ActiveCare TD-4121

Blood Glucose

Multi-Functional Monitoring System



Owner's Manual

Dear Owner of ActiveCare TD-4121 Blood Glucose Monitoring System Owner:

Thank you for purchasing the **ActiveCare TD-4121** Blood Glucose Monitoring System. This manual provides important information to help you use the system properly. Before using this product, please read the following instructions thoroughly and attentively.

Regular monitoring of your blood glucose levels can help you and your doctor gain better control of your diabetes. You can use the **ActiveCare TD-4121** to easily monitor your blood glucose levels by yourself anywhere and anytime.

If you have other questions regarding this product, please contact the local customer service or place of purchase for assistance.

IMPORTANT SAFETY PRECAUTIONS READ BEFORE USE

- 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!
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.
- Do NOT use this device to be close to your head since GPRS will be activated under two conditions to prevent any body damages.
 - Pressing phone call button, or
 - Uploading data after completion of measurement within 10 minutes
- 1. Use this device **ONLY** for the intended use described in this manual.
- 2. Do **NOT** use accessories which are not specified by the manufacturer.
- 3. Do **NOT** use the device if it is not working properly or if it is damaged.
- 4. Do **NOT**, under any circumstances, use the device on neonates or infants.
- 5. This device does **NOT** serve as a cure for any symptoms or diseases. The data measured is for reference only.
- 6. Before using this device to test blood glucose, read all instructions thoroughly. Carry out all the quality control checks as directed.
- 7. Keep the device and testing equipment away from young children. Small items such as the test strips, lancets and vial caps are choking hazards.
- 8. Use this device in a dry environment. Be aware of the presence of synthetic materials, such as clothing, carpets and so on, which might give rise to damaging static discharges that may produce incorrect results.
- 9. Do **NOT** use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the accurate operation.

10. Proper maintenance and periodically control solution test are essential to the durability of your device. If you are concerned about its accuracy, please contact TaiDoc or place of purchase for help.

Action upon Delivery: Unpacking; checking delivery for completeness; checking for damage during transport.

KEEP THESE INSTRUCTIONS IN A SAFE PLACE

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BEFORE YOU BEGIN

Important Information

- Severe dehydration and excessive water loss may cause readings which are lower than actual values. If you believe you are suffering from severe dehydration, consult a healthcare professional immediately.
- If your blood glucose results are lower or higher than usual, and you do not have any symptoms of illness, first repeat the test. If you have symptoms or continue to get results which are higher or lower than usual, follow the treatment advice of your healthcare professional.
- Use only fresh capillary whole blood samples to test your blood glucose. Using other substances will lead to incorrect results.
- If you are experiencing symptoms that are inconsistent with your blood glucose test results and you have followed all the instructions given in this owner's manual, contact your healthcare professional.
- We do not recommend using this product on severely hypotensive individuals or patients in shock. Readings which are lower than actual values may occur for individuals experiencing a hyperglycaemic-hyperosmolar state, with or without ketosis. Please consult the healthcare professional before use.

The measurement unit used for indicating the concentration of blood or plasma glucose can either have a weight dimension (mg/dL) or a molarity (mmol/L). The approximate calculation rule for conversion of mg/dL in mmol/L is as following:

mg/dL	Divided by 18	= mmol/L
mmol/L	Times 18	= mg/dL

For example:

- 1) 120 mg/dL ÷ 18 = 6.6 mmol/L
- 2) 7.2 mmol/L x 18 = 129 mg/dL approximately.

Intended Use

This system is intended for use outside the body (*in vitro* diagnostic use) by people with diabetes. It is designed for home use and by health care professionals in clinical settings as an aid to monitoring the effectiveness of diabetes control. It is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples (from the finger, palm, forearm and upper arm) and from venous whole blood. This system is intended to be used by a single person and should not be shared.

It should not be used for the diagnosis of, or screening for diabetes, or testing on neonates.

Professionals may test with capillary and venous blood sample; home use is limited to capillary whole blood testing.

