DARIO

Dario® Blood Glucose Monitoring System

User Guide

Applicable to meter model:
1021-02 Dario Meter
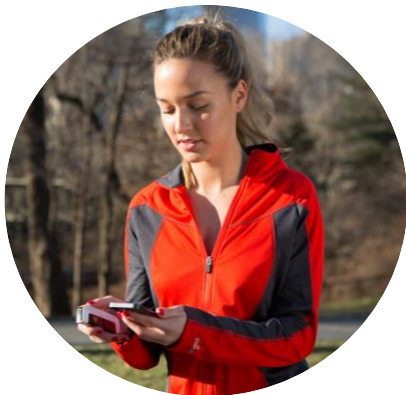
BASIC INFORMATION

Please read this user guide thoroughly. If you have questions, you can contact our customer support toll-free Monday to Friday, 9:00AM – 5:00PM EST at 1-800-895-5921 or www.mydario.com

Please contact your health care provider for questions or concerns outside of the normal customer support hours.

The photographs and screenshots provided in the User Guide feature the iPhone mobile device and iOS version of the Dario Application. The photographs and screenshots are for illustrative purposes only; the layout and function of the Android version of the Dario Application is identical. The location of the audio jack may vary by smart phone. The information provided in the User Guide is relevant to both compatible iOS and Android smart phone devices.

■ Manufacturer:

LabStyle Innovation Ltd.

8 Hatokhen St. North Industrial Park, Caesarea 3088900, Israel

Dario® is a trademark of LabStyle Innovation® Ltd.

European Patent application number 11780305.6

United States: Product is covered by one or more patents and/or patent applications – the list is detailed at the Dario website at www.mydario.com.

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CHAPTER 1
INTRODUCTION AND IMPORTANT SAFETY INSTRUCTIONS

Glucose Monitoring for a Mobile Age

Congratulations on your choice of the Dario Blood Glucose Monitoring System. The Dario System was created to make life easier for people with diabetes by providing the right tools, information, and support in your pocket. It is a smart phone-based monitoring system, featuring a pocket-sized meter with an integrated lancing device and test strips, combined with an easy-to-use mobile application.

Living with diabetes is a daily challenge. But with the Dario System in your pocket and the best support, you can thrive with diabetes.

This user guide describes how to properly setup and use your new Dario System. It is recommended that you read this guide thoroughly in order to familiarize yourself with the system and its many features.

User Guide Scope

The user guide is covering the use of the Dario Blood Glucose Monitoring System with the following meter models:

Dario meter (1021-02)	For use with selected iPhone & Android mobile devices

For the latest list of compatible devices please refer to customer support website at:
https://mydario.com/support/getting-started/

Intended Use

The Dario Blood Glucose Monitoring System consists of the Dario Blood Glucose Meter, Dario Glucose Test Strips, Dario Glucose Control Solutions and the Dario App as the display component of the Dario Blood Glucose Monitoring System. The Dario Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. The Dario Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The Dario Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home to monitor the effectiveness of diabetes control. The Dario Blood Glucose Monitoring System should not be used for the diagnosis or screening of diabetes or for neonatal use.

The Dario Blood Glucose Test Strips are for use with the Dario Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip.

The Dario Glucose Control Solutions are for use with the Dario Blood Glucose Meter and the Dario Blood Glucose Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly.

System Limitations

The Dario System 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.

Certain health conditions, such as serious illness and dehydration, can cause false test results in glucose meters. You should not use this system to test your blood glucose if you are critically ill. If you are very sick or think you are dehydrated, or are urinating frequently, call your health care provider immediately.

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.

Do not use in oxygen rich environment and with flammable anesthetics and flammable agents.

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 disinfection.

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.

For important instructions for disinfecting your meter and lancing device, refer to **CHAPTER 5 CLEANING AND MAINTENANCE** on page **60**.

The U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) have issued warnings and notifications regarding the risk of bloodborne pathogen transmission when blood glucose monitoring systems have been used by more than one individual. Refer to the following documents for more information:

- "FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens :Initial Communication" (2010). You can find this document at www.fda.gov.
- "CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010). You can find this document at www.cdc.gov.

Warning: To ensure accurate results, wash your hands with warm, soapy water and dry them before and after every test. Unwashed hands may lead to inaccurate results. Make sure there is no grease, oil, alcohol or lotion on the fingertip. Use lancets only once. Do not use any lancet or lancing device that has been used by another person.

Before Testing with the Dario System

Please read this user guide carefully and thoroughly before testing your blood glucose for the first time. These instructions provide the information that you need for safe use and handling of your Dario.

Incorrect use of this system may lead to an inaccurate glucose reading or damage to your device.

For any questions, contact customer support. Toll-free Mon to Fri, 9:00AM – 5:00PM EST at 1-800-895-5921 or www.mydario.com.

Safety Definitions

Safety instructions are provided for the protection of Dario System users. This user guide includes three types of important messages: Warnings, Cautions, and Notes. Text marked with one of these symbols requires your attention to ensure safe and accurate use of your Dario System.

Warnings

A Warning indicates precautions you need to take to prevent possible risk of injury.

Do not proceed beyond a Warning message until you fully understand the conditions and have taken the appropriate preventive action.

Cautions

A Caution indicates precautions you need to take to prevent damage to your monitoring system.

Do not proceed beyond a Caution message until you fully understand and observe the indicated conditions.

Notes

Notes provide additional information for the purpose of clarification.

Practices Used in This User Guide

The following sections describe the formats and symbols used throughout this user guide, on the Dario System packaging and inserts, and on actual system parts.

Procedure Instructions

- Procedure instructions are clearly identified and presented as numbered steps.
- If relevant, a system response is written below the step-in italics.

You should perform all procedures in the order of the steps provided.

The examples and screen images used in this User Guide are provided as examples only (unless stated otherwise).

Words in:	Description
Bold	Names of menus, buttons, and screens.
Italics	System response that occurs as a result of pressing a button or performing a task.
Bold Italics	Emphasize important information.

Symbols and Descriptions

The following table lists and describes the symbols that appear throughout this guide, on packaging or package inserts, or on the actual system parts.

Symbol	Description	Symbol	Description
	Dario logo		LabStyle Innovation Ltd. logo
	Consult instructions for use		Do not use if package is damaged
IVD	In Vitro Diagnostic	LOT	Batch code
	Expiry date	1M	Shelf life after you first opened the package
	Do not reuse		Temperature limitation
REF	Catalog number		Contains sufficient for \<n> tests
	Manufacturer: LabStyle Innovation Ltd. 8 Hatokhen St. North Industrial Park Caesarea 3088900 Israel	EC REP	Authorized Representative in the European Community: MDSS GmbH Schiffgraben 41 30175 Hannover Germany
SELF	Intended for self-testing	STERILE R	Sterilized using irradiation
	Keep away from sunlight		Keep dry
	Relative humidity limits		Warning - indicates precautions you need to take to prevent possible risk of injury
	Caution - indicates precautions you need to take to prevent damage to your monitoring system		Note - provide additional information for the purpose of clarification

General Precautions

This section provides information about potential hazards that may harm your Dario System or cause it to not function properly.

Inspect the Dario System prior to use. Avoid using any part of the system with broken seals or expired dates. Do not attach or use a component if it is damaged in any way, as it may not work properly.

- The Dario System is not water-resistant and should not get wet. If it does get wet, wipe it with a clean, dry cloth.
- Blood glucose testing with the Dario System should only be done in temperatures between 50°F-95°F (10°C-35°C) and relative humidity between 15-85%. Test results may not be correct if the room temperature and/or humidity are outside this range.
- Modifications to the Dario System not expressly approved by LabStyle Innovation Ltd. will void your warranty and could result in injury.
- Avoid testing with your Dario System in altitudes higher than 10,000 feet (3,048 meters), as accuracy cannot be assured.
- Do not leave the meter in very hot or cold places. Do not leave it near a heat source (radiator) or in a car in hot or cold weather.
- Do not store the meter or test strips in an area where the humidity is outside of the range 10-90%, such as a bathroom or kitchen.
- Do not use in oxygen rich environment and with flammable anaesthetics and flammable agents.

