TeleRPM™

Blood Glucose Test Strips Package Insert

INTENDED USE

TeleRPM Blood Glucose Monitoring System is comprised of the TeleRPM Blood Glucose Meter and the TeleRPM Blood Glucose Test Strips. TeleRPM Blood Glucose Monitoring System is intended to quantitatively measure the glucose concentration in fresh capillary whole blood samples drawn from the fingertips. It is intended for use by persons with diabetes at home as an aid to monitor the effectiveness of diabetes control. It is not intended for neonatal use or for the diagnosis of or screening for diabetes. This system is intended for self-testing outside the body (in vitro diagnostic use), and should only be used by a single person and should not be shared.

PRINCIPLE OF OPERATION

TeleRPM Blood Glucose Monitoring System is designed to quantitatively measure the glucose concentration in fresh capillary whole blood. The glucose measurement is achieved by using the amperometric detection method. The test is based on measurement of electrical current caused by the reaction of the glucose with the reagents on the electrode of the test strip. The blood sample is pulled into the tip of the test strip through capillary action. Glucose in the sample reacts with glucose oxidase and the mediator. Electrons are generated, producing a current that is positive correlation to the glucose concentration in the sample. After the reaction time, the glucose concentration in the sample is displayed.

COMPOSITION

Glucose Oxidase (from Aspergillus Niger) <25 IU; Mediator <300 µg; Buffer; Non-reactive Ingredient.
Each test strip vial contains a drying agent.

PERFORMING A BLOOD GLUCOSE TEST

- Material provided: Test Strips and Package Insert.
- Material required but not provided: Meter, User Manual, Lancing Device, Lancets and Control Solution.
- Refer to your User Manual for complete instructions for blood sample collection before use.

1. Select the punch site. Wash your hands in warm, soapy water. Dry your hands thoroughly.
2. Prepare the Lancing device and lancets.
3. Check the expiration date and discard date. The expiration date is printed on the strip vial label. Do not use expired test strips.
4. Insert the test strip into the meter. The meter turns on.
5. Lance the punch site to get a round drop of blood.
6. Touch the blood drop to the strip tip. And then the meter beeps. Do not apply blood on the top of test strip.
7. The meter counts down from 5 to 1. And then your test result appears.

EXPECTED GLUCOSE RANGE FOR PEOPLE WITHOUT DIABETES

Time	Normal plasma glucose range for adults without diabetes, mg/dL.
Before breakfast (fasting)	<100
2 hours after a meal	<140

Reference: American Diabetes Association; Standards of Care in Diabetes—2023 Abridged for Primary Care Providers.Clin Diabetes 2 January 2023; 41 (1): 4–31.

Note: Please work with your healthcare professional to determine a target range that works best for you.

PRECISION AND ACCURACY

Linearity Results:
Lot 1: y = 0.9982x-1.2760; R2= 0.9975.
Lot 2: y = 0.9945x-1.1411; R2= 0.9982.
Lot 3: y = 0.9949x+0.1534; R2= 0.9973.
All 3 Strips Lots: y = 0.9959x-0.7546; R2= 0.9976.

The results support the claimed measurement range of 20-600 mg/dL.

The TeleRPM blood glucose monitoring system was tested for within-run precision (300 measurements per glucose concentration for repeatability) using venous whole blood samples and intermediate precision (30 measurements per glucose concentration a day for 10 days) using glucose controls. See tables below for results.

Within-Run Precision- Blood			
Interval	Concentration	Standard Deviation (SD)	Coefficient of Variation (CV)
1	39.8 mg/dL	1.8 mg/dL	4.5%
2	70.5 mg/dL	2.3 mg/dL	3.2%
3	127.9 mg/dL	3.6 mg/dL	2.8%
4	199.0 mg/dL	5.9 mg/dL	3.0%
5	349.6 mg/dL	10.2 mg/dL	2.9%

Intermediate Precision - Control Solution			
Interval	Concentration	Standard Deviation (SD)	Coefficient of Variation (CV)
1	40.0 mg/dL	1.8 mg/dL	4.6%
2	70.1 mg/dL	2.0 mg/dL	2.9%
3	129.8 mg/dL	3.1 mg/dL	2.4%
4	199.5 mg/dL	4.6 mg/dL	2.3%
5	349.9 mg/dL	7.9 mg/dL	2.3%

User Evaluation:

The TeleRPM blood glucose monitoring system was tested by 352 lay users using capillary blood samples and three TeleRPM Blood Glucose Test Strips lots. The results were compared to the YSI Model 2300 STAT PLUS Glucose Analyzer, a laboratory instrument. See the table below with accuracy performance study results that shows the TeleRPM Blood Glucose monitoring system achieved 100% of results within ±15 % of the laboratory instrument. The results shown here are intended to inform you about your meter, how much results are consistent from your actual blood glucose values.