Test Principle

Your system measures the amount of sugar (glucose) in whole blood. The glucose testing is based on the measurement of electrical current generated by the reaction of glucose with the reagent of the test strip. The meter measures the current, calculates the blood glucose level, and displays the result. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

Contents of System

Your new ActiveCare system kit includes:

- 1. Meter
- 2. Owner's Manual
- 3. Quick Start User Guide
- 4. Test Strips
- 5. Protective wallet
- 6. 1 x 3.7V Li- Polymer rechargeable battery
- 7. Lancet



NOTE:

If any items are missing from your kit or opened prior to use, please contact local customer services or place of purchase for assistance.

Meter Overview



1. Test Strip Slot with Strip Indication Light

Insert test strip here for testing.

2. Power Button

Press to turn on/off the meter.

3. Recharge Indicator

4. USB Port (only for charge) For battery recharge

5. Home Button

To enter the meter function, and click for confirmation or exit.

6. Display Window and Touchscreen

The touchscreen allow users to interact with what is displayed directly by the finger.

7. Test Strip Ejector

Eject the used test strip by pushing up this button.

8. Microphone

9. Emergency Call Button

Press to call the service center directly for further assistance or critical health condition.

Display Screen

The display window and touchscreen allows you to interact with what is displayed. The meter features 4 main functions: measuring, calling, memory and setting, which are shown on the main page. Other icons on the Main Page are introduced as below:

1.	Battery	54321	
2.	Alarm Icon		
3.	Time	₁Ⅱ ↔ 04:39 PM Ø	
4.	Flight Icon	6 Dec-30 2016	
5.	GPRS Signal		
6.	Date		
7.	Measuring		
8.	Memory	89	
9.	Setting		
10.	Calling		
	Indicator	Meaning / You can do this	
Act	iveCare.		
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		meter.	
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Setting:

Set up date, time, reminder alarm, measuring units, displayed languages and so on.

You may also turn on/off airplane mode from here.

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Calling:

Call out to the service center or answer phone calls. This function activates for only 10 minutes after each measurement, allowing the service center to contact with users directly.

Test Strip





Attention

- The front side of test strip should face up when you insert test strip.
- Test results might be wrong if the contact bar is not fully inserted into the test slot.

NOTE:

The **ActiveCare TD-4121** should only be used with **ActiveCare** Blood Glucose Test Strips. Using other test strips with this system can produce inaccurate results.

SETTING THE METER

Before using your meter for the first time, you should check and update these settings.

The touchscreen allows users to communicate with the meter by simply tapping on the screen with fingers.

Meter Setting

1. Start with the system off.

Press the power button for 1 second to activate the meter.

The meter displays ActiveCare logo with a loading bar showing the process of time/date synchrony.



NOTE:

- The backlight of the meter will turn low if the meter is idle for 1 minute.
- If continually left idle with low backlight for another 10 minutes, the meter will then enter the halt state, as if the meter is turned off. Press the power button for 1 second to restart the system.
- Press the power button for 3 seconds to turn off the meter.

2. Tap on And there are 6 sections: airplane mode, measuring units, volume, time/date, reminder alarms and language on display.



Airplane Mode

The airplane mode will terminate the meter's cellular telephony and transmitting functions.

- 1. Tap on *b* to enter the airplane mode setting page.
- 2. Tap on the preferred mode (airplane or general) for preference.

Select the airplane mode when necessary, or "general mode" to activate the meter's telecommunication function.

3. Tap on 🔨 to save and exit.



Note:

The airplane mode allows users to measure their blood glucose values in flight or in places where radio-frequency signal transmission must be suspended. The measuring result will be saved in the memory, and later be transmitted to the server when the meter is set in the general mode with available GPRS signals.

Measuring Units

1. Tap on mouth to set the measuring unit.

There are two measuring units to choose from: mg/dL and mmol/L.

2. Tape on the desired one and \checkmark to save and exit.



<u>Volume</u>

- 1. Tape it to set up the volume.
- 2. Tape on the "+" or "-" to adjust the volume.
- 3. Tap on \checkmark to save and exit.

