Teladoc®
HEALTH

Blood Glucose Monitoring System
Instructions for Use

REF OFG00406 / OFG10353 / OFG000016 / OFG000017

BLOOD GLUCOSE TEST STRIPS

PRINCIPLE AND INTENDED USE

The Teladoc Health blood glucose test strips are used with the Teladoc Health connected blood glucose meter in the quantitative measurement of glucose in fresh whole capillary blood from the fingertip. The meter is intended for use by people with diabetes at home as an aid to monitor the effectiveness of a diabetes control program and should not be used for the diagnosis of/or screening for diabetes mellitus or for neonatal use. The blood glucose test strips are thin strips. The strips have a chemical reagent system. They work with the meter to measure the glucose level in whole blood. Blood is applied to the end tip of the test strip. The blood is then absorbed into the reaction cell. This is where the reaction takes place. A transient electrical current is formed during the reaction and detected by the meter. The amount of glucose is then calculated based on this current. The result is shown on the meter display. The meter is calibrated to display plasma equivalent results. The system is used to monitor how well a diabetes control program works. The blood glucose test strips can be used only outside the body. They are used by persons with diabetes for self-testing purposes. The Teladoc Health blood glucose monitoring system is for single patient use only. Do not share with others. For ***in vitro*** diagnostic use.

COMPOSITION

Each test strip has reactive and non-reactive chemicals. These chemicals are: Glucose Oxidase (from Aspergillus Niger) <25 IU, Mediator <300, Buffer, and Non-reactive Ingredient. Each test strip vial contains a drying agent.

STORAGE AND HANDLING

- Store test strips in their protective vial. Store with their cap on tight. This keeps them working properly.
- Store in a cool, dry place between 41-86°F (5-30°C) and 10-90% relative humidity (RH). Keep out of direct sunlight.
- Use the test strips at room temperature. This provides precise results.
- Keep the text side up and blank side down when you insert the strip contact bars into the strip port.
- Do not store or use the test strips in a humid place such as a bathroom.
- Do not store the meter, the test strips or control solution near bleach or cleaners with bleach.
- 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 vial expiration date. The date is printed on the vial. Otherwise, you may get incorrect test results.

  Note: All expiration dates are printed in Year/Month format. 2024/01 indicates January 2024.

- 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.

PRECAUTIONS

- For ***in vitro*** diagnostic use. The test strips are to be used only outside the body for testing purposes.
- Your blood glucose meter is for single patient use. Do not share it with others including family members. Remember to follow the required pre-cleaning and disinfection procedure. Please refer to the Chapter 11 Maintenance, "Cleaning and Disinfecting Your Meter" in your Owner's Manual on your online account. This procedure is important to prevent the potential transmission of infectious diseases.
- Do not use test strips after the expiration date that is shown on the vial. Expired test strips may give an incorrect result.
- Do not use test strips that are torn, bent, or damaged.
- Do not reuse test strips.
- Apply sample only to the tip of the test strip. Do not apply to the top of the test strip. This may result in a false reading.
- Discard the vial and any unused test strips 6 months after you first open it. Constant exposure to air may destroy chemicals in the test strip. This can cause false readings.
- Keep the test strip vial away from children and animals.
- Consult your doctor before making any changes to your treatment plan.

MATERIALS PROVIDED

• Test Strips • Instructions for Use • Lancing Device
• Meter • Sterile Lancets • Control Solution

Please contact Member Support at **800.945.4355** for information about purchasing test strips.

INSTRUCTIONS FOR USE

See your Owner's Manual for complete instructions for blood sample collection before use.

1. Open the cap of the test strip vial. Remove a test strip. Replace the cap immediately. This protects the test strips from moisture in the air.
2. Run the test following the instructions in your Owner's Manual.
3. The test result will be shown on the meter display. This result should fall within the target range. Your doctor should recommend your target range. If your results are higher or lower, ask your doctor what to do. Always consult your doctor before changing your treatment plan.

