Oxiline Blood Glucose Test Strips Insert

Intended uses:

The Oxiline Blood Glucose Monitoring System is comprised of Oxiline Blood Glucose Meter and Oxiline Blood Glucose Test Strips.

The Oxiline Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip. The Oxiline Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. It is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Oxiline Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes. The Oxiline Blood Glucose Monitoring System is not for use in neonates.

The Oxiline Glucose Control Solution is for use with the Oxiline Blood Glucose Meter and Oxiline Blood Glucose Test Strips to check meter and test strips are working together properly and that the test is performed correctly.

NOTE:
Please read this insert and the Meter user manual before using Oxiline Blood Glucose Monitoring System (hereafter as the System) to test your blood glucose level.

Cautions

1. For use with the Oxiline Blood Glucose Meter (hereafter as the Meter) to test the blood glucose levels in capillary whole blood.
2. This System is for in-vitro diagnostic use only.
3. Please review this insert and the Meter's user manual before using the Oxiline Blood Glucose Test Strips (hereafter as the Test Strips). For getting the reliable results and maintaining the manufacturer's complete service, support and warranty, use the Test Strips only.
4. Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hyperglycemichyperos-molar state, with or without ketosis. Critically ill patients should not be tested with the System.
5. The Test Strips and lancets should be kept away from children. The children may swallow it. If any items are swallowed, promptly see a doctor for help.
6. The system is for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients!
7. All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
8. This device is not intended for use in healthcare or assisted-use settings such as hospitals, physician's offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.
9. References:
"FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm
"CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010)
http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html
10. Cleaning and disinfection are referenced for cleaning and disinfection procedures in the user manual.

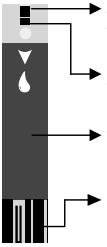
NOTE:
Do not use the Test Strips after their expiry date. Using expired Test Strips may result in inaccurate results.

Test Principle

The System uses electrochemical methodologies. The System quantitatively measures blood glucose levels using an Amperometric method. The method involves detecting the current produced from glucose oxidation. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample. The electrons generated during this reaction are transferred from the blood to the electrodes. The magnitude of the resultant current is proportional to the concentration of glucose in the specimen. The current level is converted into a readout displayed on the meter.

Product Description

Each Test Strip can be used only once. The Test Strip consists of the following parts:



Absorbent hole
Apply a blood drop here. The blood drop will be drawn in automatically.

Confirmation window
This is where you confirm if enough blood has been applied to the absorbent hole.

Test strip Handle
Hold this part to insert the strip into the port.

Contact bars
Insert this end of the Test Strip into the Meter. Push it in firmly until it will not go further.

NOTE:
Test results might be inaccurate if the contact bars are not fully inserted into the test strip port. The front side of the test strips must face up when inserting the Test Strips.

Limitations

■ The blood Monitoring System is not intended for use on neonates.
■ Altitudes above 10744 feet (3275 meters) may cause inaccurate results.
■ These following substances do not affect test results in normal concentration but may affect test results in high concentration.
■ Acetaminophen in your blood (> 8.0 mg/dL) might affect the reliability of your blood glucose results. If you are taking Tylenol, or other acetaminophen containing drugs, your glucose results may not be reliable. If you are unsure, then ask your healthcare professional.
■ If you have a disease or condition that elevates your blood uric acid level(>8.0mg/dL), such as gout, your blood glucose results may not be reliable. If you are unsure, then ask your healthcare professional.
■ Xylose: Do not test blood glucose during or soon after a xylose absorption test. Xylose in the blood can give falsely elevated results.
■ Not for use for patients in a hyperglycemic-hyperosmolar state, with or without ketosis.
■ Not for use on critically ill patients.
■ Not to be used for patients who are dehydrated, hypertensive, hypotensive or in shock.
■ Very low (less than 20%) or very high (more than 60%) red blood cell count(hemato-crit) can lead to incorrect test results. If you do not know your hemarocrit level, please consult your health care provider.
■ High temperature (more than 104°F) and low temperature (less than 50°F) may lead to incorrect test results.
■ High humidity (more than 85%) and low humidity (less than 10%) may lead to incorrect test results.

