Pops Rebel Blood Glucose Monitoring System

Owner’s Manual

Dear System Owner:

Thank you for choosing the Pops Rebel Blood Glucose Monitoring System. This manual provides important information to help you to use the system properly. Before using this system, please read the following contents thoroughly and carefully.

Regular monitoring of your blood glucose can help you and your doctor gain better control of your diabetes. Due to its compact size and easy operation, you can use the Pops Rebel Blood Glucose Monitoring System to easily monitor your blood glucose levels by yourself anywhere, any time.

If you have other questions regarding this product, please contact support ((800) 767-7268) or your healthcare professional.

Intended Use

The Pops Rebel Blood Glucose Monitoring System is comprised of the Pops Rebel blood glucose meter, the Pops Rebel blood glucose sensor modules (Pops-Ins), and the Pops Rebel mobile application as the display component.

The Pops Rebel Blood Glucose Monitoring System is intended for use outside the body (*in vitro* diagnostic use) in the quantitative measurement of glucose in fresh capillary whole blood taken from the finger. It is intended to be used by people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program.

The Pops Rebel Blood Glucose Monitoring System is intended to be used by a single patient and should not be shared. It is not intended for the diagnosis of, or screening of diabetes.

It is not intended for use on neonates.

IMPORTANT SAFETY PRECAUTIONS
READ BEFORE USE

1. The Pops Rebel Blood Glucose Monitoring System is for single patient use. Do not share any part of the system with anyone including other family members. Do not use on multiple patients.
2. All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

For more information, please visit the following:

- "FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010) http://wayback.archive-it.org/7993/20170111013014/http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm
- "CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010) http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html

1. Use this device **ONLY** for the intended use described in this manual.
2. This device 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 device on multiple patients may lead to transmission of Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), Hepatitis B Virus (HBV), or other bloodborne pathogens.
3. Do **NOT** use accessories which are not specified by the manufacturer.
4. Do **NOT** use the device if it is not working properly or if it is damaged.
5. Do **NOT**, under any circumstances, use the device on neonates.
6. This device does **NOT** serve as a cure for any symptoms or diseases. The data measured is for reference only.
7. Before using this device to test blood glucose, read all instructions thoroughly. Carry out all the quality control checks as directed.
8. Keep the device and testing equipment away from small children. If swallowed, consult a doctor immediately for advice.
9. Do **NOT** use this instrument in close proximity to sources of strong electromagnetic radiation (ex: an alternator), as these may interfere with the accurate operation.
10. Proper maintenance and periodic control solution testing are essential to the durability of your device. If you are concerned about its accuracy, please contact customer service ((800) 767-7268) for help.
11. Do not use this device with a jailbroken iOS device.
12. Mobile phone functionality, overheating, and battery power can impact the ability to perform a blood glucose test with the Pops Rebel System. Be sure to use phone in conditions recommended by the mobile phone manufacturer.
13. Lancets located within the sensor module are provided sterile. Once the foil cover has been peeled back, the lancet is no longer sterile.

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LIMITATIONS

1. Should not be used for the diagnosis of, or screening for diabetes.
2. For single patient use only.
3. Each sensor module test site (lancet and strip) is for single use only.
4. For self-testing.
5. For over the counter use.
6. For English speaking population only.
7. Should not be used if you have a physical condition or limitation that may prevent you from testing on your own.
8. Severe dehydration and excessive water loss may cause inaccurate readings.
9. This device is limited for use with capillary whole blood from the fingertip and should not be used for alternative site testing (i.e. palm, forearm, thigh, etc).
10. If you have a disease or condition in which uric acid levels in your blood may be elevated (> 10 mg/dL), such as gout, you may get inaccurate results with this system. If you are unsure, then ask your health care professional.
11. Acetaminophen in your blood (> 6.25 mg/dL) might affect the reliability of your blood glucose results. If you are taking Tylenol, or other acetaminophen containing drugs, your glucose results may not be reliable. If you are unsure, then ask your health care professional.
12. Xylose: Do not test blood glucose during or soon after a xylose absorption test. Xylose in the blood can give falsely elevated results.
13. Altitudes above 15,000 feet may cause inaccurate results.

