

On-Call[®] Pro Blood Glucose Test Strips Package Insert

REF G135-10L English

PRINCIPLE AND INTENDED USE

The *On-Call[®] Pro* Blood Glucose Test Strips are thin strips. The strips have a chemical reagent system. They work with the *On-Call[®] Pro* Blood Glucose Monitoring Systems to measure the glucose level in whole blood. Blood is applied to the end tip of the test strip. The blood is then absorbed into the reaction cell. This is where the reaction takes place. A transient electrical current is formed during the reaction and detected by the meter. The amount of glucose is then calculated based on this current. The result is shown on the meter display. The meters are calibrated to display plasma equivalent results.

For *in vitro* diagnostic use. *On-Call[®] Pro* Test Strips are used to measure the amount of glucose in fresh capillary whole blood. This blood can be from the finger, forearm or palm. The system is used to monitor how well the diabetes control programs work. *On-Call[®] Pro* Test strips can only be used outside the body.

The *On-Call[®] Pro* family of Blood Glucose Monitoring System is for single patient use only. Do not share with others.

The *On-Call[®] Pro* Blood Glucose Monitoring System is for professional use only. It is intended for multiple patient use by health care professionals in health care facilities as an aid to monitoring the effectiveness of diabetes control programs. The system should only be used with single-use, auto-disabling lancing devices. It is not intended for the diagnosis of or screening for diabetes mellitus, nor intended for use on neonates.

The *On-Call[®] Pro* Blood Glucose Test Strips are used with the *On-Call[®] Pro* Blood Glucose Monitoring Systems in the quantitative measurement of glucose in capillary blood. The *On-Call[®] Pro* Blood Glucose Control Solutions are for use with the *On-Call[®] Pro* Blood Glucose Monitoring Systems and *On-Call[®] Pro* Test Strips as a quality control check to verify the accuracy of blood glucose test results.

COMPOSITION

Each test strip contains reactive and non-reactive chemicals. These chemicals are: Glucose Oxidase (from *Aspergillus niger*) < 25 IU, Mediator < 300 µg, Buffer, and Non-reactive Ingredient. Each test strip vial contains a drying agent.

STORAGE AND HANDLING

- Store test strips in their protective vial. Store with their cap on tight. This keeps them working properly.
- Store in a cool, dry place between 41-86°F (5-30°C) and 10-90% relative humidity and keep out of direct sunlight.
- Do not freeze or refrigerate.
- Use the test strips at room temperature. This provides accurate results.
- Do not store or use the test strips in a humid place such as a bathroom.
- Do not store the meter, the test strips or control solution near bleach or cleaners with bleach.
- Do not transfer the test strips to a new vial or any other container.
- Replace the vial cap as soon as you remove a test strip.
- Use the test strip as soon as it is removed from the vial.
- Repeated insertion and removal of a test strip into the meter strip port may result in reading errors.
- Do not use test strips after the unopened expiration date printed on the vial.
Note: All expiration dates are printed in Year-Month-Date format. 2020-01-30 indicates January 30th, 2020.
- A new vial of test strips may be used for 6 months after first opening. After 6 months they will expire. Write the opened expiration date on the vial label after opening.

PRECAUTIONS

- For *in vitro* diagnostic use. The test strips are only to be used outside the body for testing purposes.
- All components that come into contact with blood samples are considered biohazards capable of transmitting viral disease, even after disinfection.
- Remember to follow the required pre-cleaning and disinfection procedure. Please refer to the "Caring for Your *On-Call[®] Pro* Blood Glucose Monitoring System" section in the User's Manual. This procedure is important to prevent the potential transmission of infectious diseases.
- You can get more safety information at FDA Public Health Notification (<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm224025.htm>) or at CDC Clinical Reminder (<http://www.cdc.gov/injectionsafety/Fingerstick-DevicesBGM.html>).
- Do not use test strips after the expiration date that is shown on the vial. Expired test strips may give you incorrect result.
- Do not use test strips that are torn, bent, or damaged.
- Do not reuse test strips.
- Apply sample only to the tip of the test strip. Do not apply to the top of the test strip. This may result in a false reading.
- Discard the vial and any unused test strips 6 months after you first open it. Constant exposure to air may destroy chemicals in the test strip. This can cause false readings.
- Keep the test strip vial away from children and animals.
- Consult with your patients' treating physician before making any changes to the treatment plans.

MATERIALS PROVIDED

- Test Strips
 - Package Insert
- Please contact Customer Support at 1-800-838-9502 for information about purchasing test strips.

MATERIALS REQUIRED BUT NOT PROVIDED

- Meter
- Auto-disabling Single Use Safety Lancets
- Alcohol Swabs
- Control Solution

Please contact Customer Support at 1-800-838-9502 to obtain a control solution kit.