RANGE OF EXPECTED VALUES

Blood glucose monitoring requires the help of a doctor. Together you can set your own range of expected blood glucose values. You can also arrange your testing times. In addition, you should discuss the meaning of your blood glucose results together. Expected blood glucose levels for people with diabetes: [1, 2]

Time	Range, mg/dL	Range, mmoL/L
Fasting and Before Meals	80 – 130	4.4 – 7.2
1-2 Hours After Meal	Less than 180	Less than 10.0

CHECKING THE SYSTEM

Be careful with your blood glucose meter. See the Owner's Manual for how to take good care of your meter. Do a quality control test to make sure that the meter and test strips are

working well together. Follow the control test procedure in your Owner's Manual. Two ranges CTRL 1 and CTRL 2 are shown on the test strip vial label. Teladoc Health control solution 1 is sufficient for most all self-testing needs. If you think your meter or strips may not be working correctly, you may also want to do a level 2 test. Contact Member Support for information on purchasing control solution.

You should confirm your control solution results. Make sure the control solution 1 tests fall within the CTRL 1 range. Make sure the control solution 2 tests fall within the CTRL 2 range. When testing with control solution 1, make sure you are matching the results to the CTRL 1 range on the vial label.

CAUTION: If your quality control test result falls outside the control range shown on the test strip vial, DO NOT use the system to test your blood. The system may not be working properly. If you cannot correct the problem, contact Member Support for help.

LIMITATIONS

- The meter, test strips, and other components have been designed, tested and proven to work together effectively to provide accurate blood glucose measurements. Do not use components from other brands.
- The meter should not be used to test critically ill patients and should not be used to test neonates.
- The blood glucose test strips test fresh capillary whole blood from the fingertip. Do not use with serum or plasma samples.
- The blood glucose monitoring system is for self-testing by users to test fresh capillary blood from the fingertip.
- Very high (above 70%) and very low (below 20%) hematocrit levels can cause false results. Talk to your doctor to find out your hematocrit level.
- The system is tested to accurately read the measurement of glucose in whole blood within the range of 20-600 mg/dL.
- Fatty substances have no major effect on test results. These include triglycerides up to 3,000 mg/dL or cholesterol up to 500 mg/dL.
- Acetaminophen, uric acid, and ascorbic acid (vitamin C) (when occurring in blood at normal or high therapeutic concentration) do not significantly affect results. However, abnormally high concentration in blood may cause inaccurately high results.
- The blood glucose monitoring system has been tested to work properly up to 8,516 ft (2,595 meters).
- Blood samples from patients in shock, severe dehydration or a hyperosmolar state (with or without ketosis) have not been tested. It's not recommended to test those samples with the blood glucose monitoring system.
- Dispose of blood samples and materials with care. Treat all blood samples as if they are infectious materials. Follow all local regulations.
- All parts of the kit are considered biohazardous and potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

PERFORMANCE CHARACTERISTICS

The precision and accuracy of the meter is calibrated by using a YSI (Model 2300 STAT PLUS) Glucose Analyzer as the reference instrument. It is traceable to the NIST reference standard.

Reproducibility, Precision

Ten replicate assays were each run on 10 meters. Heparinized venous blood samples at five concentration levels were used in the testing. The results of all three lots combined provided the following estimates.

MEAN Blood glucose, mg/dL	SD	%CV
47.33	1.77	3.73
75.7	2.37	3.2
129.37	4.31	3.3
207.67	7.14	3.43
326.63	11.33	3.43

Intermediate Precision

Ten replicate assays from three strip lots were run on 10 meters. These tests were run each day for a total of 10 days. Control solutions at three concentration levels were used in the testing. The results combined from the three strip lots provided the following estimates.

#	MEAN	Standard Deviation mg/dL or Coefficient of Variation (CV)
All Three Lots Combined	37.5 mg/dL	1.45 mg/dL
	119.0 mg/dL	2.8%
	350.0 mg/dL	2.3 %

System Accuracy

System accuracy studies were conducted independently using lay users. Each individual subject obtained their own fingertip sample and self-tested their blood glucose with the meter on three lots of test strips. Blood was taken from 102 users. The fingertip samples from the same subjects were then analyzed on a YSI Model 2300 STAT PLUS Glucose Analyzer that served as the reference standard to determine the system accuracy of the meter in the hands of lay persons. The results presented below are the results from the first replicates obtained by laypersons using the meter and blood glucose test strips.