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Time and Date

There are two ways to set date and time: automatic or manually.

IN AUTOMATIC MODE:

- 1. Tap on O to set time and date. Choose the "12" or "24" bar to set your preferred time system.
- Tap on automatic mode. In this mode, time and date are synchronized once the meter's GPRS (General Packet Radio Service) is in service. Please contact your mobile communication providers for further information on GPRS.
- 3. Tap on \checkmark to save the setting and exit.

IN MANUALLY MODE:

- 1. Tap on 🔺 or 💌 if to select the manually mode.
- 2. Tap on \checkmark to save the setting.
- 3. Tap 🗭 to continue setting time.
- 4. Tap on **A** or **V** to set time.
- 5. Tap on \checkmark to save and exit.





Reminder Alarms

1. Tap on 🖉 to set the alarm.

You may set up any or all of the reminder alarms (1 - 4).

- 2. Tap on \square to put/remove \checkmark as set/cancel the reminder alarm.
- 3. Tap ▶ on to set the time by tapping on ▲ or ▼. In 12-hour time setting, you may choose from AM and PM along with time adjustment.
- 4. Tap on \checkmark to save and exit.
- 5. Press the home button to leave the alarm setting page and back to the main page.

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Note:

At the time of your alarm, the meter will beep. Please tap on \checkmark or press the home button to dismiss the alarm. If not, the alarm will continue beeping for 10 minutes.

<u>Language</u>

- 1. Tap 😡 to set the displayed language. The default language is English.
- 2. Tap on the preferred language bar.
- 3. Tap \checkmark to save and exit.



Congratulations! You have completed all settings!

NOTE:

These parameters can **ONLY** be changed in the setting mode.

Calling

ActiveCare TD-4121 Blood Glucose Monitoring System is equipped with GPRS (General Packet Radio Service) that allows users to call out directly to the service center, receive calls and stream data to the server.

Calling feature is activated under 3 conditions and functional for 10 minutes only.

1. After every blood glucose measurement:

To transmit the test result to the server. The service center will phone in if the uploaded result is atypical.

2. At 6 o'clock every morning:

To transmit data to the server automatically, providing that the meter is not in the airplane mode.

3. Emergency:

Whenever the call button at the back of the monitor is triggered.

MESSAGE	WHAT IT MEANS
Call to Service center	Appears when the calling function is initiating. Wait for a few seconds to proceed.
Call to Service center	Appears when the meter calls out to the service center.

The following display will be shown in the calling page:

MESSAGE	WHAT IT MEANS		
Vait connect	Appears when a call is connected. Tap on [•] to end the call.		
Vait connect	Appears a call comes in. Tap on to take or to reject the call.		
ul 04:39 PM (2) □ - 43) + cm Call	Appears when you are answering the phone. Tap on "-" or "+" to adjust the volume. Tap on to hang up the phone.		
((2)) ((2)) ((2))	Appears when the meter is searching for available GPRS signal for data transmission.		
((2)) ((2)) ((2))	Data is loading.		

MESSAGE	WHAT IT MEANS
Image: state of the state o	Loading is completed.

Note:

- Press the emergency button when necessary. The emergency button at the back of the meter is designed for users to contact the service center in time of emergency, for instance, critical healthy condition, for immediate assistance.
- The phone number of the service center is programmed prior to your receipt of the meter. If not, please contact the customer service for assistance.
- Please contact your service provider for the mini-SIM Card and information such as connection speed, limitation and charges. The connection quality may vary from each service provider.
- The calling and data transmission features are disabled when the meter is set in the airplane mode.

Touchscreen Calibration

Perform touchscreen calibration when you find the meter fails to respond properly.

- 1. Start with the meter off. Press the power button for 1 second to start the meter. Wait for the main page to appear.
- 2. At the main page, press the power button for 1 second to put the meter into the halt state.
- 3. At the halt state, press the home button. Then, keep on pressing the home button with another finger pressing the power button for 1 second. Then release both fingers at the same time.
- 4. Tap on the center of \square accordingly. Frist one will be seen on the upper left corner. The next one will appear on the bottom left and so on. You will have to tap on 4 of them in total.
- 5. If the main page comes up, that means your calibration is completed. If not, please repeat step 4 until you finish the calibration.