14. Inaccurate results may occur in severely hypotensive individuals or patients in shock. Inaccurate low results may occur for individuals experiencing a hypoglycemic hyperosmolar state, with or without ketosis.
15. This system is not for use in patients with abnormally low blood pressure or those who are in shock.
16. This system should not be used on patients with impaired peripheral circulation
17. This system is not for use with neonates.
18. This system should not be used on critically ill patients.

BEFORE YOU BEGIN

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 strip within the Sensor Module. The system 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.

System Principle of Operation

The Pops Rebel System is designed to make blood glucose testing and diabetes management easier and more convenient. The traditional test kit is replaced by a low-profile meter that contains everything needed for testing and requires no assembly. The meter pairs with a mobile app installed on the user's phone via Bluetooth, allowing the meter to perform glucose testing and send the results to the app where they are communicated to the user and automatically stored.

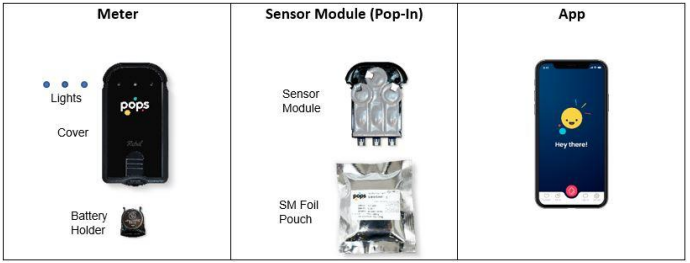
To perform a test, the user needs the Pops Rebel blood glucose meter, a smart phone with the Pops Rebel app installed, and a sensor module that fits into the meter. The meter communicates with the Pops Rebel app installed on the user's phone using Bluetooth. This allows the user to perform a test any time the phone is within a distance of 10 meters from the glucose meter. The user initiates a test via the Pops Rebel app,

uses the lancet and strip located on the sensor module to test, and reads the result displayed on the app.

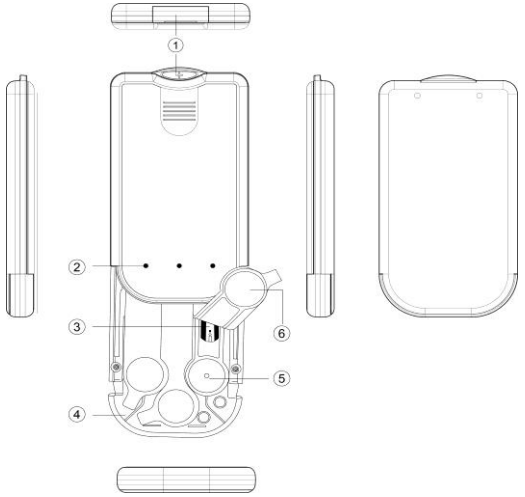
Contents of System

The Pops Rebel Blood Glucose Monitoring System kit includes:

1. Pops Rebel blood glucose meter
2. Phone mobile application (app)
3. Pops Rebel blood glucose sensor module
4. Product Labeling
5. 2032 battery



Meter Overview



1. **Battery Holder**
2. **Blue Indicator Lights**

   There are lighted indicators, one associated with each of the three test strips in the Sensor Module.

   The lit Bluetooth indicator signifies that its correspondent test strip is ready for the test.

3. **Test Strip**
4. **Sensor Module**
5. **Lancet**
6. **Test Site Foil Cover**

NOTE:
Pops Rebel Blood Glucose Monitoring System is only for use with the Pops Rebel Blood Glucose Sensor Module. Do not use other supply parts with this system, as this will produce inaccurate results.

Sensor Module Overview

Before use, insert the Sensor Module into the Pops Rebel blood glucose meter.