Linear Regression Results: Teladoc Health (y) vs. YSI Reference (x) Lay User					
Sample Site	Slope	Intercept	R	R^2	N
Fingertip	0.9987	0.4456	0.9941	0.9882	102

The sample range was 48.2 to 391.5 mg/dL for the meter testing with blood sampled from fingertip sites.

Lay User Fingertip Site: System Accuracy Results for Glucose Concentration ≥75mg/dL			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
68/93 (73.1%)	87/93 (93.5%)	92/93 (98.9%)	93/93 (100.0%)

Lay User Fingertip Site: System Accuracy Results for Glucose Concentration <75mg/dL		
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
6/9 (66.7%)	9/9 (100.0%)	9/9 (100.0%)

For complete instructions, please refer to the Owner's Manual in your online account. For additional questions or issues with this product, please contact Member Support at **800.945.4355**. Member Support is available 24 hours a day, 365 days a year.

REFERENCES

1. Standards of Medical Care in Diabetes - 2024, Diabetes Care -v47: S1 January 2024

2. “FDA Public Health Notification: Use of More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication” (2010) https://content.livongo.com/cp/Bloodborne_Pathogen_Risk.pdf

3. “CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens” (2010) https://content.livongo.com/cp/Clinical_Reminder_Fingerstick_Devices_RiskBBP.pdf

REF OFG00426 / OFG000002 / OFG000019 / OFG000020

BLOOD GLUCOSE CONTROL SOLUTION

PRINCIPLE AND INTENDED USE

Teladoc Health control solution contains a known concentration of glucose. It is used to confirm that your meter and test strips are properly working together. It also confirms that you are performing the test correctly.

You should perform a quality control test:

- Before you use your meter for the first time. This will help you get used to this test.
- Before using a new box of test strips.
- When you suspect that the meter or test strips are not working properly.
- When you suspect that your test results are inaccurate. Or if they do not match with how you feel.
- If you suspect your meter is damaged.
- At least once a week.
- After cleaning your meter.

Two levels of control solution are available. They are control solution 1 and control solution 2. Control solution 1 is sufficient for most self-testing needs. If you think your meter or strips may not be working correctly, you may also want to do a level 2 test.

COMPOSITION

Control solution 1 contains less than 0.2% glucose (active ingredient). Control solution 2 contains less than 0.4% glucose (active ingredient). Both have preservatives in an aqueous-based mixture.

STORAGE AND HANDLING

- Store the control solution at 41-86 °F (5-30 °C).
- If the control solution is cold, do not use until it has warmed to room temperature.
- Use before the unopened expiration date that is shown on the bottle.

  Note: All expiration dates are printed in Year/Month format. 2024/01 indicates January 2024.

- Use the control solution only for 6 months after you first open it. The control solution will expire 6 months after the bottle is opened for the first time. Record this opened expiration date on the bottle label.

PRECAUTIONS

- For ***in vitro*** diagnostic use. Use the control solution to test only outside the body. Do not swallow or inject. For self-testing use.
- Shake well before using.
- To get accurate results, do control solution testing between 50 and 104°F (10-40°C).
- The control ranges shown on the test strip vial are not a recommended range for your blood glucose level. Figure out your personal blood glucose target ranges with your doctor.
- Do not touch the end of the test strip to the control

- solution bottle. This could cause contaminants to enter the bottle.
- Use only Teladoc Health brand control solution with your Teladoc Health blood glucose meter and test strips.

MATERIALS PROVIDED

• Control Solution • Instructions for Use
• Meter • Test Strips

Please contact Member Support at **800.945.4355** for more information on obtaining a control solution kit.

