

Lipid Profile and Glucose Measuring System

Instructions for Use

Tests for:

- Total Cholesterol
- Triglycerides
- Glucose





Dear AimStrip® Tandem System Owner

Thank you for choosing the AimStrip® Tandem Lipid Profile and Glucose Measuring System. This operation manual includes important information about the AimStrip® Tandem Lipid Profile and Glucose Measuring System. Please read carefully prior to use.

Indications For Use

The AimStrip® Tandem Lipid Profile and Glucose Measuring System is intended for multiple patient use in professional health care settings and for testing outside the body (in vitro diagnostic use only). The AimStrip® Tandem Lipid Profile and Glucose Measuring System, which consists of meter and test strips, measures total cholesterol (TC), triglyceride (TG) and glucose in capillary whole blood. The AimStrip® Tandem Lipid Profile and Glucose Measuring System should only be used with auto-disabling, single-use lancing device.

The AimStrip® Tandem Total Cholesterol Test Strip, AimStrip® Tandem Triglyceride Test Strip and AimStrip® Tandem Glucose Test Strip are for use with the AimStrip® Tandem Lipid Profile and Glucose Meter.

The AimStrip® Tandem Total Cholesterol Test strip is used to measure total cholesterol (TC) in capillary whole blood and the measurements obtained are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid, and lipoprotein metabolism disorders. The AimStrip® Tandem Total Cholesterol Test strip is used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases. The AimStrip® Tandem Triglyceride Test Strip is used to measure triglyceride (TG) in capillary whole blood and the obtained measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, and other diseases involving lipid metabolism, or various endocrine disorders. The AimStrip® Tandem Lipid Profile Test Strip is used to measure TC and TG in capillary whole blood at the same time. The AimStrip® Tandem Glucose Test Strip 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 as an aid in the management of diabetes. Glucose measurement is not to be used for the diagnosis of or screening for diabetes and/or for neonatal use. Alternate site testing should be done during steady-state times when glucose is not changing rapidly.

The AimStrip® Tandem Total Cholesterol Control Solution, Triglycerides Control Solution, and Glucose Control Solution are used to test the precision of the AimStrip® Tandem Lipid Profile and Glucose Measuring System and to detect systematic analytic deviations that may arise from reagent or analytical variation and they are for testing outside the body (in vitro diagnostic use only). The AimStrip® Tandem Control Solutions are intended for use in hospital and professional health care settings.

Test Principle

The AimStrip® Tandem Lipid Profile and Glucose Measuring System has two different types of test methods: one for the lipid profile and another for blood glucose. The lipid profile test result is based on a reading of reflection density. When blood is applied, the color changes in the test area through an enzyme reaction. The meter records this change in color and converts the measurement to the displayed result using the data previously entered via the code. A darker color corresponds to a higher lipid level.

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 the AimStrip® Tandem Meter and displayed as your blood glucose result.

The enzyme glucose oxidase, on the blood glucose test strip, reacts specifically with blood glucose. The current generated is converted and displayed as the corresponding blood glucose value. The AimStrip® Tandem Glucose Measuring System is plasma-calibrated to allow easy comparison of results with laboratory methods. A blood glucose meter which is calibrated against a whole blood method may have different results in comparison to the AimStrip® Tandem Glucose Measuring System. The laboratory system used for calibration of the AimStrip® Tandem Glucose Measuring system is YSI 2300 STAT Plus, which is equipped with a glucose oxidase system.

Instructions for Use

This guide includes information needed to use AimStrip® Tandem for Professional use. For additional information, and specific information for each type of test, refer to the test strip Instructions for Use included with the test strips. If you experience any difficulty or have any questions, while using AimStrip® Tandem Lipid Profile and Glucose Measuring System, please email us at sales@germainelabs.com or call us at 1-800-854-8446.

Customer service is available Monday through Friday from 8:30am to 5:00pm Central Time at the following toll free number:1-800-854-8446

Important Safety Instructions

- Healthcare professionals need to adhere to Standard Precautions when handling or using this device. All parts of the glucose and lipid profile monitoring system should be considered potentially infectious and are capable of transmitting blood bome pathogens between patients and healthcare professionals. For more information, refer to "Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings2007"

www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html.

- The meter should be disinfected after use on each patient. This Blood Glucose and Lipid Profile Monitoring System may only be used for testing multiple patients when Standard Precautions and the manufacturer's disinfection procedures are followed.
- Only auto-disabling, single use lancing devices should be used with this device.

