TeleRPM
User Manual

Blood Glucose Monitoring System

All images for reference only
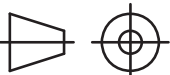
技术要求:
1、黏合不可露胶
2、保持印刷面板上的清洁
3、注意套印的准确性
4、表面处理不可爆开
5、须满足RoHS、Reach的环保要求
6、结构工艺以结构受控图为准
7、颜色参考:

广东乐心医疗电子股份有限公司

2024-04-26

产品型号	BGM2280-A		材质	封底封面157g铜版纸,内页80g书写纸	零件名称	
产品名称	血糖仪		尺寸	成品165*85mm,左侧骑马钉	TBG-2280A-GB-06-保修卡-A0	
对应结构图纸	–		印色	CMYK		
Transtek 广东乐心医疗电子股份有限公司	比例	1:1	表面处理	封底封面过哑膜	零件图号 TBG-2280A-GB-06	
	单位	mm	设计	杨红红 2024-04-26		
	审核		杨红红	2024-04-26	共 36 张	第 1 张
	批准		梁国威	2024-04-26	版本	A/0

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TeleRPM

Blood Glucose Monitoring System

Dear TeleRPM System User,

Thank you for choosing the TeleRPM Blood Glucose Monitoring System! TeleRPM Blood Glucose Monitoring System is designed for easy test of blood glucose and helps you keep blood glucose under control.

Read this User Manual carefully before you use your meter system. This manual will help you to get comfortable using the TeleRPM Blood Glucose Monitoring System and get reliable test results. Please keep your User Manual in a safe place,you may want to refer it in the future. Thank you again for choosing the TeleRPM System.

Intended Use

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

Principle of Operation

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

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CHAPTER 1: UNDERSTANDING YOUR TESTING TOOLS

Your Meter System Overview

1. TeleRPM Blood Glucose Meter
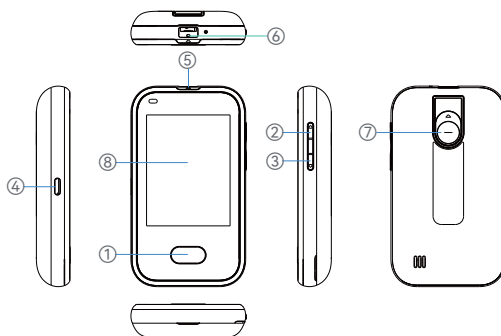
① Home Button
- Short-press to turns on/off the screen in home screen
- Short-press to back to home screen in other screen (except in test mode)
- Long-press to pop up a window with the following options: Power Off/Restart/Cancel
- Long-press for 8 seconds or above to restart the device

② Up Button
- Press to Volume up

③ Down Button
- Press to Volume down

④ Charging port   Type-C USB

⑤ Test Strip Port

⑥ LED Indicator
- The LED will light up in the test mode

⑦ Strip Ejector
- Push up button to eject test strip from meter

⑧ Display touch screen
- Shows test results and related information

2. TeleRPM Test Strips

① Electrode End
- This end is inserted into the strip port on the meter,Facing upwards in the direction of the arrows

② Sample Tip
- Where the blood is drawn in

3. TeleRPM Lancing Device & Lancets

TeleRPM Lancing device

TeleRPM Lancet

4. TeleRPM Control Soultion

TeleRPM Control Solution

Notes:

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

Unboxing the Meter for the first time

Before we begin, take a moment to go over the contents of your TeleRPM Blood Glucose Monitoring System. Your kit should include:

1.Blood Glucose Meter(battery included)
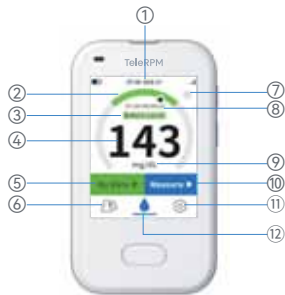

2.Type-C USB cable

3.Nylon Case

4.User Manual

5.Quick Start Guide

6.Warranty Card

The Home Screen

On the Home Screen, you can see the following:

① Status bar,including:Battery Level,Current Time,Wireless Signal,Related settings status etc.
② Blood glucose level bar   Low/Nornal/High
③ Meal tag
④ Blood glucose value of Last Reading
⑤ My Data
⑥ Support tab
⑦ Info
⑧ Date and Time of Last Reading
⑨ Unit:mg/dL
⑩ Measure mode
⑪ Setting tab
⑫ HOME screen tab