Additional Information

For your safety, observe the following recommendations when monitoring your blood glucose using the Dario System:

- It is recommended that you have a backup testing method available. Failure to test could cause a delay in treatment decisions and lead to a serious medical condition. Examples of backup testing methods include a backup glucose meter device or testing by a laboratory. Ask your health care provider about other possible backup methods.
- Do not change your treatment based on a single result that is inconsistent with how you feel or if you believe that your test result could be incorrect. The blood glucose reading displayed on your smart mobile device by Dario System should not be the only information you use to make decisions about your health. Always consult your health care provider to interpret and understand the measurement results.
- Never make changes to your diabetes control program or ignore physical symptoms without consulting with your health care provider.

CHAPTER 2
DARIO SYSTEM OVERVIEW AND FEATURES

This chapter provides an overview of the Dario System components and describes how to set up the Dario System for the first time.

Your Dario System at a Glance

The Dario System is a cloud-based diabetes management solution that combines software applications with a stylish all-in-one device. The all-in-one device features a lancing device, test strip cartridge, and a compact meter .Together with a smart mobile device, the Dario System puts everything in your pocket that you need to monitor and understand your diabetes. Our goal is to provide the right combination of tools, knowledge, and motivation that you need to succeed.

You can check your blood glucose with a small sample (0.3μl) of your blood and receive results within (6) six seconds.

You can check and track your blood glucose readings the same way you check everything else in life - on your mobile device.

The Dario Glucose Meter connects to smart mobile devices with an easy-to-use mobile app. The Dario App provides real-time and actionable information so that you always know where you stand and what to do next.

The Dario System not only logs and tracks your glucose levels, but also food, activity, moods, and more. The Dario System can even alert your caregivers when you need special attention.

Dario Components

The Dario System components are shown in the image below and described in the following table.

A — Dario meter
B — Dario meter release panel
G — Lancet depth lever
H — Test strip cartridge
D — Disposable lancet
F — Lancet loader
I — Cartridge cover (white)
C — Lancet cover (orange)
E — Lancet release button
J — Dario Housing

Component	Description
Glucose Meter (A) Dario meter (B) Dario meter release panel	The miniature glucose meter consists of the following components: • A connector that is plugged into the port of your smart mobile device. • A strip port for insertion of the test strip. The glucose meter receives its power from the mobile device. It does not require batteries or any other electrical source. When not in use, the meter snaps into its slot in the housing for protected storage.
(J) Dario Housing	The Dario Housing (also referred to as the device housing or simply "housing") is the main part of the Dario all-in-one device. It holds all the parts in place and consists of the lancing device, the meter slot, and the housing for the test strips cartridge.
Lancing Device and Cover (C) Lancet cover (orange) (D) Disposable lancet (E) Lancet release button (F) Lancet loader (G) Lancet depth lever	The lancing device is built into the housing and uses disposable Dario Lancets. The orange lancing device cover prevents the user from unintentional punctures. You must change lancets after each use. For more information about using the lancing device, refer to CHAPTER 4 TESTING YOUR BLOOD GLUCOSE LEVEL on page 42.

Component	Description
(H) Test strip cartridge	Each test strip cartridge holds 25 strips. Test strips are sold separately.
(I) Cartridge Cover (white)	The cartridge snaps into the modular Dario Housing.
Test Strip	The Dario Test Strip is the only strip which is used with the Dario System. A new test strip is inserted into the test strip port of the glucose meter prior to each glucose measurement.
Lancets	The Dario System uses a 30G lancet. To replace the lancet, remove the orange lancing device cover, pull out the used lancet, and replace it with a sterile one.
Disposable covers	To avoid the risk of transmitting bloodborne pathogens, it is advised to use the disposable sleeve to cover your smart mobile device while taking the blood glucose test. When the test is concluded, remove the cover from your smart mobile device and dispose it together with the used lancet and test strip in accordance with the instructions provided by your health care provider for biohazardous waste.

! It is recommended that you carry spare test strip cartridges and lancets in case of an emergency.

Compatible Platforms with the Dario Blood Glucose Monitoring System

The Dario Glucose Meter uses smart phone technology to view and store unlimited numbers of glucose test results .You can also track other diabetes information and view graphs and trends. You can even share your diabetes management

information with your health care provider. The Dario System is compatible for use on iOS and Android smart mobile devices. The Dario Glucose Meter currently works with the following Apple® iPhone® devices –5s, SE, 6, 6 Plus, 6s, 6s Plus running iOS version –12, 13,14.

And Android devices – LG G5, G6, G7, G8, G8s, Samsung Galaxy S5, S6, S6 Edge, S7, S7 Edge, S8, S8+, S9, S9+, S10, S10+, S10e, S10 5G. Galaxy Note 4, 5, 8, 9 running Android OS – 7, 8, 9, 10,11.

For the latest list of compatible devices please refer to www.mydario.com/support/getting-started/.

Dario System Kit Contents

As soon as you receive your Dario System Kit:

1. Carefully unpack the kit and verify that it contains the following parts:
   - Dario System, which includes the lancing device and built in blood glucose meter
   - Dario 10 Sterile Lancets
   - Dario 10 Disposable Covers (4.37"X 8.19")
   - Dario Blood Glucose Monitoring System Quick Guide
   - Dario Blood Glucose Monitoring System User Guide
   - Dario Test Strips (not provided within Dario welcome kit)

   The Dario System also includes the following components that are sold separately:

   - Dario Test Strips
   - Dario 100 Sterile Lancets
   - Dario 100 Disposable Covers (4.37"X 8.19")

- Dario Control Solution Level 1 and 2
- Super Sani Cloth® germicidal disposable wipes by PDI Healthcare.

> **!** Once you remove the exterior packaging, you will find a white package with a tamper-proof seal. If the tamper-proof seal is damaged or missing, it is recommended that you return this Dario System to where you purchased it, as it has been previously opened.

2. If anything is missing from the Dario System Kit, Error! Reference source not found., for contact information please see page 89.

3. Test strips and lancets are available online. For additional information, Error! Reference source not found., for contact information please see page 89. Contact your health care provider for questions outside of the customer support hours.

4. Additional Dario accessories (e.g., control solution, disposable covers) can be ordered from your local representatives or the Dario App, or Error! Reference source not found., for contact information please see page 89 For details on product availability, refer to Supplier and Accessories on page 88.

Getting Started with the Dario System

Your Dario Glucose Meter works seamlessly with your smart mobile device. Simply download the Dario App on your compatible smart mobile device and it will automatically synchronize with the Dario device each time it is connected.

Your data is constantly synchronized to one place so that it is always with you on the go.

Your data is saved under your username on your smart mobile devices and on the Dario cloud. You have easy access to your data through the Dario App and at www.mydario.com.

Assembling the Dario System for the First Time

To set up the Dario System for the first time, you must complete the following procedures:

- Insert a test strip cartridge, as described in Inserting the Test Strip Cartridge on page 22.
- Insert a lancet, as described in Inserting a Lancet on page 23.
- Set the lancet depth, if desired, as described in Setting Lancet Depth (Optional) on page 25.
- Download and install the Dario App to your smart mobile device, as described in Downloading and Installing the Dario App on page 26.
- Set up the Dario App on your smart mobile device using the Dario App instructions or the instructions provided on the Dario website at: USA: www.mydario.com.

⚠️ Both ends of the Dario Housing have covers that are removable. The lancet cover is orange with the small opening. Be careful not to put the cartridge cover on the lancing end. This can damage the lancet and the lancing device.

Inserting the Test Strip Cartridge

To insert the test strip cartridge for the first time:

1. Remove the paper holder from the device and open the white cover.
2. Remove the new test strip cartridge from its pouch.
3. Hold the test strip cartridge with the side that opens facing up, as shown in the image below.

4. Insert the cartridge into the housing until it snaps into place.
5. Return the white housing cover by sliding it into place until it clicks, as shown in the image below.