BEFORE TESTING

Control Solution Testing

ActiveCare Control Solution contains a known amount of glucose that reacts with test strips and is used to ensure your meter and test strips are working together correctly.

WHEN TO CONDUCT A CONTROL SOLUTION TEST:

- You first receive the meter.
- Routinely check the meter and test strips at least once a week.
- You begin using a new vial of test strips.
- You suspect the meter or test strips are not working properly.
- Your blood glucose test results are not consistent with how you feel.
- If you think the results are not accurate while practicing the testing process.
- You have dropped or think you may have damaged the meter.

Performing a Control Solution Test

- 1. Start with the meter off. Press the power button for 1 second to turn on the meter. Wait for the main page to appear.
- 2. To start the measuring process.

There are two ways to begin measuring:

- A. Insert the test strip directly, or
- B. At the main page, tap on 4 to enter the measuring page.

Wait for the meter to display the test strip symbol.

3. Select QC to mark this test as a control solution test

In QC mode, the meter will store your test result in the memory. Please make sure to mark this test as a control solution test.

WARNING:

When conducting the control solution test, you must mark it so that the test result will not be mixed with the blood glucose **TEST RESULTS** stored in the memory.

3. Apply control solution

Shake the control solution vial thoroughly before use.

Squeeze out a drop and wipe it off, then squeeze out another drop and place it on the tip of the vial cap.

Hold the meter to move the absorbent hole of the test strip to touch the drop. Once the confirmation window fills completely, the meter will begin counting down.



To avoid contaminating the control solution, do not directly apply control solution onto a strip.



4. Read and compare the result

The control solution test result will appear on the display in seconds. Compare this result with the range printed on the test strip vial and it should fall within this range. If not, please read the instructions again and repeat the control solution test.

Out-of-range Results

If you continue to have test results fall outside the range printed on the test strip vial, the meter and strips may not be working properly. Do NOT test your blood. Contact the service center for help.

NOTE:

- The control solution range printed on the test strip vial is for control solution use only. It is not a recommended range for your blood glucose level.
- See the Maintenance section for important information about your control solutions.

TESTING WITH BLOOD SAMPLE

WARNING:

To Reduce the Chance of Infection

- The meter and lancing device are for single use. Never share a lancet or the lancing device.
- Always use a new, sterile lancet. Lancets are for single use only.
- Avoid getting hand lotion, oils, dirt, or debris in or on the lancets and the lancing device.
- Wash and dry your hands thoroughly after handling the meter, lancing device, and test strips to prevent infection. For more information, please refer to the "Cleaning and Disinfection" section.
- If the meter is being operated by a second person who is providing testing assistance to the user, the meter and lancing device should be decontaminated prior to use by the second person.
- If patient is being assisted with glucose meter testing, the assistant should wear gloves throughout. Additionally, the assistant should clean and disinfect meter between each use.

Preparing the Lancing Device for Blood Testing

Please follow the instructions in the lancing device insert for collecting a blood sample.

Preparing the Puncture Site

Stimulating blood perfusion by rubbing the puncture site before blood extraction has a significant influence on the glucose value obtained.

Blood from a site that has not been rubbed exhibits a measurably different glucose concentration than blood from the finger. When the puncture site was rubbed prior to blood extraction, the difference was significantly reduced.

Please follow the suggestions below before obtaining a drop of blood:

- Wash and dry your hands before beginning.
- Select the puncture site either at fingertips or another body parts (please see section "Alternative Site Testing" (AST) on how to select the appropriate sites).

- Rub the puncture site for about 20 seconds before penetration.
- Clean the puncture site using cotton moistened with 70% alcohol and let it air dry.

Fingertip testing

Press the lancing device's tip firmly against the lower side of your fingertip. Press the release button to prick your finger, then a click indicates that the puncture is complete.



