



infopiaUSA.LLC

Manufactured Exclusively for

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www.infopia21.com

LipidPro™

Lipid Profile & Glucose Measuring System



Instructions for Use



infopia USA.LLC
www.infopiausa.com

Dear LipidPro™ lipid profile and glucose measuring system Owner

Thank you for your choosing the LipidPro™ lipid profile and glucose measuring system. This instruction for use includes important information you need know about the LipidPro™ lipid profile and glucose measuring system. Please read it carefully. Our goal for LipidPro™ lipid profile and glucose measuring system is attributed to provide the best quality healthcare products coupled with superior customer service.

Indications For Use

LipidPro™ system is intended for in home (self-testing) or health care professionals and for testing outside the body (in vitro diagnostic use only). LipidPro™ system which consists of meter and test strips, measures total cholesterol (TC), high density lipoprotein cholesterol (HDL-C), triglyceride (TG) and glucose in capillary whole blood. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis and various liver and renal diseases. Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders. Calculated LDL cholesterol values are reported only when triglycerides are ≤ 350 mg/dL; when triglycerides are > 350 mg/dL, calculated LDL-cholesterol are not reported.

Glucose measurement is for the quantitative measurement of the concentration of glucose in capillary whole blood that can be taken from the fingertip, ventral palm, dorsal hand, upper arm, forearm, calf and/or thigh by diabetic patients or health care professionals as an aid in the management of diabetes. Glucose measurement is not to be used for the diagnosis of or screening for diabetes or for neonatal use. Alternate site testing should be done during steady-state times when glucose is not changing rapidly.

Test Principle

LipidPro™ lipid profile and glucose measuring system has two kinds of test principle according to test items: one for Lipid profile and the other for glucose.

Lipid profile test result is based on a reading of reflection density. When the blood is applied, the color changes in test area through an enzyme reaction.

The meter records this change in color and converts the measurement signal to the displayed result using the data previously entered via the code. The deeper the color is, the higher the lipid level is.

Glucose in the blood sample will react to the electrodes in the glucose test strip, generating an electrical current that will stimulate a chemical reaction. This reaction is measured by LipidPro™ meter and displayed as your blood glucose result.

The enzyme glucose oxidase on the blood glucose test strip reads specifically with the blood glucose. The current generated is converted and displayed as blood glucose value. The LipidPro glucose test System is plasma-calibrated to allow easy comparison of results with laboratory methods. Blood glucose meter which is calibrated against a whole blood method may have different results in comparison to LipidPro glucose test System. The laboratory system used for calibration of the LipidPro glucose test System is YSI 2300 STAT plus which is equipped with a glucose oxidase system.

How to use Instructions for use

This guide includes all the information you need to use LipidPro™ for self-testing use. For additional information and specific information for each individual test. Please make sure you read the strip instructions for use included with the test strips.

If you experience any difficulty or have any question, while using LipidPro™ Lipid profile and glucose measuring system please, visit our website at www.infopiausa.com

Customer Service is available 24 hours a day, 7 days a week, 365 days a year. Please Call Customer Support toll free : 1-888-446-3246

Contents

1. Learning the System

LipidPro™ Testing System Kit Contents -----	7
LipidPro™ Testing Meter -----	8
LipidPro™ Testing Meter Display -----	9
LipidPro™ Test Strip Information -----	10

2. Setting Your Meter

Battery Use -----	18
Setting Mode -----	19
Before Testing – Coding the meter -----	21
Checking the System with Control Solution -----	24

3. Testing Your Blood

Instruction for Lancing Device -----	29
Testing Your Blood – Preparation -----	32
Quick reference of test procedure -----	34
Test procedure -----	36
Glucose test strip Discard Function -----	44
Alternate site testing -----	45
Performing a Blood Test using an Alternate Site -----	46

4. Reviewing Your Results -----47

5. Deleting Your Results -----49

6. Printing Your Results -----49

7. LipidPro™ Software and Thermal printer -----50

8. Cleaning Your Meter and Maintenance -----51

9. Troubleshooting -----52

10. Product Specifications -----55

11. Warranty -----58

12. Declaration of Conformity -----59

LipidPro™ lipid profile and glucose measuring system Kit Contents



- | | |
|-------------------------|----------------------|
| 1. LipidPro™ Meter | 5. Two AAA batteries |
| 2. Instructions for Use | 6. Lancing Device |
| 3. Warranty Card | 7. Lancet |
| 4. Carrying Case | |

Your LipidPro™ lipid profile and glucose measuring system has been sealed to protect the contents.

If you find your seal has been broken, please return it to the place of purchase.

Required but not provided

- LipidPro™ Brand Test Strips
- LipidPro™ Brand Control Solutions
- Capillary Rods
- Control Solution Range Cards

LipiPro™ Testing Meter



Strip Connector

Glucose Strip measurement connector

Strip discard function

Strip discard function by push toward outside

LCD Screen

Display measurement level of glucose, TC, HDL, TG, including time and message

Up button(▲)

Maneuvering button for choice of function in each mode

Down(▼) button

Maneuvering button for choice of function in each mode & RFID (RFID) operation button & Printer operation button

Mode button(⏻)

Memory mode, Setting mode, Cholesterol measurement mode, On and Off button

Cholesterol Testing part

Cholesterol strip inserting part

Buzzer sound print part

Printing part for Warning sound, Fixed sound and buzzer sound

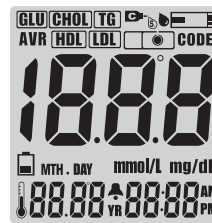
Battery Cover

Purpose for Battery replacement and fixed cover



1. Do not use LipiPro™ meter in a dry environment, especially if synthetic materials are present. Synthetic clothes, carpets, etc., may cause damaging static discharges in a dry environment.
2. Do not use LipiPro™ meter near cellular or cordless telephones, walkie talkies, garage door openers, radio transmitters, or other electronic or electrical equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.