WARNING:

- $1. \ Healthcare professionals using this system on multiple patients should follow the infection control procedure approved by their facility.\\$
- 2. All parts of the kit are considered bio-hazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- $3. \, \text{Always} \, \text{use a new, sterile disposable lancing device. Disposable lancing devices are for single use only.}$
- 4. Avoid getting hands lotions, oil, dirt or debris in and/or on the disposable single-use lancing device
- $5. Please \ refer to page 49 to 52 for cleaning and disinfecting Aim Strip § Tandem Lipid Profile and Glucose Measuring System.\\$

FDA Public Health Notification: Use of Fingerstic Devices on More than One Person Poses Risk for Transmitting Blood borne Pathogens: Initial Communication Update 11/29/2010.

www.fda.gov/medicaldevices/safety/alertsandnotices/ucm224025.htm

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

www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

Protection of Laboratory Workers from Occupationally Acquired Infections;

Approved Guideline-Third Edition. Clinical and Laboratory Standards Institute(CLSI), documen M29-A3

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AimStrip® Tandem Lipid Profile and Glucose Measuring System Kit Contents





- 1. AimStrip® Tandem Meter
- 2. Operational Manual
- 3. Warranty Card
- 4. Carrying Case

- 5. Two AAA batteries
- 6. Logbook
- 7. Cholesterol check strip

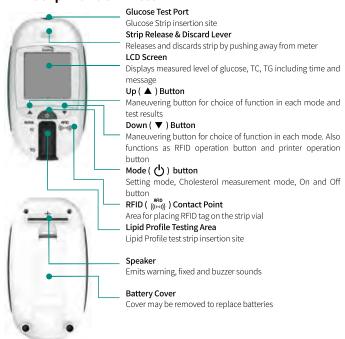
Your AimStrip® Tandem System has been sealed to protect its contents. If the seal has been broken, please return the kit to the place of purchase.

Items required for testing, but not provided in the kit:

- AimStrip® Tandem Brand Test Strips
- AimStrip® Tandem Brand Control solutions
- Capillary Rods
- Disposable single-use lancing device

Available from Germaine Laboratories Inc. or your distributor.

AimStrip® Tandem Meter



- 1. Do not use AimStrip® Tandem 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 AimStrip® Tandem 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. These sources of electromagnetic radiation may interfere with the proper operation of the meter.
- 3. The AimStrip® Tandem Meter disinfection procedures must be followed.
- 4. Health care professionals using this system on multiple patients should follow the infection control procedure approved by their facility.

AimStrip® Tandem Meter Display



GLU Blood glucose

CHOL Total cholesterol

TG Triglycerides

Blood insertion for glucose test

Blood insertion for lipid profile test

Sample blood

C► Control Solution Symbol

CODE Displays code number for Test Strips

Low battery symbol

🙏 Alarm

mg/dL Testing unit

18888 Temperature & Date of test

88:88 Time of test

AVR Average Test Result (only for glucose)

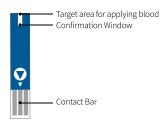
MTH . DAY Month & Day

YR Year

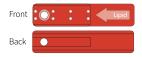
AimStrip® Tandem Test Strip Information

Use only AimStrip® Tandem Test Strips with your AimStrip® Tandem Meter.

Note: Please read appropriate AimStrip® Tandem test strip package insert for detailed information and instructions.

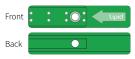


1. Total Cholesterol test strip (Red)



Red test strip is for Total Cholesterol

2. Triglycerides test strip (Green)



Green test strip is for Triglycerides

AimStrip® Tandem Test Strip Information

3. Glucose test strip



- 1. Store the AimStrip® Tandem 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 AimStrip® Tandem test strip.
- $4.\,Discard\,AimStrip@\,Tandem\,test\,strips\,three\,months\,after\,first\,opening\,a\,vial.\,Make\,note\,of\,the\,discard\,date.$
- 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. AimStrip® Tandem test strips are for single use only. Do not re-use.
- 9. Do not test if the environment temperature of AimStrip® Tandem test strips is 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 AimStrip® Tandem test strip package.
- 12. Avoid getting dirt, food, and water on the Color-Bar label (backside of glucose test strip).
- 13. Please contact your healthcare provider for instructions on dispoing test strip.
- 14. The Lipid Profile test strip packaged in a pouch should be used immediately after the pouch is open.

AimStrip® Tandem Test Strip Information

NOTE: Please carefully read detailed information included in the package insert for each type of AimStrip® Tandem Test Strip.

LIMITATIONS OF SYSTEM (for Lipid profile test):

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

Do not use neonate samples

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

- For use with capillary whole blood.
- Extremes in hematocrit may affect test results. Hematocrit levels less than 30% may cause falsely high readings and hematocrit levels greater than 55% may cause falsely low readings.
- Total cholesterol may be decreased by Dopamine and Gentisic acid.
- Triglycerides may be decreased by Dopamine, Methydopa and L-ascorbic-acid.
- EDTA, Heparin containing tubes are recommended as an anticoagulant tube.

Performance Characteristics:

Performance for the Lipid Profile Test Strips was evaluated in laboratory and in clinical testing (Please refer to strip instructions for more detailed information). Testing Range: The test range for AimStrip® Tandem is 100~400mg/dL for Total Cholesterol and 70~600mg/dL for Triglycerides.

1) Accuracy

The accuracy of lipid profile results obtained with the AimStrip® Tandem Test System were compared to results obtained with a Reference device. Lipid profile levels were measured for 1200 capillary whole blood specimens at three different centers.

Total Cholesterol

Sample Type	slope	y-intercept	R ²	
Capillary	1.0013	2.2025	0.9933	
Triglycerides				
Sample Type	slope	y-intercept	R ²	
Capillary	1.0169	-0.2810	0.9983	

2) Precision

• The precision of Total Cholesterol and Triglycerides test results was measured over 20 days with three different levels in venous whole blood samples.

