



Guangdong Transtek Medical Electronics Co., Ltd.
广东乐心医疗电子股份有限公司

Document Name: 文件名称:	USER MANUAL
Document No 文件编号:	LS-IFU-GBZ41-B-02
Rev: 版本号:	A/0
Page: 页码:	Total 41 pages

Prepared 编制	Reviewed 审核	Approved 批准
Celia Li	Yvonne Huang	Carlos Fong

◆ Revision History 修订履历

NO.	Date 日期	Update Description 变更描述	Prepared 编制	Reviewed 审核	Approved 批准
A/0	2024/8/20	Initial release	李鑫 Celia Li	黄婉婷 Yvonne Huang	冯嘉贤 Carlos Fong

TRANSTEK

BT Blood Glucose Monitoring System

USER MANUAL



Model: GBZ41-B

**All images for reference only*

TRANSTЕК

BT Blood Glucose Monitoring System

Hi there,
Thanks for choosing TRANSTЕК! This meter helps you check your blood sugar. Be sure to read this booklet before you start. It will help you learn how to use your blood sugar product (we call it a Blood Glucose Monitoring System) and make sure your results are right. Keep this guide in a safe spot. You might need it later. Thanks again for choosing the TRANSTЕК!

Intended Use

The TRANSTЕК BT Blood Glucose Monitoring System is composed of the TRANSTЕК BT Blood Glucose Meter and TRANSTЕК Blood Glucose Test Strips. The TRANSTЕК BT 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 fingertips. The system is intended for self-testing outside the body (in vitro diagnostic use), by individuals with diabetes at home as an aid to monitor the effectiveness of diabetes control. The system is intended to be used by a single person and should not be shared. The system should not be used for the diagnosis of, or screening for diabetes or for neonatal use.

Principle of Operation

Glucose in the blood sample mixes with the enzyme GDH-FAD in the test strip and a small electric current is produced. The strength of this current calculates your blood glucose level. It then displays the blood glucose result and stores it in the meter memory.

Use only TRANSTЕК Control Solutions and Test Strips with the TRANSTЕК Meter. Use of TRANSTЕК Test Strips with meters for which they are not intended may yield inaccurate results.

TABLE OF CONTENTS

1. Understanding Your Testing Tools	1
Your System Overview	1
Your Meter Display	2
Using the Glucometer the Right Way	4
Important Safety Information	5
Limitations (Who should not use this glucometer)	5
2. Setting up Your System	6
Pairing the Glucometer to a Phone or Tablet	6
Set the Date and Time	7
Other Settings	8
3. Performing a Test	11
Preparing the Test Strip	11
How to Get Your Finger Ready for a Poke	11
How to Put a Lancet (finger prick) in the Device	12
How to Take a Blood Drop	13
Throwing Away the Test Strip	14
Get Rid of the Used Lancet (finger prick)	14
Expected Glucose Range for People without Diabetes:	15
Questionable or Inconsistent Results	16
Symptoms of High or Low Blood Glucose	16
Precision and Accuracy	17
Comparing Meter and Laboratory Results	19
Testing with Control Solution	19
How to Do a Control Test	20
Understand Control Test Result	21
Using the Meter Memory	22
Viewing Your Test Results	22
4. Maintenance and Troubleshooting	24
Changing the Battery	24
Taking Care of the System	24
Cleaning Your Meter	25
Disinfecting Your Meter	26
Troubleshooting Guide	27
5. Technical Information	29
System Specifications	29
Safety Information	30
Warranty	31
EMC Guidance	32
FCC Statement	35

CHAPTER 1: UNDERSTANDING YOUR TESTING TOOLS

1. Before opening the box, check if the package is torn or damaged.
2. After opening, make sure all the parts are inside. You can check the list that came in the box to see what should be included.

Your System Overview

1. TRANSTЕК BT Blood Glucose Meter



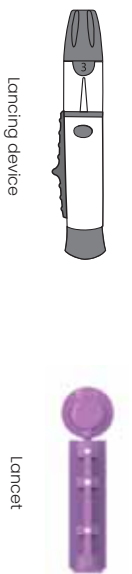
- ① **Display**
Shows test results, and related information.
- ② **HOME Button**
Press to turn on/off meter switch different function.
- ③ **Left/Right Button**
Adjust settings and review test values.
- ④ **Battery compartment**
- ⑤ **Strip Ejector**
Push up on button to eject testing strip from meter.
- ⑥ **Test Strip Port**

2. Test Strips



- ① **Sample Tip**
Where the blood is drawn in.
- ② **Electrode End**
This end is inserted into the strip port on the meter, facing upwards in the direction of the arrows.

3. Lancing Device & Lancets



4. Control Solution

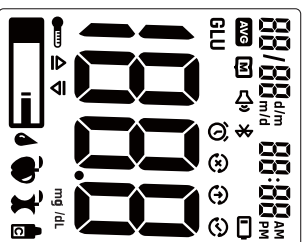


Notes:

The TRANSTEK Blood Glucose Test Strips, TRANSTEK Control Solution, TRANSTEK Lancing Device and TRANSTEK Lancets are not included in the meter box but are necessary for use, please contact 24/7 TRANSTEK Customer Support at (833) 445-5666 for purchase.