LipidPro™ Testing Meter Display

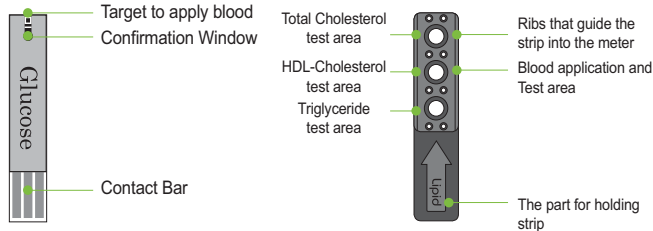


	Blood glucose
	Total cholesterol
	Triglyceride
	HDL-cholesterol
	LDL-cholesterol
	Blood insertion for glucose test
	Blood insertion for lipid profile test
	Sample blood
	Serum
	Control Solution Symbol
CODE	Displaying code number of Test Strips
	Short of batteries
	Alarm
mmol/L mg/dL	Testing unit
	Temperature & date of test
	Hour & Date of test
AVR	Average Test Result(only for glucose)
MTH . DAY	Month & Day

LipidPro™ Test Strip Information

Use only LipidPro™ Test Strips with your LipidPro™ meter.

*Note: Please read the individual Package insert of LipidPro test strip for complete detail information.



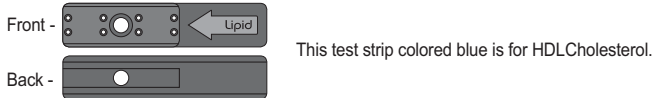
1. Lipid Profile test strip(Black)



2. Total Cholesterol test strip((Red)



3. HDL-Cholesterol test strip(Blue)

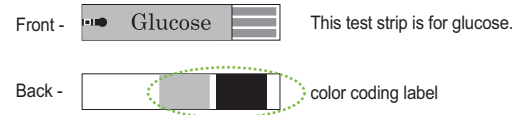


4. Triglyceride test strip(Green)



LipiPro™ Test Strip Information

5. Glucose test strip



Caution

1. Store the LipidPro™ test strip vials in a cool and dry place. Keep out of direct sunlight . Do not freeze.
2. Store test strips in their original vial only. Do not mix the test strips in new vials or in any other container.
3. Immediately replace the vial cap and close tightly after removing the LipidPro™ test strip
4. Make a note of the discard date which is three months from the date you first open a new vial of strips. Throw LipidPro™ test strip and vial away after the discard date.
5. Avoid getting dirt, food, and water on the test strip. Do not handle test strips with wet hands.
6. Do not use the test strips after the expiry date printed on the package or vial since it may cause inaccurate results.
7. Do not bend, cut, or alter the test strip.
8. LipidPro™ test strips are for single use only. Do not re-use.
9. Do not test at the following temperature condition:
 - LipidPro™ test strips below 64°F (18°C) or above 86°F (30°C).
10. Do not test with humidity below 10% or above 90%.
11. Refer to additional information in the LipidPro™ test strip package.
12. Avoid getting dirt, food, and water on the color-coding label (backside of glucose test strip).
13. Discard the used test strips carefully according to the local regulations.

LipidPro™ Test Strip Information

*NOTE: Please read individual Package of LipidPro™ test strip for complete detail information.

LIMITATIONS OF SYSTEM (for Lipid profile test):

Lipid Profile Test Strips provide accurate when the following constraints are observed :

- Do not use neonate samples

1) Physicians - Please note the following interferences that may affect the results:

- For is with capillary whole blood.
- Extremes in hematocrit may affect test results. Hematocrit levels less than 30% may cause falsely high reading and hematocrit level greater than 55% may cause falsely low reading.
- Interference: Acetaminophen, Uric acid, ascorbic acid (vitamin C), and other reducing substances (when occurring in normal blood or normal therapeutic concentrations) do not significantly affect results. However, abnormally high concentrations in blood may cause inaccurately high results.
- Use LipidPro system™ at the frequency your doctor recommends testing for total cholesterol, HDL-cholesterol, and triglyceride.

Performance Characteristics:

The performance of the Lipid Profile test strips has been evaluated in laboratory and in clinical tests (Please refer to strip instructions for use in for more details). Testing Range: The test range of Lipid Pro™ is 100 ~ 400mg/dL for Total Cholesterol, 25~80mg/dL for HDL-Cholesterol and 70 ~ 600mg/dL for Triglyceride.

1) Accuracy

The accuracy lipid profile results obtained with the LipidPro™, test system were compared to results obtained with Reference device. Lipid profile levels were measured on 1200 capillary whole blood specimens at three different centers.

Total Cholesterol

Sample Type	slope	y-interceptor	R ²
Capillary	1.0013	2.2025	0.9933

HDL-Cholesterol

Sample Type	slope	y-interceptor	R ²
Capillary	0.9935	-1.2036	0.9938

Triglyceride

Sample Type	slope	y-interceptor	R ²
Capillary	1.0169	-0.2810	0.9938

Precision

- The precision Total Cholesterol, HDL-cholesterol and Triglyceride test results were measured with Three level venous whole blood samples for 20 days.

Total Cholesterol

Mean Conc. (mg/dL)	120.0	231.8	349.7
SD (mg/dL)	1.9	3.2	4.0
CV (%)	1.6	1.4	1.1

Triglyceride

Mean Conc. (mg/dL)	130.0	357.2	530.1
SD (mg/dL)	1.9	5.0	6.1
CV (%)	1.4	1.4	1.2

HDL-Cholesterol

Mean Conc. (mg/dL)	30.9	51.9	73.0
SD (mg/dL)	0.8	1.1	1.6
CV (%)	2.5	2.1	2.2

Lipid Profile

	Level 1			Level 2			Level 3		
	TC	TG	HDL	TC	TG	HDL	TC	TG	HDL
Mean	118.9	128.5	31.5	236.0	357.6	50.2	348.0	529.0	71.2
SD	2.1	2.2	0.7	3.4	4.3	1.1	5.	6.0	1.5
CV	1.8	1.7	2.3	1.4	1.2	2.2	1.4	1.1	2.1

- The precision Total cholesterol, HDL-cholesterol and Triglyceride test results were measured with two control solutions for 20 days.

Total Cholesterol

Mean Conc. (mg/dL)	150.3	250.6
SD (mg/dL)	2.2	3.6
CV (%)	1.5	1.4

HDL-Cholesterol

Mean Conc. (mg/dL)	59.9	29.9
SD (mg/dL)	1.3	0.8
CV (%)	2.1	2.7

Triglycerode

Mean Conc. (mg/dL)	120.5	250.5
SD (mg/dL)	2.9	2.8
CV (%)	2.4	1.1

LipidPro™ Test Strip Information

*NOTE: Please read individual Package of LipidPro™ test strip for complete detail information.