Icon Definitions

Symbol	Definitions	Descriptions
	Battery	Show current battery level
	Low battery	Indicates that the battery is low and needs to be charged in time
	Charging	The meter is connected to the charging cable
	External power supply	The meter is connected to the charging cable when the battery is removed
	Airplane mode	Showing this symbol means Airplane mode is on
	Vibration mode	Showing this symbol means Vibration mode is on

🔇	Voice mode	Showing this symbol means that Voice mode is off
☒	No SIM card	SIM card not detected
🄲	Control solution symbol	Control solution mode
☁	Data upload symbol	Data uploading
☁	Data upload symbol	Data upload failed
▂▃▄▅	Signal strength	Signal strength
📋	No data	No data

Meter Use and Precautions

- The meter is indoor use.
- The meter displays blood glucose concentration in milligrams per deciliter (mg/dL) only.
- Meter will shut off by itself after 2 minutes of inactivity.
- Keep the strip port area clean.
- Keep your meter in the temperature range 41-113°F and relative humidity range 10-90%. Do not leave it in your car.
- Do not drop the meter or get it wet. If you do drop the meter or get it wet, check the meter by running a quality control test. Refer to Testing with Control Solution for instructions.
- Do not use the meter if it drops into water or other liquids or splashing water on to it.
- If the system is used in a manner not specified by the manufacturer, the protection provided by the system can be impaired.
- Do not transfer the test strips to a new vial or any other container.
- Do not drop the blood on the test strip. The blood is pulled into the tip of the test strip through capillary action:
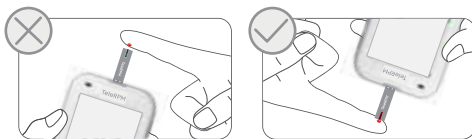
- Check the expiration dates and discard dates on your test strips vial label and control solution vial label.
- Use only TeleRPM Blood Glucose Test Strip with your TeleRPM Blood Glucose Meter.
- Use only TeleRPM Control Solution with your TeleRPM Blood Glucose Meter and TeleRPM Blood Glucose Test Strip.
- 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 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.
- For more information, please refer to the FDA Public Health Notification: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication"(2010)at:https://wayback.archive-it.org/7993/20170111013014/http:/www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm
- You may also refer to the "CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010) at http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html.
- Please contact your physician or diabetes healthcare professional if you determine to make a change on your current medical therapy or diet activity based on test results.
- Refer to the Cleaning and Disinfection section for details on cleaning and disinfecting the meter.
- Follow proper precautions and all local regulations when disposing of the meter.

Limitations

- It may cause inaccurate result if the hematocrit level is outside the range 20%~70%. Talk to your healthcare professional to find out your hematocrit level.
- Not for use on critically ill patients.
- Not for use on patients who have been diagnosed by a healthcare provider with a dehydration disease requiring hospitalization.
- Not for use on patients who have been diagnosed by a healthcare provider with a hypotensive disease requiring hospitalization.
- Do not test your blood glucose during or soon after a xylose absorption test. Xylose in the blood can give inaccurate results with this meter.
- Not for neonatal use.
- Not for screening for or diagnosis of diabetes mellitus.
- Do not use the system above 10,413 ft (3,174 meters) in altitude.
- This meter is not intended for use in healthcare or assisted-use settings such as hospitals, physician offices, or long-term care facilities because it has not been cleared by FDA for use in these settings, including for routine assisted testing or as part of glycemic control procedures. Use of this meter on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.

All the materials you will need ready before you begin testing. This includes your TeleRPM Blood Glucose Meter, TeleRPM Blood Glucose test strips, and TeleRPM lancing device and lancets.

Preparing the blood glucose meter

For the first time using, long press the HOME button or connect to the power supply to activate the device.

Long Press
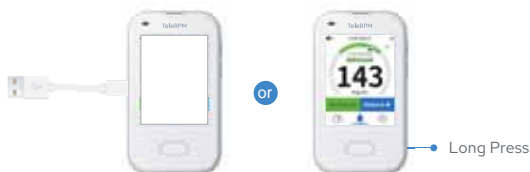
Preparing the Test Strip

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.

Notes:
Check the expiration and discard dates on the test strip vial. All expiration dates are printed in Year-Month-Day format. 2023-01-01 indicates 1st, January, 2023. Your TeleRPM test strips have 6 months shelf life after you first open the test strip vial. Write the discard date on the vial label when you first open it. Make sure the test strip does not appear damaged. Prior to testing, wipe the test site with an alcohol swab or soapy water. Use warm water 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.