Your Meter Display

The picture below shows all the symbols that appear on your meter display. Please make sure the display is working properly before testing. When the meter is off, press and hold [M] to see the complete display. All display segments will appear. If you need more time to check the display, repeat the above operation. All display segments should be clear and exactly like the picture below. If not, contact 24/7 TRANSTEK Customer Support at (833) 445-5666 for help.



Icon	What It Means
	The top left area on the screen indicates date.
	The top right area on the screen indicates year or time.
	Morning time or afternoon time.
	Indicates the display form of day and month (d/m) or month and day (m/d).
	Data transmitted successfully.
	Data not transmitted.
	In data transmission.
	Indicates test result history.
	Indicates average value.
	Indicates the battery level is low.
	High blood glucose test results remind you of high blood glucose.
	The low glucose test result may indicate hypoglycemia.
	The Bluetooth symbol flashes to indicate Bluetooth connection, and remains on after connection.
	Center area on the display that shows test results or error codes.
	Indicates the temperature is not suitable for testing.
	Test results are displayed as mg/dL.
	Flashing to indicate the user to insert the test strip.
	When strip is inserted, the drop will flash, indicating the system is ready to test.
	Before meal marker.
	After meal marker.
	Control test result.
	Indicates volume is on.

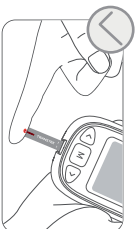
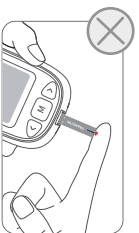
Notes :

Your glucose meter makes beeping sounds to help you. It will beep when:

- *You turn it on.*
- *You put in a test strip and it is ready for blood or test liquid.*
- *It gets enough blood or liquid.*
- *The test is done.*
- *Something goes wrong*

Using the Glucometer the Right Way

- The glucometer shows your blood sugar in mg/dL (that stands for milligrams per deciliter).
- If you do not press anything for 2 minutes, the glucometer turns off by itself.
- Keep it clean and dry.
- Do not leave it somewhere too hot or cold, like a car. It works between 41°F – 113°F.
- Do not drop it or let it get wet. It works between 10% – 90%.
- If it falls into water or gets splashed, do not use it until you test it with control solution.
- Always follow the directions in this guide. Using it the wrong way can break it.
- Do not move test strips to a different container.
- Do not drip blood on top of the strip. Let the strip pull the blood in by touching the strip to a drop of blood.



- Check the expiration dates and discard dates on your test strips vial label and control solution vial label.
- Use only TRANSTEK Blood Glucose Test Strip with your TRANSTEK BT Blood Glucose Meter.
- Use only TRANSTEK Control Solution with your TRANSTEK BT Blood Glucose Meter and TRANSTEK Blood Glucose Test Strip.
- 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

- The glucometer and the finger-poking tool (lancing device) are for one person only. Do not share them, even with family.
- Used parts can carry germs from blood—even after cleaning.
- Be very careful when using the glucometer and lancing device.
- Do not change how you check your blood sugar or treat your diabetes without asking your doctor.
- Clean and disinfect the glucometer the right way (you will find those instructions later in the guide).
- Throw away the glucometer the right way by following local safety rules.

Limitations (Who should not use this glucometer)

- Not for use on critically ill patients, patients in shock or in a hyperglycemic-hyperosmolar state with or without ketosis.
- Not for use on patients with severe dehydration.
- Do not perform test during or soon after xylose absorption testing. High xylose level in the blood will cause inaccurate results.
- Not for use on babies (this is not for newborns).
- Not for use on people who are using this to see if someone has diabetes—this glucometer is not for screening or diagnosis of diabetes.
- Not for use when people are more than 10,000 feet above sea level (like on a high mountain).
- Doctors or nurses using this on many patients—this glucometer is not approved for hospitals or care centers.
- If used on more than one person, it could spread serious viruses like HIV, Hepatitis B, or Hepatitis C, or other bloodborne pathogens.

CHAPTER 2: SETTING UP YOUR SYSTEM

Before using your meter for the first time, make sure to set up your meter properly.

Pairing the Glucometer to a Phone or Tablet

You can connect your glucometer to Online app to save and send your blood sugar results.

- Once paired, the date and time on the glucometer will set themselves.
- When you put in new batteries, the glucometer will try to pair with your phone again.
- If you do not pair within 60 seconds, the glucometer will skip to the year setting.

Here is how to pair it:

1. Turn on the Bluetooth and the app on your smart device.
Make sure both are ON when pairing is proceeding.
2. When the meter is off, press and hold the **[M]** to start pair-up, the Bluetooth symbol will flash.
3. If successful, the Bluetooth symbol will not flash any more and the meter will automatically shut off after several seconds.