LIMITATIONS OF SYSTEM (for Glucose test):

The LipidPro™ Glucose Test Strips provide accurate results when the following constraints are observed:

- Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemic hyperosmolar state, with or without ketosis. Critically ill patients should not be tested with blood glucose meters.
- Use only the LipidPro™ glucose test strips with the LipidPro™ meter.
- Use fresh capillary whole blood only.
- Do not use neonate samples.
- The test strips are for single use only. Do not reuse.
- Dehydration may lower test results.
- Glucose test strips used above altitudes of 10,000 feet will have an effect on test results.

Physicians - Please note the following interferences that may affect test results:

- Extremes in hematocrit may affect test results. Hematocrit levels less than 30 % may cause falsely high reading. Hematocrit levels greater than 55 % may cause falsely low readings.
- Interferences: Acetaminophen, Uric acid, Ascorbic acid (Vitamin C), and other reducing substances when occurring in normal blood or normal therapeutic concentrations do not significantly affect results. However, abnormally high concentrations may cause inaccurately high results.
- Lipemic samples; Cholesterol up to 500 mg/dL or triglyceride up to 3000 mg/dl do not significantly affect the results. Values beyond these levels should be interpreted with caution.
- Blood samples that contain a high concentration of dissolved oxygen may lower the test result.
- EDTA containing tube is recommended as an anticoagulant tube.

Performance Characteristics:

The performance of the glucose test strips has been evaluated in laboratory and in clinical tests.

Measurement Range: The measurement range of the LipidPro™ Glucose Testing is 20 to 600 mg/dL.

Accuracy:

The accuracy results obtained with the LipidPro™ lipid profile and glucose measuring system were compared to glucose results obtained with the Hitachi Glucose Auto meter 747, a laboratory instrument. Glucose levels were measured on 160 patients at three different clinical centers.

System accuracy results for glucose concentration <75 mg/dL

Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
24/27 (93%)	27/27 (100%)	27/27 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL

Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL	Within ± 20mg/dL
84/133 (63%)	119/133 (89%)	129/133 (97%)	133/133 (100%)

Alternate site :

Alternate site glucose test results obtained from alternative sites were compared to the glucose results obtained with the Hitachi Glucose Auto meter 747 (reference method), a laboratory instrument. Glucose levels were measured at three different clinical centers.

Test results of **DORSAL HAND** were compared to the reference method.

System accuracy results for glucose concentration <75mg/dL

Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
4/5 (80%)	5/5 (100%)	5/5 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL

Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL	Within ± 20mg/dL
84/133 (63%)	119/133 (89%)	129/133 (97%)	133/133 (100%)

Test results of **VENTRAL HAND** were compared to the reference method.

System accuracy results for glucose concentration <75mg/dL

Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
4/5 (80%)	5/5 (100%)	5/5 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL

Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL	Within ± 20mg/dL
111/145 (77%)	143/145 (99%)	145/145 (100%)	145/145 (100%)

Test results of VENTRAL HAND were compared to the reference method.

System accuracy results for glucose concentration <75mg/dL

Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
4/5 (80%)	5/5 (100%)	5/5 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL

Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL	Within ± 20mg/dL
111/145(77%)	143/145 (99%)	145/145 (99%)	145/145(100%)

Test results of UPPER ARM were compared to the reference method.

System accuracy results for glucose concentration <75mg/dL

Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
4/5 (80%)	5/5 (100%)	5/5 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
1.9/145(75%)	143/145 (99%)	145/145 (100%)	145/145(100%)

Test results of FORE ARM were compared to the reference method.

System accuracy results for glucose concentration <75mg/dL

Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
4/5(80%)	5/5 (100 %)	5/5 (100 %)

System accuracy results for glucose concentration ≥ 75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
95/145(66%)	137/145 (94%)	143/145 (99%)	145/145(100%)

Test results of THIGH were compared to the reference method.

System accuracy results for glucose concentration <75mg/dL

Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
3/5(60%)	5/5 (100%)	5/5 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL

Within ± 5mg/dL	Within ±10%	Within ±15%	Within ±20%
103/145(71%)	137/145 (94%)	144/145 (99%)	145/145(100%)

Test results of CALF were compared to the reference method.

System accuracy results for glucose concentration <75mg/dL

Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL
2/5(40%)	5/5 (100 %)	5/5 (100%)

System accuracy results for glucose concentration ≥ 75 mg/dL

Within ±5%	Within ±10%	Within ±15%	Within ±20%
100/145(69%)	138/145 (95%)	145/145 (100%)	145/145(100%)

Precision:

Repeatability evaluation for venous blood samples.

Mean (mg/dL)	45.0	84.7	130.8	206.2	341.8
CV (%)	3.1	2.1	2.2	2.6	2.4

Intermediate evaluation for control solutions.

Mean (mg/dL)	49.7	100.5	300.3
CV (%)	2.3	1.7	0.7

Setting Your Meter

Battery Use

The LipidPro™ requires two(2) AAA 1.5 volt alkaline batteries.

When to replace the batteries:

The meter will give you an indication on the display that the batteries need to be changed. When the display reads battery sign, no more tests can be run until the batteries are changed. Always replace the batteries with high quality alkaline batteries. It is recommended to keep a spare set of batteries on hand. To extend battery life, remove the Test Strip as soon as a result is displayed.

How to install /replace the batteries:

1. Open the battery door on the back of the LipidPro™ .
2. Remove old batteries from the compartment and safely discard.
3. Insert the new batteries into the battery compartment as marked on the inside compartment.
4. Replace the battery door. To make sure the batteries were installed correctly, push either one of the two buttons on the front of the meter to turn the LipidPro™ on.

Caution

Remove both batteries from the battery compartment and dispose of them according to your institution's guidelines.

Setting Your Meter

Setting Mode

It is recommended to set your LipidPro™ meter properly before using.



The meter enters setting mode with a beep sound by pressing the mode (⏻) button for 3 or more seconds in the stand-by status. Press mode (⏻) button for the next step.



By pressing ▲▼, adjust year and press MODE (⏻) button.

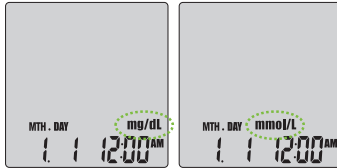


By pressing ▲▼, adjust date, month and time, and then press MODE (⏻) button.

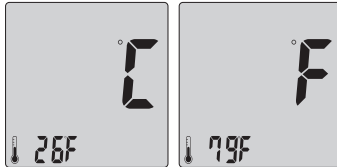
Caution

Make sure that the date and time are set properly to enable your data to be stored and downloaded properly.