Preparing the Lancing Device

For fingertip sampling, adjust the depth penetration to reduce the discomfort. You do not need the clear cap for fingertip sampling.

1. Unscrew the lancing device cover from the body of the lancing device. Insert a sterile lancet into the lancing device and push it until the lancet comes to a complete stop in the lancing device.
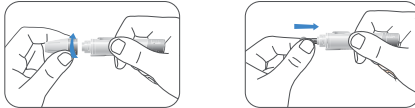
Notes:
The TeleRPM lancing device uses ONLY TeleRPM sterile lancets.

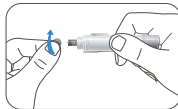2. Hold the lancet firmly in the lancing device and twist the safety tab of the lancet until it loosens, then pull the safety tab off the lancet. Save the safety tab for disposing the used lancet.

3. Carefully screw the cover back onto the lancing device. Avoid contact with the exposed needle. Make sure the cover is fully sealed on the lancing device.
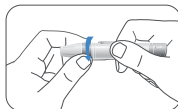
4. Adjust the puncture depth by rotating the lancing device cover. There are several different puncture depth settings. To reduce discomfort, use the lowest setting that still produces an adequate drop of blood.
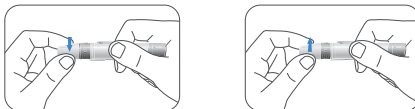
Adjustment:
1	for delicate skin
2 and 3	for normal skin
4 and 5	for calloused or thick skin

Notes:
Greater pressure of the lancing device against the puncture site will also increase the puncture depth.

Getting a Blood Drop for Testing

1. Pull the cocking barrel back to set the lancing device. You may hear a click to indicate the lancing device is now loaded and ready for obtaining a drop of blood.

2. Press the lancing device against the side of the finger to be lanced with the cover resting on the finger. Push the release button to prick your fingertip. You should hear a click as the lancing device activates.

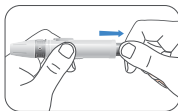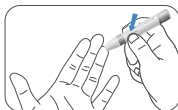3. Wipe away the first drop of blood with a clean paper towel to ensure a more accurate result. Gently massage from the base of the finger to the tip of the finger to obtain the required blood volume (half the size of a match head). Avoid smearing the drop of blood. For the greatest reduction in pain, lance on the side of the fingertips. Test immediately after a good blood drop has formed.
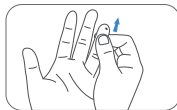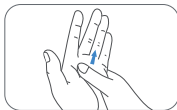
4. Immediately touch the tip of the test strip to the drop of blood. The blood will be pulled into the test strip through the tip. Make sure that the blood sample has fully filled the check window of the tip of the strip. Hold the tip of the test strip in the blood drop until the meter beeps.

Notes:
If the blood sample does not fill the check window, do not add a second drop. Discard the test strip and start over with a new test strip.

5. The meter counts down 5 seconds and your result appears on the display, and accompanied by voice broadcasting of the results. The test result will automatically be stored in the meter memory. Please do not touch the test strip during the countdown as this may result in an error.

6. When the blood glucose results are displayed, the meal tag can be selected.
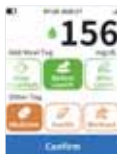
You can choose the following tag:

The device will intelligently recommend meal tag based on the current system time and mark them as "R". When swiping left/right, other meal tag can be selected.

7. After clicking the "Confirm" button, the measurement results are automatically uploaded.

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

8. After the data is uploaded successfully, it will automatically return to the HOME screen.

Discard the Used Test Strip

You can eject and discard the used test strip by using the strip ejector.

⚠ Potential Biohazard

Dispose of the used test strips as a potential medical waste.

Removing the Used Lancet

Unscrew the lancing device cover. Place the safety tab of the lancet on a hard surface and carefully insert the lancet needle into the safety tab.
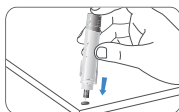
Press the release button to make sure that the lancet is in the extended position.Slide the ejection button forward to release the used or contaminated lancet in an appropriate container with a potential biohazard identification. Do not use your fingers to pull the used lancet out to prevent injury from the lancet. Dispose of used lancets and follow local regulations for proper disposal to prevent injury from the lancets.