!   If the cover does not close properly, the cartridge may not have been inserted correctly. Ensure you have properly inserted the cartridge, as described in steps 3 and 4.

Inserting a Lancet

To insert a lancet:

1. Remove the orange lancet device cover from the Dario Housing, as shown in the images below.

2. Remove the used lancet, if one exists, by grasping and pulling it straight out of its housing.

⚠️ To avoid accidental injury, dispose of used lancet in accordance with the instructions provided by your health care provider for biohazardous waste.

3. Remove a new lancet from the packaging.

⚠️ Do not use the lancet if the cap is missing or damaged.

4. Insert a sterile lancet as far as it will go and ensure it is firmly set.

⚠️
- Only use a lancet authorized by LabStyle Innovation Ltd. (30G).
- If the lancet does not set into place or the lancet holder does not hold the lancet properly, insert another sterile lancet.
- If the problem persists, you may need to replace your Dario Housing. Error! Reference source not found., for contact information please see page 89.

5. Carefully twist off the lancet cap, as shown in the image below. Ensure that you do not bend the lancet while removing the cap.

Setting Lancet Depth (Optional)

You can adjust the puncture depth of the lancet by moving the lever between the numbers 1 and 4 (printed on the dial). 1 is the shallowest depth and 4 is the deepest. It is recommended that you start with the lancet depth set to 1 and adjust the level upwards if necessary.

To set lancet depth:

1. Move the lancing device lever so that the line on the lever is aligned with the correct depth number, as shown in the image below.

2. Replace the lancing device cover by sliding it into place until it clicks. Be careful not to touch or bend the lancet.

The Dario App

The Dario App is available on the App Store for iPhone and on Google Play for Android devices. To ensure maintenance of service, please review the list of compatible devices in **Compatible Platforms with the Dario Blood Glucose Monitoring System** on page **19** or on www.mydario.com/support/getting-started. for the latest operating system and mobile device compatibility.

Your Dario Glucose Meter is operated from the Dario App displayed on the screen of your smart mobile device. The mobile device displays and stores information received from the glucose meter. The Dario App also provides a step-by-step quick guide for operating the system. Additionally ,instructional videos about the Dario App are located at www.mydario.com/support/getting-started .

You can use the Dario App to conveniently store and manage your diabetes information, review trends, or share information with your health care provider.

Downloading and Installing the Dario App

You can download and install the Dario App to your smart mobile device using the Apple App Store or Google Play. The Dario App downloads and installs just like any other app on your smart mobile device. The Dario App is free of charge and is customized for your smart mobile device.

! Downloading the Dario App from the Apple App Store or Google Play requires data connectivity.

! For accurate use of the Dario System with the app, the time and date must be correctly set

on your smart mobile device. For instructions on setting the time and date, refer to the documentation for your device.

To download the Dario App:

1. Turn on your smart mobile device and launch the Apple App Store (for iPhones) or Google Play (for Android). Alternatively, for quicker access, you can use an app that scans QR codes to scan the following code:

2. Search for the Dario App by LabStyle Innovation Ltd. and tap on the **Dario icon**.
3. Install the App.
4. Follow the registration flow as shown on App.
   The application downloads. Once installed, the orange Dario icon appears on your smart mobile device home screen, as shown in the image below.

> **!** The Dario App needs to be installed once on each of your smart mobile devices.

> **!** Updates may be downloaded periodically from the App Store or Google Play.

Creating Your Account and Personalizing Your Settings

To setup your Dario App:

1. After installing the Dario App on your mobile device, press the orange **Dario icon** . The icon appears on your smart mobile device's Home screen.
2. Select **Sign Up** to register a Dario user. Dario App registration requires email and Password to create your account.
3. Continue by following the instructions on the screen to register. You can register by entering your email address and password; or, alternatively, you can connect with Facebook.

> **!** Your password must have at least seven (7) characters and include an upper-case letter, a lower-case letter, and a number.

> **!** Your email address and password will be used to log in to the Dario App and the Dario web portal.

> **!** If you already have a Dario account, you can skip the next steps.

4. Press **Create Account** when done.
   The First Entry screen appears, as shown in the image below.

! You can edit your email address and password and set the Dario App language and region by tapping the **Menu icon** and selecting **SETTINGS > ACCOUNT INFORMATION**.

Setting Your Personal and Diabetes Profiles

To set your personal profile:

1. Tap the **Menu icon** in the upper left corner and select **MY PROFILE**.
2. Tap the **pencil icon** in the upper right corner to edit the information.
3. Enter your gender, weight, height, and date of birth in the appropriate fields. You can also upload a photo from your device by tapping **UPLOAD PHOTO**.
4. Press **DONE**

To set your diabetes profile:

1. Tap the **Menu icon** in the upper left corner and select **SETTINGS > DIABETES PROFILE**, and under **SETTINGS** > **SET MY GOALS**

2. Tap the **pencil icon** in the upper right corner to edit the information.

3. Select your preferred carbs measurement unit.

4. Press **DONE**

!   You can complete the Walkthrough at any time by selecting **HELP&INFO > VIDEO GUIDES**.

CHAPTER 3
CHECKING YOUR DARIO GLUCOSE METER

This chapter provides information on checking the accuracy of your meter with a control solution.

To ensure that your results are always accurate, you need to check the performance of your meter in the following cases:

- If you drop the meter.
- Whenever your result is inconsistent with how you feel.
- If you have repeated a test and the blood glucose result is still lower or higher than expected.
- Whenever you want to check the performance of the meter and a test strip.

Dario Control Solution

The Dario Control Solution confirms that the meter and test strips are performing as expected. A drop of control solution is placed on the edge of the test strip, allowing the test strip to automatically draw the control solution into the yellow window. Compare the results on the meter with the values displayed on the test strip cartridge.

The Dario Control Solution package can be ordered separately. Contact your local representative for ordering information. The Dario Control Solution package comes with two bottles of control solution (Level 1 (M), Level 2 (H)).

Control Solution Precautions

Note the following about the control solution:

- Avoid contact with your eyes. Contact your health care provider immediately if solution is swallowed, injected, or comes in contact with your eye.
- The dye in the control solution may stain skin, clothing, or surfaces.
- Store the control solution in an area where the temperature is between 46°F-86°F (8°C-30°C). Keep away from direct sunlight, fluorescent light, and heat.
- Do not freeze.
- Once you open a new bottle of control solution, mark the date on the bottle.
- Ensure that your control solution has not expired. Check the expiration date on the bottle.
- Ensure that your control solution was not opened more than three (3) months ago.
- Keep the control solution out of reach from children.
- Shake the control solution well before using.
- After each use, wipe the container tip clean and close the container tightly.
- No reconstitution or dilution of the control solution is necessary.

Control Solution Test Principle

The Dario Control Solution contains a known amount of glucose that reacts with chemicals on the Dario Test Strip.

Following the same procedure, you would use to check your blood, you will apply a drop of control solution to a test strip. The glucose in the control solution reacts with chemicals in the test strip.

The result displayed on the meter should fall within the expected range printed on the test strip cartridge label. You only need to obtain a single result within the expected range to verify system performance. A result outside the range printed on the test strip cartridge label may indicate the system is not performing correctly.

> **!** The control solution is not for use as a cleaning solution.

Chemical Composition

Dario Control Solution is an aqueous solution that contains d-glucose as the reactive ingredient in the approximate concentration.

The remaining chemical components of the Dario Control Solution are:

- Buffer 75mM
- Polyvinylpyrolidone 5%
- Polyethylene glycol 5%
- SDS 0.1%
- Preservative 0.1%

Checking Your Glucose Meter with Dario Control Solutions

To perform a control solution test, you must perform the following three procedures:
- Removing the Glucose Meter from the Housing
- Removing a Test Strip from the Cartridge
- Performing a Control Solution Test

Removing the Glucose Meter from the Housing

Before performing a control solution test or testing your blood, remove the glucose meter from the

housing. You should always store the glucose meter in the housing when you are not using it.