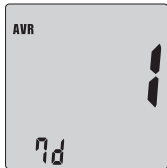
Setting Your Meter



By pressing Up(▲) or Down(▼) button, select testing unit and press Mode(⏻) button.



By pressing ▲▼, select temperature unit and press MODE (⏻) button.



By pressing ▲▼, select average date and press MODE (⏻) button.



By pressing ▲▼, select Alarm ON/OFF and press MODE (⏻) button. If you select Alarm ON, you can set the time by pressing ▲▼ and press MODE (⏻) button (you can set 2 alarms).



By pressing ▲▼, select print ON/OFF and press Mode(⏻). If you select 'ON' and press Mode(⏻) button to activate it. If you select print, this setting mode is completed.

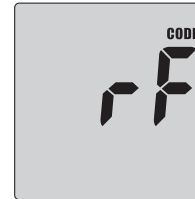
Before Testing – Coding the meter

LipidPro™ has two coding systems:

Lipid Profile test - each vial of test strip has RFID-tag which enables the meter to recognize its code number automatically.

Glucose test - each test strip has color-tag on the back of the strip which enables the meter to recognize its code number automatically.

• Coding for Lipid Profile test



Press RFID(▼) button for 3 or more seconds.



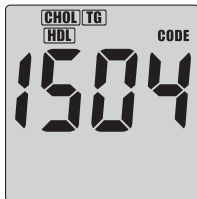
Place the RFID-tag on the strip bottle to the area of the RFID symbol((RF)) on the meter.

Caution

The radiation of RFID recognition is within 2 cm.

The meter will be back to stand-by status if there is no operation within 5 seconds.

Before Testing – Coding the meter



Once it recognizes the code number, the meter displays the code value and test item(s) for 2 second and return to the stand-by status.



Check the code number on the display on the meter with that on the strip bottle.

Before Testing – Coding the meter

• Coding for Glucose test



1. Firmly insert the glucose test strip into the test port of LipidPro™ meter, and then the power will automatically turn on with the code number, temperature and time.



2. Make sure the code number on the display of the meter correspond with that on the test strip bottle. The color tag of the back on the test strip automatically recognizes the code number in this system.

Caution

1. If the code is not displayed after 3 seconds, pull the test strip out of the port and re-start the procedure from the beginning.
2. If the code on the display 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 re-insert the test strip.
4. Avoid testing under direct sunlight, for a more accurate test result.
5. If you apply your sample too early, Error message will appear on the display(refer to page 52).

Checking the system with control solution

Quality control by control solution

Control testing, also known as quality control testing, is used to ensure all the parts of the test system are working properly together and the test results are accurate and reliable within the limits of the system. It is available online at www.infopiausa.com or call at 1-888-446-3246.

The users should follow their facility's policies on when controls should be tested (for example: with each new Test strip lot; monthly as a continued check on storage conditions; whenever issues (storage, operator, or other) are identified or there are questions about the results).

The control solution should be used

- Whenever you suspect the meter or test strip is not functioning properly.
- If your blood glucose test results are not consistent with your symptoms or if you think they are not accurate.
- If you have dropped the meter
- For quality control in the point of care
- For Teaching or learning the system

Caution

The LipidPro™, Control Solutions are sold separately. The TC(Level 1, Level 2), TG(Level 1, Level 2), HDL(Level 1, Level 2) and Glucose(Low, Normal and High) control solutions can be obtained though.

Checking the system with control solution

Caution

Please check the expiry date on the instructions for use provided with each control solution.

Total Cholesterol strip or Lipid profile test strip in Total Cholesterol test area should be used only Total Cholesterol control level 1, level 2.

HDL Cholesterol strip or Lipid profile test strip in HDL Cholesterol test area should be used only HDL Cholesterol control level 1, level 2.

Triglyceride strip or Lipid profile test strip in triglyceride test area should be used only triglyceride control level 1, level 2.

Glucose test strip should be used only Glucose control solution Low, Normal and High.

It is recommended that the control solution is stored at room temperature before testing.

Please keep the control solution range card until you use up the applicable strip.

• Lipid Profile test

Testing procedure

1. Press RFID(▼) button for 3 or more seconds.



2. Place of the RFID-tag on the strip bottle to the area of the RFID symbol on the meter.



Caution




The radiation of RFID recognition is within 2cm.

The meter will revert back to stand-by status if there is no operation within 5 seconds.

Checking the system with control solution

3. Check the code number on the display of the meter with that on the strip bottle.



4. Insert the test strip and press Mode () button. Press Up () button and the meter displays the symbol of control solution ().



5. In 5 seconds the symbol of sample blood is blinking.



6. Place a drop of solution on a clean, dry surface (for example: the lid of your test strip vial).



7. Apply the prepared control solution to the test strip by using capillary rod.



8. Apply the control solution to the test area.



Caution : If you want to test all three test items (TC, HDL and TG), please collect the control solution with each capillary rod.

9. The test results will be displayed in about 2 minutes.

Caution : Whenever you change the test strip vial, Please follow the code recognition procedure.



Checking the system with control solution

Testing tips:

- Please make a test after reading the instructions for use of control solution thoroughly.
- Keep clean of the test area on the meter.
- Keep test strips and control solutions in proper condition according to the instructions for use provided, such as expiry date, storage condition and so forth.
- Before testing, make sure that the test strips and the meter for lipid profile are at the temperature of 18-30°C(64-86°F) and those for glucose at 10~40°C(50~104°F).

Caution

If your control solution test falls out of range, please follow the next steps before contacting customer support:

- Check the expiry dates on all the products you are using.
- Try another control solution test.
- If this test falls out of range, try another control solution test with a new unopened bottle of strips.
- After following the appropriate steps and the control solution test still falls out of range, do not perform a test. Please contact the infopia customer service at +82-31-423-6170 or sales@infopia21.com.
- The control solution range is not the recommended range for your test.
- Discard the used control solution and the test strips carefully according to the local regulations.

• Glucose test

Testing procedure

1. Shake the control solution before use.



Checking the system with control solution

2. Discard the 1st drop of control solution, this will eliminate any residue.



3. Place a drop of control solution on a clean, dry surface(ex. The lid of the test strip vial).



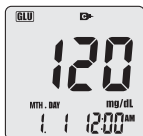
4. Insert a test strip into the port firmly and press Up(▲) button. The symbol of control solution(☒) will appear on the display of meter. This will allow you to differentiate between a control solution test and an actual blood test for future reference.



5. Apply the test strip to the control solution.



6. Results appear in 3 seconds. Compare the result to the range printed on the test strip vial, the results should fall within that range.