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:

- *Lancing device is intended only for a single user and should not be shared.*
- *Check and do not use the lancet if the safety tab is missing or loose when you take the lancet out from the package.*
- *Do not use the contaminated or dropped lancet that safely tab has been removed.*
- *Be cautious when the lancet needle is exposed.*
- *Do not reuse lancet, and do not share lancet with anyone including family members.*

Expected Diabetes Control Goal:

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

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

Notes:
Please work with your healthcare professional to determine a target range that works best 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):
• shakiness • sweating • fast heartbeat • blurred vision • confusion	• passing out • irritability • seizure • extreme hunger • dizziness	• frequent urination • excessive thirst • blurred vision • increased fatigue • hunger

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 between 41–113°F.
- Make sure that the test strip vial has been tightly capped.
- Make sure the test strip has been stored at 36-86°F, 10-90% humidity.
- Make sure the test strip was used immediately after removing from the test strip vial.
- Make sure that you 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 TeleRPM Customer Support at +1-888-969-6928 for technical support or questions.

As glucose levels range for self-monitoring may vary from person to person, please check with your healthcare professional to determine the levels range you need to monitor, and

- Please contact your healthcare professional if your test result is below the lower limit of your level range or you see LO (less than 20 mg/dL).
- Please contact your healthcare professional If you test result is above the upper.
- Please contact your healthcare provider if you obtain results that are not consistent with the way you feel, and to not change your medication or food regimen without approval from a healthcare provider.

Testing with Control Solution:

Why Perform Control Tests

Performing a control test lets you know that your meter and test strips are working properly to give reliable test results. You should perform a control test when:

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

About the Control Solutions

- Only use TeleRPM Control Solutions (1, 2 or 3) to practice on the system.
- Your meter automatically recognizes the control solution.
- The control solution results are not including in the average value calculation.
- Store the control solution at 36-86°F, 10-90% humidity.
- All expiration dates are printed in Year-Month-Day format. 2023-01-01 indicates 1st January, 2023.
- Do not use control solution that is out of the expiration date or discard date (the control solution will expire 6 months after the bottle is opened for the first time).
- Shake the bottle well before use.
- Close the bottle tightly after use.

Performing a Control Test

1. Remove a test strip from the test strip vial. Tightly close the vial cap immediately after you have removed the test strip.

Notes:
Check the expiration and discard dates of the test strips. Do not use the expired test strip.

2. Insert a test strip into the meter in the direction of the arrows.

3. The meter turns on after a beep. A symbol with a test strip and finger will appear letting you know the meter is ready to test.

4. Shake the control solution bottle thoroughly. Squeeze the control solution bottle gently and discard the first drop. Squeeze out a second small drop on a clean nonabsorbent surface.

5. Immediately touch the tip of the test strip to the drop of control solution. The control solution is pulled into the test strip through the strip tip.

6. Hold it in the drop until the meter beeps, and then you see the meter count down on the screen, followed by your control test result.

Understand Your Control Test Result

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

The ranges in the picture 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:

- *Check the expiration dates and discard dates of the test strip and control solution. Make sure that the test strip vial and the control solution bottle have not been opened for more than 6 months. Discard any expired test strips or control solution.*
- *Confirm the temperature in which you are testing is between 50-104°F.*
- *Make sure that you stored strip and control solution at 36-86°F, 10-90% humidity.*
- *Make sure that the test strip vial and the control solution bottle have been tightly capped.*
- *Make sure the test strip was used immediately after removing from the test strip vial.*
- *Make sure the control solution was mixed well.*
- *Confirm that you are using TeleRPM brand control solution.*
- *Make sure that you followed the test procedure correctly.*

After checking all the conditions listed above, repeat the control solution test with a new test strip. If your results still fall out of the range indicated on the test strip vial label, your meter or test strips may not be working properly. DO NOT use the system to test blood. Contact 24/7 TeleRPM Customer Support at +1-888-969-6928. Please contact your healthcare professional if you need help.

To turn your meter off, just remove the test strip. Dispose of the used test strips as medical waste. The result will be automatically marked and stored in the meter memory. Control results will be not included in your blood glucose averages.

Functions and Settings

View Your Logs on the Meter

View your logs on your meter Your Blood glucose meter can store at least 2,000 logs. Each log is stored with date,time and meal tag.