Blood from sites other than the fingertip

Replace the lancing device cap with the clear cap for AST. Pull the cocking control back until it clicks. When lancing the palm, the forearm, and the upper-arm, you must avoid lancing the areas with obvious veins because of excessive bleeding.

NOTE:

 Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.

- Please consult your health care professional before you begin AST.
- It is recommended that you discard the first drop of blood as it might contain tissue fluid, which may affect the test result.

Alternative Site Testing

Important: There are limitations with AST (Alternative Site Testing). The alternative site testing of the system can only be used in during steady-state blood glucose conditions. Please consult your health care professional before you perform AST.

Measurements from alternative site testing should never be used to calibrate a continuous glucose monitoring systems (CGMs) or entered into insulin dose calculators for insulin dosing recommendations.

What is AST?

Alternative site testing (AST) means that people use parts of the body other than the fingertips to check their blood glucose levels. This system allows you to test on the palm, the forearm, or the upper arm with results equivalent to fingertip testing.

What is the advantage?

Fingertips feel pain more readily because they are full of nerve endings (receptors). At other body sites, since nerve endings are not so condensed, you will not feel as much pain as on the fingertips.



When to use AST?

Food, medication, illness, stress and exercise can affect blood glucose levels. Capillary blood at the fingertip reflects these changes faster than capillary blood at other sites. Thus, when testing blood glucose during or immediately after a meal, physical exercise, or any other event, **take a blood sample from your finger only.**

We strongly recommend that you perform AST **ONLY** at the following times:

- In a pre-meal or fasting state (more than 2 hours since the last meal).
- Two hours or more after taking insulin.
- Two hours or more after exercise.

Do **NOT** use AST if:

- You think your blood glucose is low.
- You are unaware of hypoglycemia.
- You are testing for hyperglycemia.
- Your AST results do not match the way you feel.
- Your routine glucose results often fluctuate.

Performing a Blood Glucose Test

Please have the meter, test strips, lancets and lancing device ready before you start performing blood glucose tests.

1. Starting with the meter off. Press the power button to activate the meter. Or you may directly insert the test strip into the strip slot to start measuring.

When the main page appears, tap on 4 to initiate the blood glucose measurement procedure



2. Perform the blood glucose test as directed on the display.

Insert a test strip.



3. Obtaining a blood sample

Use the pre-set lancing device to puncture the desired site.

After penetration, discard the first drop of blood with a clean cotton swab. Gently squeeze the punctured area to obtain another drop of blood. Be careful **NOT** to smear the blood sample.



4. Apply blood onto the strip

Hold the blood drop to touch the absorbent hole of the test strip and blood will be drawn in automatically.

Make sure to provide the minimum required sample volume to fill the confirmation window completely with blood before your finger leaves the absorbent hole or meter will give inaccurate glucose results.

5. Wait a few seconds for the measurement to process.

When the page of measuring mode appears, tap on A or V to choose the mode that fits you the best: General or after/before breakfast, lunch or dinner. The meter provides you with 8 modes for measuring: General, QC, along with before and after each meal (breakfast, lunch and dinner) respectively.

When your preferred measuring mode is included in the green column, tap on for the next step.

Then, you will see the measuring result on the display.



6. Data Transmission

The measuring data will be uploaded to the server after every measurement, providing that the meter's GPRS is in service.

If GPRS is not in service or connection fails, the measurement data will be stored in the memory and waited to be uploaded at 6 o'clock every morning.



- 7. Tap on \checkmark or press home button to exit and back to the main page.
- 8. Eject the used test strip and remove the lancet
- 9. Eject the test strip by sliding up the eject button on the side. Use a sharp bin to dispose of used test strips.

NOTE:

- Do not press the punctured site against the test strip or try to smear the blood.
- If you do not apply a blood sample to the test strip within 10 minutes, the meter will automatically turn into the halt state. You must remove and reinsert the test strip to start a new test.
- Do not leave the absorbent hole until the confirmation window is filled with blood.
- NEVER try to add more blood to the test strip after the drop of blood has moved away. Discard the used test strip and retest with a new one.
- If you have trouble filling the confirmation window, please contact your health care professional or the local customer service for assistance.