Storage and Handling

In order to ensure the Test Strips are effective, observe proper storage and handling procedures as below.

1. Write the expiry date on the Test Strips vial after opening it. The Test Strips expire 90 days after first opening.
2. Store the Test Strips in a cool, dry place between 39.2°F~104°F and 10%~85%RH.
3. Keep the Test Strips away from direct sunlight.
4. Do not store the Test Strips in high humidity areas. Do not freeze.
5. The Test Strips must be stored in their original vial ONLY. Do not transfer them to a new vial or other container.
6. Do not touch the Test Strips when your hands are wet.
7. Use each Test Strip promptly after removing it from the vial. Close the vial lid quickly and firmly.
8. Keep the vial lid closed at all times.
9. Do not bend, cut or alter the Test Strips. Doing so will lead to inaccurate results.

How It Works

The Test Strips provide a quantitative measurement of glucose level in whole blood. The absorbent hole fills automatically when the test strip contacts with a blood drop through simple capillary action. The blood drop is drawn into the absorbent hole. The Meter reads the glucose level. Only 0.7 microliters of blood sample are required. The reaction time is 6 seconds. The meter displays glucose levels from 40 to 600 mg/dL.

Blood Collection Procedure

You can obtain a blood drop from your fingertip through the following procedures:

1. Clean the puncture site with warm, soapy water. Then rinse and thoroughly dry.
2. If an alcohol swab is used, make sure the puncture site is completely dry before lancing.
3. Lance the puncture site. Wipe off the first blood drop. Rub gently to form a new blood drop.
4. Do not squeeze puncture site excessively.

Performing A Blood Glucose Test

1. Wash hands with warm, soapy water.
2. Remove a test strip from its vial with clean, dry hand. Do not bend, cut or modify the test strips in any way. Remove the test strip from the vial. Use it promptly.
3. Insert the Test Strip into the Meter. The Meter will turn on automatically.
4. Use the lancing device to obtain the blood samples.
5. Apply the blood sample to the Test Strip. Do not apply the blood sample twice.
6. Read the test results. Eject the used test strip.
7. Discard the used test strip and the lancet into the waste container for sharp objects.
8. The Meter will switch itself off automatically after the test strip is ejected.

For detailed information of the testing procedures, please refer to the Meter User Manual

Control Solution Test

To ensure proper performance of the System and accurate test results, it is important to perform control solution test with the control solutions regularly. The Oxiline Glucose Control Solution (hereafter as the Control Solution) is used to check the performance of the System and the user's test skill. The System is performing adequately if the control solution test result falls within the expected control range printed on the vial. Please contact the Oxiline company to purchase the Control Solution.

A control solution test shall be performed:
1. When the System does not work properly;
2. When the test result is unusual or inconsistent.

Results falling outside of the control range may be caused by:
1. Improper skill in performing the test;
2. Contaminated or expired control solution;
3. The Meter or the Test Strip has deterioration or malfunction

NOTE:
The control range can vary with each new control solution vial. Always use the control range on the current control solution vial.
Before you can get the control solution test result falling within the control range on the vial, do not use the System to measure your blood glucose level.
If the problem is persistent, contact Oxiline company. Or call toll-free customer service line: +1(833)694-5463, 9AM-5PM, Monday through Friday, EST. Call your healthcare professional when it is outside of the above-mentioned hours.

Test Results

The meter displays the blood glucose test results from 40 to 600 mg/dL.

1. If your result is lower than 40 mg/dL, the Meter will display "Lo". Repeat your test with a new test strip to confirm this reading.
2. If your result is higher than 600 mg/dL, the Meter will display "Hi". Repeat your test with a new test strip to confirm this reading.