Notes:

- *If there are already 2000 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 today, 7 and 30 day average calculation.*

1. Power on the Blood glucose meter by using the HOME button.

2. Press on the [My Data] icon to access logs. you can view Data by Trends or Data list.

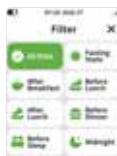3. Press on the [Trends&Overview] icon to view the logs by trends, Select Today/7days/30days tag to view more detials.
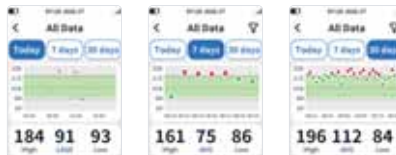
Press on the [▽] icon to filter the logs by meal tag.

4. Press on the [Data List] icon to view the logs by list. press ◀ or ▶ to view other date of the logs.

5. To exit the Logs menu, press the HOME button.

Make a material order on the Meter

You can send the order request to the server on the Glucose meter, and the customer service personnel will contact the user after receiving the order request.
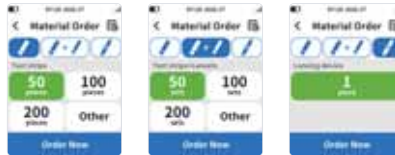
Notes:
Glucose meter does not support online payment.

1. Press the 👥 tap to view the order page, press [Mattrial Order] to enter the order page.

2. You can choose [Test strips], [Test strips+Lancets], or [Lancing device], as well as choose different order quantities and select [Order Now] to send the order request to the server.

3. After submitting the order, there will be feedback of successful or failed submission.

After successfully submitting the order, the request will be sent to the server, and the device will save the order record locally.

View order List

You can Click on 📇 icon to view order list.To return to the Home Screen, press the HOME button.
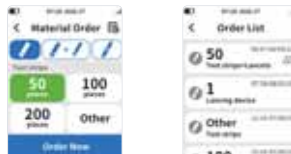
Notes:
The device displays the message within the past 3 months or 100 items, and orders exceeding 3 months or 100 items will not be displayed.

Reminders

Create reminders

1. Press the ⬤ tap to view the setting page, press [Reminder] to enter the reminder setting.Swide the switch to ON/OFF the reminder.
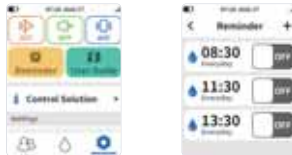
2. You can create a new reminder by press   icon.Choose the type of reminder, including measurement reminder, medication reminder, insulin injection reminder, and reminder frequency: Everyday /Once.

Up to 20 reminders can be set, and when exceeded, a pop-up prompt will pop up.

Click one of the reminders in the list to edit or delete the reminder.
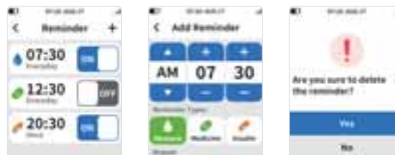
On reminders

When the reminder time is reached, the device will pop up a reminder page, accompanied by intermittent vibrations (if enabled) and audible reminders (if enabled);
Different reminder types correspond to different displays on reminder pages.

After selecting [Remind me later] , it will be reminded again in the 10th minute, with a maximum of 3 reminders.
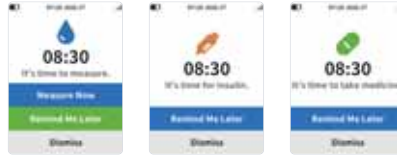
Settings

Your blood glucose meter time is automatically updated with the local date and time when a cellular connection is established.
If you would like to view your meter's preset settings, navigate to the Settings screen.

Quickly setting

Press the ⚙ tap to view the setting page, Click on the following buttons to quickly turn on/off the relevant modes.

	ON	OFF
Airplane Mode		
Volume		
Viberation		

Setting Options
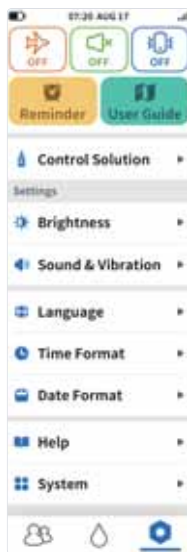
Create reminders
Change the brightness of your meter's screen.

Sound & Virbation
 Change the volume and virbation of your meter.

Language
Change the language displayed by your meter.

Time Format
Change the time display as 24-hour or 12-hour.

Date Format
Change the date display format.

Help
Some frequent question for help.

System
This screen provides a listing of device software and related information about your meter. This is helpful if you need technical support.

CHAPTER 3   MAINTENANCE AND TROUBLESHOOTING

Proper maintenance is recommended.