The Sensor Module contains 3 lancets and 3 test strips; individually packaged in the Sensor Module to create 3 test sites. After **all** 3 tests sites are used, replace with a new Sensor Module. The Sensor Modules come with four lance levels to give blood drops of different sizes (level 1 = smallest drop, level 4 = largest drop). Two of each lancet levels have been provided in your Welcome Kit. You will be prompted via the mobile app to enter your lancet level preference after your first few days of testing. This level will be what is sent to you for future sensor module shipments. If your preference changes, you can change your lancet level at any time under the 'Settings' tab in the mobile app. The lancet level is can be found on the label for each individually packed sensor module as well as on the outside of the sensor module box.

Test Strip

The test strips are embedded and individually packaged in a Sensor Module. There are 3 test strips in every Sensor Module.

1. **Absorbent Hole**
   Apply a drop of blood here. The blood will be automatically absorbed
2. **Confirmation Window**
   This is where you confirm if enough blood has been applied to the absorbent opening in the test strip.
3. **Contact Bars**
   Insert this end of the sensor module into the meter. Push it in firmly until you hear a “click”.

Sensor Module Insertion

Tear open the foil pouch and remove the Sensor Module. Slide the cover to open the meter. With one hand holding the meter slowly push the Sensor Module into the meter with the other hand until you hear a “click.”

Sensor Module Replacement

Squeeze the sensor module on both sides to release and pull the sensor module out of the meter.

NOTE:
Pops Rebel Blood Glucose Monitoring System is only for use with the Pops Rebel Blood Glucose Sensor Module. Do not use other supply parts with this system, as this will produce inaccurate results.

POPS REBEL APP

Installing Pops Rebel App

The Pops Rebel Blood Glucose Monitoring System is designed to conduct blood glucose testing through the Pops Rebel mobile application, which is available on the App Store and the Google Play Store for free download. You must connect to the internet to download the App. The app stores can be accessed by tapping the App Store or Google Play icon on your mobile devices.

iPhones supported	6 plus, 6S, 6S plus, 7, 7 plus, 8, 8 plus, X, XR, XS, XS max, 11, 11 pro, 11 pro max
iOS system requirements	iOS 10+, iOS 11+, iOS 12+, iOS 13+
Android phones supported	Samsung Galaxy: S6, S7, S8 S9 Huawei: P8 LG: G6, 5X Motorola: Moto G Play
Android system requirements	6+, 7+, 8+, 9+

Pops Rebel App Updates

When new features are added to the **Pops Rebel App**, the app stores will notify you automatically. Please perform the updates accordingly to provide you with the latest features that we have developed.

Creating Your Account

1. Tap the icon of Pops Rebel App on your mobile device to open the App.
2. Tap on “sign up” to create your personal account. Provide information as requested in the App.

NOTE: Password should be a combination of at least 6 characters, including one upper case and one lower case letter, and one number.

Congratulations! You have created your own account.

Bluetooth Pairing

Pairing your meter to the Pops Rebel App is done via Bluetooth when you perform your first test. Therefore, before starting your first test, assure that the Bluetooth function on your phone is turned on. When you tap the Check button on the App home screen for the first time and open your meter cover to turn on the meter the pairing will be complete.

The meter will only pair with one mobile device at a time, so if you replace your meter you will need to select ‘forget your meter’ in the settings tab of the App to allow pairing with a new meter.

NOTE:

Make sure the Bluetooth setting on your device is turned on and the meter is within the receiving range. The operating range is within 10 meters.

Pops Rebel App: Settings Tab

Tap on the “settings” tab at the bottom of the screen to enter settings page where you may do the following:

- Edit personal information
- Change password
- Set your glucose range target
- Change desired lancet level
- Disconnect the Bluetooth pairing of the App with the meter
- Log out of the App
- Perform QC test

Pops Rebel App: Support Tab

Tap on the Support tab at the bottom of the screen to enter the Support page where you may do the following:

- Contact Customer Support
- Reorder sensor modules
- View product training video(s)

PROTECTING YOUR DATA

All systems that transmit information wirelessly or over the internet face additional security risk to that information. While that is true for

the Pops Rebel System, we have implemented industry standard encryption and other security controls in all transmissions of information to highly protect all information. Additional details can be found in the Pops Privacy Policy (located under the Settings tab in the Pops Rebel app).