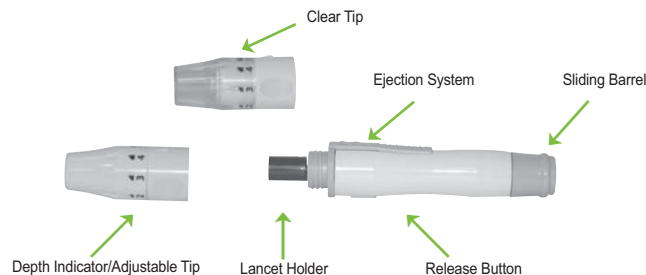


INSTRUCTIONS FOR LANCING DEVICE

PRECAUTIONS

- Never use a lancet that has been used by someone else. This could lead to contamination.
- If the lancing device is to be used by another person, the unit must be properly disinfected and a new tip and lancet must be used.
- Do not leave the lancet in the device after use.
- A new lancet must only be placed into the lancing device directly before testing.
- This device has many small parts and could be a choking hazard for children if swallowed.
- In the case of hospital use, hospitals need to consult their own infection control protocols in order to avoid any contamination.
- Always dispose of the used lancet in a biohazard garbage container.

COMPONENTS



HOW TO USE

Wash your hands carefully with warm water to increase the circulation of the blood into the fingers.

Dry hands thoroughly until the finger to be pricked is completely dry. Please read the following steps with corresponding illustrations to understand how to use the lancing device.



1. Unscrew the tip of the lancing device by turning it counter-clockwise while holding the base firmly.



2. With two fingers, pull out the lancet carrier and hold it in place.



3. While holding the lancet carrier, insert a new sterile lancet into the bottom of lancet carrier.



4. Twist the cap of the lancet off.



5. Put the tip of the lancing device back on and turn it clockwise.



6. Hold the tip firmly in one hand then pull out the sliding barrel with the other hand. This will cock the lancing device.



7. Place the lancing device in place. Hold the lancing device firmly against the side of the finger, with the cap resting on the finger. (The harder it is pressed the deeper the puncture.) Press the release button to take a sample.



8. Unscrew the tip of the lancing device by turning it counter-clockwise.



9. Push the lancet ejector forward with the thumb and simultaneously pull out the sliding barrel to dispose of the used lancet in a proper biohazard container.

RECOMMENDED AVAILABLE LANCETS

Some general sterilized lancets are BD-Ultra Fine, Cleanlet Fine, E-Z Ject, G-P Lite, Microlet, Monolet, One Touch, Soft Touch, Therasense, Ultra TLC and Unilet GP.

Note: Some less known lancets may not work properly with the lancing device due to their dimensions.

Please, contact your supplier to make sure you are using proper lancets.

Testing Your Blood - Preparation

Blood testing

A strip instructions for use is included with each box of test strips. Please read the strip instructions for use along with this section completely and carefully before testing.

Testing supplies



To perform a blood test you need:

- LipidPro™ meter
- Test strips
- Sterile lancet
- Capillary rod
- Lancing device

Caution

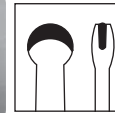
- 1) To reduce the chance of infection.
 - The Lancing Device and sterile lancets should NOT be shared with others.
 - Always use a new, sterile lancet.
 - Lancets are for single use only.
 - Avoid getting hand lotion, oils, dirt, or debris in or on the Lancets and the Lancing Device
- 2) Do not operate the meter in direct light.
- 3) 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.

Testing Your Blood - Preparation

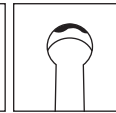
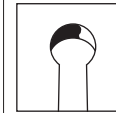
1. Lipid Profile test

Capillary blood process

When you collect the sample, please use the capillary rod provided with the test strip package. Make sure enough sample has been collected to the capillary rod.



[Correct]



[Incorrect]

Caution

If blood is stained outside the sample area, carefully wipe the stain out with a tissue. Do not allow the wiping tissue to touch the open end of the sample area of the collecting leg.

2. Glucose test



Place your fingertip to the top edge of glucose test strip.

Correct : Completely filled



completely filled

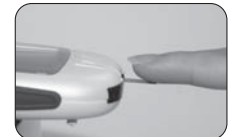


[Correct]

Incorrect : Poorly filled




poorly filled



[Incorrect]

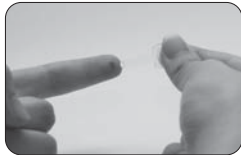
Quick reference of test procedure -Lipid test



1) After coding the meter, insert the test strip and press Mode () button



2) Prick the finger with a lancing device for the sample blood.



3) Collecting the sample blood to the capillary rod. Make sure the enough sample has been collected to the capillary rod.



4) Contact the capillary rod with the sample to the test area of the strip so as to start the test.

Caution

- If the test result is out of the test range, the Hi/Lo message will be shown on the LCD.
- Safely discard used test strips, lancets and capillary rods.
- It is required to insert the blood sample on the Lipid Pro test strip within 3 minutes while the blood inserting icon is blinking.

Quick reference of test procedure -Glucose test



1) Insert the glucose test strip. Code number is automatically displayed. Compare with code number printed on test strip vial. If not identical discard the test strip and restart.



2) Prick the finger with a lancing device for the sample blood.



3) Apply blood sample until confirmation window is completely filled. Meter automatically begins to countdown. If the countdown does not start, do not add more blood to the test strip! Discard the test strip a restart testing.



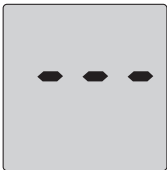
4) Test results appear in 3 seconds.


Caution

- If the test result is out of the test range, the Hi/Lo message will be shown on the LCD.
- Safely discard used test strips and lancets.

Test Procedure

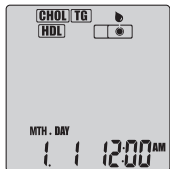
1. Lipid test - Test for multi items



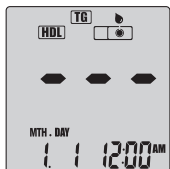
Press mode () button after a test strip is inserted and confirm if the meter recognizes the right test strip by checking out the corresponding symbol on its display.



The meter displays the code number and the testing symbols (**CHOL** , **HDL** , **TG**) together. In 5 seconds the meter automatically enters into testing mode.

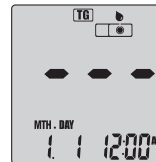


The symbol of blood is blinking.