Notes:

- *If the Bluetooth connection is successful, date and time will be automatic acquisition via Bluetooth.*
- *Before your first use of the meter for testing, please adjust the meter settings to set the correct date and time, ensuring that results stored in the memory are shown with the correct date and time.*

Specifications for Bluetooth Transmission	
Throughput	>2.5Kbps
Latency	<200 ms
PER	<10%
Operating Frequency	2402-2480 MHz
Transmission Power	0±2 dbm
Transmission Distance	10 m

Notes:

1. The necessary Quality of Service (QoS) is fully considered here for wirelessly enabled functions.
2. Interference may occur in the vicinity of equipment marked with the following symbol . And GHz4-B may interfere the vicinal electrical equipment.
3. To enable the data transmission function, this device shall be paired to an appropriate BT mobile terminal.

Warning:

This meter operates in the 2.4 GHz ISM band, which is an unlicensed frequency range. If used near other wireless devices—such as microwaves or wireless LAN equipment that also use the 2.4 GHz band—interference may occur.

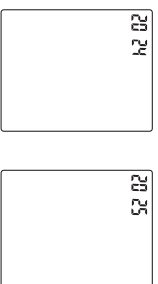
If you experience interference, please try one of the following:

- Turn off other wireless devices,
- Move the meter farther away from them, or
- Avoid using the meter near other wireless devices.

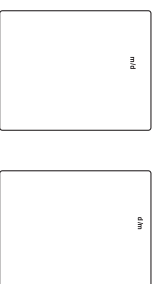
Set the Date and Time

When the meter is off, press and hold  until the meter enter the set up mode.

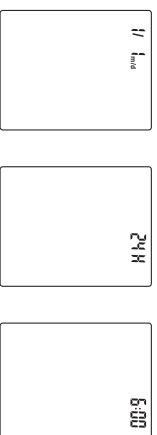
1. It will display the Bluetooth symbol first.
No operation within 60s or Press the  again, it will skip Bluetooth pairing and enter the [Year] setting.
Press the  or  to change the year.
Press and hold the  to quickly advance the years.
Press and hold the  button to quickly go backwards through the years.



2. Press **[M]** to confirm the year, then the [date format] will flash. Press the **[<]** or **[>]** to switch the date format between [month/day] and [day/month].



3. Press **[M]** to confirm the date format, then the [month] will flash. Repeat the same steps to set the month, day, time format, hour and minute.

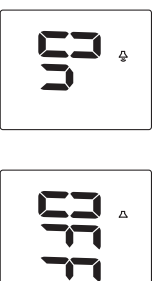


Other settings

The device provides other personalized settings, these settings will be performed in sequence after the [Date and Time] settings are completed.

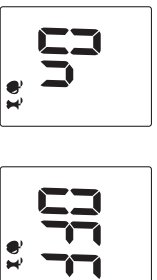
1. Settings the Buzzer

After you set the time, press **[<]** or **[>]** to adjust "On" or "Off". Press **[M]** to set.



2. Settings the Meal Marker

After setting the audio feature, the symbols of  will now flash, press  to  adjust "On" or "Off" on the display, press  to set.

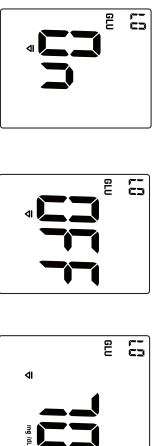


3. Set the Hypoglycemia (Hypo) Reminder

After you have confirmed the meal marker setting, the LO flashes on the display.

Press  or  to adjust the LO reminder function "On" or "Off", then press button to set. If you select the LO reminder to be "On", the display shows 70 mg/dL as default.

Press  or  to adjust blood glucose level (the level increases by 1 mg/dL). You can adjust the range from 60 to 80 mg/dL. Press  button to confirm.



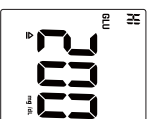
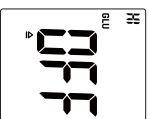
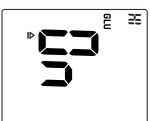
Notes:

- **Hypo reminder:** This is a reminder on your meter. It reminds you that your glucose level is at or below a value recommended by your doctor.
- To use it: Turn the Hypo reminder "On". It will show a "Hypo" reminder if your test result is below your set level.
- Your healthcare professional will help you decide and set the best glucose level for your needs.

4. Settings the High Glucose Reminder

The icon is to provide a 'high glucose' reminder that after the LO reminder setting is completed, the HI symbol will now flash, along with word "On" or "Off" on the display. Press  or  to adjust the 'high glucose' reminder on or off. If you select the HI reminder to be "On", the display shows 140 mg/dL as default.

Press  or  to adjust blood glucose level (the level increases by 1 mg/dL). You can adjust the range from 140 to 200 mg/dL. Press  to set.



5. Set up Reading Reminders (alarms)

The meter starts with all alarms OFF — but you can set up to 5 reminders each day. Here are the pre-set times:

- A1 – 7:00 AM
- A2 – 8:00 AM
- A3 – 14:00 (2:00) PM
- A4 – 18:00 (6:00) PM
- A5 – 22:00 (10:00) PM

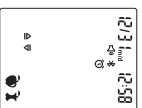
But you can change them, here is how:

1. Press the **<** BUTTON — the first time (A1) will flash.
2. Use the **>** BUTTON to turn it ON, and the **<** BUTTON to turn it OFF.
3. Press the **M** BUTTON to save.
4. If you choose ON, find the hour you had like, like 7, with the arrows.
5. Then press the **M** BUTTON.
6. Next, choose the minutes: 00, 15, 30, or 45.
7. Press the **M** BUTTON again.
8. Then, A2 (the next alarm) will flash.
9. Do the same steps for each one.

