



Dario® Blood Glucose Test Strips
Instructions for Use

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IMPORTANT: DARIO TEST STRIPS ARE DESIGNED FOR USE WITH THE Dario®/Dario® LC/ Dario® Type-C BLOOD GLUCOSE MONITORING SYSTEMS (BGMS). PLEASE READ THESE INSTRUCTIONS FOR USE BEFORE USING THIS PRODUCT.

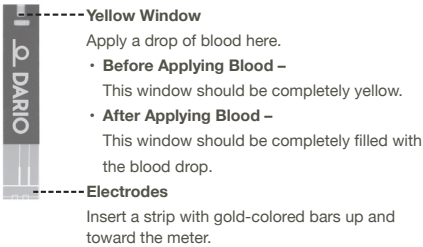
IF YOU HAVE ANY QUESTIONS, CONTACT CUSTOMER SUPPORT AT 1-800-895-5921, 9:00AM – 5:00PM EST MONDAY THROUGH FRIDAY, OR VISIT WWW.MYDARIO.COM.

For the latest version of the Dario®/Dario® LC/ Dario® Type-C User Guides, download the Dario® App or go to www.mydario.com/support.



INTRODUCTION

Testing your blood glucose regularly helps you better manage your diabetes. Medical studies show that, with your doctor's care, you may be able to manage your glucose to near normal levels. This can prevent or slow the development of diabetes complications.



INTENDED USE

Dario® Blood Glucose Test Strips are for use with the Dario®/Dario® LC/Dario® Type-C Blood Glucose Meters to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip.

PRODUCT DESCRIPTION AND THE PRINCIPLE OF THE USE

Dario® Blood Glucose Test Strip is designed with an electrode that measures glucose levels. Glucose in the blood sample mixes with reagent on the test strip that cause a small electric current. The amount of current that is created depends on how much glucose is in the blood.

Dario®/Dario® LC/Dario® Type-C meters measure the current that is created and convert the measurement to the amount of glucose that is in the blood. The blood glucose result is displayed on Dario App screen.

By touching a drop of blood to the tip of Dario® Blood Glucose Test Strip, the strip's reaction chamber automatically draws the blood into the strip through capillary action. When the chamber is full the Dario®/Dario® LC/Dario® Type-C meters start to measure the blood glucose level. It is a simple and practical system for the daily monitoring of your blood glucose level.

Upon receiving Dario® Blood Glucose Test Strips Package, please verify the following contents exist:

- 25 Dario® Blood Glucose Test strips package Content:
 - 1 Test Strip Cartridge contains 25 test strips
 - Dario® Blood Glucose Test Strips Instructions for Use
- 50 Dario® Blood Glucose Test strips package Content:
 - 2 Test Strip Cartridges each contains 25 test strips
 - Dario® Blood Glucose Test Strips Instructions for Use
- 100 Dario® Blood Glucose Test strips package Content:
 - 4 Test Strip Cartridges each contains 25 test strips
 - Dario® Blood Glucose Test Strips Instructions for Use

Reagent Composition (per strip)

Glucose oxidase (<i>Aspergillus sp</i>)	1.5 unit
Potassium ferricyanide	0.093mg
Binder	0.052mg
Stabilizer	0.031mg

IMPORTANT SAFETY INSTRUCTIONS

- 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 bio-hazardous and can potentially transmit infectious diseases even after you have performed cleaning and disinfection.
- The user manual should be referenced for cleaning and disinfection procedures

PRECAUTION

1. Use only fresh capillary whole blood by finger prick for blood glucose testing.
2. A test strip should be used according to the specified intended use.
3. A test strip is for single use only. Do not reuse.
4. Dario® Blood Glucose Test strips should be used with Dario®/Dario® LC/Dario® Type-C meters only.
5. Insert a test strip into the test strip port in the glucose

- meter with gold-colored bars facing up and toward the meter.
6. A test strip is sensitive to humidity. Therefore, you should keep a test strip in the specified cartridge, and after pulling out the test strip from its cartridge, close the test strip cartridge cap immediately.
7. After removing a test strip from its cartridge, you should use it within 3 minutes.
8. Do not use a test strip expired 1 month from opening. Discard the cartridge 1 month after opening.
9. Insert a test strip in the meter port gently until it will go no further.
10. The blood sample for a test strip must be at least 0.3µl in volume. If there is not enough blood sample an inaccurate test may result.
11. Do not apply blood to any site except the yellow window of a test strip.
12. Do not touch the yellow window of a test strip.
13. Do not bend, cut or modify a test strip.
14. Discard the used test strip as a biohazard.