There are also measures you can take to be certain that your data is protected. These include:

- Utilize log-in security options offered on your phone, such as secure log-in password, fingerprint access, or facial recognition.
- Enable the auto-lock features on your phone that require the user to log-in again after a specific period of non-use.
- Create a unique, complex password for your Pops Rebel app and do not share this password with anyone.

PERFORMING CONTROL SOLUTION TESTS

The Pops Rebel App, Sensor Module and control solution are essential to perform a control solution test. You may request a bottle of Glucose Control Solution (W2-Level 2) by emailing us at supportsquad@popsdiabetes.com or calling support at (800) 767-7268.

Please make sure you have the items needed for a control solution test before you begin.

When to do a control solution test:

- You suspect the Monitoring System is not working properly
- Your test results are not consistent with how you feel, or if you think the results are not accurate
- Practicing the testing process
- You have dropped or think you may have damaged the meter

How to Perform a Control Solution Test

1. **Log in to the App**

   On your mobile device, tap the icon of the Pops Rebel App (be sure your phone Bluetooth function is on).

2. **Enter the QC Test page**

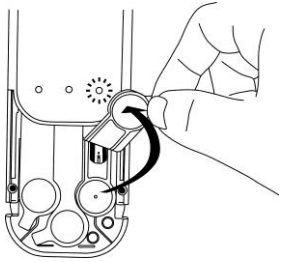
   Tap on the “settings” icon and scroll down to find “QC Test” and tap on it. Now you are at the QC Test page.

3. **Initiate the Test**

   Tap on “Check” and turn on the meter by sliding the meter cover open. You will see 3 flashing blue indicator lights.

4. **Prompt to begin test**

   The App will tell you when it is ready, and you will see one solid blue light on the meter indicator lights. Pull back the foil on the corresponding test site exposing the lancet and test strip. Stop at the point where the strip is fully exposed. Do not pull the foil off.

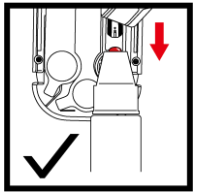


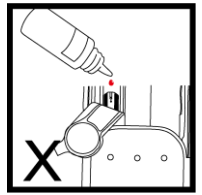
5. **Shake the control solution vial**

Shake the control solution vial thoroughly before use. Squeeze out the first drop and wipe it off, then squeeze out another drop and place it on the tip of the vial cap.

6. **Apply control solution to the test strip.**

Hold the meter to move the absorbent hole of the test strip to touch the drop. Fill the confirmation window of the strip completely





NOTE:

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

7. **Read and compare the result**

The control solution test result will appear on the App. Compare this result with the range printed on the Sensor Module box or foil package. The result should fall within this range. If not, please read the instructions again and repeat the control solution test. When “QC Test” is displayed, the meter will **NOT** store the control solution test result.

Out-of-Range Results

If you continue to have test results fall outside the range printed on the Sensor Module box, the meter and the Sensor Module may not be working properly. Do NOT test your blood. Review the possible causes below, and if your results are still out of range, contact support ((800) 767-7268) for help.

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

NOTE:

- The control solution range printed on the Sensor Module box is for control solution use only. It is not a recommended range for your blood glucose level.
- See the **MAINTENANCE** chapter for important information about your control solution.

TESTING WITH BLOOD SAMPLE

All products or objects which come in contact with human blood, even after cleaning, should be handled as if capable of transmitting viral disease.

WARNING:

To reduce the chance of infection:

- Never share your meter or sensor module with another person.
- Always use a new, sterile lancet. Lancets are for single use only. Lancets should not be shared.
- Avoid getting hand lotion, oils, dirt, or debris in or on the lancets.
- Wash and dry your hands thoroughly after handling the meter, and Sensor Module to prevent infection. For more information, please refer to the “MAINTENANCE” section.
- If the meter is being operated by a second person who is providing testing assistance to the user, the meter should be cleaned and disinfected prior to use by the second person.

Preparing the Puncture Site

Stimulating blood perfusion by rubbing the puncture site before blood extraction is important for accurate results. Blood from a site that has not been rubbed exhibits a measurably different glucose concentration than blood from the rest of the finger. When the puncture site is rubbed prior to blood extraction, that difference is significantly reduced.