Reference Values

Time of day	Normal plasma glucose range for people without diabetes
Fasting and before meals	Less than 100 mg/dL
2 hours after meals	Less than 140 mg/dL

Source: American Diabetes Association. Standards of Medical Care in Diabetes-2022. Diabetes Care December 2021，Vol45,S1-S2.doi. https://doi.org/10.2337/dc22-Sint

Questionable or Inconsistent Results

If you get the test results that are unusual or inconsistent with how you feel, then

1. Check if the Meter model matches the Test Strip.
2. Make sure that the blood drop completely fills the confirmation window of the Test Strips.
3. Check that the Test Strips are still within their expiry date.
4. Check the performance of the Meter and the Test Strips by performing a control solution test.

High or low blood glucose levels can indicate a possibly serious medical condition. If you continue to get unusually high or low results, consult your healthcare professional.

Chemical Components

- Glucose oxidase (A niger) 10%
- Electron shuttle 50%
- Enzyme protector 8%
- Non-reactive ingredients 32%

Performance Characteristics

Precision study

Data summary of within-run precision study
(300 Venous Blood Tests per Glucose Level)

Glucose concentration interval（mg/dL）		30~50	51~110	111~150	151~250	251~400
YSI mean(mg/dL)		40.3	89.9	131.5	199.3	323.8
Lot 1	Mean (mg/dL)	40.0	89.7	130.8	200.0	322.1
	SD	2.7	3.1	4.6	7.2	11.1
	CV(%)	6.6%	3.5%	3.5%	3.6%	3.4%
Lot 2	Mean (mg/dL)	40.2	90.2	130.0	199.9	323.2
	SD	2.7	3.1	4.7	6.5	10.9
	CV(%)	6.7%	3.5%	3.6%	3.3%	3.4%
Lot 3	Mean (mg/dL)	40.0	89.9	130.7	201.3	320.9
	SD	2.5	3.1	4.6	7.0	10.1
	CV(%)	6.3%	3.4%	3.5%	3.5%	3.1%
Pooled	Mean (mg/dL)	40.1	89.9	130.5	200.4	322.1
	SD	2.6	3.1	4.6	6.9	10.7
	CV(%)	6.5%	3.5%	3.6%	3.4%	3.3%

Data summary of between-run precision study

Glucose concentration interval（mg/dL）		30~50	51~110	111~150	151~250	251~400
YSI mean(mg/dL)		41.9	94.0	131.1	199.2	325.3
Lot 1	Mean (mg/dL)	40.1	90.5	116.8	193.0	315.6
	SD	2.0	2.5	3.2	4.8	6.3
	CV(%)	5.1%	2.8%	2.8%	2.5%	2.0%
Lot 2	Mean (mg/dL)	40.1	90.3	116.9	192.4	314.2
	SD	2.0	2.7	3.2	4.6	6.2
	CV(%)	5.1%	3.0%	2.8%	2.4%	2.0%
Lot 3	Mean (mg/dL)	40.0	89.8	117.3	192.1	315.0
	SD	1.9	2.5	2.9	4.0	6.0
	CV(%)	4.9%	2.8%	2.5%	2.1%	1.9%
Pooled	Mean (mg/dL)	40.1	90.2	117	192.5	314.9
	SD	2.0	2.6	3.1	4.5	6.2
	CV(%)	5.0%	2.9%	2.7%	2.3%	2.0%

User performance study

The study data indicate that the System can be operated properly by lay users, even in the case of absence of any guidance.

Your Oxiline Blood Glucose Meter result may vary slightly from your actual blood glucose value. This may be due to slight differences in technique and the natural variation in the test technology.
The chart below shows the results of a study where 351 typical users used the Oxiline Blood Glucose Meter to test their blood glucose level. In this study, the Oxiline Blood Glucose Meter gave result within 15% of their true blood glucose level 346 out of 351 times.

Difference range between the true blood glucose level and the Oxiline Blood Glucose Meter result	Within ±5%	Within ±10%	Within ±15%	Within ±20%
The percent (and number) of meter results that match true blood glucose level within x%	49.29% (173/351)	83.48% (293/351)	98.58% (346/351)	100% (351/351)

Traceability of Oxiline Blood Glucose Monitoring System, G-427B

The results of Oxiline Blood Glucose Monitoring System, G-427B, were compared to parallel results obtained on YSI-2300. YSI-2300 is the manufacturer's standard measurement equipment.

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