Always follow the instructions in the lancing device insert when removing the lancet.

WARNING:

- The used lancet and test strip may be biohazards. Please discard them carefully according to your healthcare provider's instructions.
- Wash and dry your hands thoroughly after handling the meter, lancing device, and test strips to avoid contamination. For more information, please refer to the "Cleaning and Disinfection" section.

Reviewing Memory Record

The meter stores the most recent blood glucose test results, up to 450 sets, along with respective dates and times in the memory feature.

If the memory bank is full, the latest result will overwrite the oldest one.

1. Turn on the Meter

Start with the meter off. Press and release the power button to activate the meter. Wait for the main page to show up.

2. Enter the memory feature

Tap on it to enter the memory feature.

3. Review Records

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Tap on **A** or **V** to review the stored records.

The right icon shows the measuring mode: before or after a meal. For the record taken in the general mode, the right corner is left empty.

	i Before each meal
120 mg/dt	I After each meal
120 mg/dt.	 The record has sent to the server.

4. Exit the memory feature

Press the home button to exit and back to the main page.

NOTE:

If using the meter for the first time, You will find ""Empty" showing on the display, indicating that there is no test result in the memory.

MAINTENANCE

Battery

- Your meter comes with one 3.7V Li-Polymer rechargeable battery.
- Please recharge the meter if the battery icon on the upper right flickers. That means the battery is low.
- The meter will shut down immediately once the battery is dead.

Recharging the Battery

There are 2 ways to charge the internal battery in your meter:

- Plug the meter into a powered-on computer or laptop with a Micro-USB cable.
- Use an AC power adapter. Plug the meter into a wall outlet to initiate the charging process.

The battery charging indication will light red when charging is in process. When the indicator light green, it means the battery is full. You may now remove the USB cable.

You may also refer to the battery icon on the upper right for the capacity of the battery.

NOTE:

- Recharging the battery affects neither the test result stored in the memory, nor the functions other than glucose measuring.
- Measuring during battery recharging is prohibited.
- The AC power adapter and the micro-USB cable may not come with the kit. They may be purchased separately. It is recommended to use the AC adapter of MEAN WELL (Model No.: GSM06E05-TD) which provides 6 Watts of continuous output power. The wide operating voltage is 100 to 240 VAC, 47 to 63 Hz.

Caring for Your Meter

To avoid the meter and test strips attracting dirt, dust or other contaminants, please wash and dry your hands thoroughly before and after the measurement.

<u>Cleaning</u>

- 1. To clean the meter exterior, wipe it with a cloth moistened with tap water or a mild cleaning agent, then dry the device with a soft dry cloth. Do NOT rinse with water.
- 2. Do **NOT** use organic solvents to clean the meter.

Meter Storage

- Storage conditions: -20°C to 60°C (-4°F to 140°F), below 95% relative humidity.
- Always store or transport the meter in its original storage case.
- Avoid dropping and heavy impact.
- Avoid direct sunlight and high humidity.

Meter Disposal

The used meter should be treated as contaminated that may carry a risk of infection during measurement. The batteries in this used meter should be removed and the meter should be disposed in accordance with local regulations.

The meter falls outside the scope of the European Directive 2002/96/EC-Directive on waste electrical and electronic equipment (WEEE).

Caring for Your Test Strips

- Storage conditions: 2°C to 30°C (35.6°F to 86°F) and below 85% relative humidity. Do NOT freeze.
- Store your test strips in their original vial only. Do not transfer to another container.
- Store test strip packages in a cool dry place. Keep away from direct sunlight and heat.
- After removing a test strip from the vial, immediately close the vial cap tightly.
- Touch the test strip with clean and dry hands. Use each test strip immediately after removing it from the vial.

- Do not use test strips beyond the expiration date. This may cause inaccurate results.
- Do not bend, cut, or alter a test strip in any way.
- Keep the strip vial away from children since the cap and the test strip may be a choking hazard. If swallowed, promptly see a doctor for help.

For further information, please refer to the test strip package insert.