Table 1- Linear Regression Results

Slope	0.9933mg/dL
Intercept	0.3766
Correlation coefficient (R)	0.9941
Number of sample	352
Range tested	46.1 to 450.5mg/dL

Table 2-Consumers Accuracy Results

Accuracy for Home Use by Lay-Users.
TeleRPM 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 352 typical users used the TeleRPM Blood Glucose Meter to test their blood glucose level.
In this study, TeleRPM Blood Glucose Meter gave results within ±15% of their true blood glucose level 352 out of 352 times.

Difference range between the true blood glucose level and TeleRPM 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%	68.5% (241/352)	96.0% (338/352)	100% (352/352)	100% (352/352)

CHECKING THE SYSTEM

Use only TeleRPM Control Solutions.
For complete details about checking the system, refer to your User Manual.
When to check:

- Once a week.
- When using or when opening a new vial of test strips.
- When you suspect that the meter and test strips are not working together properly.
- After cleaning and disinfecting your meter.
- You dropped the meter.
- Always perform a quality control test if you suspect your results are inaccurate or do not match how you are feeling.

Make sure the Control Solution 1 tests fall within the level 1 range on the strip vial label.
Make sure the Control Solution 2 tests fall within the level 2 range on the strip vial label.
Make sure the Control Solution 3 tests fall within the level 3 range on the strip vial label.

CAUTION:If your control test result falls outside the range, DO NOT use the system to test. The system may not be working properly. Please contact 24/7 Customer Support at (833)445-5666 for support.

Comparing Meter and Laboratory Results

Before you go to the lab:
- Perform a control test to make sure the meter is working properly.
- If your doctor requested you go fasting, then this would be a good time to do this comparison.
- Bring your meter and test strips.

While you stay at the lab :
- Wash your hands before obtaining a blood sample.
- Obtain and test the blood samples immediately for your tests.
- Follow User Manual for performing a blood glucose test.

Note:
Users should periodically review their technique, and compare a result obtained with their meter to a result obtained using a laboratory method or a well-maintained and monitored system used by your healthcare provider.

STORAGE AND PRECAUTION.

- Store test strips in their protective vial. Store with their cap on tight. This keeps them working well.
- Store between 36-86°F. Store at 10-90% RH. Avoid heat and direct sunlight.
- The operating conditions for meter and test strips are 41-113°F, relative humidity 10-90%.
- Do not store or use the test strips in a humid place such as the laundry room or bathroom. Do not touch test strip with bleach or detergent containing bleach to avoid affecting the appearance or performance of test strip.
- Do not transfer the test strips to a new vial or any other container.
- Replace the vial cap as soon as you remove a test strip.
- Use the test strip as soon as it is removed from the vial.
- Repeated insertion and removal of a test strip into the meter strip port may result in reading errors.
- Do not use your test strips past the unopened expiration date. The date is printed on the vial label. Otherwise, you may get incorrect test results.

Note: All expiration dates are printed in Year-Month-Day format. 2023-01-01 indicates 1st January, 2023.

- A new vial of test strips may be used for 6 months after first opening. After 6 months they will expire. Write the opened expiration date on the vial label after opening.
- Do not use the torn, bent, or damaged test strips. Do not reuse test strips.
- Keep the meter and all associated parts out of reach of children.
- Do not alter your blood glucose management or treatment without first consulting your doctor or healthcare professional.
- The meter and lancing device are for single patient use. Do not share them with anyone including other family members! Do not use on multiple patients.
- Refer to the user manual for cleaning and disinfection instructions.

LIMITATIONS

- Not for use on critically. ill patients, severely hypotensive individuals, patients in shock, dehydrated patients, or in a hyperglycemic- hyperosmolar state with or without ketosis. Do not test your blood glucose during or soon after a xylose absorption test. Xylose in
- the blood can give inaccurate results with this meter.
  Not for neonatal use.
- Not for screening for or diagnosis of diabetes mellitus.
- Do not use the system above 10,413 ft (3,174 meters) in altitude.
- This meter is not intended for use in healthcare or assisted-use settings, such as
- hospitals, physician 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 meter on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

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