Recharging the Battery

When the meter needs to be recharged, the Empty Battery symbol (▭) will appear.
When the Empty Battery symbol (▭) appear by itself on the screen, the meter cannot be used. You must recharge the battery before using your meter.

The meter battery may be charged using one of the following options:
• Type-C USB cable (computer charging)
• Type-C USB cable with the AC adapter (wall charging)
If you need the Type-C USB cable or AC adapter which are not included in your kit, please contact your local distributor.

⚠️ Caution:

- *Do Not charge the meter outdoors or in a wet area.*
- *Do Not use the Micro USB cable, AC adapter or meter if it is damaged, discolored, abnormally hot, or has an unusual odour. Contact your local distributor.*
- *Do Not plug the AC adapter into a wall socket and leave it unattended.*
- *Verify that the wall socket voltage matches the AC adapter voltage.*
- *Do Not allow unsupervised children to charge the meter battery.*

⚠️ Caution:

- *Do Not insert a test strip when the meter is connected to a computer or wall outlet.*

Notes:
- *Using the Micro USB cable or AC adapter charges the battery in about 3 hours.*
- *When using the USB port on your computer to charge the battery, be sure the computer is turned on and not in standby mode. If the meter does not charge, try using another USB port on your computer.*
- *To optimise battery life, it is best to recharge the battery when the Low Battery symbol (▭) appears.*

⚠️ Caution:

- *Contact seller to confirm whether the AC adapter meets following specifications before purchasing it:*
  - Input: 100-240V~, 50/60Hz, 0.2A Max;
  - Output: 5.0V ⎓ , 1.0A;

- Standard ANSI/AAMI ES 60601-1 or IEC 60601-1.
- *If you use the USB port on your computer to charge the battery, please ensure the computer meets the standard IEC 60950.*

Warning:
Please note that the battery is not removable. If the battery needs to be separated for 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.
- MIO 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 CloroxTM Healthcare Bleach Germicidal Wipes, which has been proven to be safe to use with the MIO Blood Glucose Meter. CloroxTM Healthcare Bleach Germicidal Wipes are available by visiting and purchasing at http://www.walmart.com, http://www.-staples.com/, and https://www.amazon.com/.

The meter should be cleaned and disinfected a minimum of once per week. This 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 of the meter.

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 that have not been proved to be safe and effective for use with the device.*
- *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 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 including the front, back, left, right, top and bottom sides of the meter, and specifically also including the test strip port, test strip ejector, button, material seams and USB port for one minute. This cleaning is to prepare a clean meter surface for a disinfection process.

| Front side | Back side | Right side |

| Left side | Top side | Bottom side |
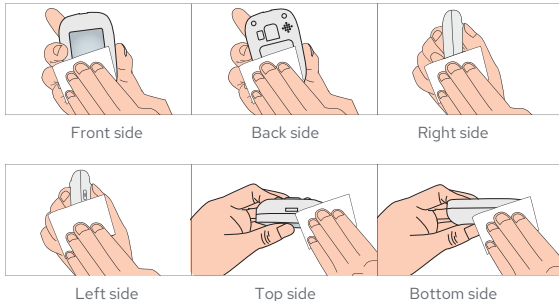
Disinfecting Your Meter

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 by a back-and-forth movement including the front, back, left, right, top and bottom sides 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 USB port.

Front side	Back side	Right side
Left side	Top side	Bottom side
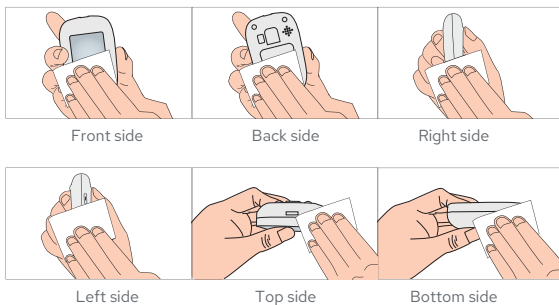
Step 3:
Cover the meter with the same wipe and then keep the meter surface wet for one minute.

Step 4:
Remove the wipe and wait for the meter's surface 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 meter's 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 24/7 TeleRPM Customer Support at +1-888-969-6928 for help.

If you have questions about cleaning or disinfection, contact 24/7 TeleRPM Customer Support at +1-888-969-6928.