Important Control Solution Information

- Use only ActiveCare control solutions with your meter.
- Do not use the control solution beyond the expiration date or 3 months after first opening. Write the opening date on the control solution vial and discard the remaining solution after 3 months.
- It is recommended that the control solution test be done at room temperature 20°C to 25°C (68°F to 77°F). Make sure your control solution, meter, and test strips are at this specified temperature range before testing.
- Shake the vial before use, discard the first drop of control solution, and wipe off the dispenser tip to ensure a pure sample and an accurate result.
- Store the control solution tightly closed at temperatures between 2°C to 30°C (35.6°F to 86°F). Do NOT freeze.

NOTE:

- Do **NOT** clean and disinfect the meter while performing tests.
- If the meter is being operated by a second person, the meter and lancing device should be decontaminated prior to use by the second person.
- Do **NOT** allow cleaning and disinfecting solution to get in the test slot, battery compartment, or strip-ejection button.
- If you do get moisture in the test strip slot, wipe it away with a corner of tissue.
- Always dry the meter thoroughly before using it.
- Do not spray the meter directly with cleaning solutions especially those containing water (i.e. soapy water), as this could cause the solution to enter the case inside and damage the electronic components or circuitry.

SYSTEM TROUBLESHOOTING

If you follow the recommended action but the problem persists, or error messages other than the ones below appear, please call your local customer service. Do not attempt to try to repair the meter yourself and never try to disassemble the meter under any circumstances.

Result Readings

MESSAGE	WHAT IT MEANS
LOW	< 20 mg/dL (1.1 mmol/L)
HIGH	> 600 mg/dL (33.1 mmol/L)

Error Messages

MESSAGE	WHAT IT MEANS	WHAT TO DO		
used Strip	Appears when a used			
	test strip is inserted.			
Timeout	The procedure has	Repeat the test with a new test		
Timeout	taken too long.	strip. Contact the service center if		
	Appears when the	the problem persists.		
Sample not enough	amount of blood taken			
	is not enough.			
Glucose module Error				
GPRS module Error	Problem with the	Reboot the meter, or contact		
EEPROM Error	meter.	service center for assistance if the problem persists.		
Wrong BGM Version				
ACode Error				
Rcode Error	Problem with the	Repeat the test with a new test strip. Contact the service center i		
HCT-Value error	meter or the strip.	the problem persists.		
ExpiryDate Error				
Internet Error	Internet connection	Please try again later or contact		
Server No Responded	failure.	your service provider.		

MESSAGE	WHAT IT MEANS	WHAT TO DO	
	Blood glucose tests		
Can not Measure when	are prohibited when	Please plug out USB before	
Charging	the battery is	performing a blood glucose test.	
	recharging.		
Battony low	Appears when the	Recharge the battery immediately	
	battery is too low.		
	Fail to detect SIM	Please check the SIM card or	
SIM card Error		re-insert it. Contact the service	
	card.	center if the problem persists	
	In the airplane mode,	Turn off the airplane mode in the	
Airplane Mode	phone communication	Setting	
	is prohibited.	County.	
	Appears when the	Please re-insert the strip and	
No Strip detect	strip is not inserted	make sure its front side is facing	
	correctly.	up.	
	Appears when	System operation range is 10°C to	
I EMP. too low	ambient temperature	40°C (50°F to 104°F). Repeat the	
	is above or below	test after the meter and test strip	
TEMP. too high	system operation	are in the above temperature	
5	range.	range.	
Carry Error	Appears when failing	Contact your service provider for	
	to find the GPRS		
	signals.		
No phone number	Appears when no	Please check phone number or	
	phone number is	contact the sustamer convice	
	found	contact the customer service.	
Data Full		Please upload measuring results	
	The memory is full.	immediately. The latest record will	
		replace the oldest one.	

Troubleshooting

1. If the meter does not display a message after inserting a test strip:

POSSIBLE CAUSE	WHAT TO DO	
Battery exhausted.	Recharge the battery.	
Test strip inserted upside down or	Insert the test strip with contact bars end	
incompletely.	first and facing up.	
Defective meter or test strips.	Please contact customer service.	