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
Triglycerides			
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

• The precision of total cholesterol and triglycerides test results was 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

Triglycerides

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

AimStrip® Tandem Test Strip Information

NOTE: Please carefully read detailed information included in the Instructions for Use for each type of AimStrip® Tandem Test Strip

LIMITATIONS OF SYSTEM (for Glucose test):

The AimStrip® Tandem 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 AimStrip® Tandem Glucose Test Strips with the AimStrip® Tandem Meter.
- Use fresh capillary whole blood only.
- · Do not use neonate samples.
- Test Strips are for single use only. Do not reuse.
- Dehydration may be a cause of higher test results.
- Using glucose test strip above an altitude of 10,000 feet will have an effect on test results.

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

- Extremes in hematocrit may affect test results. Hematocrit levels less than 30% may cause falsely high readings. Hematocrit levels greater than 55 % may cause falsely low readings.
- 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 may cause inaccurately high results.
- Pemic samples; Cholesterol up to 500 mg/dL or triglycerides 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 testing.

Measurement Range: The measurement range for AimStrip® Tandem Glucose Testing is 20 to 600 mg/dL.

Accuracy:

The accuracy results obtained with the AimStrip® Tandem 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
27/27(100%)	27/27(100%)	27/27(100%)

System accuracy results for glucose concentration ≥ 75 mg/dL

	-		
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
100/133(75%)	130/133(98%)	133/133(100%)	133/133(100%)

Alternate Site Testing Accuracy:

Glucose test results obtained from alternate 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 for DORSAL HAND were compared to the reference method.

System accuracy results for glucose concentration < 75 mg/dL

Within ± 5mg/dL	Within ± 10mg/dL	Within ± 15mg/dL		
4/5(80%)	5/5(100%)	5/5(100%)		
System accuracy results for alucase concentration > 75 mg/dl				

System accuracy results for glucose concentration $\geq 75 \, \text{mg/dL}$

•	•	-	
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
112/145(77%)	143/145(99%)	145/145(100%)	145/145(100%)

Test results for VENTRAL PALM were compared to the reference method.

System accuracy results for glucose concentration < 75 mg/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

5,555			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
111/145(77%)	143/145(99%)	145/145(100%)	145/145(100%)

145/145(100%)

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

System accuracy results for glucose concentration < 75mg/dL

Within ± 5mg/dL Within ± 10mg/dL		± 10mg/dL	Within ± 15mg/dL
4/5(80%) 5/5(100%)		(100%)	5/5(100%)
System accuracy results for glucose concentration ≥ 75 mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
109/145(75%)	143/145(99%)	145/145(100%)	145/145(100%)

Test results for FOREARM 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			L
Within + 5%	Within ±10%	Within + 15	% Within + 20%

143/145(99%)

Test results for THIGH were compared to the reference method.

137/145(94%)

System accuracy results for glucose concentration < 75mg/dl

95/145(66%)

by stern about any results for glasses content auton reing/a=				
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 ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
103/145(71%)	137/145(94%)	144/145(99%)	145/145(100%)

Test results for 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%	6	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 AimStrip® Tandem requires two(2) AAA 1.5 volt alkaline batteries.

When to replace the batteries:

The Meter indicates on the display when the batteries need to be changed. When the battery symbol is displayed, no additional tests may 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 cover on the back of the AimStrip® Tandem Meter.
- 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 cover. To verify that the batteries were installed correctly, push either one of the two buttons on the front of the AimStrip® Tandem Meter to turn it on.

After replacing batteries:

- 1. Check meter quality control with control solution
- 2. Retest using capillary whole blood sample.

Caution

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

Setting Your Meter

Setting Mode

It is recommended to select AimStrip® Tandem Meter settings properly prior to use.



The meter enters set-up mode with a beep sound by pressing the Mode((b)) button for 3 or more seconds while in stand-by status.

Press Mode(**(**) button for the next step.



By pressing $Up(\triangle)$ or $Down(\nabla)$ button adjust year and press Mode((1)) button.



By pressing $Up(\triangle)$ or Down(∇) button, adjust day, month and time, and then press Mode ($\langle b \rangle$) button.

Caution

Correct date and time must be set prior to use to enable data to be stored and downloaded properly.

Setting Your Meter





By pressing $Up(\Delta)$ or $Down(\nabla)$ button, select temperature unit and press $Mode(\underline{O})$ button.



By pressing $Up(\triangle)$ or $Down(\nabla)$ button, select average date and press $Mode({\bf (b)})$ button.

Note: The average date applies to glucose testing only.



By pressing Up(\triangle) or Down(∇) button, select Alarm ON/OFF and press Mode(\bigcirc) button. If you select Alarm ON, you can set the time by pressing Up(\triangle) or Down(∇) button and then pressing Mode(\bigcirc) button (2 alarm times can be set).



By pressing Up(♠) or Down(▼) button, select Printer (Ptr) "ON" or "OFF" and press Mode(₺) button. If Printer "ON" is selected, test results will print to the connected printer. If the printer is not connected or printed results are not desired, select Printer "OFF".