Note: If you are already using the meter at the reminder time, it will not beep.

6. Setup is done — check your settings

1. After you set everything up, press the **M** BUTTON for 2 seconds.
2. The screen will show all the symbols you have chosen — the meter will turn off by itself.



Ready to test?

1. When you are ready to check your blood sugar, press the **M** BUTTON.
2. A picture of a flashing test strip will appear — this means the meter is ready for you to test your blood sugar.

Want to change your settings?

If you want to go back and change any settings, press and hold the **M** BUTTON for 3 seconds when the meter is off. This will take you back into setup mode.

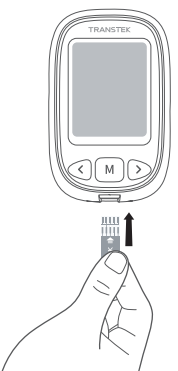
CHAPTER 3: PERFORMING A TEST

Before we test, we need to have everything ready:

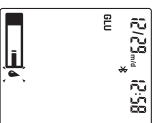
- Glucose meter
- Test strips
- Lancing device and lancets (these poke the finger)

Preparing the Test Strip

1. Wash and dry your hands well before testing.
2. Remove a test strip from the test strip vial. Tightly close the vial cap immediately after you have removed the test strip.
3. Insert the test strip into the meter in the direction of the arrows. Meter turns on after a beep.



4. A symbol with a flashing blood drop will appear letting you know the meter is ready to test.



Notes:

- The meter turns off if we wait too long (about 2 min).
- Check the expiration date on the strip bottle. (Your test strips have 6 months shelf life after you first open the test strip vial)
- Do not use strips that look damaged.
- Prior to testing, wipe the test site with an alcohol swab or soapy water. Use warm water to wash hands to increase blood flow if necessary. Then dry your hands and the test site thoroughly. Make sure there is no cream or lotion on the test site.
- The TRANSTEX Blood Glucose Monitoring System has not been evaluated for Alternative Site Testing (AST). Use only fingertips when testing with the system.

How to Get Your Finger Ready for a Poke

You will use the lancing (finger prick) device to poke your finger. Make sure to use a clean, unused lancet.

How to Put a Lancet (finger prick) in the Device

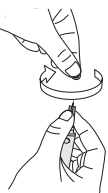
1. Take off the device cap
- Twist and pull off the top of the lancing device.



Notes:

The TRANSTEK lancing device uses ONLY TRANSTEK sterile lancets.

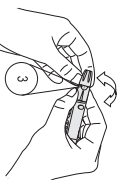
2. Put in a new lancet
- Push the lancet (finger prick) with the cap on, all the way in until it stops.



3. Remove the safety tab
- Twist the little cap on the lancet and pull it off.
- Save this piece — we will use it later to throw the lancet away safely.



4. Screw the device cap back on
- Do not touch the lancet needle.



Adjustment:

- 1 for delicate skin
- 2 and 3 for normal skin
- 4 and 5 for calloused or thick skin

Notes:

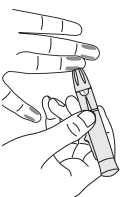
Pressing harder on the skin makes the poke deeper. Clean the spot you will use with warm water — it helps get blood flowing.

How to Take a Blood Drop

1. Get the lancing device ready
 - Pull back the handle until you hear a click — this means it is ready to use.



2. Prick your finger
 - Press the lancing device against the side of your finger tip — it usually hurts less. Push the button to make a tiny poke — you will hear a click.



3. Wipe off the first drop
 - Use a clean paper towel to wipe away the first little drop of blood. Then gently squeeze from the bottom of your finger to the tip until you get another small drop. Do not smear it. The drop should be about half the size of a match head.



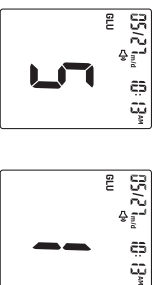
4. Touch the tip of the test strip (in your meter) to the blood drop
 - The blood will go into the strip on its own — hold it there until the window on the strip fills with blood and your meter beeps.



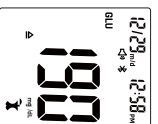
Notes:

If the strip does not fill all the way, you will get an error (E5). Do not add more blood. Throw the strip away and use a new one.

5. The meter will count down from 5 seconds and beep — your result will show on the screen. Do not touch the strip while it is counting, or it might give an error.



6. Press the [M] to adjust before or after meal, press [M] to set.



** If you do not select "Confirm", the testing result will be automatically uploaded after the screen is turned off, and the testing result will be marked as no meal tag.*

7. The meter sends the result to your health record in your app.

Throwing Away the Test Strip

Treat it like medical waste — use the strip ejector to pop out the used strip into the trash.

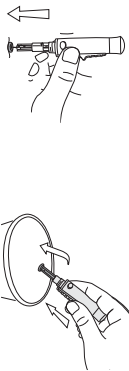


Potential Biohazard

Dispose of the used test strips as medical waste.