SYSTEM LIMITATIONS

The Dario®/Dario® LC/Dario® Type-C Systems should not be used for the following purposes:

- The diagnosis of, or screening for, diabetes.
- Testing the glucose levels of neonates (children younger than 4 weeks of age).
- Testing glucose levels of arterial or venous blood.
- Testing glucose from sites other than the fingertip.
- Testing patients who are critically ill, in shock, or dehydrated.

If you are taking acetaminophen containing drugs (e.g. Tylenol) or Vitamin C (ascorbic acid) you may get inaccurate results with this system. If you have a disease or condition in which uric acid levels in your blood may be elevated (> 11 mg/dL), such as gout, you may get inaccurate results with this system. If you have very high levels of triglyceride (> 810 mg/dL), you may get inaccurate results with this system. This system should not be used when undergoing xylose absorption tests.

PERFORMING A TEST

Blood Glucose Test

1. Open Dario® App. and use the Dario® Disposable Cover over the Smart Mobile Device.
2. Connect Dario®/Dario® LC/Dario® Type-C meter to the Smart Mobile Device.
3. Remove a new test strip from cartridge. Be sure to tightly close cartridge cap after removing the test strip.
4. Insert the test strip (yellow window facing up) into the port of the glucose meter until it will go no further.
5. Obtain a drop of blood sample using the lancet and lancing device.
6. Touch and hold drop of blood to the edge of the strip until the yellow window is completely filled with blood. The blood will be drawn into the strip automatically.



7. When blood is applied to strip, your result appears on Dario App screen in just 6 seconds.
8. Remove and discard the used test strip.

UNDERSTANDING YOUR TESTING RESULT

Normal blood glucose result

- The American Diabetes Association suggests that the following expected glucose values for individuals without diabetes:
 - Before eating (FPG) < 100 mg/dL
 - Two hours after meals (OGTT) < 140 mg/dL
- Consult with your healthcare professional for the blood glucose range that is appropriate for you.

Test Result Range

Dario®/Dario® LC/Dario® Type-C meters read blood glucose results between 20 ~ 600 mg/dL (1.1 ~ 33.3 mmol/L).



Note: If anything is missing or damaged do not use the product and please contact customer support at 1-800-895-5921 toll free number in the US 9:00 a.m to 5:00 pm Monday through Friday or visit our website at www.mydario.com



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UNEXPECTED RESULTS

High or low blood glucose results can indicate potentially serious medical conditions. In case of an unexpected result, you should repeat the test immediately using a new test strip. If your reading is still unexpected or the reading is not consistent with how you feel, you should treat as prescribed by your healthcare professional and/or contact your healthcare professional immediately.

- 1. If “High! Measure with a new strip, if recurs contact your physician immediately” is displayed, your blood glucose result may be higher than 600 mg/dL (33.3 mmol/L). You may have high blood glucose.
- 2. If “Low! Measure with a new strip, if recurs contact your physician immediately” is displayed, your blood glucose result may be lower than 20 mg/ dL(1.1 mmol/L). You may have low blood glucose.

CONTROL OF THE UNEXPECTED RESULTS

If your blood glucose result seems unusually high, low, or inconsistent with your previous results or glucose trends and does not reflect the way you feel, check the following:

- 1. Repeat the test with a new strip.
- 2. Run a control solution test with Dario® Glucose Control Solution.
- 3. If the control solution test result is within the acceptable range, review proper testing procedure and repeat your blood glucose test with a new test strip. If your blood glucose value is still inconsistent with your previous results, glucose trends, or how you feel, please contact your healthcare professional. Follow the advice of your healthcare professional before you change your therapy.

CAUSES OF UNEXPECTED RESULTS

- 1. Was the blood sample applied to the test strip within 3 minutes of removing it from the cartridge?
- 2. Was the size of the blood sample sufficient to fill the yellow window?
- 3. Was the test strip cartridge cap tightly sealed?
- 4. Was the test strip used before the expiration date?
- 5. Were the test strips stored at extreme temperatures such as in the car during very cold or hot weather?
- 6. Were the test strips stored in areas of high humidity such as the kitchen or the bathroom?

CHECKING BY A CONTROL SOLUTION

Control solution test

Control solution check ensures that you are doing a test correctly and that your system is working properly. Make sure you use the proper control solution for the test strips you have: Dario® Blood Glucose Test Strips require Dario® Glucose Control Solution.


When should I run a control solution test?

- 1. If you leave the cartridge cap open.
- 2. Before using your meter for the first time.
- 3. When you open a new cartridge of test strips.
- 4. If you drop the meter.
- 5. Whenever your result does not agree with the way you feel.
- 6. If you have repeated a test, and the blood glucose result is still lower or higher than expected.
- 7. When you want to check the performance of the meter and test strip.