⚠️ When not in use, store the meter in the Dario Housing. Do not leave your meter connected to your smart mobile device with the screen in ON mode for more than two (2) minutes, as the meter can get warm which can affect the accuracy of the reading.

To remove the meter from the housing:

1. Hold the housing so that the ridged orange panel is close to you and the end with the lancing device is facing away from you.
2. Slide your thumb back on the ridged orange panel in the direction indicated by the arrow, as shown in the image below. The meter will pop up.

3. Grasp the meter with two fingers and remove it from the housing.

⚠️ Do not plug the Dario Glucose Meter into any device other than a compatible smart mobile device port. For a list of compatible devices, refer to www.mydario.com/support/getting-started/.

Removing a Test Strip from the Cartridge

You should have a test strip cartridge already inserted in your Dario Housing. If this is not the case, refer to Inserting the Test Strip Cartridge on page 22.

To remove a test strip from the cartridge:

1. Remove the cartridge cover of the Dario Housing by pushing it outwards until it comes off (use the removal indication lines), as shown in the images below.

2. Snap open the test strips cartridge cap by pushing up the edge.

3. Remove a test strip from the cartridge, as shown in the image below.

4. Close the cartridge cap immediately and return the white cartridge cover to the closed position by pushing it into place until it clicks.

! You should use the test strip immediately after removing it from the cartridge. It is not recommended that you use a test strip that has been outside of the cartridge for more than three (3) minutes.

! If the cover does not close properly, the cartridge may not have been inserted correctly. Ensure that you have correctly returned the cartridge cover to the closed position as described in step 4.

⚠ • Do not touch the yellow testing site when handling the test strip.
• Do not use a damaged test strip.

Performing a Control Solution Test

To perform a control test:

1. Tap the **Dario icon** on your smart mobile device to launch the Dario App.

*The **First Entry** screen appears, as shown in the image below.*
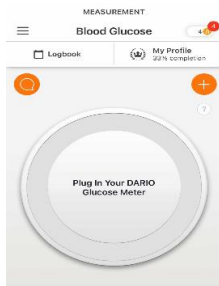
2. Insert the meter into the port of your smart mobile device, as shown in the image below.

   A "Connecting..." message appears in the Dario App and then the screen displays the following instruction: INSERT A NEW STRIP.

The Dario Meter should be inserted with logo facing up.

The screen notification changes.

! Verify that the meter is inserted as far as it can go into the port of the smart mobile device and no other device or cable is connected to the smart mobile device.

3. Hold the test strip with the gold contacts facing the meter.

4. Without bending the strip, insert it into the test strip port (marked in orange) of the Dario Glucose Meter as far as it will go.

⚠️ Verify the test strip direction, as shown in the image below.

The Dario App screen instructs you to place a drop of blood on the test strip, as shown in the image below.
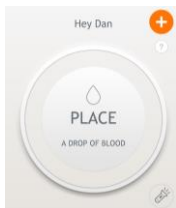
5. Shake the control solution container and apply a drop of control solution onto the edge of the test strip, allowing the test strip to automatically draw the control solution into the yellow window.

❗ Important: Verify that you apply enough control solution to fill the window so that it

turns red. Do not put control solution on top of the test strip.

When the meter detects the solution, the "Measuring..." message appears. The orange rotating in the circle indicates that the test is in progress, as shown in the image below.
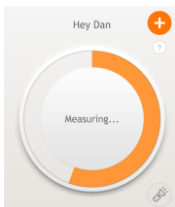
The glucose test result appears on the screen after six (6) seconds and is automatically saved to memory.

! You can delete this control test from memory, if desired. Alternatively, the Dario System includes a function for specific control solution tests. Control solution tested values must be tested under the "Control solution test" function: **Menu icon** ☰ , selecting **HELP&INFO > CONTROL SOLUTION TEST** or the results will be included in the blood glucose averaging functions of the device.

6. Compare the results on the meter with the values displayed on the test strip cartridge. If the results are:

   • Within the acceptable target values, then your meter is ready for use.

- Outside of the acceptable target values, perform the test again with a new test strip. If the problem recurs, Error! Reference source not found., for contact information please see page **89.**

7. When the test is done, remove the test strip and follow your health care provider's instructions for disposal.

8. Disconnect the meter from your smart mobile device.

9. Wipe the tip of the control solution container clean and tightly seal the container.

! The Dario Control Solution target values printed on the test strip cartridge label are intended for the Dario Test Strip Cartridge only.

! When measured by systems other than the Dario System, the glucose concentrations in these solutions may differ.

! Applying too much or too little control solution to the test strip may cause out-of-range results.

⚠ Do not use your Dario System to test your blood if your control solution result falls outside of the acceptable target values.

⚠ The Dario Blood Glucose Monitoring System includes a function for specific control solution tests. Control solution tested values must be tested under the "Control solution test" function: **Menu icon** ☰ , selecting **HELP&INFO > CONTROL SOLUTION TEST** if not

done the results will be included in the blood glucose averaging functions of the device.

10. Place the meter back into the housing by holding the meter at an angle with the part that connects to the smart mobile device facing away from the ridged orange panel. Then, push the meter into the housing at an angle and push downwards until the meter clicks into place.

CHAPTER 4
TESTING YOUR BLOOD GLUCOSE LEVEL

The Dario Glucose Meter measures the amount of glucose in your blood. Once you place a small drop of blood from your fingertip onto the test strip, the result will display in six (6) seconds on the screen in the Dario App.

Carefully read and follow the instructions provided in this chapter and in the package inserts for the test strips and control solutions. It is very important to follow the instructions to prevent an incorrect result or improper treatment.

⚠️ Do not put any fluids into the test strip port.

Once you start the Dario App, follow the prompts on the screen.

Blood Glucose Testing Precautions

⚠️ The meter, test strips, and control solutions are only intended for use outside the body (in vitro). Do not eat the test strips. Do not swallow or inject control solutions, or use control solutions for any purpose other than testing your blood glucose.

⚠️ FDA Public Health Notification: "Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010). You can find this document at www.fda.gov.

⚠️ CDC Clinical Reminder: "Use of Fingerstick Devices on More than One Person Poses Risk

for Transmitting Bloodborne Pathogens"
(2010). You can find this document at
www.cdc.gov.

The meter and lancing device are for single-patient use only. Do not share them with anyone including other family members. Do not use on multiple patients.

It is advised that you wash your hands thoroughly with soap and warm water before and after handling the meter, lancing device, or test strips.

Incorrect test results may result in the wrong therapy recommendation and may lead to serious adverse health conditions. Therefore, follow the proceeding instructions carefully and read the items listed in Test Strip Precautions below.

Test Strip Precautions

- Only use Dario Test Strips. Using other test strips with the Dario Glucose Meter can produce inaccurate results.
- Inspect each test strip cartridge before opening it for the first time. If you see any damage to the cartridge lid, or if anything prevents the lid from closing properly, do not use the test strips.
- Run a control test every time you open a new test strip cartridge. For additional information, refer to Checking Your Glucose Meter with Dario Control Solutions on page 33.

- Store unused test strips in their original cartridge. Do not remove test strips from the test strip cartridge and put them into another container.
- Close the cartridge tightly right after you remove a test strip. This helps to keep the test strips dry.
- Check the "Use by" date on the test strip cartridge. Do not use the test strips after that date.
- Write down the date the test strip cartridge was first opened. Check this date before you use a test strip from this cartridge. If the current date exceeds the shelf life, do not use the test strips from this cartridge. Refer to the Instructions for Use information on the test strip cartridge packaging.
- Do not move tests strips from one cartridge to another.
- Use the test strip immediately after removing it from the cartridge.
- Use the test strips as indicated in this guide.
- Do not store your test strips in temperatures below 36°F (2°C) or above 90°F (32°C).
- Store your test strips in an area where the relative humidity is between 10-90%.
- Do not place the test strips in a freezer.
- Do not expose your test strips to direct sunlight or moisture.
- Do not apply blood or control solution to the test strip before inserting it into the glucose meter.
- Do not reuse test strips. Once control solution or blood is placed on a test strip, discard the strip. If you need to retest, use a new test strip.