Get Rid of the Used Lancet (finger prick)

1. Twist off the cap off the device.
2. Press the lancet (finger prick) back into its safety tab (the little cap you saved) — you can put the cap on a table to do this.
3. Press the button so the needle comes out.
4. Slide the button to push out the lancet (finger prick) into a sharps container — something like an old laundry detergent bottle works.
5. Never use your fingers to pull it out — follow local rules for medical waste.
6. Put the cap back on the device.



Place the lancing device cover back on the lancing device.
Please wash hands thoroughly with soap and water after handling the meter, lancing device, or test strips.

⚠ Potential Biohazard

Always dispose of the used or contaminated lancet properly to prevent potential injury or infections to others.

⚠ Caution

- This lancing device is for use by a single person only. Do not share it with others.
- Before use, check the lancet. If the safety tab is missing or loose when removed from the package, do not use it.
- Do not use a lancet that is contaminated, dropped, or whose safety tab has been removed.
- Always be careful when the lancet needle is exposed.
- Do not reuse a lancet, and do not share lancets with anyone—including family members.

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 2023;41(1):4–31.

Notes:

Always ask your doctor or a provider what numbers are healthy for you.

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):	High blood glucose (Hyperglycemia):	Ketones (ketoadicosis) :
• shakiness • sweating • fast pulse rate • blurred vision • confusion	• passing out • irritability • seizure • extreme hunger • dizziness	• frequent urination • excessive thirst • blurred vision • increased fatigue • hunger
		• shortness of breath • nausea or vomiting • very dry mouth

What if values do not match how you feel?

Sometimes your values might seem too high or too low, but you feel okay—or you feel bad and the value looks normal.

When that happens :

1. Check the strip — Is it expired? Has the bottle been open too long(more than 6 months)?
2. Check your environment — Is it too hot or cold where you are testing? (between 41–113°F)
3. Did you store the strips right? (They should be kept between 36°F and 86°F, and away from moisture.)
4. Try a control solution test — That checks if your glucometer is working.
5. If your value still looks wrong and you feel strange, call your doctor.

Notes:

- If your number is LO (less than 10 mg/dL), call your doctor right away.
- If your number is HI (more than 600 mg/dL), call your doctor right away.
- Never change your medicine or food plan without talking to your doctor first.
- If you still get strange numbers, test again with a new strip. If things still do not make sense call us at (833) 445-5666. (24/7).

Precision and Accuracy

Linearity Results:

Lot 1: $y = 0.9819x + 9.3521$; $R^2 = 0.9968$.
Lot 2: $y = 0.9891x + 11.812$; $R^2 = 0.9987$.
Lot 3: $y = 0.9893x + 13.107$; $R^2 = 0.9986$.
All 3 Strips Lots: $y = 0.987x + 11.283$; $R^2 = 0.9979$.
The results support the claimed measurement range of 10–600 mg/dL.
The 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:

Within - Run Precision - Blood			
Interval	Glucose Concentration	Standard Deviation (SD)	Coefficient of Variation (CV)
1	40.2 mg/dL	1.6 mg/dL	4.0%
2	81.6 mg/dL	2.6 mg/dL	3.2%
3	134.9 mg/dL	4.5 mg/dL	3.3%
4	212.4 mg/dL	8.9 mg/dL	4.2%
5	318.2 mg/dL	9.4 mg/dL	3.0%

Intermediate Precision:

Intermediate Precision - Control Solution			
Interval	Glucose Concentration	Standard Deviation (SD)	Coefficient of Variation (CV)
1	35.5 mg/dL	1.2 mg/dL	3.4%
2	75.9 mg/dL	2.4 mg/dL	3.2%
3	124.2 mg/dL	4.1 mg/dL	3.3%
4	199.4 mg/dL	6.3 mg/dL	3.2%
5	308.3 mg/dL	9.3 mg/dL	3.0%

User Evaluation:

The Blood Glucose Monitoring System was tested by xxx lay users using capillary blood samples and three blood glucose test strips lots. The results were compared to the YSI 2900C Glucose Analyzer, a laboratory instrument. See the table below with accuracy performance study results that shows the Blood Glucose Monitoring System achieved 100% of results within $\pm 15\%$ of the laboratory instrument. The results shown here are intended to inform you about your meter, how much results are consistent with your actual blood glucose values.

Table 1- Linear Regression Results

Slope	xxxxmg/dL
Intercept	xxxx
Correlation coefficient (R)	xxxx
Number of sample	xxxx
Range tested	xxxxmg/dL

Table 2 - Consumers Accuracy Results

Accuracy for Home Use by Lay-Users TRANSTEX BT 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 xxx typical users used the TRANSTEX BT Blood Glucose Meter to test their blood glucose level. In this study, TRANSTEX BT Blood Glucose Meter gave results within $\pm 15\%$ of their true blood glucose level xxx out of xxx times.				
Difference range between the true blood glucose level and TRANSTEX BT Blood Glucose Meter result	Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
The percent (and number) of meter results that match true blood glucose level within x%	xxx% (xxx/xxx)	xx.x% (xxx/xxx)	xxx% (xxx/xxx)	xxx% (xxx/xxx)

Comparing Meter and Laboratory Results

Before you go to the lab:

- Do a control test first to make sure your glucometer is working properly.
- If the doctor said to come in while fasting (not eating), this is a good time to compare.
- If there is a difference between your fingertip blood sugar level and your venous blood sugar level just after eating or within two hours of eating, please consult your doctor.
- Bring your glucometer and test strips with you.