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

1. **Wash and dry your hands before starting.** Contaminants on your skin may affect test results, so be sure to thoroughly wash hands with soap and water and dry your skin before testing.
2. Select the puncture site at fingertips
3. Rub the puncture site for about 20 seconds before puncture.
4. Clean the puncture site using cotton moistened with 70% alcohol and **let it air dry**.

Performing a Blood Glucose Test

To perform a blood glucose test, you will need the Pops Rebel App, meter, and Sensor Module

1. **Log in to the App**

On your mobile device, tap the icon of the Pops Rebel App (be sure your phone Bluetooth function is on). Enter your log-in information if prompted.

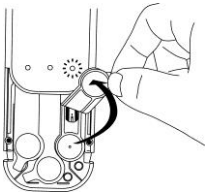
2. **Initiate the Test**

Tap on “Check” on the App screen and turn on the meter by sliding the meter cover open. You will see 3 flashing blue indicator lights on the meter.

3. **Prompt to begin test**

The App will tell you when it is ready, and you will see one of the blue indicator lights turn solid blue.

Pull back the foil on the corresponding test site exposing the lancet and test strip. Stop at the point where the strip is fully exposed. **Do not pull the foil off.**



NOTE:

- After the test is initiated, perform the test immediately; otherwise, the meter will shut itself down automatically in 4 minutes. In this case, close and re-open the meter cover and tap “Check” again on the App screen to initiate a new test.
- Use test site (lancet and strip) immediately after you peel back the foil cover. Lancets sterility and strip accuracy are not maintained after being exposed to the air.

4. **Obtaining a blood sample**

While you are first learning to use the lancet, it works best to keep the meter on a hard surface while lancing.

Place your fingertip over the hole in the center of the lancing device. Press your fingertip **quickly and confidently** downward on the lancet. Do this in one smooth motion – do not press slowly or hold your finger on the lancet.

Wipe off the first appeared drop of blood with a clean cotton swab. Gently squeeze the punctured area to obtain another drop of blood. The size of the drop should be at least as big as • (actual size), which is 0.5 microliter (μL) of volume. Be careful **NOT** to smear the blood sample.

If you have difficulties drawing blood or the blood sample is consistently too small, you can try a sensor module with a different lance level.

NOTE:

- Choose a different spot each time you test. Repeated punctures at the same spot may cause soreness and calluses.
- It is recommended that you discard the first drop of blood as it might contain tissue fluid, which may affect the test result.

5. **Apply the Sample**

Line up the blood drop until it almost touches the end of the test strip. Gently apply the drop of blood to the absorbent hole at the tip of the test strip. Do not wipe or smear the drop on the test strip.

Let the test strip confirmation window wick up the blood to completely fill the window. If the test strip does not wick up enough blood in the initial application, you will need to start over. You cannot add more blood to the test strip once the initial drop has been applied.

Once blood fills the test strip window, the blue indicator light on the meter will flash, and the App screen will have three animated dots while performing the reading.

NOTE:

- If you have trouble filling the confirmation window, consider using a higher-level lancet to obtain a larger blood droplet.Contact support (800) 767-7268 for assistance.

6. **Read Your Result**

The result of your test will appear on the App screen. You can slide the white button to mark the reading as pre-meal, post-meal or neither. Then touch the “Done” button to return to the test screen.

NOTE:

If your blood glucose results are lower or higher than expected, 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 expected, follow the treatment advice of your healthcare professional.

7. **Finish**

Push the foil back down to cover the used test site and attach to the small sticky glue spot. Slide the meter cover closed while holding the end of the sensor module in place.

WARNING:

The used Sensor Module may be a biohazard. Please follow your healthcare provider’s recommendations for proper disposal.

MEMORY & TRENDS

Your blood glucose test results are stored in the section of “trends” on the Pops Rebel App automatically. Three months of your most recent testing data is stored on your phone. A scatter chart and a ring chart are provided as an overview of your diabetes management.

Review Test Results

1. **Open the Pops Rebel App**

   Tap the icon of the Pops Rebel App on your mobile device to enter the App and log in.