- Do not bend, cut, or alter the test strips.
- Do not get dirt, food, or other substances on the test strip.
- It is recommended that you use the test strip immediately after removing it from the cartridge. It is not recommended that you use a test strip that has been outside of the cartridge for more than three (3) minutes.
- Do not touch the yellow testing site when handling the test strip.
- Do not use a damaged test strip.
- Make sure that the gold contact area of the test strip is clean from dirt, blood, moisture, and any other material. An unclean test strip will affect the test result and can cause an inaccurate blood glucose level result.

Factors That Interfere with Blood Glucose Testing

Certain substances can interfere with the blood glucose system and cause inaccurate results. For more information, refer to the test strip package insert or CHAPTER 6 TEST STRIPS on page 66. If you are taking medication or dietary supplements, consult your health care provider. Refer to System Limitations on page 7 for full list of interfering substances.

Certain health conditions, such as serious illness and dehydration, can cause false test results in glucose meters. If you are very sick or think you are dehydrated, or are urinating frequently, call your health care provider immediately.

You should not use this system to test your blood glucose if you are critically ill (examples include: severe hypotension or shock, hyperglycemic-hyperosmolar state, hypoxia, and diabetic ketoacidosis).

Unwashed hands could affect your results. Alcohol can affect test results.

Interpreting the Results

If the displayed test result is consistent with how you feel, continue as instructed by your health care provider.

If the test result is inconsistent with how you feel, check your Dario System by running a control solution check, as described in Performing a Control Solution Test on page 36. Repeat the blood glucose test afterward. If your blood glucose result is still inconsistent with how you feel and you have followed the instructions provided in this chapter, follow your health care provider's instructions.

Do not change your treatment based on a single result that is inconsistent with how you feel or if you believe that your test result is incorrect. The blood glucose reading displayed on your smart mobile device by Dario System should not be the only information you use to make decisions about your health. Always consult your health care provider to interpret and understand the measurement results.

Measurement Range

Your meter measures blood glucose results in the range of 20 mg/dL to 600 mg/dL (1.1 - 33.3 mmol/L). Results outside of this range should be reviewed according to the following information.

- If your test result is lower than 20 mg/dL (1.1 mmol/L), "LOW! Measure with a new strip, if recurs contact your physician immediately" displays instead of a result.

 LOW may indicate that your blood glucose is very low (possibly severe hypoglycemia). Follow your health care provider's instructions immediately and repeat the test.

- If the result is higher than 600 mg/dL (33.3 mmol/L), "HIGH! Measure with a new strip, if recurs contact your physician immediately" displays instead of a result.
- If your blood glucose test results in a **LOW!** or **HIGH!** message, repeat the blood glucose test following all instructions in Step Five: Testing Your Blood Glucose on page 51.
- If your blood glucose test results in a **LOW!** or **HIGH!** message a second time, follow the protocol established by your health care provider or contact your health care provider immediately.
- Note that many factors determine whether your blood glucose reading is outside the range of 20 mg/dL to 600 mg/dL (1.1 - 33.3 mmol/L), including individual differences and the time since your last meal.

The American Diabetes Association suggests that the following expected glucose values for individuals without diabetes:

Before eating (FPG) < 100 mg/dL (5.6 mmol/L)

Two hours after meals (OGTT) < 140 mg/dL (7.8 mmol/L)

Reference: American Diabetes Association (2017). Standards of Medical Care in Diabetes – 2017. Diabetes Care, 40 (Supplement 1): S1-S132.

Factors That May Lead to Inaccurate Results

Certain medications, food supplements, medical treatments, and health conditions can interfere with the blood glucose system and cause inaccurate results.

Incorrect testing technique or improper storage or handling of the Dario System may also lead to inaccurate test results which are inconsistent with how you feel. The following conditions could lead to incorrect results:

- Your hands may not have been washed thoroughly.
- Your glucose meter test strip port may be contaminated.
- Your test strip has been bent.
- The test strip is expired. Check the 'Use By' date.
- The length of time that has passed since first opening the test strip package exceeds the shelf life.
- Test strips were stored incorrectly.

- Testing was done in a humid environment (for humidity specifications, refer to General Precautions on page 14).
- Your glucose meter has been dropped.

If your meter has been dropped and you are receiving error messages or implausible results, Error! Reference source not found., for contact information please see page 89.

Do not rely on the blood glucose measurement alone in making health care decisions.

Step One: Inserting a New Lancet into the Lancing Device

To prevent infection, always use a new, sterile lancet in your lancing device each time you test your blood glucose.

Insert a new lancet into the lancing device, as described in Inserting a Lancet on page 23.

If necessary, set the depth of the lancing device. For more information, refer to Setting Lancet Depth (Optional) on page 25.

Return the lancing device (orange) cover by sliding it into place until it clicks. Be careful not to touch or bend the lancet.

Step Two: Opening the Dario App

Before connecting the Dario Glucose Meter into your smart mobile device, open the Dario App by tapping the **Dario icon** on your smart mobile device Home screen.

Step Three: Inserting the Smart Mobile Device into the Disposable Cover

Before starting the testing procedure, you should cover your phone with a disposable cover.

! To avoid the risk of transmitting bloodborne pathogens, it is recommended that you use a disposable sleeve to cover your smart mobile device while taking the blood glucose test. The disposable cover protects the mobile device from direct contact with blood during the glucose measurement.

Insert your smart mobile device into the disposable cover so that the opening at the bottom of the sleeve fits over the audio jack port, as shown in the image below.

Step Four: Removing the Glucose Meter from the Housing

Before starting the testing procedure, remove the meter from the housing, as described in Removing the Glucose Meter from the Housing on page 33. You should always store the meter in the housing when you are not using it.

Place the glucose meter connector into the smart mobile device port at the bottom of the disposable cover. Verify that the meter is inserted as far as it goes into the port of the smart mobile device and no other device or cable is connected to the smart mobile device.

A "Connecting..." message appears in the Dario App, and then the screen displays the following instruction: INSERT A NEW STRIP.

The Dario Meter should be inserted with logo facing up.

The screen notification changes.

Step Five: Testing Your Blood Glucose

You are now ready to test your blood glucose. Before beginning the test, ensure you understand the information provided in Testing Information and Guidelines.

Testing your blood glucose consists of the following two procedures:

- **Removing a Test Strip from the Cartridge**
- **Performing a Glucose Test**

Testing Information and Guidelines

- To perform the test, the meter requires only a small drop of blood about the size of a sugar grain (0.3µL). For best results, select a puncture site along the side of the fingertip.
- While applying blood to the test strip, verify that you apply enough blood to fill the test strip window so that it turns completely red.
- Testing blood from sites other than the fingertip may generate inaccurate results.
- If you have not applied enough blood to the test strip, an alert displays that informs you that the sample size is too small and you should try again with a new strip. Blood glucose results are automatically saved to mobile App memory.
- If a test strip error occurs (e.g. "used strip"), perform another test with a new test strip.
- If an error message or symbol appears on the screen, refer to CHAPTER 7 TROUBLESHOOTING on page 74 for additional information.
- Unwashed hands could affect your test results.
- Alcohol can affect test results.
- When not in use, store the meter in the Dario Housing. Do not leave your meter connected to your smart mobile device with the screen in ON mode for more than two (2) minutes, as it can get warm and can affect the accuracy of the test.

⚠️ To prevent malfunction of the meter, keep the test strip port free of blood, moisture,

dirt, or dust. Always store the glucose meter in the Dario Housing when not in use.

⚠️ In case of a meter error, you may need to remove and insert the meter to allow the meter to reconnect to the smart mobile device.

⚠️ In case of a test strip error you may need to replace the test strip and test with a new test strip.

Removing a Test Strip from the Cartridge

❗ You should have a test strip cartridge already inserted in your Dario Housing. If this is not the case, refer to **Inserting the Test Strip Cartridge** on page **22**.