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.

Notes:

- *Every so often, it is a good idea to check how your home test matches a lab test.*
- *Your glucometer might be a little different from lab results, and that is normal, but they should be close.*

Testing with Control Solution

What is a control test?

A control test checks if your glucometer and test strips are working the right way. You use control solution (which is like fake blood with a known sugar level).

When to do a control test?

- When you open a new vial of test strips.
- If you suspect that the meter or test strips are not working properly.
- If you have had repeated unexpected blood glucose readings.
- If you drop or damage the meter.
- If you left the test strip container open or you think the test strips have been damaged.
- If the test strips were stored in extreme temperatures and/or humidity.
- Your test result does not match how you feel.

Use the right control solution

- The glucometer will know it is a control test and mark it for you.
- Only use TRANSTEK Control Solutions (1, 2 or 3) to practice on the system.
- These results do not count in your 7, 14, or 30-day averages.
- Keep the control solution between 36°F and 86°F and in 10–90% humidity (not too dry or wet)
- The expiration date is written as Year–Month–Day (Example: 2025-01-01 means January 1, 2025).

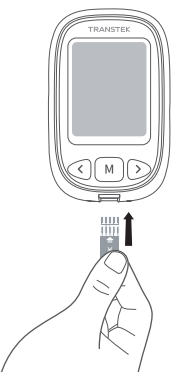
- Once opened, the control solution is good for 6 months. Write the open date on the bottle.
- Shake the bottle before using.
- Close the bottle tightly after using it.

How to Do a Control Test

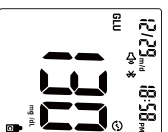
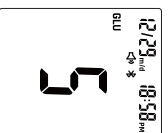
1. Take one test strip out of the bottle. Close the lid tightly right after. (Do not use expired strips.)



2. Put the strip into the glucometer (follow the arrows); it will beep and turn on. A flashing blood drop means it is ready.



3. Shake the control solution bottle well. Squeeze out the first drop and wipe it away.
4. Squeeze out a second drop onto the top of the bottle cap or a clean surface. (Never drop the liquid directly onto the strip from the bottle.)
5. Touch the tip of the strip to the drop. It will pull the liquid in by itself.
6. Hold the strip in the drop until the glucometer beeps.
7. You will see the glucometer count down and show the result.

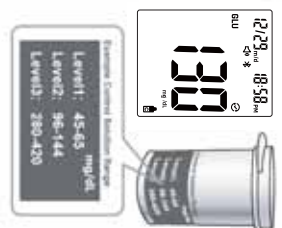


Notes:

- The glucometer knows this is a control test and it will mark the result for you.
- Control test results will not be included in your blood sugar averages (like 7-day or 30-day).
- Always wash your hands after handling test strips or control solution.

Understand Control Test Result

Compare your control test result with the ranges printed on the test strip vial label.



Remark : The ranges in the image above are only example and the ranges on the vial in use should be referenced.

Notes :

If your control test result is out of range, please check:

- Is the test strip or control solution expired?
- Has it been more than 6 months since you opened the bottle?
- Was the temperature between 50°F and 104°F while you tested?
- Did you store your strips and control solution between 36°F and 86°F in a dry place?
- Did you close the bottle lids tightly after opening them?
- Did you use the strip right after taking it out of the bottle?
- Did you shake the control solution before using it?
- Did you use TRANSTEK brand control solution?
- Did you follow the steps exactly?

Still not right?

- Try the test again with a new strip.
- If the number is still wrong, your glucometer or strips might not be working right.
- Do not use the glucometer to test your blood until the control test gives a number in the safe range.

Need help?

Call us at (833) 445-5666, (24/7) if it is after hours, leave a message. They will call you back in 2 business days.

Using the Meter Memory

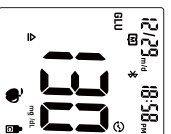
Your meter automatically stores up to 1000 results with time, date and meal marker. Test results are stored from the newest to the oldest. The meter will also calculate the average values of blood glucose records from the last 7, 14 and 30 days.

Notes:

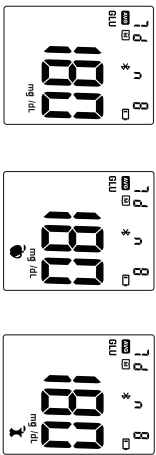
- If there are already 1000 records in memory, the oldest record will be erased to make room for a new one.
- Control results of blood glucose are not included in the 7, 14 and 30 day average calculation.