2. **Tap on “trends” icon in the bottom of the screen**

Your test results are sorted by “day”, “week”, “month” and “3 months.” Tap on each tab to see the lowest/ average/highest blood glucose level of each time frame.

MAINTENANCE

Battery

Your meter comes with one 2032 lithium battery.

Low Battery Signal

The App will display “Please change your meter’s battery.” to alert you when the meter power is not enough for a test. Please replace with new one immediately.

Replacing the Battery

To replace the battery, make sure that the cover of the meter is closed so the system is turned off.

1. Pull out the battery holder.
2. Remove the old battery and replace with one 3V 2032 lithium battery with the “+” mark facing up.
3. Insert the battery holder back. If it is inserted correctly, you will hear a “click” sound.

NOTE:

- As with all small batteries, these batteries should be kept away from children. If swallowed, promptly seek medical assistance.

- Battery might leak chemicals if unused for a long time. Remove the battery if you are not going to use the device for an extended period (i.e. 3 months or more).
- Properly dispose of the battery according to your local environmental regulations.

Caring for Your Meter

To avoid the meter and Sensor Module attracting dirt, dust or other contaminants, users should wash hands thoroughly with soap and water before and after handling the meter and sensor module.

The Difference Between Cleaning and Disinfection

Cleaning and disinfection are different. Cleaning is the process of removing dirt (e.g. food debris, grease, dust), while disinfection is the process of killing germs (e.g. bacteria and viruses).

When to clean and disinfect the meter

Clean the meter when you see any dirt on it. The meter should be cleaned and disinfected once per week. If the meter is being operated by a second person who is providing testing assistance, clean and disinfect the meter prior to use by the second person.

How to clean and disinfect the meter

We recommend using the Micro-Kill+™ (Micro-Kill Plus™) disinfecting wipes manufactured by Medline (EPA Reg. No. 59894-10-37549). The active ingredient in this product, isopropyl alcohol, has been shown to be safe for use with the Pops Rebel Blood Glucose Monitoring System: To obtain disinfecting wipes and other information, please contact Medline at 1-800-MEDLINE (1-800-633-5463) or visit www.medline.com. You can also purchase it at Amazon (www.amazon.com) or Walmart

(www.walmart.com).

Cleaning procedure

Step 1: Remove the sensor module

Step 2: **Remove the meter cover** by sliding cover open about one inch, placing your fingers underneath the cover on one side and slowly lifting-up. Once one side of the cover has released, ease the cover off on the opposite side.

Step 3: **Clean all surfaces of the meter body** by wiping with a disinfecting wipe to remove visible dirt, blood, or other substances.

Step 4: Clean the meter cover by wiping both sides with a disinfecting wipe to remove visible dirt, blood, or other substances.

Disinfection Procedure

Step 1: Complete the cleaning procedure prior to starting disinfection.

Step 2: Disinfect the interior surfaces of the meter with a new disinfecting wipe, making three passes in both directions over each surface.

Step 3: Disinfect each meter track by wiping with three passes back and forth along each track.

Step 4: Disinfect the exterior surfaces of the meter and the meter cover, making three passes with a disinfecting wipe in both directions over each surface.

Step 5: Keep the whole meter wet, including interior and exterior surfaces, with the disinfection solution contained in the wipe for a minimum of 2 minutes. Allow all the surfaces to dry completely before using.

Step 6: When meter is dry, replace the meter cover by setting on top of the meter in the same position as removal (about 1 inch open) and push down on the cover until you hear it click into place.

Step 7: Discard used wipes and never reuse them.

CAUTION:

- Failure to properly clean and disinfect the meter can damage

the device or transmit bloodborne pathogens.

- Never spray or immerse the meter in water or any other liquid.
- Do NOT use organic solvents to clean the meter.

This device has been validated to withstand 260 cleaning and disinfection cycles using the recommended disinfecting wipe/towelette. The tested number of cycles is estimated by 1 cleaning and disinfection cycle per meter per week for 5 years, the expected life of the meter. The meter should be replaced after the validated number of cleaning and disinfection cycles or the warranty period, whichever comes first.

