

Teladoc[®] HEALTH BG500 Blood Glucose Meter Package Insert




Intended Use

The Teladoc Health blood glucose monitoring system is comprised of the Teladoc Health BG500 blood glucose meter and the Teladoc Health blood glucose test strips (model: MTS01).

The Teladoc Health 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

The Teladoc Health 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 reagents on electrode of the test strip. The blood sample is pulled into the tip of test strip through capillary action. Glucose in the sample reacts with glucose oxidase and 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 value is reported in plasma equivalents and is displayed on meter.

Symbol	Definition	Description
mg/dL	Measurement unit	Unit of glucose measurement The meter displays glucose concentration in milligrams per deciliter only.
	In vitro diagnostic medical device	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device
	Consult instructions for use	Indicates the need for the user to consult the instructions for use
	Keep away from sunlight	Indicates a medical device that needs protection from light sources

Meter Use and Precautions

- Meter will enter into sleep mode after 2 minutes of no operation.
- Refer to the section Cleaning and Disinfection to keep the entire meter clean.
- Keep your meter in 41-113°F and 10-90% humidity.
- Do not leave the meter in your car.
- Do not drop the meter or get it wet. If you drop the meter or get it wet, check the meter by doing a control solution test. Refer to Testing with Control Solution for instructions.
- Do not use the meter if it has been submerged in liquid or exposed to water splashes.
- You should use the meter as described in the user manual, and any use of the meter beyond the scope of instructions may impair normal operation of the meter and battery.
- Do not drop blood on the test strip. The blood is pulled into the tip of the test strip through capillary action:
- Use only Teladoc Health blood glucose test strip with your BG500 blood glucose meter.
- Use only Teladoc Health control solution with your Teladoc Health blood glucose monitoring system.
- Keep the meter and all associated parts out of reach of children.
- Wash and dry your hands well before and after testing.

Important Safety Information

1. 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.
2. All parts of the kit are considered biohazardous, and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
3. Do not alter your blood glucose management or treatment without first consulting your healthcare professional.
4. Refer to the Cleaning and Disinfection section for details on cleaning and disinfecting the meter.
5. Follow proper precautions and all local regulations when disposing the meter.
6. For more safety information, please refer to table below:

Name of safety information reference	Link
Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication	https://downloads.regulations.gov/FDA-2016-N-0400-0003/content.pdf
Considerations for Blood Glucose Monitoring and Insulin Administration	https://www.cdc.gov/injection-safety/hcp/infection-control/?CDC_AAref_Val=https://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

Limitations

- 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 or diagnosis of diabetes mellitus.
- Not for Alternative Site Testing (AST).
- Do not use the system above 10413 ft (3174 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. It has not been cleared by the 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, Hepatitis C Virus, Hepatitis B Virus, or other bloodborne pathogens.
- Not for use on the specific patients listed in table below:

Critically ill patients
Patients in shock
Patients in a hyperglycemic- hyperosmolar state with or without ketosis
Patients with severe dehydration
Patients with severe hypotension

Questionable or Inconsistent Results:

Symptoms of High or Low Blood Glucose:

You can better understand your test results by being aware of the symptoms of high or low blood glucose. According to the American Diabetes Association, some of the most common symptoms are:

Low blood glucose (Hypoglycemia):

- shakiness
- sweating
- fast heartbeat
- blurred vision
- confusion
- passing out
- irritability
- seizure
- extreme hunger
- dizziness

High blood glucose (Hyperglycemia):

- frequent urination
- excessive thirst
- blurred vision
- increased fatigue
- hunger

If you have such symptoms, please contact your healthcare professional.

If your blood glucose result does not match how you feel, please:

- Check the expiration date and the discard date of the test strip. Make sure that the test strip vial has not been opened for more than 6 months.
- Confirm the temperature in which you are testing is 41-113°F.
- Make sure that the test strip vial has been tightly capped.
- Make sure that the test strips are stored in 36-86°F, 10-90% humidity.
- Make sure that the strip was used immediately after removing from the test strip vial.
- Make sure that you have followed the test procedure correctly.
- Perform a control solution test (See Testing with Control Solution for instructions).
- After checking all the conditions listed above, repeat the test with a new test strip. Please contact 24/7 Member Support 800-945-4355 and membersupport@teladohealth.com for technical support or questions.

As glucose target ranges for self-monitoring at home vary from person to person.

Please check with your healthcare professional to determine your target range.

- If your test result is below the lower limit of your target range and does not match how you feel, or you see an error message of "Low Result (E10: The test result is below 20 mg/dL. It is outside of the measurement range)". Please perform a control solution test to verify whether the system works properly, or contact your healthcare professional.
- If your test result is above the upper limit of your target range and does not match how you feel, or you see an error message of "High Result (E11: The test result is above 600 mg/dL. It is outside of the measurement range)". Please perform a control solution test to verify whether the system works properly, or contact your healthcare professional.
- If the test result does not match how you feel, please do not change your medication or food regimen before contacting your healthcare professional.