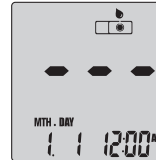


Please apply the sample to the total cholesterol test area of test strip until you hear beep sound. Then, the symbol, **CHOL** disappears.

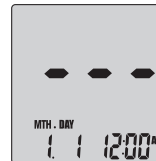
Test Procedure



Please apply the sample to the HDL-cholesterol test area of test strip until you hear beep sound. Then, the symbol, **HDL** disappears.



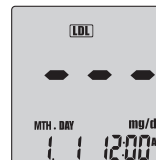
Please apply the sample to the triglyceride test area of test strip until you hear beep sound. Then, the symbol, **TG** disappears.



The meter displays **---**, blinking in order, which means it is under test.



Total cholesterol is displayed with 3 times of buzzing sound.



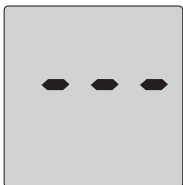
In the case of LDL-cholesterol, if density of triglyceride is over 350mg/dL, and/or TC, HDL, TG measurement range are displayed as Hi(above the measurement range) or Lo(below the measurement range), it cannot be measured.


In order to check each test item, please press up or down button. You can check out each result of Total Cholesterol, HDL-Cholesterol and Triglyceride.

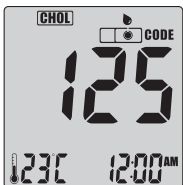
Test Procedure

2. Test for each single item

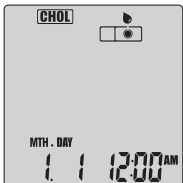
1) Total Cholesterol test



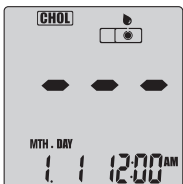
Press Mode () button after a test strip is inserted and confirm if the meter recognizes the right test strip by checking out the corresponding symbol on its display.



The meter displays the code number and the testing symbols (**CHOL**) together. In 5 seconds the meter automatically enters into testing mode.

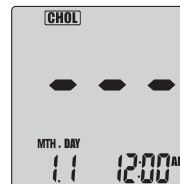


The symbol of blood is blinking.

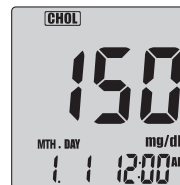


Please apply the sample to the test area of test strip until you hear beep sound.

Test Procedure

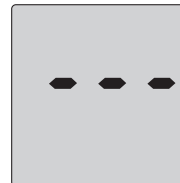



The meter displays , blinking in order, which means it is under test.

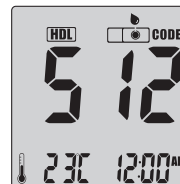


When the test is completed (in about 2 minutes), the meter displays the test result of **CHOL** with the symbol.

2) HDL-Cholesterol test

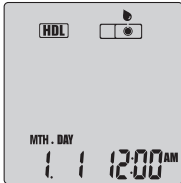


Press Mode () button after a test strip is inserted and confirm if the meter recognizes the right test strip by checking out the corresponding symbol on its display.

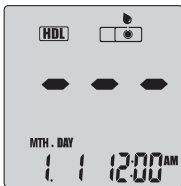


The meter displays the code number and the testing symbols (**HDL**) together. In 5 seconds the meter automatically enters into testing mode.

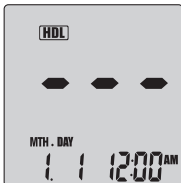
Test Procedure



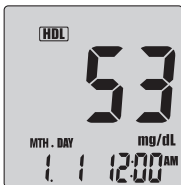
The symbol of blood is blinking.



Please apply the sample to the test area of test strip until you hear beep sound.



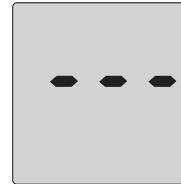
The meter displays **---**, blinking in order, which means it is under test.




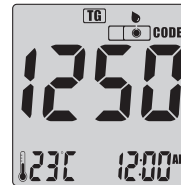
When the test is completed (in about maximum 2 minutes), the meter displays the test result of **HDL** with the symbol.

Test Procedure

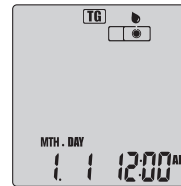
3) Triglyceride test



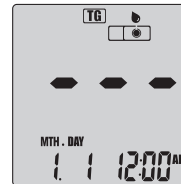
Press mode () button after a test strip is inserted and confirm if the meter recognizes the right test strip by checking out the corresponding symbol on its display.



The meter displays the code number and the testing symbols (**TG**) together. In 5 seconds the meter automatically enters into testing mode.

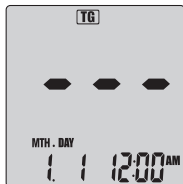


The symbol of blood is blinking.



Please apply the sample to the test area of test strip until you hear beep sound.

Test Procedure



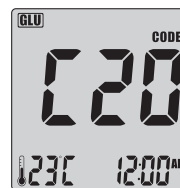
The meter displays **---**, blinking in order, which means it is under test.



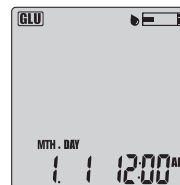
When the test is completed (in about 2~4 minutes), the meter displays the test result of **TG** with the symbol.

Test Procedure

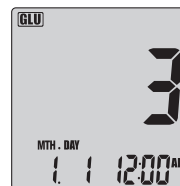
3. Glucose test



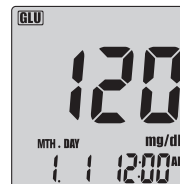
When the test strip is inserted, the meter displays the code number for 3 seconds.



The symbol of blood is blinking.



Once the sample is applied, the meter displays 3, 2, 1 in order.



Then, the meter completes the test with the test result.

Glucose test strip Discard Function



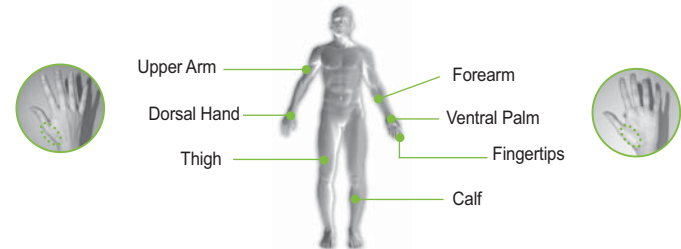
1. After checking your test result, slide the ejector button twice forward to remove the test strip from the meter.
2. Discard the used strip and lancet to a proper place, according to the local regulation.