To remove a test strip from the cartridge:

1. Wash your hands with warm, soapy water and dry thoroughly. If you use alcohol wipes to clean your fingers, ensure the puncture area is completely dry before lancing your finger.
2. Remove the cartridge cover of the Dario Housing by pushing it outwards until it comes off (use the removal indication lines), as shown in the following image.

3. Open the lid by pushing up the edge, as shown in the image below.

4. Remove a test strip from the cartridge, as shown in the image below.

5. Close both the lid and cartridge cover.

   ! If the cover does not close properly, you may not have inserted the cartridge correctly.

6. Hold the test strip with the gold contacts facing upward.

7. Without bending the strip, insert it into the test strip port of the Dario Glucose Meter as far as it will go.

   ⚠ Verify the test strip direction, as shown in the image below.

The Dario App instructs you to place a drop of blood on the test strip, as shown in the image below.

Performing a Glucose Test

 If you receive a phone call while the glucose measurement is in progress, Dario will stop the test and the results will not be saved. To avoid interruption of the glucose test, you can set your phone to airplane mode before beginning this procedure. For more information, refer to your mobile device's instructions.

1. Set the lancing device for activation by sliding it with two fingers as far as it will go, as shown in the following image.

2. Place your fingertip over the hole on the lancing device and press the orange release button with your thumb to prick your finger, as shown in the images below.

3. Apply a drop of blood to the tip of the yellow window of the test strip, as shown in the images below. Capillary action will pull the blood into the strip.

! Important: Continue applying blood to the test strip until the window turns red, which indicates that enough blood has been collected to take a reading. Do not put blood on top of the test strip.

When the meter detects that blood has been applied, the "Measuring..." message appears in the Dario App. The border of the circle gradually fills with orange, indicating that the test is in progress.

4. Remove your finger from the strip once the above message appears.

Do not add blood to the test strip once you have removed your finger because you may receive an inaccurate result.

5. The test result appears on the screen after approximately six (6) seconds.
The glucose test result is automatically saved to memory. If a result does not display, you can view it in your Logbook in the Dario App.

In case an error message appears, you may need to start the measurement process again. If error recurs, refer to CHAPTER 7 TROUBLESHOOTING on page 74 section for further information.

If you receive a phone call while a measurement is in progress, the test will stop and the results will not be saved. The following message will display on the result screen: "The Test Strip Is Used" and you will have to start the test over with a new test

strip. To avoid an interruption of your glucose test, you may want to set your smart mobile device to airplane mode prior to starting your test.

6. You may continue to complete the information about the glucose measurement that displays on the Dario App screen (e.g., measurement setting, carb consumption, exercise, insulin intake).

7. When the test is done, remove the test strip and disposable cover and dispose of them in accordance with the instructions provided by your health care provider for biohazardous waste.

8. Remove the lancet from the lancing device, as described in step 2 in Inserting a Lancet on page **23** and dispose of the used lancet in accordance with the instructions provided by your health care provider for biohazardous waste.

When the test strip is removed from the glucose meter, the following message appears in the Dario App: "Please insert new test strip."

Step Six: Returning the Meter to the Dario Housing

To return the meter to the Dario Housing:

1. Disconnect the meter from your smart mobile device.

2. Hold the meter at an angle with the meter plug facing away from the ridged orange panel.

3. Push the meter into the housing at an angle and then push downwards until the meter clicks into place.

Test Strip Limitations

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.

Packed cell volume: Dario BGMS Test Strip suitable range is 20~60%.

CHAPTER 5
CLEANING AND MAINTENANCE

This chapter provides information for cleaning and disinfecting for your Dario Glucose Monitoring System.

The Dario System should be cleaned and disinfected once a week. The Dario System should be properly maintained for safe and accurate use. The meter should be properly cleaned and disinfected to prevent the spread of infectious diseases.

Cleaning and Disinfection

The outer surfaces should be cleaned when you notice that your Dario is visibly dirty. It is advised to clean and disinfect your Dario System once a week to avoid transmitting bloodborne pathogens.

If someone else is operating the meter to assist you with testing, he or she should clean and disinfect the meter, housing, orange lancet cover and white cartridge cover prior to use.

"Cleaning and disinfection" is a two steps process and should be done once a week. Cleaning and disinfection refer to different actions. Cleaning removes dirt and blood while disinfection kills the bloodborne pathogens. Before disinfecting your system, first clean the meter, housing, orange lancet cover, and white cartridge cover.

 Failure to properly clean your device prior to disinfection can damage your device and/or transmit blood borne pathogens

Wash your hands thoroughly with soap and water before and after handling the meter, housing,

orange lancet cover and white cartridge cover, or
test strips.

Step 1: Cleaning

Clean the meter, housing, orange lancet cover, and white cartridge cover using a Super Sani-Cloth Germicidal Disposable Wipe to remove visible dirt, blood, or other substances. Super Sani-Cloth Germicidal Disposable Wipes have been proven safe for use with the Dario meter, housing, orange lancet cover, and white cartridge cover. Super Sani-Cloth Germicidal Disposable Wipes are manufactured by Professional Disposables International, Inc. and are available online through amazon.com and officedepot.com. Before cleaning, remove the meter from its housing. The meter must not be connected to the mobile device while cleaning.

Clean the meter, housing, orange lancet cover, and white cartridge cover by wiping the outside surfaces with a Super Sani-Cloth Germicidal Disposable Wipe to remove all visible dirt. Remove the white cartridge cover and wipe the cartridge cap as well. Before you begin, squeeze out any excess liquid from the wipe so that it is damp but not dripping wet. Take extreme care not to get liquid on the test strip port connector.

Step 2: Disinfection

Prior to disinfection ensure you have properly cleaned your device as recommended in **Step 1: Cleaning**. Disinfect the meter, housing, orange lancet cover, and white cartridge cover using a clean Super Sani-Cloth Germicidal Disposable Wipe to kill the bloodborne pathogens that may spread infection.

Using a second clean Super Sani-Cloth Germicidal Disposable Wipe:

- Disinfect the meter on all four (4) surfaces and the audio plug by wiping up and down at least two (2) times to each direction, as shown in the images on the following page. Do not allow any moisture to get into the test strip port.
- Disinfect the housing, orange lancet cover, and white cartridge cover by wiping the outer surfaces. Ensure that you wipe all parts including the housing, the white cartridge cover, and the orange lancet cover up and down at least two (2) times in each direction as demonstrated in the images on the following page.
- Remove the white cartridge cover and disinfect the cartridge cap by wiping up and down thoroughly at least two (2) times in each direction as demonstrated in the images on the following page.
- It is very important to let the liquid from the wipe sit on the outer surface for at least two (2) minutes. Be extremely careful to avoid getting liquid onto the test strip port.

The following images demonstrate how to wipes to clean and disinfect your Dario System.

To ensure effective disinfection, let the solution sit on the meter, housing, orange lancet cover, and white cartridge cover for at least two (2) minutes. Allow the meter, housing, orange lancet cover, white cartridge cover and cartridge cap to completely dry before use. Wipe off any remaining residues with a clean, soft, and dry paper cloth.

Your Dario System has an expected life of three (3) years. It should withstand the cleaning and disinfection recommended (156 cycles) in this user guide.

It is recommended that you clean and disinfect the entire system as least once per week and whenever you notice blood, dirt, or visible residue.

If you notice changes in appearance (such as color fading, cracking, discoloration or display malfunctions) or you are obtaining results that are not accurate, stop using the meter or lancing device and call customer support toll-free in the U.S. at 1-800-895-5921, 9:00 AM-5:00 PM EST Monday through Friday. Please contact your health care provider for questions outside of the customer support hours.

The cleaning and disinfection performance testing on the Dario System was done using the Super Sani-Cloth Germicidal Disposable Wipes with EPA registration number 9480-4 (Active ingredient: Quaternary ammonium chlorides and isopropanol).