Warnings for Charging Battery:

- Do not disassemble the meter and take battery out for charging.
- Do not use the USB cable, AC adapter or meter if it is damaged, discolored or deformed.
- Do not insert a test strip when charging. The meter is designed that blood glucose testing can't be performed during meter charging.
- Do not put the meter on the thermally insulating materials such as clothing, carpet, blanket, or plastic surface for charging. Otherwise, this may potentially pose a risk of overheating, smoking or catching fire.
- Do not recharge the meter outdoors, sunlight, a wet area or a heating area. Otherwise, this may potentially pose a risk of overheating, smoking, catching fire or impairing normal operation of the meter.
- Do not charge the meter in environmental temperature above 104°F. The meter can be safely recharged at normal indoor temperatures.
- Do not allow unsupervised children to charge the meter battery.



Warning:

Please note that the battery is not removable. If the battery requires sorting and discarding due to scrap of the product, please keep it away from children. A lithium battery is poisonous. If swallowed, immediately contact your doctor or poison control center. Discard battery according to your local environmental regulations.

Caring for Your Glucose Monitoring System

- Store meter in the carrying case provided whenever possible.
- Wash and dry hands well before handling to keep the meter and test strips free of water and other contaminants.
- BG500 blood glucose meter is a precision electronic instrument. Please handle it with care.
- Avoid exposing meter, test strips and control solution to excessive humidity, heat, cold, dust, or dirt. The operating conditions for meter and test strips are 41-113°F, relative humidity 10-90%. The operating conditions for control solution are 50-104°F, relative humidity 10-90%. Avoid heat and direct sunlight.

Cleaning and Disinfection

The purpose of cleaning step is to remove the potential dirt and dust particles, and make clean surface for the next disinfection step. The purpose of disinfection step is to disinfect the microorganism on whole surface of meter.

Use only Clorox™ Healthcare Bleach Germicidal Wipes. It has been proven to be safe to use with the Meter. The wipes are available by visiting and purchasing at <http://www.walmart.com>, <http://www.staples.com/>, or <https://www.amazon.com/>.

The meter should be cleaned and disinfected at a minimum of once per week. The process has been validated for 608 cycles, which is equivalent cleaning and disinfecting your meter every 3 days for 5 years. This is to ensure that your meter will operate properly over the 5-year life.

Warning: If the meter is being operated by a second person who is providing testing assistance to you, the meter should be cleaned and disinfected prior to use by the second person.

Notes:

- Do not use alcohol or any other solvent. These have not been proved to be safe and effective for use with the meter.
- Do not allow liquid, dirt, dust, blood, or control solution to enter the test strip port or the USB port.
- Do not squeeze the wipe or gauze into test strip port.
- Do not spray the cleaning solution on the meter.
- Do not immerse the meter in any liquid.
- Please refer to the safety instruction in the labeling of Clorox™ Healthcare Bleach Germicidal Wipes before using wipes.

Cleaning Your Meter

Step 1: Take one piece of Clorox™ Healthcare Bleach Germicidal Wipes (EPA Registration No. 67619-12) from the container.

Step 2: Clean the entire surface of the meter. It includes the front, back, left, right, top and bottom sides of the meter, test strip port, test strip ejector, button, material seams and USB port for one minute.

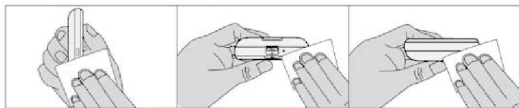
This cleaning is to prepare a clean surface for a disinfection process.



Front side

Back side

Right side



Left side

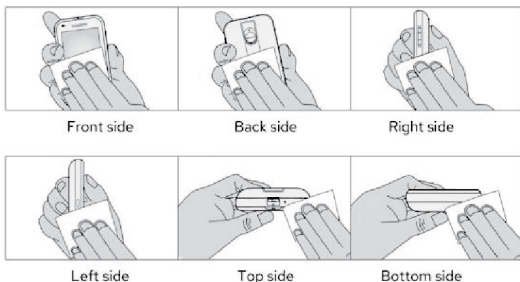
Top side

Bottom side

Disinfecting Your Meter

Step 1: After cleaning your meter, take out another new piece of Clorox™ Healthcare Bleach Germicidal Wipes.

Step 2: Wipe the entire surface of the meter. The parts of meter that are particularly susceptible to blood contamination should be wiped. These include the front housing, middle housing, back housing, strip ejector, buttons, test strip port, display screen, LED indicator, material seams and charging port. Keep the meter wet for one minute.



Step 3: Please do not touch the meter. And wait for one minute at least to make the meter's surface to be dry after performing the step 2 above.

Step 4: Please wash hands thoroughly with soap and water after completing the disinfection procedure.