Note:

- Do not use Dario Control Solution expired 3 months from opening. Therefore, please check the date to open first for the accurate review of the meter and the test strip.
- Test control solution at 64–86°F (18–30°C) environment.

CONTROL SOLUTION PROCEDURE

- 1. Open Dario App.
- 2. Test Control Solution under the “Control Solution test” function: Menu icon  , selecting HELP&INFO > CONTROL SOLUTION TEST
- 3. Remove the Dario®/Dario® LC/Dario® Type-C meters from the housing.
- 4. Plug the meter into your smart mobile device.
- 5. Remove a blood glucose test strip from the cartridge. Be sure to tightly close cartridge cap after removing a test strip.
- 6. Insert a test strip (yellow window facing up) into test strip slot.
- 7. Shake a control solution bottle.
- 8. Apply one drop of the control solution to the edge of the strip, and allow the strip to automatically draw the control solution into the yellow window.
- 9. The control solution result appears on the smart mobile device display after 6 seconds.
- 10. Remove the used test strip from the meter and discard it.

UNDERSTANDING YOUR CONTROL SOLUTION TEST

- If your glucose control solution test result is within the acceptable range, you can feel confident that your test strips and meter are working correctly.
- If your glucose control solution test result is outside of the acceptable range, your system may not be working properly.

Check the following:

- 1. Did you use control solution or test strips that were past their expiration date?
- 2. Did you leave the cap off the cartridge of test strips or control solution?
- 3. Did you follow the testing steps exactly?
- 4. Did you use the proper control solution for the test strips you used?

Repeat the glucose control solution test. If the result still is not acceptable contact Labstyle Innovation Ltd. at 1-800-895-5921, 9:00AM – 5:00PM EST Monday through Friday, or visit www.mydario.com or the distributor.

STORAGE AND HANDLING

- 1. Store the test strips at room temperature between 36°F and 90°F (2°C and 32°C). Do not freeze. Frozen and thawed reagents may cause incorrect glucose results.
- 2. Keep the test strip port free of dust.
- 3. The test strip is sensitive to humidity, keep it in 10%-90% Relative Humidity and cool environment.
- 4. Do not store in direct sunlight.
- 5. After pulling out the test strip from its cartridge, seal the cap of the cartridge tightly to protect test strips.
- 6. Do not transfer test strips from one cartridge to another.

PERFORMANCE CHARACTERISTICS*

Precision

The criteria are within 95% for standard deviation (STD) 3mg/dL at the below 100mg/dL(5.55mmol/L), for coefficient of variation(CV) 4% at the above 100mg/dL(5.55mmol/L).

The precision studies using control solution (Intermediate Precision) and blood (Repeatability Precision) are shown below:

iOS Precision:

Intermediate Precision: Dario® BGMS				
Glucose Concentration range mg/dL	30-50	96-144	280-420	
Average mg/dL	48.5	103.9	295.6	
Standard Deviation mg/dL	2.3	3.1	7.2	
Coefficient of Variation, %	4.8	2.9	2.4	
Max mg/dL	57	114	320	
Min mg/dL	42	97	280	
Max-Min mg/dL	15	17	40	

Repeatability Precision: Dario® BGMS						
Glucose Concentration range mg/dL	30-50	51-110	111-150	151-250	251-400	
Average mg/dL	47.9	74.0	126.3	214.5	343.1	
Standard Deviation mg/dL	1.3	1.8	2.3	5.4	7.3	
Coefficient of Variation, %	2.6	2.4	1.8	2.5	2.1	

Android Precision:

Intermediate Precision: Dario® BGMS				
Glucose Concentration range mg/dL	30-50	96-144	280-420	
Average mg/dL	43.2	121.3	350.7	
Standard Deviation mg/dL	2.1	3.3	8.6	
Coefficient of Variation, %	4.9	2.7	2.4	
Max mg/dL	48	129	370	
Min mg/dL	38	117	340	
Max-Min mg/dL	10	12	30	

Repeatability Precision: Dario® BGMS						
Glucose Concentration range mg/dL	30-50	51-110	111-150	151-250	251-400	
Average mg/dL	40.2	82.9	135.2	201.7	330.4	
Standard Deviation mg/dL	1.7	2.5	3.6	5.2	8.6	
Coefficient of Variation, %	4.3	3.0	2.7	2.6	2.6	

iOS for Dario® LC Precision:

Intermediate Precision: Dario® LC BGMS						
Glucose Concentration range mg/dL	30-50	51-110	111-150	151-250	251-400	
Average mg/dL	48.6	85.6	128.0	203.7	286.8	
Standard Deviation mg/dL	2.3	3.0	4.8	7.8	9.9	
Coefficient of Variation, %	4.7	3.5	3.8	3.8	3.4	
Max mg/dL	55	95	139	228	322	
Min mg/dL	40	76	114	183	266	
Max-Min mg/dL	15	19	25	45	56	

Repeatability Precision: Dario® LC BGMS						
Glucose Concentration range mg/dL	30-50	51-110	111-150	151-250	251-400	
Average mg/dL	49.5	103.4	133.3	196.1	349.1	
Standard Deviation mg/dL	1.6	3.5	5.0	5.5	13.4	
Coefficient of Variation, %	3.3	3.3	3.8	2.8	3.8	

Influence Quantities

- 1. Packed cell volume: Dario BGMS Test Strip suitable range is 20–60%.
- 2. If you are taking acetaminophen containing drugs (e.g. Tylenol) or Vitamin C (ascorbic acid) you may get inaccurate results with this system. If you have a disease or condition in which uric acid levels in your blood may be elevated (> 11 mg/dL), such as gout, you may get inaccurate results with this system. If you have very high levels of triglyceride (> 810 mg/dL), you may get inaccurate results with this system. This system should not be used when undergoing xylose absorption tests.

User Performance

This study is for evaluating glucose values from fingertip capillary blood samples obtained by lay persons showed the following results;

Dario Blood Glucose Monitoring System “100% within ±15mg/dL (0.83 mmol/L) of the medical laboratory values at glucose concentrations below 75 mg/dL(4.16mol/L), and 98.88% within ±20% of the subjects samples at glucose concentrations at or above 75mg/dL (4.16mmol/L).”

User Performance is performed in accordance with “Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use - Guidance for Industry and Food and Drug Administration Staff” - October 2016, for Android OS. The study showed the following results for all subjects samples: “96.6% within ±15% and 100% within ±20% of the medical laboratory values at the entire glucose concentrations range.”

Method Comparison: Dario® BGMS for Android							
for glucose concentrations < 75 mg/dL				for glucose concentrations ≥75 mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL		Within ±5%	Within ± 10%	Within ± 15%	Within ± 20%
Samsung Galaxy Note 3							
7 / 10 (70.0%)	8 / 10 (80.0%)	10 / 10 (100.0%)		53/107 (49.5%)	89 / 107 (83.2%)	105/ 107 (98.1%)	107 / 107 (100%)
Samsung Galaxy S3							
13 / 15 (86.7%)	15/ 15 (100.0%)	15 / 15 (100.0%)		51/102 (50%)	81 / 102 (79.4%)	99 / 102 (97.1%)	102 / 102 (100%)
LG G2							
3 / 10 (30.0%)	8/ 10 (80.0%)	10 / 10 (100%)		57/106 (53.8%)	91 / 106 (85.8%)	103 / 106 (97.2%)	106 / 106 (100%)

The Dario® LC study showed the following results for all subjects' samples: ”96.3% within ±15% and 99.4% within ±20% of the medical laboratory values at the entire glucose concentrations range”.

Method Comparison: Dario® LC BGMS							
for glucose concentrations < 75 mg/dL				for glucose concentrations ≥75 mg/dL			
Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL		Within ±5%	Within ± 10%	Within ± 15%	Within ± 20%
23 / 38 (60.5%)	34 / 38 (89.5%)	38 / 38 (100.0%)		168 / 312 (53.8%)	261 / 312 (83.7%)	304/ 312 (97.4%)	311 / 312 (99.7%)





*The Dario® Type-C meter is equivalent to the Dario® LC and can be used with android SMDs

BIBLIOGRAPHY

- 1. American Diabetes Association (2017). Standards of Medical Care in Diabetes – 2017. Diabetes Care, 40 (Supplement 1): S1-S132.
- 2. Stedman, T.L. Stedman's Medical Dictionary, 27th Edition, 1999, p.2082.
- 3. Ellen T. Chen, James H. Nichols, Show-Hong Duh, Glen Hortin, MD:Diabetes Technology & Therapeutics, Performance Evaluation of Blood Glucose Monitoring Devices, Oct 2003, Vol. 5, No. 5: 749 -768.

Disclaimer: While every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by environmental factors and / or user error. A person who is the subject of the test should consult a doctor for further confirmation of the result.

Warning: The Manufacturers and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

	Dario® logo
	Manufacturer: LabStyle Innovation™ Ltd. 8 Hatokhen St., North Industrial Park Caesarea 3088900, Israel
	Do not use if seal is broken or missing.
	Catalogue number