Caution

1. If you push the discard button forward too much, it may be damaged.
2. Do not give strong impact to meter.

Alternate site testing

Note : This alternate site testing is applied to glucose testing only.



Important Information About Using Alternative Sites Testing :

- Alternate sites where you can test are dorsal hand, ventral palm, upper arm, forearm, calf, and thigh.
- Under certain conditions, blood glucose test results obtained using samples taken from your alternate sites may differ significantly from fingertip samples. Do not use alternate sites when your blood glucose is changing rapidly such as following a meal, as insulin dose, or associated with physical exercise.
- When blood glucose is changing rapidly, fingertip samples show these changes more quickly than alternate sites samples.
- When your blood glucose is falling, testing with a fingertip sample may identify a hypoglycemic (low blood glucose) level sooner than a test with an alternate sites sample.
- Use alternate sites samples only for testing prior to or more than two hours after meal, insulin doses, or physical exercise.
- Testing performed within two hours after meals, insulin doses, or physical exercise or whenever you feel that your glucose levels may be changing rapidly should be done from the fingertip.
- You should also use fingertip testing whenever you have a concern about hypoglycemia (insulin reactions) such as when driving a car, unawareness (lack of symptom to indicate a sp ainrsticuilnla rrlay aifc ytiouon)s, uafsfe fro rfreoarmr h tyepsotignlyc memayic fail to detect hypoglycemia.

Performing a Blood Test using an Alternate site

Important :

We recommend that you test on your fingertip if you are testing for hypoglycemia (low blood glucose) or if you have a history of reoccurring hypoglycemia.



To ensure accurate results when lancing your forearm, upper arm, hand, thigh, or calf, wash the test site with soap and water.

Make sure there is no cream or lotion on the test site. Thoroughly dry your hands and test site.

- Consult your healthcare professional(doctor) before you begin using the alternate site

Caution

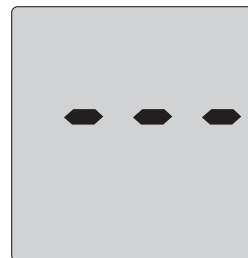
- To ensure accurate results when lancing your arm (Upper arm or forearm), leg (calf or thigh) or palm (ventral palm or dorsal hand), wash your hand and test site with soap and water.
- To receive accurate test results, at least 0.3µg minimum sample volume is required.

Reviewing Your Results

Every test result is stored with its date and time of test.

The meter stores up to 200 memories regardless of test items.

When the test results is over the capacity memory, the recent test result will replace with the oldest test result.



When there is no memory in the meter

How to enter into Memory Mode


In order to enter into Memory mode, please press the MEM(▲) button in standby mode.

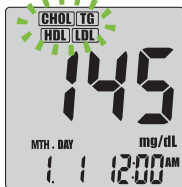
By using ▲▼, you can recall lipid profile and glucose test results. Press the mode button after you select between lipid profile and glucose test results you would like to review.

Reviewing Your Results

Lipid Profile test results

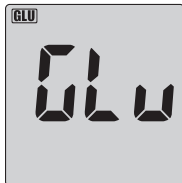



Press Mode () button.

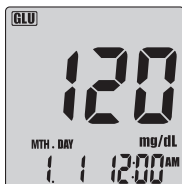


Press ▲▼ Button for reviewing the test result.

Glucose



Press Mode () button.

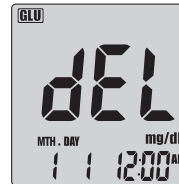


Press Up(▲) button and the meter displays the average data and the symbol (**AVR**) you had set previously.
please press ▲▼, button for reviewing.

Note:

Control solution reading are not included in the average.

Deleting Your Results



deleting individual test result

To delete any individual test result in the memory press ▲ or ▼ button for 3 or more seconds, while the test result to delete is displayed. Then, **dEL** is blinking. After the third beep sound the test result is deleted.

If the print is set "ON", press ▼ button in 3 or more seconds can be print memory results.



deleting all test results

To delete all test results press ▲ and ▼ button at the same time for 3 or more seconds, while any test result is displayed.

Then, **ALL** is displayed and **dEL** is blinking. After the third beep sound all test results are deleted.

Printing Your results



Printing test result

Press ▼ button in 3 or more seconds can be print memory results. (If the print is set "ON")

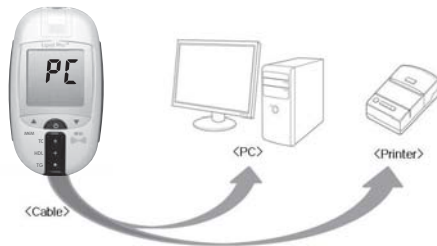
Caution

The deleted test results can't be recovered. Please be careful in deleting the test results.

Lipid pro™ Software and Thermal Printer

The Lipid Pro™ results can be transmitted to a personal computer. Lipid Pro™ software and an interface cable are required for transmitting results of lipid profile and glucose measurement system to a personal computer.

The software is available free of charge from <http://www.infopia21.com> Interface(PC)cable and Thermal printer can be bought from your local distribute proviver.



Cleaning Your Meter and Maintenance

Meter

Your meter does not require special maintenance or cleaning. Avoid getting dirt, dust, blood, control solution, or liquids on the meter, the test port, or data port.

Your meter operation temperature is 64~86°F(18~30°C).

It is recommended that you store the meter in its carrying case after each use.

A cloth dampened with water and mild detergent can be used to wipe down the outside of the meter. Your LipidPro™ meter is a precision instrument. Please handle it with care.

- 1) Do not disassemble or modify the meter.
- 2) Do not place the meter in places with high humidity.
- 3) Do not place the meter in polluted or dusty areas.
- 4) Do not expose the meter to impact, shock, vibration, inclination, etc. and keep it in a safe place.
- 5) Do not place the meter with chemical products or with gases.
- 6) Keep it away from direct sunlight.
- 7) Close the vial, immediately after taking out the Test Sensor for the test.
- 8) Keep the Test Sensor away from children.
- 9) Keep the lancing device clean by using alcohol or soap and water.
- 10) The meter should be cleaned with soft cloth or paper tissue, in case of dirt.

Lancing Device:

Clean the lancing device and caps with soap and luke warm water. To disinfect the lancet device, prepare a disinfectant solution of one part household bleach to 10 parts water. Dampen a cloth with this solution and wipe the lancet device thoroughly. Soak only the cap for at least 30 minutes in the disinfectant solution.