Improper system cleaning and disinfection may result in meter malfunction. If you suspect your meter is not working properly, perform a control solution test. If your test result is not within the control range, please contact customer service for assistance.

Stop using meter and contact customer service for a replacement meter if any signs of deterioration are noted. This includes but is not limited to:

- Meter cannot be turned on.
- Meter outer casing cracks.
- Color or printing on the meter housing is abnormal.
- Scratches or abrasions on meter interfere with ability to read printing, visualize indicator lights, or perform a blood glucose test.

Please contact support ((800) 767-7268) for a replacement meter if any of the signs of deterioration are noticed.

NOTE:

Do **NOT** clean and disinfect the meter while performing tests.

Do NOT expose the Sensor Module to the cleaning and disinfecting solution.

Caring for Your Sensor Module

- Storage conditions for blood glucose Sensor Module: 35.6°F to 86°F (2°C to 30°C), 10% to 85% relative humidity. Do not freeze.
- Store your Sensor Module in the original foil package. Tear open the foil package only when you replace the Sensor Module.
- Store Sensor Module packages in a cool dry place. Keep away from direct sunlight and heat.
- Only tear open the foil cover of the specific test site directed by the blue indicator light.
- Touch the Sensor Module with clean and dry hands.
- Use each test strip immediately after tearing open its foil cover.
- Do not use Sensor Module after the expiration date. This may cause inaccurate results.
- Use the Sensor Module within three days after removing it from the foil package.
- Do not bend, cut, or alter a test strip inside the Sensor Module in any way.
- Do not reuse test strips inside the Sensor Module.

For further information, please refer to the Sensor Module manual.

Important Control Solution Information

- Use only our Control Solutions with your meter.
- Do not use the control solution after 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 (68°F ~ 77°F / 20°C ~ 25°C). Make sure your control solution, meter, and Sensor Module 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 35.6°F ~ 86°F (2°C ~ 30°C). Do **NOT** freeze.

For further information, please refer to the control solution insert.

SYSTEM TROUBLESHOOTING

The App will provide information and suggested actions in the case of an error. If you follow the recommended action but the problem persists, or error messages are not consistent with what you see, please contact support ((800) 767-7268). Do not attempt to repair yourself or try to disassemble the Monitoring System.

DETAILED INFORMATION

The system provides you with plasma equivalent results.

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)

Source: American Diabetes Association. Standards of medical care in diabetes-2018; 41 (supp.1 Diabetes Care)

Please consult your doctor to determine a target range that works best for you.

Comparing Meter and Laboratory Results

The meter provides you with whole blood equivalent results. The result you obtain from your meter may differ somewhat from your laboratory result due to normal variation. Meter results may be affected by factors and conditions that do not affect laboratory results in the same way. To make an accurate comparison between meter and laboratory results, follow the guidelines below.

Before going to the lab:

- Perform a control solution test to make sure that the meter is working properly.
- Fast for at least eight hours before doing comparison tests, if possible.
- Take your meter with you to the lab.

NOTE:

Please consult with your healthcare professional regarding instructions for conducting a fasting blood glucose test.

While staying at the lab:

- Make sure that the samples for both tests are taken and tested within 15 minutes of each other.
- Wash your hands before obtaining a blood sample.

You may still have a variation from the result because blood glucose levels can change significantly over short periods of time, especially if you have recently eaten, exercised, taken medication or experienced stress[*1]. In addition, if you have eaten recently, the blood glucose level from a finger prick can be up to 70 mg/dL (3.9 mmol/L) higher than blood drawn from a vein (venous sample) used for a lab test[*2]. Therefore, it is best to fast for eight hours before doing comparison tests. Factors such as the amount of red blood cells in the blood (a high or low hematocrit) or the loss of body fluid (dehydration) may also cause a meter result to be different from a laboratory result.

*1: Surwit, R.S., and Feinglos, M.N.: Diabetes Forecast (1988), April, 49-51.

*2: Sacks, D.B.: “Carbohydrates. “ Burtis, C.A., and Ashwood, E.R. (ed.), Tietz Textbook of Clinical Chemistry. Philadelphia: W.B. Saunders Company (1994), 959.