INSTRUCTIONS FOR USE

1. Insert a new test strip to turn on the meter. Refer to your meter's Owner's Manual for details on how to record the result as a quality control test, and more details on operating the meter.
2. Shake the control solution bottle thoroughly.
3. Squeeze the control solution bottle gently. Discard the first drop. If the tip clogs, tap the tip gently on a clean, hard surface. Shake again, and then use.
4. Squeeze out a second small drop on a clean nonabsorbent surface. Touch the sample tip of the test strip to the control solution drop. Ensure the strip gets enough sample.

   Notes: Do not apply control solution to the test strip straight from the bottle. If the control solution sample does not completely fill the check window, do not add a second drop. Discard the test strip and start over with a new test strip.
5. Read the result from the meter display. The meter will automatically detect the control solution and mark it as a control test separate from normal blood glucose test results.

EXPECTED RESULTS

Make sure the control solution test results are in the control range. The ranges for both CTRL 1 and CTRL 2 are displayed on the test strip vial. For confirmation of results, control solution 1 tests should fall within the CTRL 1 range. Control solution 2 tests should fall within the CTRL 2 range. If the test results are in the respective ranges, this means your blood glucose monitoring system is working right and you are doing the procedure correctly.

If the control solution test results do not fall within the respective ranges:

- Check the expiration date of the test strip and control solution. Make sure that the test strip vial and the control solution bottle have not been open for more than 6 months. Throw away any expired test strips or control solution.
- Make sure you are testing at a temperature between 50 and 104°F (10-40°C).
- Make sure that the test strip vial and the control solution bottle have been tightly capped.
- Confirm that you are using the proper control solution.
- Make sure that you followed the test procedure correctly.

After checking everything listed above, repeat the control solution test with a new test strip. If your results still fall outside the range indicated on the test strip vial label, your meter may not be working properly. DO NOT use the system to test blood. Contact Member Support for help. For complete instructions, please refer to the Owner's Manual in your online account. For additional questions or issues with this product, please contact Member Support at **800.945.4355**. Member Support is open 24 hours a day, 365 days a year.

REF OFG00405 / OFG000018

LANCING DEVICE

PRINCIPLE AND INTENDED USE

The lancing device is used with compatible disposable sterile lancets to draw capillary blood from the fingertip for blood glucose testing. The lancing device is intended to be used by a single patient and should not be shared.

INSTRUCTION FOR USE

Before testing, choose a clean, dry work surface. Familiarize yourself with the procedure and make sure you have all the items needed to obtain a drop of blood.

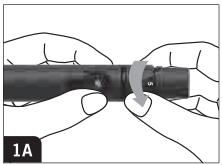
IMPORTANT: Prior to testing, wipe the test site with an alcohol swab or soapy water. Use warm water to increase blood flow if necessary. Then dry your hands and the test site thoroughly. Make sure there is no alcohol, soap or lotion on the test site.

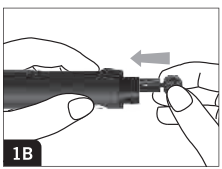
The lancing device is for fingertip sampling only. Adjust the depth penetration to reduce the discomfort.

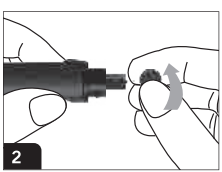
1A-1B. Unscrew the lancing device cover from the body of the lancing device. Insert a sterile lancet into the lancing device and push it until the lancet comes to a complete stop in the lancing device.

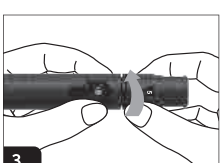
2. Hold the sterile lancet firmly in the lancing device and twist the safety tab of the lancet until it loosens, then pull the safety tab off the lancet. Save the safety tab for lancet disposal.

3. Carefully screw the cover back onto the lancing device. Avoid contact with the exposed needle. Make sure the cover is fully sealed on the lancing device.









4A-4B. Adjust the puncture depth by rotating the lancing device cover. There are a total of 11 puncture depth settings. To reduce discomfort, use the lowest setting that still produces an adequate drop of blood.