"Cleaning and disinfection" is important to prevent the spread of disease. If you are interested in additional information about the importance of disinfection, refer to the following articles:

- "FDA Public Health Notification: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication" (2010). You can find this document at www.fda.gov.
- "CDC Clinical Reminder: Use of Fingerstick Devices on More than One Person Poses Risk for Transmitting Bloodborne Pathogens" (2010). You can find this document at www.cdc.gov.

⚠️ Do not:
- Allow any moisture to get into the test strip port.
- Spray any cleaning solution directly onto the glucose meter or the lancing device.

- Submerge any part of the Dario System in liquid.
- Attempt to clean any internal parts.
- Attempt to dry any parts using a blow dryer.

Please observe the following cautions when cleaning the Dario System to avoid damaging the device:

⚠️ If the device becomes wet, wipe off all moisture and allow sufficient time for the device to dry before using.

⚠️ To avoid the risk of transmitting bloodborne pathogens, it is recommended that you use a disposable sleeve to cover your smart mobile device while taking the blood glucose test. For more information about using the disposable cover, refer to instruction on how to use Disposable Covers on page 50.

⚠️ If you notice signs of deterioration such as clouding, cracking, crazing, etc., or the meter stops functioning as expected (such as the control results falling out of range, etc.), stop using the meter and Error! Reference source not found., for contact information please see page 89.

Please contact your health care provider for questions outside of the customer support hours.

CHAPTER 6
TEST STRIPS

Important: Dario test strips are designed for use with the Dario®, Dario® LC and Dario USB-C Blood Glucose Monitoring Systems. Please read these instructions for use before using this product.

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.

The Dario, Dario LC and Dario USB-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 and Dario USB-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.

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.

The Dario Test Strip is structured as follows:

Yellow Window
Apply a drop of blood here.
- **Before Applying Blood** –
  This window should be completely yellow.
- **After Applying Blood –** This window should be completely filled with the blood drop.

Electrodes
Insert a strip with gold-colored bars up and toward the meter.

Reagent Composition (per strip)

Glucose oxidase (*Aspergillus sp*)	1.5 unit
Potassium ferricyanide	0.093mg
Binder	0.052mg
Stabilizer	0.031mg

Precautions

- Use only fresh capillary whole blood by finger prick for blood glucose testing.
- A test strip should be used according to the specified intended use.
- A test strip is for single use only. Do not reuse.

- Dario Blood Glucose Test strips should be used with Dario/Dario LC/Dario USB-C meters only.
- Insert a test strip into the test strip port in the glucose meter with gold-colored bars facing up and toward the meter.
- 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.
- After removing a test strip from its cartridge, you should use it within 3 minutes.
- Do not use a test strip expired 1 month from opening. Discard the cartridge 1 month after opening.
- Insert a test strip in the meter port gently until it will go no further.
- 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.
- Do not apply blood to any site except the yellow window of a test strip.
- Do not touch the yellow window of a test strip.
- Do not bend, cut or modify a test strip.
- Discard the used test strip as a biohazard.

System Limitations

Refer to System Limitations on page for full list of interfering substances.

Performing a Test

Refer to Chapter 4 for full list of interfering substances.

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 (5.5 mmol/L)
    Two hours after meals (OGTT) < 140 mg/dL (7.8 mmol/L)
- Consult with your healthcare professional for the blood glucose range that is appropriate for you.

Test Result Range

The Dario meter read blood glucose results between 20-600 mg/dL (1.1-33.3 mmol/L).

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.

- 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.

- 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:

- Repeat the test with a new strip.
- Run a control solution test with Dario Glucose Control Solution.
- 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

- Was the blood sample applied to the test strip within 3 minutes of removing it from the cartridge?
- Was the size of the blood sample sufficient to fill the yellow window?
- Was the test strip cartridge cap tightly sealed?

- Was the test strip used before the expiration date?
- Were the test strips stored at extreme temperatures such as in the car during very cold or hot weather?
- 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?

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

> ! 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

To conduct a control solution test, refer to Performing a Control Solution Test on page .

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:

- Did you use control solution or test strips that were past their expiration date?
- Did you leave the cap off the cartridge of test strips or control solution?
- Did you follow the testing steps exactly?
- 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, Error! Reference source not found., for contact information please see page .

! 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.

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.

Bibliography

1. American Diabetes Association (2017). Standards of Medical Care in Diabetes – 2017. Diabetes Care, 40 (Supplement 1): S1-S132.

2. Stedman, TL. Stedman's Medical Dictionary, 27th Edition, 1999, p.2082.

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Glen Hortin, MD:Diabetes Technology & Therapeutics, Performance Evaluation of Blood Glucose Monitoring Devices, Oct 2003, Vol. 5, No. 5: 749 -768.

CHAPTER 7
TROUBLESHOOTING

This chapter provides information about all the symbols and error messages that may display in the Dario App. To ensure safe and accurate use of Dario, pay attention to all symbols and messages that occur while using the system as they provide you with important information.

If you still have questions after reading this chapter, Error! Reference source not found., for contact information please see page Please contact your health care provider for questions outside of the customer support hours.

An error message can appear in the Dario App as a message within the results area, as shown in the images below.
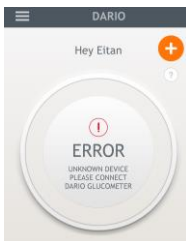
Troubleshooting

The following table lists some typical conditions that may occur with the Dario System.

Message Content	Possible Cause / Recommended Action
Insufficient blood detected, try again with a new strip	There is not enough blood on the test strip.
	Repeat the measurement with a new test strip.
The strip is used, please insert a new strip	A test strip was used more than once.
	Perform a new measurement with a new test strip.
Temperature out of range. Move to an area between 50°-95°F (10-35°C), wait 30 minutes and try again	The meter was left in an extreme temperature environment.
	Move to a cooler or warmer area, wait at least 30 minutes and repeat the measurement with a new test strip.
HIGH! Measure with a new strip, if recurs contact your physician Immediately	Glucose level is above operating range.
	Measurement result is above 600 mg/dL (33.3 mmol/L). Repeat the measurement with a new test strip. If this message recurs, contact your health care provider Immediately. If your measurement results are inconsistent with the way you feel, contact customer support.

Message Content	Possible Cause / Recommended Action
LOW! Measure with a new strip, if recurs contact your physician immediately	Glucose level is below operating range
	Measurement result is below 20 mg/dL (1.1 mmol/L). Repeat the measurement with a new test strip. If this message recurs, contact your health care provider Immediately. If your measurement results are inconsistent with the way you feel, contact customer support.
Dario device failure (0x00). If the problem occurs again, please contact Dario's customer support.	Communication failure.
	Try disconnecting and reconnecting the meter.
Dario device failure (0x01). If the problem occurs again, please contact Dario's customer support.	Firmware software failure.
	Try disconnecting and reconnecting the meter.
Dario device failure (0x02). If the problem occurs again, please contact Dario's customer support.	Voltage failure.
	Try disconnecting and reconnecting the meter.

Message Content	Possible Cause / Recommended Action
Unknown device, please connect Dario.	Another device is connected to your smart mobile device's audio plug port.
	If another device is connected to the audio plug, disconnect it and connect the Dario Glucose Meter. You can still use the Dario App if another device is connected.
	If you received this message while the Dario Glucose Meter is connected, disconnect and reconnect the meter. If this message still appears, contact customer support.
Hypo warning	A hypoglycemia event occurred.
	You received a measurement result lower than defined in the hypo warning section under Blood Glucose Thresholds. Contact your health care provider immediately.

Problem Solving

Test strip inserted but "Please insert a new strip" keeps appearing on the screen.

The test strip was removed before the reading was completed or test strip or meter is defective.

- Repeat the measurement using a new test strip.
- Check the meter with control solution, as described in Checking Your Glucose Meter with

Dario Control Solutions on page 33). If the result is outside of the acceptable target values, Error! Reference source not found., for contact information please see page 89. If the result is within the acceptable target values, test your glucose again with a new test strip.

You cannot pierce skin with lancet.