INSTRUCTIONS FOR USE

- See the User's Manual for complete instructions for blood sample collection before use.
- Open the cap of the test strip vial. Remove a test strip. Replace the cap immediately. This protects the test strips from moisture in the air.
 - Perform the test following the instructions in the User's Manual.
 - The test result will be shown on the meter display window. This result should fall within the target range. The treating physician should recommend the target range for each patient. If test results are higher or lower, ask the physician what to do. Always consult your patients' treating physician before change their treatment plan.

IMPORTANT: *On-Call[®] Pro* Blood Glucose Monitoring Systems allow alternative site testing (AST). This includes testing capillary blood from forearm and palm. There are important differences for each site. Important information about forearm and palm glucose testing:

- Blood from the fingertip may show sudden changes in blood levels. Other sites may not. Blood glucose levels may change instantly after a meal, insulin dose, or exercise.
- If testing within 2 hours of a meal, insulin dose or exercise, test with fingertip. Any time you feel the patient's glucose levels may be changing rapidly, test with fingertip.
- Test with the fingertips anytime there is a concern for hypoglycemia or your patients suffer from hypoglycemia unawareness.
- Alternative site testing should not be used to calibrate continuous glucose monitors (CGMs). Do not use AST to calculate an insulin dose.

RANGE OF EXPECTED VALUES

Blood glucose monitoring requires the help of a physician. Together with the treating physician you can set your patients' range of expected blood glucose values. This will help you schedule the patients' testing times. In addition, you may want to discuss the blood glucose results together.

Expected blood glucose levels for people without diabetes¹:

Time	Range, mg/dl	Range, mmol/L
Fasting and Before Meals	70 – 100	3.9 – 5.6
2 Hours After Meal	Less than 140	Less than 7.8

CHECKING THE SYSTEM

Be careful with your blood glucose meter. See your User's Manual for proper care instructions. Do a quality control test to make sure that the meter and test strips are working well together. Follow the control test procedure in the User's Manual. Three ranges (CTRL 0, CTRL 1 and CTRL 2) are shown on the test strip vial label. Control Solution 1 is sufficient for most needs, but you should consult the policies of your institution. If you think your meter or strips may not be working correctly, you may also want to do a level 0 or level 2 test. Contact Customer Support for information on purchasing control solution.

You should confirm your control solution results. Make sure the Control Solution 0 tests fall within the CTRL 0 range, the Control Solution 1 tests fall within the CTRL 1 range and the Control Solution 2 tests fall within the CTRL 2 range. When testing with Control Solution 1, make sure you are matching the results to the CTRL 1 range on the vial label.

CAUTION: If your quality control test result falls outside the control range shown on the test strip vial, DO NOT use the system to test your blood. The system may not be working properly. If you cannot correct the problem, contact Customer Support for help.

LIMITATIONS

- The *On-Call[®] Pro* meters, test strips and other components have been designed, tested and proven to work together effectively to provide accurate blood glucose measurements. Do not use components from other brands.
- The *On-Call[®] Pro* Test Strips test fresh capillary whole blood. Do not use with serum or plasma samples.
- The *On-Call[®] Pro* Blood Glucose Monitoring Systems are for professional users to test fresh capillary blood.
- Very high (above 60%) and very low (below 25%) hematocrit levels can cause false results. Consult with your patients' physician to find out their hematocrit level.
- The system gives accurate glucose readings between 20 and 600 mg/dl.
- Fatty substances have no major effect on test results. These include triglycerides up to 3,000 mg/dl or cholesterol up to 500 mg/dl.
- Certain substances from therapeutic treatments (ascorbic acid, acetaminophen) or occurring in the blood naturally (uric acid, bilirubin) will not significantly affect results. Interference might occur when the values of the limiting concentrations of these compounds are greater than those listed below.

Ascorbic acid	> 3 mg/dl	Bilirubin	> 50 mg/dl
Acetaminophen	> 20 mg/dl	Uric Acid	> 23.5 mg/dl
- The *On-Call[®] Pro* Blood Glucose Monitoring Systems have been tested to work properly up to 8,516ft (2,595 meters).
- Not for use on critically ill patients, patients in shock, severely dehydrated patients or hypersmolar patients (with or without ketosis).
- Not for neonatal testing.
- Not for persons undergoing Oxygen therapy.
- Dispose of blood samples and materials with care. Treat all blood samples as if they are infectious materials. Follow all local regulations for disposal.

PERFORMANCE CHARACTERISTICS

The *On-Call[®] Pro* meter is calibrated by using YSI (Model 2300 STAT PLUS) Glucose Analyzer reference instrument. It is traceable to NIST reference standard.