Before Testing - Coding the Meter

AimStrip® Tandem Meter has two coding systems:

Lipid Profile test

Each vial (RFID Card) of test strips has a RFID tag which enables the meter to recognize its code number automatically.

Glucose test

Each test strip has the Color Bar 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 vial (or RFID Card) next to the RFID symbol $\binom{\mathsf{RFID}}{\binom{\mathsf{RFID}}{\mathsf{RFID}}}$ on the meter

- The RFID tag must be placed a distance of 0.75 inches (2cm) or less from the meter.
- $\bullet \ \ \text{The meter will return to stand-by status if there is no operation within 5 seconds.}$

Before Testing - Coding the Meter



Once it recognizes the code number, the meter will display the code value for 2 seconds before returning to stand-by status.



Check the code number on the meter display carefully. It must match the code on the strip vial. (If you have a package of pouch, it must match the code on the RFID Card provided.)

Before Testing - Coding the Meter

Coding for Glucose test



Firmly insert the glucose test strip into the test port of AimStrip® Tandem Meter. The power will automatically turn on with the code number, temperature, date and time displayed on meter.



Check the code number on the display of the meter. It must correspond with the code number on the test strip vial. The meter automatically reads the test strip code number from the Color Bar on the back of the glucose test strip.

- 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 55).

Checking the system with control solution

Quality control using 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. Controls may be purchased by calling Customer Service at 1-800-854-8446 or contacting your distributor.

The user 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 point of care settings.
- · When teaching or learning how to use the system.

Note

The AimStrip® Tandem Control Solutions are sold separately.

The TC(Level 1, Level 2), TG(Level 1, Level 2) and Glucose(Level 1, Level 2, Level 3) control solutions can be obtained through your distributor or Germaine Laboratories Inc.

Checking the system with control solution

Caution

Please check the expiration date printed on the Instructions for Use provided with each control solution.

- To test the Total Cholesterol strip use only AimStrip® Tandem Total Cholesterol Controls: level 1 and level 2.
- To test the Triglycerides strip, use only AimStrip® Tandem Triglycerides Controls: level 1 and level 2.
- To test the Glucose test strip, use only the AimStrip® Tandem Glucose Control Solutions: level 1, level 2 and level 3.
- It is recommended that the control solutions be stored at room temperature before testing.

Lipid Profile Testing procedure



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



Place the RFID tag on the strip vial (or RFID Card) next to the RFID symbol ($\binom{nFID}{(((i-1)))}$) on the Meter.

- The RFID symbol on the vial (or on the RFID Card) must be held less than 0.75 inches(2cm) from the RFID symbol on the meter.
- The meter will return to stand-by status if there is no operation within 5 seconds.

Checking the System with Control Solution



Check the code number on the meter display with that on the strip vial (or on the RFID Card). The code number must match.



Insert the test strip and press the Mode(\circlearrowleft) button. Press the Up(\blacktriangle) button and the meter will display the control solution symbol.(\blacksquare)



In 5 seconds, the sample blood symbol will blink.



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



Obtain a sample of control solution by placing the tip of the capillary rod on the drop of the control solution.



Apply the control solution to the appropriate test area of the test strip using the capillary rod.

Checking the System with Control Solution



The test results will be displayed in about 2 minutes.

Caution

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

Testing tips

- Please read the control solution Instructions for Use thoroughly before beginning test.
- · Keep the test area on the meter clean.
- Store test strips and the control solutions appropriately, as described in the Instructions for Use. Note information regarding expiration and discard dates.
- Before testing, make sure the test strips and the meter are at a temperature of 64~86°F(18~30°C).

Caution

If your control solution test falls out of range, please follow these steps before Contacting customer support:

- Check the expiration dates on all the products you are using.
- Try another control solution test.
- If this test falls out of range, repeat control solution test using a new unopened vial of test strips.
- After following the appropriate steps and the control solution test still falls out of range, do not perform a test, please contact our Customer Service at 1-800-854-8446, Monday through Friday from 8:30am to 5:00pm Central Time.
- The control solution range is not in the recommended range for your test.
- Discard the used control solution and the test strips according to local regulations.

Checking the System with Control Solution

Glucose Testing procedure



Shake the control solution before use.



Remove cap from bottle. Gently squeeze inverted bottle to obtain a drop. Discard the 1st drop of control solution to eliminate any residue.

Place a drop of control solution on a clean, dry surface. (For example, the lid of the test strip vial.)



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



Dip the test strip into the control solution.



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

Checking the system with the Cholesterol check strip



The Cholesterol check strip is to verify whether the Lipid profile testing module component (Photo sensor) inside the meter operates normally or not. If you use the meter for the first time, check the status of the meter using the Cholesterol check strip. It is for Lipid profile testing module only (all lipid testing).

When to use check strip:

- Whenever you suspect the meter does not function properly.
- If you have dropped the meter.
- Before using your meter for the first time.
- If the meter has not been used for a long time.

Testing procedure



Insert check strip and press Up (\triangle) and Down (∇) buttons at the same time more than 3 seconds while in stand-by status. Check mode will be operated.



