

POPS! one Sensor Module Manual

Intended Use

The POPS! one Blood Glucose Monitoring System is comprised of the POPS! one blood glucose meter, the POPS! one blood glucose sensor modules, and the POPS! mobile application as the display component.

The POPS! one 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! one 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 Instructions

For more information, please visit the following:

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

- The POPS! one 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!
- All parts of the kit are considered biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection. Please follow your healthcare provider's recommendations for proper disposal of a used sensor module.
- Keep the sensor module away from small children. If swallowed, consult a doctor immediately for advice.
- 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.

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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 fresh 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.

Storage and Handling

IMPORTANT: Do not use the Sensor Modules if they have expired.

- Store the sensor modules in a cool, dry place between 35.6°F and 86°F (2°C and 30°C) and 10% to 85% relative humidity.
- Keep the sensor modules away from direct sunlight. Do not store the sensor modules in high humidity.
- Store the sensor modules in the original aluminum package **ONLY**. Do not transfer them to a new package or any other containers.
- Use each test site immediately after tearing open its peelable cover.
- Use each Sensor Module within three days after removing it from the foil package.
- Do not touch the Sensor Modules with wet hands.
- Do not bend, cut, or alter the Sensor Modules.

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Sensor Module

Blood glucose test strips are embedded in the sensor module. There are three blood glucose test sites (lancet and strip) in every sensor module. Before use, you should insert the sensor module into the POPS! one blood glucose meter. Replace with a new sensor module if you have used up all three test sites.

Appearance-Sensor Module



1. **Peelable Cover**
Tear it open until the strip inside appears. Keep the peelable cover intact. To prevent cross-contamination, reattach the peelable cover to seal up the used strip.
2. **Test Strip**
3. **Lancets**

Insertion

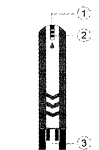
Tear open the foil pouch and remove the Sensor Module. Slide the cover to open the meter. With one hand holding the meter slowly push the Sensor Module into the meter with the other hand and press down until you hear a "click".

Replacement

Slide the cover to open the meter. Hold the bottom (the widest part) of the Sensor Module with your thumb and fingers. First lift the Sensor Module up slightly, and then pull it out of the meter.

Strip Appearance

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 drawn into the absorbent hole of the strip.
3. **Contact Bars**
Insert this end of the sensor module into the meter. Push it in firmly until you hear a "click".

Please refer to your Owner's Manual for more information.

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Reading Your Result

Your blood glucose readings deliver plasma equivalent results and are displayed in milligrams of glucose per deciliter of blood (mg/dL).

The measurement range of this meter is from 20 to 600 mg/dL (1.1 to 33.3 mmol/L).

Reference values:

Time of Day	Normal Plasma Glucose Range for People without Diabetes
Fasting and before meal	Less than 100 mg/dL (5.6 mmol/L)
2 hours after meals	Less than 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.

Questionable or inconsistent results

If the test results are unusual or inconsistent with how you are feeling:

- Check the expiration date of the sensor modules.
- Check the performance of your meter and sensor module with the control solutions.

PLEASE NOTE: If most of your results are unusually high or low, please contact your healthcare professional.

Quality Control Testing

Our control solution contains a known amount of glucose that can react with test strips.

When to do a control solution test:

- You first receive the Monitoring System
- At least once a week to routinely check the Monitoring System
- You begin using a new box of sensor modules
- You suspect the Monitoring System is not working properly
- Your test results are not consistent with how you feel, or you think the results are not accurate
- Practicing the testing process
- You have dropped or think you may have damaged the meter

You can check the performance of meter, sensor module and your technique by comparing the control solution results with the range printed on the sensor module box. Checking regularly can ensure your test results are accurate. If the quality control check fails, conduct the quality control check again or contact customer service if the quality control check continues to fail. Please refer to the Owner's Manual for complete testing instructions.

IMPORTANT: The reference range of the control solutions may vary with each new pack of sensor module. Make sure you check the range on your current sensor module box.

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Chemical Components

> Glucose dehydrogenase (GDH) (<i>E. coli</i>)	8%
> Electron shuttle	55%
> Enzyme protector	8%
> Non-reactive ingredients	29%

Performance Characteristics

Sample Size: 0.5 µL

Reaction Time: 6 seconds

System Measurement Range: 20 to 600 mg/dL (1.1 to 33.3mmol/L)

Hematocrit Range: 20% to 60%

Accuracy

The POPS! one 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 362 typical users used the POPS! one Blood Glucose Monitoring System to test their blood glucose level. For example, in this study, the POPS! one meter gave results within 15% of their true blood glucose level 362 out of 362 times.

Table 1. Summary of data within specified mg/dL of the comparator method for glucose concentrations across the entire range:

Difference range between the true blood glucose level and the POPS! one 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%	67.1% (243/362)	93.9% (340/362)	100% (362/362)	100% (362/362)

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Precision

Precision studies using control solutions (intermediate precision) and blood samples (repeatability) are shown as below:

Table 2. Intermediate precision

Control solutions	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1	49.7	2.06	4.14
Level 2	95.2	3.47	3.65
Level 3	134.7	4.07	3.02
Level 4	245.0	7.54	3.08
Level 5	308.8	8.22	2.66

Table 3. Repeatability

Blood samples	Mean (mg/dL)	SD (mg/dL)	CV (%)
Level 1	48.6	2.00	4.11
Level 2	105.5	3.27	3.10
Level 3	143.4	4.22	2.94
Level 4	245.7	7.03	2.86
Level 5	391.7	11.19	2.86

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.

Use only with POPS! one Blood Glucose Monitoring System.

For *in vitro* diagnostic use.

Read instructions before use.

Store at 35.6°F to 86°F with 10% to 85% R.H.



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