Reproducibility and Precision

Ten replicate assays were each run on ten *On-Call[®] Pro* Blood Glucose Meters. Heparinized venous blood samples at five concentration levels were used in the testing. The results provided the following estimates.

MEAN	43.1 mg/dl	84.6 mg/dl	128 mg/dl	189 mg/dl	317 mg/dl
Standard Deviation mg/dl or Coefficient of Variation (CV)	1.20 mg/dl	2.3%	2.6%	1.9%	2.7%

Intermediate Precision

Ten replicate assays drawn from three strip lots were performed on ten *On-Call[®] Pro* Blood Glucose Meters. These tests were performed each day for a total of ten days. Control solutions at three concentration levels were used in the testing. The results provided the following estimates.

#	MEAN	Standard Deviation mg/dl or Coefficient of Variation (CV)
Strip Lot 1	41.8 mg/dl	1.52 mg/dl
	122 mg/dl	2.7%
	332 mg/dl	3.9%
Strip Lot 2	41.0 mg/dl	1.31 mg/dl
	118 mg/dl	2.8%
	332 mg/dl	2.2%
Strip Lot 3	40.0 mg/dl	1.26 mg/dl
	116 mg/dl	2.4%
	332 mg/dl	3.5%

System Accuracy

A trained technician tested the capillary blood using the *On-Call[®] Pro* Blood Glucose Meter (y). The blood samples were from more than 100 participants. Capillary blood samples were taken from fingertip, palm and forearm. Fingertip samples from the same subjects were also analyzed with the YSI Model 2300 STAT PLUS Glucose Analyzer (x). The results were compared.

Linear Regression Results: On Call [®] Pro (y) vs. YSI Reference (x)				
Sample Site	Slope	Intercept (mg/dl)	R	N
Fingertip	0.9486	5.3824	0.9937	111
Palm	1.0030	5.0984	0.9880	103
Forearm	0.9918	5.4330	0.9882	103

Fingertip samples were used for YSI reference measurement. The sample range was 40.9 to 574 mg/dl for *On-Call[®] Pro* Blood Glucose Meter testing with blood sampled from fingertip sites. The sample range was 50.4 to 498 mg/dl for *On-Call[®] Pro* Blood Glucose Meter testing with blood sampled from palm and forearm sites.

Fingertip Site: System Accuracy Results for Glucose Concentration ≥ 75 mg/dl			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
52/96 (54.2%)	85/96 (88.5%)	95/96 (99.0%)	96/96 (100%)

Fingertip Site: System Accuracy Results for Glucose Concentration < 75 mg/dl			
Within ± 5 mg/dl	Within ± 10 mg/dl	Within ± 15 mg/dl	
11/15 (73.3%)	15/15 (100%)	15/15 (100%)	

Palm Site: System Accuracy Results for Glucose Concentration ≥ 75 mg/dl			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
42/93 (45.2%)	72/93 (77.4%)	91/93 (97.8%)	93/93 (100%)

Palm Site: System Accuracy Results for Glucose Concentration < 75 mg/dl			
Within ± 5 mg/dl	Within ± 10 mg/dl	Within ± 15 mg/dl	
6/10 (60.0%)	10/10 (100%)	10/10 (100%)	

Forearm Site: System Accuracy Results for Glucose Concentration ≥ 75 mg/dl			
Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
45/93 (48.4%)	71/93 (76.3%)	91/93 (97.8%)	93/93 (100%)

Forearm Site: System Accuracy Results for Glucose Concentration < 75 mg/dl			
Within ± 5 mg/dl	Within ± 10 mg/dl	Within ± 15 mg/dl	
5/10 (50%)	10/10 (100%)	10/10 (100%)	

Consumer Study

A consumer study was conducted using three test strip lots. Participants and a trained technician used the *On-Call[®] Pro* Blood Glucose Monitoring System. This study shows that the patient can run the test as well as a trained technician.

On-Call[®] Pro tests: Linear regression of Participant (y) versus YSI Reference value and Linear regression of Technician (y) versus YSI Reference value

Strip Lot	Tested By	Slope	Intercept (mg/dl)	R	N
Lot 1	Layperson	0.9762	1.8373	0.9899	103
Lot 1	Technician	0.9452	6.3951	0.9906	103
Lot 2	Layperson	0.9599	4.1229	0.9901	103
Lot 2	Technician	0.9449	6.0753	0.9910	103
Lot 3	Layperson	0.9627	5.0504	0.9917	103
Lot 3	Technician	0.9422	6.4116	0.9909	103

For complete instructions, please refer to the User's Manual included with your meter. For additional questions or issues with this product, please contact Customer Support at 1-800-838-9502, 24 hours a day, 365 days a year.

REFERENCES

- ADA Clinical Practice Recommendations 2013.



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