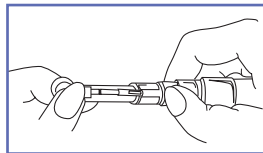
1. Unscrew the lancing device tip and insert a lancet firmly into the carrier.
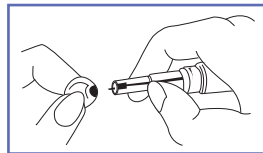
2. Pinch the lancet and twist off the protective cover. Do not discard the cover.

3. The tip of the lancing 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.

**Note :** For even finer adjustment, the arrow may be placed between any two numbers.

CAUTION :
· Use a new, sterile lancet every time you test.
· Do not use lancet if protective cover has been removed or damaged.
· Never share a lancet with anyone.

Collecting a Drop of Blood
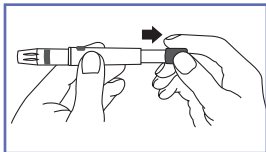
4. Hold the tip in one hand and pull on the sliding barrel with other hand. Pull the ends apart and you will feel a click. This indicates that the lancing device is in a locked position ready for lancing.
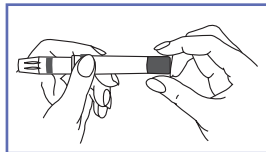
5. Release the sleeve. It will automatically contract and move back to its original position near the trigger hub.
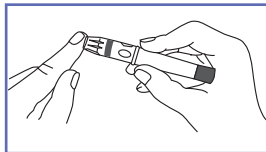
6. Place the lancing device against the tip of the finger. Press the trigger button. Your blood sample should now be ready to be applied on the test strip. Lift the lancing device out and away.

Maintaining your Lancing Device
- Unscrew the lancing device tip. Carefully stick the protective disk cover back on the used lancet.
- Grip the holder firmly and pull the lancet safely out of holder. Screw the tip back on the lancing device.
- Discard the used lancet to a proper place. Clean the lancing device if blood or stain remains.

CAUTION :
· Use a new sterile lancet every time you test.
· Do not use lancet if protective cover has been removed or damaged.
· Never share a lancet with anyone.

Testing Your Blood

Before testing, be sure to read this section and the test strip package insert found in the test strip box carefully. Make sure you have all the necessary items to begin testing:

· *finetest*™ Meter
· *finetest*™ Blood Glucose Test Strip
· Lancing Device
· Sterile Lancets

WARNING : **To reduce the chance of infection:**
· The Lancing Device and Sterile Lancets should NOT be shared with others. It is only for your own personal use.
· Always use a new, sterile lancet. Lancets are for single use only.
· Avoid getting hand lotion, oils, dirt, or debris in or on the Lancets and the Lancing Device.
· Dry your hands completely before testing.

Testing Your Blood

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.

STEP 1.

Firmly insert the *finetest*™ Test Strip into the *finetest*™ Meter test port. With the Arrow side "⬇" facing up and in the direction of the arrow, insert it into the test port of the Meter firmly. The meter will automatically turn on and display the code number. Make sure the code number on display matches the code number on the test strip vial. If the code number does not match, code the meter correctly. See "Coding The Meter" page.

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

> **CAUTION :**
> · If you did not confirm the code in 3 seconds, pull the electrode out of the port, and re-start the procedure from the beginning.
> · If the codes on the LCD display window and on the test strip vial do not match, do the "Coding The Meter" procedure for accurate result.

Testing Your Blood

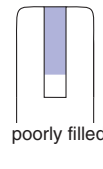STEP 2. Place your fingertip to the top edge of *finetest*™ Test Strip.
The blood on your finger will automatically draw into the applying channel of the test strip (on the electrode). Allow your finger to remain untill you hear a "beep" sound from the *finetest*™ Meter. A sample volume of $1.5\mu\ell$ is required.
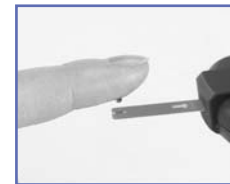

completely filled

correct

poorly filled

incorrect

> **CAUTION :**
> · If you do not conduct the test after 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 3. After you hear the "beep" sound, the test will begin automatically and your results will appear after 9 seconds. It should begin counting down from 9 seconds to 1 second on the LCD display window. The LCD display window will indicate the result of your blood glucose level.