SPECIFICATIONS

Model No.: TD-4142
Dimension & Weight: 43.47 (L) x 39.28 (W) x 24.23 (H) mm, 13 g
Power Source: One 2032 lithium battery
Functionality:
Auto sample loading detection
Auto reaction time count-down
Auto switch-off after 4 minutes without action
Temperature Warning
Operating Condition:
50°F to 104°F (10°C to 40°C), 10% to 85% R.H. (non-condensing)
Meter Storage/Transportation Conditions:
-4°F to 140°F (-20°C to 60°C), 10% to 95% R.H.
Sensor Module Storage/Transportation Conditions:
35.6°F to 86°F (2°C to 30°C), 10% to 85% R.H.
Measurement Units: mg/dL
Measurement Range: 20 ~ 600 mg/dL (1.1 ~ 33.3 mmol/L)
Expected service life: 5 years

Compliance with Electrical and Safety Standards
This device has been tested to meet the electrical and safety requirements of: IEC/EN 61010-1, IEC/EN 61010-2-101, IEC/EN 61326-1, IEC/EN 61326-2-6

QUALITY OF SERVICE SUMMARY

Quality of Service for the **Pops Rebel System** wireless communication using Bluetooth Low Energy is assured within the effective range of 10 meters, unobstructed, between the **Pops Rebel meter** and paired smartphone with Pops Rebel app **from the time the user presses the "Check" button in the app to the time the blood glucose result is displayed.** If the connection is lost between the **Pops Rebel meter** and paired smartphone with Pops Rebel app, the app will revert to the test screen and Bluetooth connection will have to be re-established.

The **Pops Rebel System** is designed to only accept radio frequency (RF) communications from recognized and paired display devices.

Compliance with Electrical and Safety Standards

This device has been tested to meet the electrical and safety requirements of: IEC/EN 61010-1, IEC/EN 61010-2, IEC/EN 60601-1-2.

<table>
<tr><th colspan="4">Manufacturer's declaration-electromagnetic immunity</th></tr>
<tr><td colspan="4">The Pops Rebel System is intended for use in the electromagnetic environment specified below. The user of the Pops Rebel System should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 test level</td><td>Compliance level</td><td>Electromagnetic environment guidance</td></tr>
<tr><td>Conducted RF
IEC 6100-4-6</td><td>3 Vrms:
0,15 MHz—80 MHz
6 Vrms:
In ISM and amateur radio bands between 0,15 MHz and 80 MHz

80 % AM at 1 kHz</td><td>Not applicable</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the Pops Rebel System including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance:
d = 1,2 $\sqrt{P}$
d = 1,2 $\sqrt{P}$ 80 MHz to 800 MHz
d = 2,3 $\sqrt{P}$ 800 MHz to 2,7 GHz

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Interference may occur in the vicinity of equipment marked with the following symbol:  </td></tr>
<tr><td>Radiated RF
IEC 6100-4-3</td><td>10 V/m
80 MHz – 2,7 GHz
80 % AM at 1 kHz</td><td>10 V/m
80 MHz – 2,7 GHz
80 % AM at 1 kHz</td></tr>
<tr><td colspan="4">NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</td></tr>
<tr><td colspan="4">a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Pops Rebel System is used exceeds the applicable RF compliance level above, the Model should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Pops Rebel System.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less</td></tr>
</table>

than 3 V/m.

Upon admission to our service, all Owners and Caregivers are informed of provider's complaint protocol explaining how complaints are reported, reviewed and resolved. The following information will be provided to the patient in writing: *I*n the event your complaint is not resolved to your satisfaction you can contact our accrediting organization The Compliance Team at www.thecomplianceteam.org or by calling 1-888-291-5353.

Pops Diabetes Care Inc.
5600 Memorial Ave N
Oak Park Heights, MN 55082
Toll Free Customer Support Number: (800) 767-7268
Technical Support Hours of Attention:
Monday through Friday, 8:00 AM to 5:00 PM Central Time
For assistance outside of these hours, please contact your healthcare professional