Do not soak the lancet device in liquid. Rinse the lancet device and cap with water and dry thoroughly. Properly discard the used lancet.

Troubleshooting

Message	Probable cause	Action required
	<p>This message appears when the hardware defects. Ex) The Flash ROM write/read function does not work. Oxidization voltage is out of range, etc.</p>	<p>Reboot the meter by placing the batteries again when no test strip is inserted. Please contact your local representative or customer support when the problem persists.</p>
	<p>This message appears when test strip may be contaminated or reused. (Only for Blood glucose measurement)</p>	<p>Please insert a new test strip and perform your test again.</p>
	<p>This message appears when the blood is not enough (Only for Blood glucose measurement)</p>	<p>Please insert a new test strip and apply the sufficient sample blood.</p>
	<p>This message appears when strip signals without any Blood or Control solution or other sample applying. (Only for Blood glucose measurement)</p>	<p>Please insert a new test strip and perform your test again.</p>

Troubleshooting

Message	Probable cause	Action required
	<p>This message appears when blood sample is input before the symbol for blood blinks.</p>	<p>Please wait for the meter displays the icon blinking before applying your blood sample.</p>
	<p>This message appears when the color bar of the strip is dirty or not good or there is too much light.</p>	<p>Please insert a new test strip and perform your test again. Avoid testing under direct sunlight.</p>
	<p>This message appears when Lipid strip is removed during the test or measured value of TC is over 600mg/dL</p>	<p>Test again with a new strip if the strip is removed during the test. Unless the strip is removed during the test, the test result is out of measurable range. Please consult your physician.</p>
	<p>Problem with transmit of PC or Printer.</p>	<p>Check your connection port of PC/printer and reconnection. If the problem is still unsolved, Please contact your local representative or customer support.</p>
	<p>The test result is higher than the following. Glucose : more than 600mg/dL TC : more than 400mg/dL TG : more than 600mg/dL HDL : more than 80mg/dL</p>	<p>Please retest with a new test strip. If the problem persists, please contact your local representative or customer support.</p>

Troubleshooting

Message	Probable cause	Action required
	The test result is lower than the following. Glucose : less than 20mg/dL TC : less than 100mg/dL TG : less than 70mg/dL HDL : less than 25mg/dL	Please retest with a new test strip. If the problem persists, please contact your local representative or customer support.
	Lipid profile : The ambient temperature is over 86°F(30°C). Glucose : The ambient temperature is over 104°F(40°C)	Place the meter at the temperature between 64~86°F(18~30°C) for lipid profile test and 50~104°F(10~40°C) for glucose test for more than 10 minutes and test again
	Lipid profile : The ambient temperature is less than 64°F(18°C) Glucose : The ambient temperature is less than 50°F(10°C)	Place the meter at the temperature between 64~86°F(18~30°C) for lipid profile test and 50~104°F(10~40°C) for glucose test for more than 10 minutes and test again.
	This message appears with 3 times of beep sound if the mode button is pressed while no test strip of lipid profile is inserted.	Please make sure to insert a test strip of lipid profile when performing the test.
	This message appears with 3 times of beep sound with 'CODE' and 'Er' on the display are none memory code and/or unrecognized strip used.	Please recognize the code and retest (refer to page 21)

Product Specifications

Inconsistent or unexpected test results
 If you continue to get unexpected results, check your system with control solution.
 If you experience symptoms that are not consistent with your lipid and glucose results, first be sure you have followed all instructions in this Instructions for use, then, contact Infopia Customer Service. Never ignore symptoms or make significant changes to the control program.

Product Specification

Lipid Profile Test	Devison	Content
	Sample type	Capillary whole blood, Serum, Venous blood
	Measuring principle	Spectroscopy
	Testing Types	Total cholesterol HDL-cholesterol Triglyceride LDL-cholesterol
	Testing method	Enzymatic-colorimetric method
	Testing range	Total cholesterol : 100~400mg/dL, Triglyceride : 70~600mg/dL, HDL-cholesterol : 25~80mg/dL
	Testing time	About 2mins
	Calibration	Plasma_Equivalent
	Sample volume	7uL
	Operating Humidity	10 ~ 90 %
Operating Temperature	64 ~ 86°F(18 ~ 30°C)	
Storage Humidity	10 ~ 90 %	
Storage Temperature (meter, Strip)	36 ~ 86°F(2 ~ 30°C)	
HCT Range	30 ~ 55%	

Product Specification

	Devison	Content
Glucose test	Sample type	Capillary whole blood, Serum, Venous blood
	Measuring principle	Electrochemical
	Testing Types	Glucose
	Test range	10~600 mg/dL
	Sample volume	0.3uL
	Testing time	3sec
	Calibration	Plasma - Equivalent
	Operating Humidity	10 ~ 90 %
	Operating Temperature	50~104°F(10~40)°C
	Storage Humidity	10 ~ 90 %
	Storage Temperature	36 ~ 86°F(2 ~ 30)°C
	HCT Range	30 ~ 55%
RFID	Standard Supported	ISO/IEC 15693
	Nominal Read/Write Range	< 2cm
	Antenna	Integrated
	Frequency	13.56 MHz

Product Specification

Devison	Content
Size(W*D*H)	61*109*23(mm)
Weight	77.5g (including battery)± 1g
Power supply	(AAA) 1.5V x 2
Battery life time	Running over 1,000 times
PC Port	For cable connection between PC (or thermal printer) and Meter.

Warranty

Manufacturer's Warranty:

INFOPIA USA, LLC warrants to the original purchaser that this instrument will be free from defects in workmanship for 3 years from the date of original purchase.

Limitations of Warranty:

This warranty is subject to the following exceptions and limitations:

1. INFOPIA USA, LLC shall not be required to replace any unit which are damaged or malfunction due to abuse, accidents, alteration, neglect, misuse, maintenance by someone other than INFOPIA USA, LLC or failure to operate in accordance with the instructions.
2. INFOPIA USA, LLC reserves the right to make changes in design without obligation to incorporate such changes into previously manufactured instruments.
3. INFOPIA USA, LLC has no knowledge of the performance of the instrument when the test strip is altered or modified in any manner.

For warranty service :

Purchaser must contact the local representative for assistance and/or instructions for obtaining service of this instrument.

Important:

Speak to the INFOPIA USA, LLC local representative before returning your instrument for any reason. She/he will give you the information needed to resolve your problem correctly and efficiently.

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.

Caution

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

NOTE:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.