2. If the test does not start after applying the sample:

POSSIBLE CAUSE	WHAT TO DO	
Incufficient blood comple	Repeat the test using a new test strip	
	with larger volume of blood sample.	
Defective test strip.	Repeat the test with a new test strip.	
Defective meter.	Please contact customer service.	

3. If the control solution testing result is out of range.

POSSIBLE CAUSE	WHAT TO DO	
Error in performing the test.	Read instructions thoroughly and	
	repeat the test again.	
Control solution vial was poorly	Shake the control solution vigorously	
shaken.	and repeat the test again.	
Expired or contaminated control	Check the expiration date of the	
solution.	control solution.	
Control solution that is too warm or too cold.	Control solution, meter, and test strips should be at room temperature 20° C to 25° C (68° F to 77° F/) before testing.	
Defective test strip.	Repeat the test with a new test strip.	
Meter malfunction.	Please contact customer service.	
Improper working of meter and test strip.	Please contact customer services.	

DETAILED INFORMATION

Time of day	Normal plasma glucose range for people without diabetes (mg/dL)	
Fasting and before meal	< 100 mg/dL (5.6 mmol/L)	
2 hours after meals	< 140 mg/dL (7.8 mmol/L)	

The meter provides you with plasma equivalent results.

Source: American Diabetes Association (2014).

Clinical Practice Recommendations. Diabetes Care, 37 (Supplement 1): S16.

SPECIFICATIONS

Model No.: TD-4121

Dimension: 99 mm(L) x 59 mm(W) x 15.6 mm(H)

Weight: 88.6 g (With the battery)

Power Source: one Li- Polymer rechargeable battery

Display: LCD

Memory: 450 measurement results with respective date and time

External Output: General Packet Radio Service (GPRS)

Auto electrode insertion detection

Auto sample uploading detection

Auto reaction time count-down

Temperature Warning

Operating Condition: 10° C to 40° C (50° F to 104° F), below 85% R.H.

(non-condensing)

Meter Storage/Transportation Conditions: -20 $^{\circ}$ C to 60 $^{\circ}$ C (-4 $^{\circ}$ F to 140 $^{\circ}$ F),

below 95% R.H.

Strip Storage/Transportation Conditon: 2° C to 30° C (35.6° F to 86° F), below 85% R.H. (non-condensing) Measurement Units: mg/dL or mmol/L Measurement Range: 20 to 600mg/dL (1.1 to 33.3mmol/L) Expected Service Life: 5 Years This device has been tested to meet the electrical and safety requirements of: IEC/EN 61010-1, IEC/EN 61010-2-101, EN 61326-1, IEC/EN 61326-2-6.

This device complies with the R&TTE Directive (1999/5/EC) issued by the Commission of the European Community.

A minimum separation distance of 0.5 cm must be maintained between the user's body and the device, including the antenna during body-worn operation to comply with the RF exposure requirements in Europe.

To compliance with RF Exposure requirements in Europe, third-party belt-clips, holsters or similar accessories used by this device should not contain any metallic components. The use of accessories that do not satisfy these requirements may not comply with RF exposure requirements, and should be avoided.

SYMBOL INFORMATION

SYMBOL	REFERENT	SYMBOL	REFERENT
IVD	In vitro diagnostic medical device		Caution, consult accompanying documents
Ţį	Consult instructions for use	Ŵ	Humidity Limitation
	Temperature limitation	<u>R</u>	Collection for electrical and electronic equipment
\sum	Use by	CE	CE mark
LOT	Batch code		Manufacturer
SN	Serial number	EC REP	Authorized representative in the European Community

Federal Communication Commission Interference Statement

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.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursua

nt 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 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.

FCC Caution:

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

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Radiation Exposure Statement:

This device meets the government's requirements for exposure to radio waves.

This device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government.

The exposure standard for wireless device employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6W/kg.

*Tests for SAR are conducted using standard operating positions accepted by the FCC with the device transmitting at its highest certified power level in all tested frequency bands.



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