Notes:

Although it has not been observed, some alterations may appear on your meter due to the cleaning and disinfection procedure, such as: cloudy display window, plastic housing cracking, meter's button does not function, partial display on screen, unable to execute the meter's initial set up. If you notice any of these, please stop using the meter and contact 24/7 Member Support 800-945-4355 and membersupport@teladochealth.com for help. If you have questions about cleaning or disinfection, contact 24/7 Member Support 800-945-4355 and membersupport@teladochealth.com.

System Specifications:

Feature	Specification
Measurement Range	20 - 600 mg/dL
Measurement Result	Plasma equivalent
Sample	Fresh capillary whole blood
Sample Volume	0.8 μ L
Test Time	5 seconds
Power Source	Rechargeable, 3.7 Volt Lithium Ion Battery
Charging Time	\leq 3h, --- Direct current
Battery Type	Rechargeable, 1300 mAh, 3.7 Volt DC nominal. Lithium polymer battery (5V input charge voltage)
Unit of Measure	mg/dL
Memory	2,000 records
Automatic Shutoff	2 minutes after last action
Dimensions	105.2 mm x 60.2 mm x 17.5 mm
Weight	Approximately 123g
Operating Temperature	41 - 113°F
Operating Relative Humidity	10-90% (non-condensing)
Hematocrit Range	20 - 70%
Charging Port	USB Type-C
Data Transmission	This meter features automatic transfer of glucose results to the Cloud, using 4G wireless mobile communication.
AC Adapter	Model: BLJ06L050100U-U Input: 100-240V~, 50/60Hz, 0.2A (200mA) Max. Output: 5.0V --- 1.0A (1000mA).

4G Specifications:

Item Name	Design Specification
Transmit Frequencies	1850-1910 MHz. 1710-1755 MHz. 699-716 MHz. 777-787 MHz.
Receive Frequencies	1930-1990 MHz. 2110-2155 MHz. 729-746 MHz. 746-756 MHz.
Throughput	Downlink≥500Kbps. Uplink≥1000Kbps.
Latency	≤25ms.
Data Integrity	Data shall be transmitted correctly and completely.
Accessibility	Accessibility is high since 4G is broadband.
Signal Priority	Routine priority using 4G access standard.

A List for Interface: Receive and/or Send Testing Results:

Interface Name	Functionality	Incoming, Outgoing, or Both	Destination End-point
4G Module	Glucose testing results transmission	Outgoing (sending) from meter to AWS Cloud.	AWS Cloud.

Electromagnetic Compatibility Instructions:

The device is intended for home use. Classified as CISPR 11 Group 1, Class B.

Use of accessories, transducer, and cable other than those specified or provided by the manufacturer may result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and may result in improper operation.

Portable RF communications equipment such as antenna should be used no closer than 30 cm (12 inches) to any part of this device.

Although the device is intended for home use only, we still remind that please do not expose your device to unique medical emitters such as electrocautery, MRI, electrosurgical units, diathermy devices. Please try to increase distance between the device and source of the interference if it is suspected that function or performance may be affected by electromagnetic interference.

Please follow all instructions in the user manual for maintaining the device's basic safety and essential performance regarding electromagnetic disturbances. You can contact the distributor for technical support using the contact information listed in the user manual or outer box.

It is recommended that the user should not use the device and then check above items if the functions or performance of the device may be lost or degraded due to electromagnetic disturbances.

FCC Requirement**Test Frequency:**

Test Mode	Nominal Bandwidth (MHz)	RF Channel		
		Low (L)	Middle (M)	High (H)
		MHz	MHz	MHz
CatM1 Band 2	1.4	1850.7	1880	1909.3
	3	1850.87	1879.37	1909.13
	5	1850.79	1878.29	1909.21
	10	1851.22	1876.22	1908.78
	15	1851.47	1873.97	1908.53
	20	1851.9	1871.9	1908.1
CatM1 Band 4	1.4	1710.7	1732.5	1754.3
	3	1710.87	1731.87	1754.13
	5	1710.79	1730.79	1754.21
	10	1711.22	1728.72	1753.78
	15	1711.47	1726.47	1753.53
	20	1711.9	1724.4	1753.1
CatM1 Band 12	1.4	699.7	707.5	715.3
	3	699.87	706.87	715.13
	5	699.79	705.79	715.21
	10	700.22	703.72	714.78
CatM1 Band 13	5	777.79	780.29	786.21
	10	778.22	778.22	785.78

This meter has been tested and found to comply with the standards below:
47 CFR part 2, part 15 subpart B, part 24 subpart E, part 27 subpart C, and IEEE standard C95.1.

Meter Manufactured by:
Guangdong Transtek Medical Electronics Co., Ltd.
Zone A, No. 105, Dongli Road, Torch Development District, 528437 Zhongshan, Guangdong,
China

Manufactured for Teladoc Health, Inc.
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800-945-4355
24/7 Member Support



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