Troubleshooting Guide

What You See	What It Means	What You Should Do
No display or Low Battery symbol (⬛) appears	Running out of battery.	Please charge your meter in time.
E1 error	Blood or control solution was applied to the test strip before the ready symbol appeared on the display.	Discard the test strip and repeat the test with a new test strip. Wait until you see the ready symbol on the display before testing.
E2 error	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 ready symbol on the display before testing.
E3 error	Incorrect test strip.	Discard the test strip and repeat the test with a new test strip. Make sure that you are using the TeleRPM test strip.
E4 error	Incorrect sample.	Discard the test strip and repeat the test with a new test strip. Make sure that only human capillary blood and TeleRPM control solution are used for the test.
E5 error	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.
E6 error	Potential hardware error.	Restart the meter. If the problem continues, contact 24/7 TeleRPM Customer Support at (833)445-5666.
E7 error	Insufficient sample.	Repeat the test and apply enough sample to fill the test strip check window.

E8 error	Potential hardware error.	When the charge is completed (about 3 hours for charging an empty battery), remove the Type-C USB cable from the meter, and then take a test.
EB error	Potential hardware error.	Restart the meter. If the problem continues, contact 24/7 TeleRPM Customer Support at (833)445-5666.
Operation error	Unable to test during charging process.	Please unplug the charging wire and measure again.
Operation error	During the testing process, the charging cable cannot be connected.	Please connect the charging cable in non test mode.
Operation error	The test strip has been remove.	Please insert a new test strip and try again.
Abnormal results	The test result is above 600 mg/dL.	Wash and dry your hands well and the test site. Repeat the test using a new test strip. If your result still Abnormal, contact your healthcarepro-fessional as soon as possible.
Abnormal results	The test result is below 20 mg/dL.	Wash and dry your hands well and the test site. Repeat the test using a new test strip. If your result still Abnormal, contact your healthcare professional as soon as possible.
Network anomalay	The device may be in airplane mode or under the environment of a less of wireless signal trength,and the data will be uploaded after the next uccessful connection.	If Airplane mode is turned on, the network is normal after turning off. If you are in a weak signal environment, please move to a strong signal environment (such as a balcony), press the button to light up the screen once, and the device will automatically connect to the network and resend data.

System Specifications:

Feature	Specification
Measurement Range	20 – 600 mg/dL
Measurement Result	Plasma Glucose
Sample	Fresh capillary whole blood
Sample Volume	0.8 µL
Test Time	5 seconds
Power Source	Rechargeable 3.7 Volt Lithium Ion battery
Charging Time	⩽3h, ⎓ Direct current
Battery Type	Rechargeable, 1380 mAh, 3.7 Volt DC nominal, lithium polymer battery (5V input charge voltage)
Units of Measure	mg/dL
Memory	2000 results
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	Type-C USB
Data Transmission	4G

4G Specifications

Item Name	Design Specification
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

Warranty

Please complete the warranty card that came with this product and mail it to
Mio Labs Inc.
#1023, ZGC Innovation Center,
4500 Great America Pkwy, Santa Clara, CA 95054

If the meter fails to work for any reason other than obvious abuse within the first five (5) years from purchase, we will replace it with a new meter free of charge. 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:
Don't 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 Immunity		
Immunity Test	IEC 60601-1-2 Test L evel	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_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T; 1 cycle 70% U_T; 25/30 cycle Single phase: at 0° 0% U_T; 250/300 cycle	0% U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T; 1 cycle 70% U_T; 25/30 cycle Single phase: at 0° 0% U_T; 250/300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC 61000-4-6	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 IEC 61000-4-3	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_T 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				Compliance Level
	Test Frequency	Modulation	Maximum Power	Immunity Test Level	
Radiated RF IEC 61000-4-3	385 MHz	**Pulse Modulation: 18Hz	1.8W	27 V/m	27 V/m
	450 MHz	*FM+ 5 kHz deviation: 1kHz sine	2W	28 V/m	28 V/m
	710 MHz	**Pulse Modulation: 217Hz	0.2W	9 V/m	9 V/m
	745 MHz				
	780 MHz				
	810 MHz	**Pulse Modulation: 217Hz	2W	28 V/m	28 V/m
	870 MHz				
	930 MHz				
Radiated RF IEC 61000-4-3	1720 MHz	**Pulse Modulation: 217Hz	2W	28 V/m	28 V/m
	1845 MHz				
	1970 MHz				
	2450 MHz	**Pulse Modulation: 217Hz	2W	28 V/m	28 V/m
	5240 MHz	**Pulse Modulation: 217Hz	0.2W	9 V/m	9 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.