Viewing Your Test Results

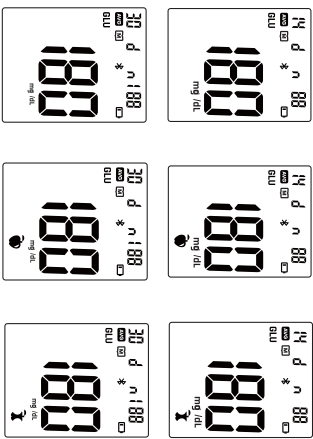
When your meter is off, press **[M]** button to turn meter on. After a beep, a symbol of a test strip flashes on the display. Press **[M]** button to review previous results in order. Results will be shown starting with the most recent. Each result will show the date and time the test was taken. When you see the last result, will display "End", then press **[M]** to turn off the device.



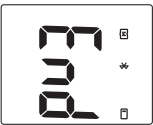
Continue press **M** button, the 7-day average of blood glucose appears in the center of the display.



Continue to press **M** button to view the 14-day average of blood glucose, then press **M** button again to review the 30-day average of blood glucose.



When END appears on the display, you have viewed all of the results in the memory.



CHAPTER 4 : MAINTENANCE AND TROUBLESHOOTING

Proper maintenance is recommended.

Changing the Battery

When the meter is out of power, the Empty Battery Symbol () will appear. When the Empty Battery Symbol () and 'E 9' appear on the screen, the meter cannot be used. You must change the battery before using your meter.



Warning:

Keep batteries away from kids. If a battery is swallowed, call a doctor or poison control center right away. Throw away old batteries the right way—follow your local rules.

Taking Care of the System

- Keep your glucometer in its case when you are not using it.
- Always wash and dry your hands before touching the glucometer or test strips.
- The glucometer is a precision tool, so treat it gently.
- Do not let it get too hot, too cold, too wet, or too dusty.
- It works best between 41°F and 113°F and with 10–90% humidity.
- Control solution should be stored between 36°F and 86°F and also in 10–90% humidity.
- Keep the product away from heat and sunlight.

Why it matters?

- Cleaning gets rid of dirt and dust.
- Disinfecting kills any germs or bacteria on the glucometer.

What to use?

- Use only Clorox Healthcare Bleach Germicidal Wipes. These wipes are safe to use on your glucometer and will not damage it.
- Your glucometer should be cleaned and disinfected at least once a week. It is been tested to last for 5 years if you clean it once every 7 days.

Warning for Helpers and Caretakers

If someone else (like a nurse or caregiver) is helping you use the glucose meter, they should clean and disinfect it before they touch it or use it.

- Notes:
- Do not use alcohol or other cleaners unless the manual says they are safe.
 - Do not let water or cleaner get inside the test strip port.
 - Do not squeeze wipes into any openings.
 - Do not spray anything directly on the glucose meter.
 - Do not dip the glucose meter in water.
 - Always read the label on the wipes before using them.

Cleaning Your Meter

Step 1:

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



Step 2:

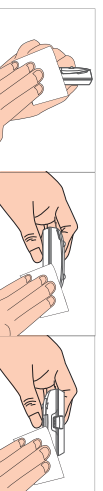
- Use the wipe to clean every part of the glucometer. Rub each part gently for one minute.
- Front
- Back
- Left side
- Right side
- Top
- Bottom
- Buttons
- The strip port (where you insert the test strip)
- The strip ejector
- Any seams or cracks in the plastic



Front side

Back side

Right side



Left side

Top side

Bottom side

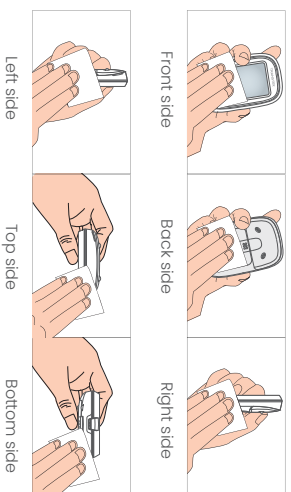
Disinfecting Your Meter

Step 1:

After cleaning your meter, take a fresh Clorox™ Healthcare Bleach Germicidal Wipe.

Step 2:

Wipe the entire surface of the meter. The parts of the meter that are particularly susceptible to blood contamination should be wiped, which include the test strip port, test strip ejector, button, material seams and forth movement.



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:

Remove the wipe and wait for the surface of the meter to be dry.

Step 5:

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 full screen, unable to execute the meters initial set up, etc.
- If you notice any of these external changes to your meter or any changes to the performance of your meter stop using the meter and please contact TRANSTEX Customer Support anytime for help at (833) 445-5666.
- If you have questions about cleaning or disinfection, contact TRANSTEX Customer Support at (833) 445-5666.

Troubleshooting Guide

What You See	What It Means	What You Should Do
The display screen does not light up.	Batteries are exhausted.	If the battery is low, please replace it with a new one.
	Batteries are installed incorrectly.	Install the batteries properly.
Display screen dims &  shows.	Low battery.	Replace the batteries with two new AAA batteries.
	The screen is stuck in setup mode.	The screen is stuck in setup mode. It is waiting for you to set or confirm the time, alarms, or other settings.
	The meter is sensing a used or contaminated test strip.	Discard the test strip and repeat the test with a new test strip. Wait until you see the flashing blood drop on the display before testing.
	Incorrect test strip.	Discard the test strip and repeat the test with a new test strip. Make sure that you are using a TRANSTEK test strip.
	Incorrect sample.	Discard the test strip and repeat the test with a new test strip. Make sure that only human capillary blood and TRANSTEK control solution are used for the test.