ADJUSTMENT:
0 – 1.5 for delicate skin • 2 – 3.5 for normal skin • 4 – 5 for callused or thick skin

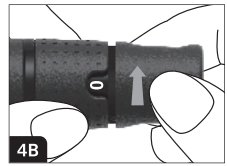
Note: Greater pressure of the lancing device against the finger will also increase the puncture depth.

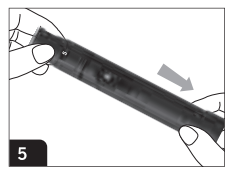
5. Pull the cocking barrel back to set the lancing device. The release button will turn yellow and you may hear a click. The lancing device is now loaded and ready for obtaining a drop of blood.

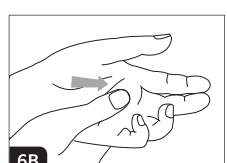
6A-6B. Prior to testing, wipe your hands with an alcohol swab or wash your hands with soap. Use warm water to increase blood flow in your fingers if necessary. Then dry your hands thoroughly. Massage the hand from the wrist up to the fingertip a few times to encourage blood flow.

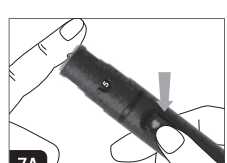
7A-7B. Hold the lancing device against the side of the finger to be lanced with the cover resting on the finger. Push the release button to prick your fingertip. You should hear a click as the lancing device activates. Gently massage from the base of the finger to the tip of the finger to obtain the required blood volume. Avoid smearing the drop of blood.

For the greatest reduction in pain, lance on the sides of the fingertips. Rotation of sites is recommended. Repeated punctures in the same spot can make your fingers sore and callused.



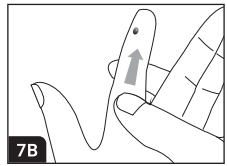


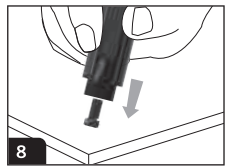


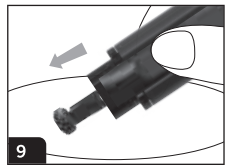


8. Unscrew the lancing device cover. Place the safety tab of the lancet on a hard surface and carefully insert the lancet needle into the safety tab.

9. Press the release button to make sure that the lancet is in the extended position. Slide the ejection button forward to discard the used lancet. Place the lancing device cover back on the lancing device.







CARE OF THE LANCING DEVICE

Cleaning and Disinfection
(please refer to your Owner's Manual)

First use DisCide Ultra Disinfecting wipes to clean the entire device surface. This pre-cleaning is to prepare the device surface for a disinfection process. Then please use another fresh DisCide Ultra Disinfecting wipe to wipe the entire lancing device surface. Make sure the lancing surface is thoroughly damp. This disinfection process has been validated through repeated disinfection cycles equivalent to 5 years of lancing device usage.

DisCide Ultra Disinfecting Wipes are available through Palmero Health Care at **800.344.6424** and at www.palmerohealth.com. DisCide Ultra Disinfecting Wipes are also available at internet retailers such as www.amazon.com.

PRECAUTIONS

- Do not use the lancet if the safety tab is missing or loose when you take the lancet out of the bag.
- Do not use the lancet if the needle is bent.
- Use with caution whenever the lancet needle is exposed.
- Do not share with anyone including other family members! Do not use on multiple patients!
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- In order to reduce the risk of infection from prior use of the instrument, always use a new, sterile lancet. Do not reuse lancets.
- Avoid getting the lancing device or lancets dirty with hand lotion, oils, dirt, or debris.
- For Alternative Site Testing (AST), if current lancet is not obtaining enough blood due to skin or other conditions, please contact Member Support at **800.945.4355** for information on different lancet options.

LIMITED WARRANTY

If the lancing device does not work for any reason other than obvious abuse in the first 5 years after purchase, we will replace it with a new or equivalent lancing device free of charge. Please contact Member Support at **800.945.4355** for more information.

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Made in China and Mexico

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