STEP 4. Record the result value in your *finetest*™ logbook. This will help you reference your blood glucose levels historically. When the testing is complete, discard the used test strip and lancet to a proper place. Make sure to retain all necessary *finetest*™ items in the leather case for your next test. Clean the meter if necessary according to "Maintaining the *finetest*™ Meter".

CAUTION : If you receive any error messages please refer to the "Troubleshooting" section of this Manual.

Reviewing Your Results

The *finetest*™ (Meter saves up to 200 test results in built-in memory and records the average glucose level for the number of days in which you had preset to be calculated and saved. These values will appear on the LCD display window by recalling any time you want to see it. The newest result will replace the oldest beyond the 200 saved data.

The meter enters "Reviewing Your Results" mode by pressing the MEM button.
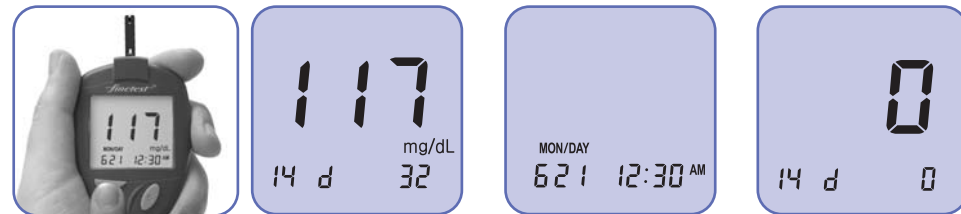
The first display shows the current date and time, then the average glucose level calculation over the period that was already pre-set.

If no data was saved, the meter will not display any result and powers off automatically after 3 seconds.

If no data was saved for the pre-set days for the average glucose calculation, the meter will display a zero and display each value of the past results

Reviewing Your Results

To delete test results individually, press the SET button for 5 seconds until you hear 3 beep sounds and the LCD display shows the test result and time you want to delete.

To delete all test results in memory, press the SET button and the MEM button for 5 seconds until you hear 3 beep sounds. Please be careful, once the results is deleted it cannot be restored.

CAUTION : If you do not set the Meter properly, the average glucose level for the days you set and the results in memory will not show proper value but indicate an error message. Improper settings will cause an "Er3" message to appear on the LCD window. Refer to "Setting the Meter."

Maintaining the *Finetest*™ Meter

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

1. The lancing device should be cleaned if blood or stain remains after testing to prevent infectious diseases.

2. 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 cleansing the meter with rubbing alcohol, DO NOT pour directly onto the meter, but use the cloth soaked with a small amount of alcohol. After cleansing the meter, dry completely at a cool place avoiding the sun rays.

3. After testing, place the *finetest*™ Meter in the leather 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 the sun.

4. For detailed instructions of the *finetest*™ Test Strip, refer to the test strip package insert found in the *finetest*™ Test Strip box.

5. When you need to purchase the lancing device, the lancets and the test strips, visit your local pharmacy or contact your local representative.

6. Do not soak the meter and test strips into water or liquid.

7. Do not subjet the meter and the strips to exesive heat.

8. Use your *finetest*™ Meter according to the instuctions in the manual.

Battery

Your *finetest*™ Meter comes with one 3.0V (CR2032 or equivalent) lithium batteries. The batteries will provide you with enough power to perform about 5,000 tests. When replacing the battery, 3.0V (CR2032 or equivalent) lithium battery can only be used.

The meter will alert you when the power is getting low by displaying this symbol (symbol of battery and its low sign) or when the meter does not power on by any means.

To replace the battery, make sure that the Meter is in the OFF position when changing the battery.

When changing the battery, be careful of the polarity of the battery which is printed in the battery deck of the meter.

After changing the battery, "Setting The Meter", MUST be done again for secure and accurate test results.

```
 REPLACE
   ▭
  1 1 7
MON/DAY        mg/dL
 6 2 1  12:30 AM
```
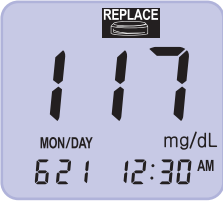
Troubleshooting

Problems that you may encounter : Following may help you to identify certain problems but may not represent all the problem that occurs. Please avoid any IMPROPER use of the meter and the parts associated with the *finetest*™ System.