If the meter works properly, symbol "ooo" will be displayed



If the meter has problems, symbol "Err" will be displayed. Please contact your local representative, if "Err" persists.

- Cholesterol check strip test is no substitute for control solution test.
- Keep the Cholesterol check strip out of direct sunlight for accurate test.

Testing Your Blood - Preparation

Blood Testing

A package insert with test strip instructions for use is included in each test strip box. Read instructions for use along with this section completely before testing.

Testing supplies

To perform a blood test you need:

- AimStrip® Tandem Meter
- Test strips
- · Capillary rod
- Disposable single-use lancing device

Only disposable-single use lancing device should be used with this device.

Caution

- 1. All parts of the kit are considered bio hazardous and can potentially transmit infectious disease, even after you have performed cleaning and disinfection.
- 2. Please refer to the following practice guidelines:
- Biosafety in Microbiological and Biomedical Laboratories (BMBL) found at www.cdc.gov/biosafety/publications/bmbl5/"Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline-Third Edition" Clinical and Laboratory Standards Institute (CLSI) M29-A3.
- 3. Only auto-disabling, single use lancing devices should be used with this device.
- 4. Before testing, please wash your hands with soap and water, and dry well. A new pair of clean gloves should be worn before testing each patient. Your patient should also wash their hands with soap and water and dry well.
- 5. Avoiding getting hand lotion, oil, dirt or debris in or on the lancet.
- 6. The meter should be disinfected after use on each patient. Please refer to page 49 to 52.
- 7. This blood glucose and lipid profile monitoring system can only be used for testing multiple patients when Standard Precautions and the manufacturer's disinfection procedures are followed.
- 8. Do not operate the meter in direct sunshine.
- $9. \ Practice \ using \ auto-disabling, single \ use \ lancing \ devices. \ Become \ familiar \ with \ their \ use.$
- 10. Wash your hands thoroughly with soap and clean water after handling the meter, lancing device and/or test strip.

Testing Your Blood - Preparation

Lipid Profile test

Caution

You may get an inaccurate result if the blood sample is not completely filled in a single action. Always use a different capillary rod for each sample. Never reuse the capillary rod or reapply it to the finger after it has touched the test strip or meter. This is important for both infection control and accuracy purposes.

Use the capillary rod provided with the test strip package to collect the blood sample. Make sure enough sample has been collected into the capillary rod.











Caution

If blood is stained outside the sample area, carefully wipe the stain away with a tissue. Do not allow the tissue to touch the open end of the sample area of the capillary rod. Apply the blood sample to the Lipid Profile test strip. Do not remove the capillary rod from the test strip until you hear a beeping sound. The test will automatically start.

Glucose test

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





Correct: Completely filled









Incorrect: Poorly filled

Caution

Apply the blood sample to the glucose test strip. Do not remove your finger until you hear a beeping sound. The test will automatically start.

Quick Reference-Lipid Test Procedure



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



Prick the finger with a lancing device to obtain sample blood. Collect the sample blood into the capillary rod. Make sure that enough sample blood has been collected into the capillary rod. Blood sample must fill the capillary rod collection area.



Place the capillary rod with the blood sample in contact with the test area of the strip to begin the test.

Quick Reference- Glucose Test Procedure



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



Prick the finger with a lancing device to obtain blood sample. Apply blood sample until test strip 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 and start over.



Test results appear in 3 seconds.

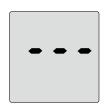
Caution

- \bullet If the test result is out of the test range, the High(HI) or Low(Lo) message will be shown on the LCD.
- Safely discard used test strips, lancets and capillary rods.
- The blood sample must be placed on the AimStrip® Tandem Test Strip within 3 minutes, while the blood insertion icon is blinking.

- If the test result is out of the test range, the High(HI) or Low(Lo) message will be shown on the LCD.
- \bullet Safely discard used test strips and lancets.

Test Procedure

Total Cholesterol test



Press Mode (\bigcirc) button after a test strip is inserted. Confirm that the meter recognizes the correct test strip by checking the corresponding symbol on its display.



The meter displays the code number and the testing symbol([CHOL]) together.

In 5 seconds the meter automatically enters into testing mode.



The blood symbol blinks when meter is ready for the blood sample.



Apply the sample to the test area of the test strip until you hear a beep.

Test Procedure



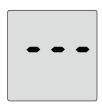
The meter displays $\quad \bullet \quad \bullet \quad$, blinking in order while testing is in progress.



When the test is completed (in about 2 minutes), the meter displays the cholesterol test result and the (**[CHOL]**) symbol.

Test Procedure

• Triglycerides test



Press Mode (\bigcirc) button after a test strip is inserted. Confirm that the meter recognizes the correct test strip by checking the corresponding symbol on its display.



The meter displays the code number and the testing $symbol(T_{\bullet})$ together.

In 5 seconds the meter automatically enters into testing mode.



The blood symbol blinks when meter is ready for the blood sample.



Apply the sample to the test area of the test strip until you hear a beep.

Test Procedure



The meter displays $\bullet \bullet \bullet$, blinking in order while testing is in progress.