- The needle depth may be incorrect. Adjust the lancet depth lever to a different depth. For more information, refer to Setting Lancet Depth (Optional) on page 25.
- The lancet needle may be bent. Replace the lancet. For more information, refer to Step One: Inserting a New Lancet into the Lancing Device on page 23.
- The cartridge cover may be in the place of the lancing device cover. Please be careful to return each cover to the correct end.

The lancet does not fit correctly into the lancing device.

The lancet may be faulty or you may be using a lancet that is not approved for use with the Dario System. Replace the lancet with a different Dario Lancet. If the problem persists, you may need to replace the Dario Housing. Error! Reference source not found., for contact information please see page 89

Cannot remove the used needle from the lancing device.

The lancet may be faulty or you may be using a lancet that is not approved for use with the Dario

System. Pull the needle carefully and straight out from lancet.

Replace the lancet with a different Dario Lancet. If the problem persists, you may need to replace the Dario Housing. Error! Reference source not found., for contact information please see page **88**.

Lancing device does not operate correctly.

The lancing device spring or handle may be faulty. Ensure that you set the lancing device for activation by sliding it with two fingers until it clicks. Then, press the button to puncture your skin. For more information, refer to step 1 in Performing a Glucose Test on page **49**).

Lancet Depth Indicator lever is stuck.

The indicator lever may be faulty. Replace the Dario Housing. Error! Reference source not found., for contact information please see page **88**.

Lancing device release button does not work properly.

The lancing device is faulty. Replace the Dario Housing. Error! Reference source not found., for contact information please see page **88**.

"Strip is used and should be replaced" message appears in the Dario App.

This message appears if you receive an incoming call. It is recommended that you set your smart mobile device to airplane mode before performing a test.

I forgot my Dario password.

If you forget your password, tap on **FORGOT PASSWORD** on the **LOG IN screen**. You will receive

an email with instructions for resetting your password.

My smart mobile device battery died.

If the battery of your smart mobile device is out of power, charge your device or use a different device. Download the Dario App onto that device and login to your account.

CHAPTER 8
TECHNICAL INFORMATION AND SPECIFICATIONS

This chapter provides technical information about your Dario System.

How the Glucose Meter Works

The Dario System determines the amount of glucose in fresh capillary blood using electrochemical biosensor technology. An electrical current is generated by the reaction of glucose with the reagent on the test strip (glucose oxidase). The strength of the current produced by the reaction depends on the amount of glucose in the blood sample. The glucose meter detects the current and converts it into a blood glucose reading.

Compatibility

Dario is compatible for use on iOS and Android smart mobile devices. For a complete list of compatible devices, please refer to www.mydario.com/support/getting-started/.

Performance

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%)	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%)

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

Technical Specifications

Meter Specifications	
Result Range	20-600 mg/dL (1.1-33.3 mmol/L)
Calibration	Plasma-equivalent
Sample	Fresh capillary whole blood
Test Sample	0.3 microliter
Test Time	6 seconds
Assay Method	Glucose Oxidase Biosensor

Meter Specifications	
Hematocrit Range	20% - 60%
Operating Temperature	50°F-95°F (10°C-35°C)
Operating Relative Humidity	15-85%
Altitude	Up to 10,000 feet (3,048meters)
Memory	Unlimited results. Memory is limited to smart mobile device memory
Power Source	From the smart phone or mobile device
Meter Size	1.3 x 0.63 x 0.39 in (32.9 x 16.1 x 9.9 mm)
Weight	1.4 oz. (40 grams)
Meter Lifetime	5 years
Protection degree from ingress of water or particulate matter	IP 21
Meter part number	1021-02

⚠ Do not store near solvents and ionizing radiation sources.

Compliance with Electrical and Safety Standards

The Dario Blood Glucose Meter has been tested for:

• Electrostatic discharge as specified in IEC 61000-4-2.

- Immunity to radio frequency interference at the frequency range and test levels specified in IEC 61000-4-3.
- EMC and is in compliance with IEC 60601-1-2.
- Electro-magnetic emission requirements as per EN 61326

Disposing of Used Products

The product may come into contact with blood during measurement. Used products (i.e., test strips and lancets) therefore carry a risk of infection.

Please dispose of used products according to the regulations applicable in your state. For information about correct disposal, please contact your health care provider.

The product falls outside the scope of the European Directive 2002/96/EC (Directive on waste electrical and electronic equipment (WEEE)).

Information Security and HIPAA

Dario smart mobile device App has been tested within the iOS and Android development environment and has been determined to be malware free. The Dario meter shipped by the manufacturer is malware free. Dario glucose meter device does not connect to the mobile device wirelessly. Users are required to unlock their smart mobile device prior accessing the Dario App to take a glucose measure test, as such they are assured of ongoing authorization access.

The Health Insurance Portability and Accountability Act of 1996 ("HIPPA") privacy rule provides guidance on security standards for the protection of EPHI (Electronic Protected Health Information), Labstyle

Innovation Ltd. has performed a risk analysis and has implemented the standard and applicable security safeguards and is compliance with the HIPAA Security Rule and HITECH Act requirements for breach notification. Labstyle Innovation Ltd. ongoing compliance program includes policies and procedures for secure cloud operations.

Labstyle Innovation uses commercially reasonable standards of technology and operational security to protect users' glucose measurements data within the Dario App and cloud servers. Users data is stored and transmitted through the Dario App and/or web portal to and from the remote server in encrypted form.

We are committed to protect the security, confidentiality and privacy of personal data we collect from our users. To learn more about how we comply with GDPR, HIPAA and other Information Security regulations, please read our Privacy Policy at https://mydario.com/privacy-policy/.

CHAPTER 9
WARRANTY, REPAIRS AND SUPPLIES

This chapter provides repair, warranty, service support, and ordering information for your Dario System.

Repair Policy

When under warranty, repair must be performed by LabStyle Innovation Ltd. When the LabStyle Innovation Ltd. warranty is not applicable, repairs may be performed by LabStyle Innovation Ltd. on a parts and labor basis.

After replacement, verify that the unit is fully functional by performing the normal setup procedure.

⚠️ Do not remove the covers of the device components. Only perform maintenance procedures specifically described in this user guide.

Manufacturer's One Year Warranty

It is important to LabStyle Innovation Ltd. that you are completely satisfied with your Dario Blood Glucose Monitoring System. LabStyle Innovation Ltd. warrants that your new Dario will be free from defects in materials and workmanship for a period of one (1) year from the date of the original purchase. If during this time the Dario does not work properly because of a defect in materials or workmanship, LabStyle Innovation Ltd. agrees to replace or repair, free of charge, any and all parts proven to be defective and subject to warranty. This warranty is in lieu of all other warranties, expressed or implied, including any implied warranty of merchantability or

fitness for any purpose, other than stated herein. This warranty does not apply to the performance of a Dario Blood Glucose Monitoring System that has been damaged by accident or has been altered, misused, tampered with, or abused in any way. This warranty only applies to the original purchaser of the meter and/or its agents.

Supplies and Accessories

Dario System supplies and accessories are available from LabStyle Innovation Ltd. or from customer support.

Item	Catalog Number
System	1015-01 – Dario Welcome Kit 1146-05 – Dario Starter Kit 1173-05 – Dario BGMS and Dario Membership
Test Strip Cartridge	1120-05 – Dario Test Strip (1 x 25)
	1024-05 – Dario Test Strip (2 x 25)
	1074-05 – Dario Test Strip (4 x 25)
Lancet	1121-05 – Dario Lancet (1 x 100)
Control Solution	1054-05 – Dario Glucose Control Solution (2x2.5 ml)
Disposable Covers	1128-05 – Dario Disposable Covers (1 x 100)
Software	1022-01 – Smart mobile device application iOS 1022-02 - Smart mobile device application Android

Contact Customer Support

You may contact customer support with any questions or issues about Dario and its accessories using one of the following methods:

- By phone toll-free Monday to Friday, 9:00AM – 5:00PM EST at 1-800-895-5921.
- On the website at www.mydario.com.
- Through email by sending a message to mailto:support@mydario.com.

Please contact your health care provider for questions outside of the customer support hours.