MESSAGE	CAUSED BY	WHAT TO DO
Err	Problem with the Meter	If problem persist,contact your local representative.
Er2	Problem with the test strip	With a new test strip and sufficient blood sample, re-test.
Er3	The meter has not been properly set	See "Setting The Meter"

Troubleshooting

MESSAGE	CAUSED BY	WHAT TO DO
MON/DAY 6 2 1 12 30 AM	No saved data	
LoC °C MON/DAY 6 2 1 12 30 AM	The ambient temperature is too low	Place the meter at the operating temperature range for more than 10 minutes, and re-test.
H IC MON/DAY 6 2 1 12 30 AM	The ambient temperature is too high	Place the meter at the operating temperature range for more than 10 minutes, and re-test.

Troubleshooting

MESSAGE	CAUSED BY	WHAT TO DO
Lo MON/DAY 6 2 1 12 30 AM	The test result is lower than 10mg/dL (0.6mmol/L)	If you believe that your result is incorrect, recheck the meter by using the *finetest*™ Control Solution. With normal result, re-test with blood samples two or three times. "LO" results indicate severe hypoglycemia (low blood glucose). If the "LO" message persists, please contact your physician or diabetes healthcare professional.
H I MON/DAY 6 2 1 12 30 AM	The test result is higher than 600mg/dL (33.3mmol/L)	If you believe that your result is incorrect, recheck the meter by using the *finetest*™ Control Solution. With normal result, re-test with blood samples two or three times. "HI" results indicate severe hyperglycemia (high blood glucose). If the "HI" message persists, please seek medical attention immediately.

Troubleshooting

Please refer to the table below to identify problems that persist with no messages appearing.

PROBLEM	CAUSED BY	WHAT TO DO
The meter does not power on	Batteries are dead or there is a problem with the meter.	Change the batteries and if the problem persists, 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. Re-test with a new strip.
	Problem with the test strip	
The result is doubtful	There may be a problem with the test strip	Re-test with a new strip.
	The codes of the meter and of the test strip vial do not match	Re-code the meter and re-test.

Specifications

Specifications

Model	IGM-0005A		Hematocrit	30 ~ 55%
Test Range	0.6 ~ 33.3 mmol/L (10 ~ 600 mg/dL)		Sample Volume	Minimum 1.5 µl
Reading Time	9 sec		Display Type	LCD
Memory Capacity	200 test results		Size (D X W X H)	81 x 56 x 23 (mm)
Operating Temperature	50 ~ 86˚F(10 ~ 40˚C)		Weight	Less than 40g ± 1(including batteries)
Operating Humidity	10 ~ 90%		Power Source	3V Li Battery (CR2032) x 1
Sample Type	Capillary Whole Blood		Battery Life	running 5000 tests
Calibration	Plasma-Equivalent		Glucose Unit	Either mmol/L or mg/dL

Warranty

Three-Year Warranty

If, at any time during the first three years after purchase, the meter does not work for any reason with the exception of obvious abuse, misuse, or disastrous damage, Infopia Co.,Ltd. will replace your *finetest*™, Meter or equivalence free of charge.

The Warranty Policy of Infopia Co.,Ltd. only applies to the original purchaser of the Meter and will not include the batteries supplied with the Meter set.

Please fill in the warranty card attached to the set.
Mail or fax it back to us.

The *finetest*™, Meter has a full three-year warranty from the original date of your purchase. For your convenience, please include your date and place of purchase.

Note

Symbol	Description	Symbol	Description
S/N	Serial number		Consult operating instructions
CE 0123	This product fulfills the requirements of Directive 98/79/EC on invitro diagnostic medical devices.		Used by
⚠	Caution, consult accompanying documents		Manufactuing date
IVD	In vitro diagnostic device		Keep away from sunlight
LOT	Batch code	SELF-TESTING	Self-testing Used
REF	Catalogue number		Waste electrical and electorinic equipment
	Store at		

Memo

Memo