When the test is completed (in about 2 minutes), the meter displays the TG test result and the TG symbol.

Test Procedure

Glucose test



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



The blood symbol blinks when meter is ready for blood sample.



After the sample is applied, the meter displays 3, 2, 1 (while testing is in progress).



The meter then displays the test result.

Glucose Test Strip Discard Function



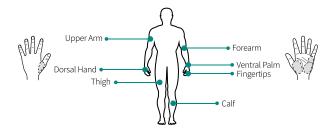


- 1. After checking the test result, gently slide the ejector button forward twice to remove the test strip from the meter.
- 2. Please contact your healthcare provider for instructions on disposing test strip.

- 1. If you push the discard button forward too much, it may be damaged.
- 2. Handle meter carefully avoiding any strong impact.

Alternate Site Testing

Note: The following alternate site testing information applies to glucose testing only.



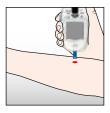
Important Information About Using Alternate Site Testing:

- 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 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, an insulin dose, or associated with physical exercise.
- When blood glucose is changing rapidly, fingertip samples show these changes more quickly than alternate site 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 site sample.
- Use alternate site 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, particularly if you suffer from hypoglycemic unawareness (lack of symptoms to indicate an insulin reaction), as forearm testing may fail to detect hypoglycemia.
- Alternate Sites Testing (AST) should not be used to calibrate continuous glucose monitors (CGMs) and should not be used in insulin dose calculations.

Performing a Blood test Using an Alternate Site

Important

Fingertip testing is recommended 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.

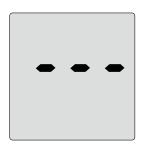
- To ensure accurate results when lancing your arm (Upper arm or forearm), leg (calf or thigh) or palm (ventral palm or dorsal hand), wash your hands and test site with soap and water.
- To receive accurate test results, at least 0.3µl minimum sample volume is required.

Reviewing Your Results

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

The meter stores up to 200 test results.

When the test results exceed the memory capacity, the most recent test result will replace the oldest test result.



The appearance of three lines indicate that no test results remain in meter's memory.

How to enter into Memory Mode

In order to enter into Memory mode, please press the $Up(\triangle)$ button in standby mode. By using $Up(\triangle)$ or $Down(\nabla)$ button, you can recall lipid profile and glucose test results. Press Mode(b) button after you select between the lipid profile and glucose test results you would like to review.

Reviewing Your Results

Lipid Profile test results



Press Mode ((1)) button.



Press $Up(\triangle)$ or $Down(\nabla)$ button to review the test results.

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Glucose test results



Press Mode ((1)) button.



Please press Up(\triangle) or Down(∇) button for reviewing. If you want to check the average of your glucose result ($\triangle VR$), press Up(\triangle) button on the latest result.

lote

Control solution results are not included in the average.

Deleting Your Results

Deleting individual test results



To delete any individual test result in the memory, press $Up(\triangle)$ or $Down(\nabla)$ button for 3 seconds or more, while the test results you want to delete is displayed.

The symbol($d\mathbf{E}$) will appear and blink, then meter will beep three times.

After the third beep, the test result will be deleted.

Deleting all test results



To delete all test results press Up(\triangle) and Down(∇) button at the same time for 3 or more seconds, while any test result is displayed.

The symbol (dEL ÁLL) will appear and blink.
The meter will beep three times. After the third beep, all the test results will be deleted.

Caution

The deleted test results are permanently removed and can't be recovered. Please use caution in deleting the test results.

Printing Your Results



Printing test results

Press the Down(♥) button for 3 or more seconds to print results from memory. Results appearing on screen from selected time stamp will be printed.

Note The Printer must be set to "ON" (See page 20)

AimStrip® Tandem Software and Thermal Printer

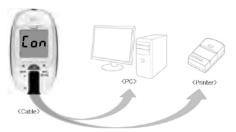
The AimStrip® Tandem results can be transmitted to a personal computer.

AimStrip® Tandem software and an interface cable are required for transmitting results to a personal computer.

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You may download the software from the Germaine Laboratory Inc. web site. www.germainelabs.com

A computer communication cable and thermal printer are available for purchase from a local AimStrip® Tandem representative.





When AimStrip® Tandem Meter is connected by interface cable, "Con" is displayed on the LCD.



When AimStrip® Tandem Meter and PC are connected by interface cable, "PC" symbol will be displayed on the LCD. To connect AimStrip® Tandem and PC, the PC Software must be started first.



When AimStrip® Tandem Meter and the Printer are connected by interface cable, "Ptr" symbol will be displayed on the LCD. To connect AimStrip® Tandem and the Printer, the Printer must be turned on first.

Caring for your AimStrip® Tandem Lipid Profile and Glucose Measuring System

Cleaning and disinfecting your AimStrip® Tandem Lipid Profile and Glucose Measuring System

Why should cleaning and disinfecting the meter and the lancing device be performed? Blood glucose and lipid profile measuring systems are at the high risk of becoming contaminated with blood born pathogens such as Hepatitis B Virus(HBV). Transmission of this virus has been documented due to contaminated blood glucose devices. According to the Centers for Disease Control and Prevention, cleaning and disinfecting meter and lancing devices can prevent the transmission of this virus through indirect contact. The cleaning is to remove gross soil and dirt on the all surfaces of the devices while the disinfecting is to kill the blood borne pathogen stated above.

FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication.(2010) www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm

CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens. (2010) www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

Materials needed

(ex. www.amazon.com / www.staples.com).

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Cleaning and disinfecting can be completed by CaviWipes™ Disinfecting Towelettes (EPA-reg#46781-8), which is a commercially available EPA-registered disinfectant. The CaviWipes™ are pre-moistened towelettes manufactured by Metrex and readily available through major medical distributors and online shopping malls

Please refer to the disinfectant labeling for additional instructions on the safe use of the disinfectant. If you have difficulty getting the CaviWipes™ towelettes, please contact our Customer Service at 1-800-854-8446.

NOTE

- 1. For cleaning and disinfecting the meter, use CaviWipes™ which has been shown to be safe for use with this meter. Please note any disinfectant product with the EPA registration number of 46781-8 may be used on this device. Other cleaning agents have not been validated with the meter.
- 2. please contact Customer Service at 1-800-854-8446, if you have any questions regarding proper cleaning and disinfection procedure or purchasing materials needed for this procedure.

Caring for your AimStrip® Tandem Lipid Profile and Glucose Measuring System

Cleaning and disinfecting procedures



- 1. Wash your hands before performing cleaning and disinfecting procedures.
- 2. Remove a wipe from the container.





- 3. Check if the meter is turned off.
- 4. Wipe the outside of the meter carefully (3 passes horizontal and 3 passes vertical).
- To clean the meter, wipe it with a CaviWipes™ towelette.
- To disinfect the meter, wipe it with another CaviWipes™ towelette and leave it wet for 2 minutes.

NOTE

- 1. The meter should be cleaned prior to disinfection. (Two CaviWipes™ disinfecting towelettes in total.)
- 2. To achieve disinfection of the stated efficacy kill claim, the meter should remain visibly wet for 2 minutes right after disinfecting treatment.

CAUTION

Take extreme care not to get liquid in the test strip port and data port. Do not use spray of any sort.

- 5. Dispose used wipes.
- 6. Wash your hands thoroughly with soap and water after handling the meter, lancing device or test strips.

Caring for your AimStrip® Tandem Lipid Profile and Glucose Measuring System

It must be cleaned and disinfected after use on each patient.

CAUTION

- 1. Please clean and disinfect the meter after each use to prevent the transmission of blood-borne pathogens when meter is used on multiple patients.
- 2. The meter must be properly cleaned and disinfected after every use following the guideline found in the cleaning and disinfection section.
- 3. Healthcare professionals should wear gloves when cleaning and disinfecting the meter. Wash hands after taking off gloves. A new pair of gloves should be worn before testing on a new patient.

Your AimStrip® Tandem System has an expected life of 3 years and should withstand the cleaning and the disinfecting recommended in this Owner's Manual. We tested the meter and the lancing device with CaviWipes™ representing daily cleaning and disinfecting (two separate steps) for three years(once per day(365 days) x 3 years x 1 cleaning/disinfecting cycle for a total of 1,095 times/ meter and reusable lancing device) and did not observe any change in performance, accuracy, or appearance. The meter and reusable lancing device can withstand up to 1,095 cleaning and disinfecting cycles which represents cleaning and disinfecting once per day for 3 years. In another word, it can withstand cleaning and disinfecting once per week over the 3 year life of the device.

Caring for your AimStrip® Tandem Lipid Profile and Glucose Measuring System

NOTE

- 1. After cleaning and disinfection procedures, check if the meter and the reusable lancing device works properly or not.
- 2. If any of the following physical and functional signs of deterioration appear after cleaning and disinfecting of the devices, stop using the device and please contact our Customer Service at 1-800-854-8446.
- · Cloudy meter display.
- · Meter displays broken character or icons.
- · Meter will not power on.
- Meter button or strip ejector does not function.
- · Control solution test falls out of range.
- · Lancing device does not function.

Storage Condition

- · Do not disassemble or modify the meter.
- Do not place the meter in areas with high humidity.
- Do not place the meter in polluted or dusty areas.
- Do not expose the meter to impact, shock, vibration or inclination.
- Keep it in a safe place.
- Do not place the meter with chemical products or with gases.
- Keep meter away from direct sunlight.
- · Close the test strip vial, immediately after removing a test strip.
- Keep the test strip away from children.
- The meter should be cleaned with a soft cloth or tissue if dirty.

Troubleshooting

Message	Probable Cause	Action Required	
MTH. DAY	Hardware is defective. (ie: The Flash ROM write/read function does not work. Oxidation voltage is out of range, etc.	Reboot the meter by removing and then replacing the batteries when no test strip is inserted.	
MTH. DAY	Test strip may be contaminated or used. (Only for blood glucose measure- ment)	Insert a new test strip and perform test again.	
MTH. DAY	Not enough blood was placed on blood glucose strip.	Insert a new test strip and apply sufficient sample of blood.	
MTH. DAY	Absence or inadequate sample of Blood or Control Solution on test strip (Only for Blood Glucose measurement)	Insert a new test strip and perform test again.	