Frequency Requirement

Frequency Band	Transmit (MHz)	Receive (MHz)
Band 2	1850 - 1910	1930 - 1990
Band 4	1710 -1755	2110 - 2155
Band 12	699 - 716	729 - 746
Band 13	777 - 787	746 - 756

TX POWER

Frequency Band	Max Power	Min Power
Band 2/4/12/13	20dBm ± 2dB	< -39 dBm

FCC Information

RF Exposure Compliance

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End user must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

The portable device is designed to meet the requirements for exposure to radio waves established by the Federal Communications Commission (USA). These requirements set a SAR limit of 1.6 W/kg averaged over one gram of tissue. The highest SAR value reported under this standard during product certification for use when properly worn on the extremity, with 00mm separation.

FCC Regulatory Compliance

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.

Supplier's Declaration of Conformity

47 CFR § 2.1077 Compliance Information
Unique Identifier Trade Name: Blood Glucose Monitoring System, Model No.: BGM 2280-A

Responsible Party – U.S. Contact Information
Guangdong Transtek Medical Electronics Co., Ltd.
Zone A, No.105, Dongli Road, Torch Development District, 528437
Zhongshan, Guangdong, China
Telephone: +86-760-85166220

FCC Compliance 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.

Precision and Accuracy

Linearity Results:
Lot 1: y = 0.9982; R2= 0.9975.
Lot 2: y = 0.9945; R2= 0.9982.
Lot 3: y = 0.9949; R2= 0.9973.
All 3 Strips Lots: y = 0.9959; R2= 0.9976.
The results support the claimed measurement range of 20-600 mg/dL.

Within-Run Precision:

Interval	Glucose Concentration	Standard Deviation (SD) or Coefficient of Variation (CV)	SD 95% CI or CV 95% CI
1	39.8 mg/dL	1.8 mg/dL	[1.2mg/dL,2.4mg/dL]
2	70.5 mg/dL	2.3 mg/dL	[1.3mg/dL,2.9mg/dL]
3	127.9 mg/dL	2.8%	[1.5%, 3.9%]
4	199.0 mg/dL	3.0%	[1.6%, 3.6%]
5	349.6 mg/dL	2.9%	[1.5%, 3.9%]

Intermediate Precision:

Interval	Glucose Concentration	Standard Deviation (SD) or Coefficient of Variation (CV)	SD 95% CI or CV 95% CI
1	40.0 mg/dL	1.8 mg/dL	[1.0mg/dL,2.5mg/dL]
2	70.1 mg/dL	2.0 mg/dL	[0.9mg/dL,3.0mg/dL]
3	129.8 mg/dL	2.4%	[1.1%, 3.4%]
4	199.5 mg/dL	2.3%	[1.2%, 3.2%]
5	349.9 mg/dL	2.3%	[1.3%, 3.2%]

User Evaluation:
352 samples were tested using three TeleRPM Blood Glucose Test Strips lots. The results were compared to the YSI Model 2300 Analyzer.

Table 1- Linear Regression Results

Slope	0.9933mg/dL
Intercept	0.3766

Correlation coefficient (R)	0.9941
Number of samples	352
Range tested	46.1 to 450.5mg/dL

Table 2-Consumers Accuracy Results

Accuracy for Home Use by Lay-Users TeleRPM Blood Glucose Meter result may vary slightly from your actual blood glucose value. This may be due to slight differences in technique and the natural variation in the test technology.

The chart below shows the results of a study where 352 typical users used the TeleRPM Blood Glucose Meter to test their blood glucose level. In this study, TeleRPM Blood Glucose Meter gave results within 15% of their true blood glucose level 352 out of 352 times.

Difference range between the true blood glucose level and TeleRPM Blood Glucose Meter result.	Within 5%	Within 10%	Within 15%	Within 20%
The percent (and number) of meter results that match true blood glucose level within x%	68.5% (241/352)	96.0% (338/352)	100% (352/352)	100% (352/352)

Comparing Meter and Laboratory Results

Before you go to the lab:
  Perform a control test to make sure the meter is working properly.
  If possible, fast for at least eight hours before testing.
  Bring your meter and test strips.
While you stay at the lab:
  Wash your hands before obtaining a blood sample.
  Obtain and test the blood samples immediately for your tests.
  Follow User Manual for performing a blood glucose test.

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

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