E5	Insufficient sample.	Discard the test strip and repeat the test and apply enough sample to fill the test strip check window.
E6	Temperature out of range.	Move to an area that is within the operating range for the meter. Let the meter adjust to this temperature for 20 minutes before performing a test.
E7	Potential hardware error.	Restart the meter. If the problem continues, contact 24/7 TRANSTEK Customer Support at (833) 445-5666.
E9	Low battery	Replace the batteries with two new AAA batteries.
H1	The test result is above 500 mg/dL.	Wash and dry your hands well and the test site. Repeat the test using a new test strip. If your result still flashes "H1", contact your healthcare professional as soon as possible.
LO	The test result is below 10 mg/dL.	Wash and dry your hands well and the test site. Repeat the test using a new test strip. If your result still flashes "LO", contact your healthcare professional as soon as possible.

CHAPTER 5: TECHNICAL INFORMATION

System Specifications:

Feature	Specification
Measurement Range	10 - 600 mg/dL
Measurement Result	Plasma Glucose
Sample	Fresh capillary whole blood
Sample Volume	0.7 µL
Test Time	5 seconds
Power Source	2 AAA batteries, 3V 
Unit of Measure	mg/dL
Memory	1000 records
Automatic Shutoff	2 minutes after last action
Dimensions	96.1 mm x 60.6 mm x 19.3 mm
Display Size	37 mm x 47 mm
Weight	Approximately 64g
Normal Working Condition (Blood Glucose Meter & Test Strips)	41 - 113°F 10-90% (non-condensing)
Normal Working Condition (Control Solution)	50 - 104°F 10-90% (non-condensing)
Storage & Transportation Condition (Blood Glucose Meter)	14-122°F 10-90% (non-condensing)
Storage & Transportation Condition (Test Strips & Control Solution)	36-86°F 10-90% (non-condensing)
Hematocrit Range	10 - 70%
Altitude	≤10000ft(3048 meters)
Maximum sound pressure level	< 65 dB
Data Transmission	Bluetooth

Safety Information

The symbols below might be in the user manual, labeling or other component. They are the requirement of standard and using.

Symbol	Explanation	Symbol	Explanation
	Manufacturer		Consult instructions for use or consult electronic instructions for use.
	Date of manufacture		Recyclable
	Serial Number		In vitro diagnostic medical device.
	Humidity limitation		Temperature limitation
	Direct Current		The symbol shows that this device can be expected to comply with part 15 of the FCC Rules.
	The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.		

Warranty

Please complete the warranty card that came with this product and mail it to
Guangdong Transtek Medical Electronics Co., Ltd.
Zone A, No.105, Dongli Road, Torch Development District, 528437 Zhongshan, Guangdong, China

If the meter fails to work for any reason other than obvious abuse within the first five years from purchase, we will provide maintenance services. For your records, also write the purchase date of your product here.
Date of purchase: _____

Notes:

This warranty applies only to the meter in the original purchase, and does not apply to the battery supplied with the meter.

EMC Guidance

Warning: Do not use near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 in (30 cm) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
Immunity Test	IEC 60601-1-2 Test Level	Compliance Level
Electrostatic discharge(ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV line(s) to line(s)	± 0.5 kV, ± 1 kV line(s) to line(s)
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U _r : 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U _r : 1 cycle 70% U _r : 25/30 cycle Single phase: at 0° 0% U _r : 250/300 cycle	0% U _r : 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U _r : 1 cycle 70% U _r : 25/30 cycle Single phase: at 0° 0% U _r : 250/300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	3 V r.m.s. 150 kHz to 80 MHz 6 V RMS in the ISM and amateur bands between 0.15 MHz and 80 MHz	3 V r.m.s. 150 kHz to 80 MHz 6 V RMS in the ISM and amateur bands between 0.15 MHz and 80 MHz
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz

NOTE: U_r is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration- IMMUNITY to proximity fields from RF wireless communications equipment				
Immunity Test	IEC60601 Test Level			
	Test Frequency	Modulation	Maximum Power	Immunity Test Level Compliance Level
	385 MHz	**Pulse Modulation: 18Hz	1.8 W	27 V/m
	450 MHz	*FM+ 5 KHz deviation: 1kHz sine	2 W	28 V/m
	710 MHz	**Pulse Modulation: 27Hz	0.2 W	9 V/m
	745 MHz			
	760 MHz			
	810 MHz			
	870 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m
	930 MHz			
	1720 MHz			
	1845 MHz	**Pulse Modulation: 27Hz	2 W	28 V/m
Redacted RF IEC 61000-4-3	1970 MHz			
	2450 MHz			
	5240 MHz	**Pulse Modulation: 27Hz	2 W	28 V/m
	5500 MHz			
	5785 MHz			

Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.

FCC Statement

FCC Regulatory Compliance

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.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 00 cm between the radiator and your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

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

Part No: 30400023624
Version: A/D