Troubleshooting

Message	Probable Cause	Action Required
E-5	Blood sample was placed on the test strip before blood symbol begins blinking.	Wait for the meter to display the blinking icon before applying your blood sample.
MTH. DAY	The Color Bar of the strip is dirty, defective or there is too much light.	Insert a new test strip and perform test again. Avoid testing under direct sunlight.
MTH. DAY 12:00 PM	Lipid strip was removed during testing.	Test again with a new test strip, ensuring that the test strip was inserted into the correct area. Do not remove the test strip from the meter during the test.
E-B MTH. DAY	Problem with transmission of data to PC or Printer.	Check to see if meter is connected correctly to PC or printer. If problem is unresolved, please contact your local representative or Customer Service.
MITH DAY	The test result is higher than the following: Glucose: more than 600mg/dL. TC: more than 600mg/dL TG: more than 600mg/dL	If "HI" appears on the LCD screen for the Glucose result, the measured concentration is above 600mg/dL. The test should be repeated to ensure that the test procedure was done correctly. If you are certain that the meter is functioning correctly, that no errors were made during the test procedure, and the blood glucose is still consistently measured as "HI", the result may indicate severe hyperglycemia (high blood glucose). You should inform your health care professional immediately.

Troubleshooting

Message	Probable cause	Action required	
MTH. DAY 1 12:00 pm	The Test result is lower than the following: Glucose: less than 20mg/dL TC: less than100mg/dL TG: less than 70mg/dL	If "Lo" appears on the LCD screen for the Glucose result, the measured concentration is below 20mg/dL. The test should be repeated to ensure that the test procedure was done correctly. If you are certain the meter is functioning correctly, that no errors were made during the test procedure, and the blood glucose is still consistently measured as "Lo", the result may indicate severe hypoglycemia (low blood glucose). You should treat yourself for hypoglycemia immediately as recommended by your healthcare professional. Call your health care professional immediately.	
H !F	The ambient temperature is over 86°F (30°C).	Place the meter at a temperature between of 64~86°F(18~30°C) for more than 10 minutes and test again.	
LoF	The ambient temperature is less than 64°F (18°C)	Place the meter at a temperature between of 64~86°F(18~30°C) for more than 10 minutes and test again.	
Er	This message appears when test strip may be contaminated, reused or not inserted.	Please insert a new test strip of lipid profile and perform your test again.	
CODE	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 test results, check your system with control solution. If you experience symptoms that are not consistent with your lipid and /or glucose results, check to be sure that you have followed instructions in this manual correctly. Contact Customer Service for assistance. Never ignore symptoms or make significant changes to your diabetes or lipid control program. Inform your health care professional of symptoms and/or concerns.

	Feature	Specification
	Sample type	Capillary whole blood
	Measuring principle	Spectroscopy
	Testing Types	Total cholesterol, Triglycerides
	Testing method	Enzymatic-colorimetric method
	Testing range	Total cholesterol : 100~400 mg/dL, Triglycerides : 70~600 mg/dL
Lipid Profile	Testing time	About 2 minutes
Test	Calibration	Plasma-Equivalent
	Sample volume	5uL
	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 Specifications

	Feature	Specification
	Sample type	Capillary whole blood
	Measuring principle	Electrochemical
	Testing Types	Glucose
	Test range	20~600 mg/dL
	Sample volume	0.3uL
Glucose	Testing time	3sec
test	Calibration	Plasma - Equivalent
	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%
	Standard Supported	ISO/IEC 15693
RFID	Nominal Read/Write Range	<2cm
MID	Antenna	Integrated
	Frequency	13.56 MHz

Product Specifications

Feature	Specification
Size (W \times D \times H)	$61 \times 109 \times 23 (mm)$
Weight	77.5g (including battery) \pm 1g
Power supply	(AAA) $1.5V \times 2$
Battery lifetime	Aproximately 1,000 tests
PC Port	For cable connection between Meter and PC or thermal printer.

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Warranty

Manufacturer's Warranty:

Germaine Laboratories Inc. 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. Germaine Laboratories Inc. shall not be required to replace any unit which is damaged or malfunctions due to abuse, accidents, alteration, neglect, misuse, maintenance by someone other than Germaine Laboratory Inc. or failure to operate in accordance with the instructions.
- 2. Germaine Laboratory Inc. reserves the right to make changes in design without the obligation to incorporate such changes into previously manufactured instruments.
- 3. Germaine Laboratory Inc. takes no responsibility for the performance of the instrument when the test strip is altered or modified in any manner.

For warranty service:

Purchaser must contact the local distributer or Germaine Laboratory Inc.

Important

Contact Germaine Laboratories Inc. or your local representative before returning your meter for any reason. They will give you all 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.





11030 Wye Drive, San Antonio, TX 78217 Phone: 1-800-853-8446 www.germainelabs.com

Customer service is available Monday through Friday from 8:30am to 5:00pm Central time at the following toll free number: 1-800-854-8446.

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