



Dario™ User Guide



Thriving with diabetes

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BASIC INFORMATION

Please read this user guide thoroughly and feel free to contact our customer support (www.mydario.com) or your healthcare provider with any questions, concerns or remarks you may have.

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Dario™ is a trademark of LabStyle Innovations™ Ltd.

European Patent application number 11780305.6

US: Product is covered by one or more patents and /or patent applications – the list is detailed at the Dario™ website.

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DARIO

TABLE OF CONTENTS

CHAPTER 1 – INTRODUCTION & USER SAFETY

Glucose Monitoring for a Mobile Age	1
Intended Use	1
Contraindications	2
About These Instructions for Use	2
Before Testing With Dario™	2
Safety Definitions.....	2
Practices Used in This Advanced User Guide.....	3
Procedure Instructions	3
Symbols and Descriptions	4
General Precautions.....	5
Additional Information.....	5

CHAPTER 2 – DARIO™ SYSTEM OVERVIEW AND FEATURES

Your Dario™ System at a Glance	7
Dario™ Components.....	7
Dario™ Welcome Kit Contents.....	9
Getting Started With Dario™	9
Assembling Dario™ for the First Time	10
Inserting the Test Strip Cartridge	10
Inserting a Lancet	11
Setting Lancet Depth (Optional)	12
The Dario™ Application	13
Downloading & Installing the Dario™ Application.....	13
Creating Your Account & Personalizing Your Settings.....	14
Setting Your Personal Profile	15

CHAPTER 3 – CHECKING YOUR DARIO™ GLUCOSE METER

Control Solution	17
Control Solution Test Principle.....	18
Chemical Composition.....	18
Checking Your Glucose Meter With Dario™ Control Solutions	18
Removing the Glucose Meter From the Housing	18
Removing a Test Strip From the Cartridge	19
Performing a Control Test	21

CHAPTER 4 – TESTING YOUR BLOOD GLUCOSE LEVEL

Blood Glucose Testing Precautions	25
Test Strip Precautions.....	25
Factors That Interfere With Blood Glucose Testing	26
Interpreting the Results.....	27
Measurement Range	27

Factors That May Lead to Inaccurate Results.....	28
Step One - Inserting a New Lancet Into the Lancing Device.....	29
Step Two - Removing the Glucose Meter From the Housing	30
Step Three- Remove a Test Strip From the Cartridge	32
Step Four - Testing Your Blood Glucose	33
Step Five - Returning the Meter to the Dario™ Housing.....	36
Test Limitations	37
Performance Analysis	37
CHAPTER 5 – CLEANING AND MAINTENANCE	
Cleaning and Maintenance.....	39
CHAPTER 6 – TROUBLESHOOTING	
Troubleshooting	41
Problem Solving.....	42
CHAPTER 7 – TECHNICAL INFORMATION & SPECIFICATIONS	
How the Glucose Meter Works	46
Compatibility	46
Technical Specifications.....	47
Compliance with International Standards.....	46
Disposing of Your Meter.....	48
CHAPTER 8 – WARRANTY, REPAIRS SERVICE & SUPPLIES	
Repair Policy	49
Manufacturers One Year Warranty.....	49
Service Support	50
Supplies and Accessories.....	50
Contact Customer Support.....	51

CHAPTER 1 – INTRODUCTION & USER SAFETY

GLUCOSE MONITORING FOR A MOBILE AGE

Congratulations on your choice of the Dario™ Blood Glucose Monitoring System (BGMS). Dario™ was created to make life easier for people with diabetes - with the right tools, information and support in your pocket. It is a smartphone-based monitoring system, featuring a miniature 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 Dario™ in your pocket and the best support, we can thrive with diabetes.

This user guide will guide you through the proper setup and use of your new Dario™ BGMS. We suggest that you read this guide thoroughly in order to familiarize yourself with the system and its many features

INTENDED USE

Dario™ Blood Glucose Monitoring System (BGMS) is indicated for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips. The system is intended to be used by a single patient and should not be shared.

The Dario™ BGMS is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid in monitoring the effectiveness of diabetes control. The Dario™ BGMS is not to be used for the diagnosis of or screening of diabetes or for neonatal use.

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

CONTRAINDICATIONS

The Dario™ BGMS should *not* be used:

- To diagnose and screen diabetes.
- On children younger than four weeks old.
- To test blood taken from an artery or vein.

Glucose monitoring with the Dario™ BGMS is not recommended for independent use by people who are:

- Unable to follow the instructions provided with the system.
- Visually impaired.

ABOUT THESE INSTRUCTIONS FOR USE

Before Testing With Dario™

Please read this User Guide carefully and thoroughly before testing your blood glucose for the first time. These instructions will provide you with all the information you need for safe use and handling of your Dario™.

Incorrect use of this system, or failure to apply, implement or follow the instructions and important information contained in this User Guide, may lead to a misdiagnosis or damage to your device.

If you have any questions, please contact customer support at 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



Warning: indicates precautions needed to prevent possible risk of injury or damage to your health.

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

Cautions



Caution: indicates precautions needed 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 are used to provide additional information for the purpose of clarification.

Practices Used in This Advanced User Guide

Procedure Instructions

- When appropriate, procedures start with a “❖” symbol, followed by a short description of the procedure to be performed.
- Procedure instructions are clearly identified and presented as numbered procedure steps.
- If relevant, a system response is written below the procedure step and appears in italics.
- All procedures should be done 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
<i>Italics</i>	System response that occurs as a result of a button press
<i>Bold Italics</i>	Used to emphasize important information

SYMBOLS AND DESCRIPTIONS

The following table shows a list of symbols which may appear throughout this guide, on packaging or package inserts, or on the actual system parts. An explanation is provided next to each symbol.

Symbol	Description	Symbol	Description
	Dario™ logo		LabStyle Innovations™ logo
	Consult instructions for use		Do not use if seal is broken or missing
	In Vitro Diagnostic		Batch code
	Expiry date		Shelf life following first opening
	Do not reuse		Temperature limitation
	Catalogue number		Contents
	Manufacturer: LabStyle Innovations™ Ltd. 9 Haramish St. North Industrial Park Caesarea 3890000 Israel		Authorized Representative in the European Community; MDSS GmbH Schiffgraben 41 30175 Hannover, Germany
	Intended for self-testing		Sterilized using Gamma Radiation
	Keep away from sunlight		Keep Dry

Symbol	Description	Manufacturer
	Dario™ Blood Glucose monitoring system Under Directive IVDD 98/79/EC	LabStyle Innovations™ Ltd.
	Dario™ Lancing Device Under Directive MDD 93/42/EEC	LabStyle Innovations™ Ltd.
	Sterile Lancets (25) Under Directive MDD 93/42/EEC	Gentrol Co., Ltd.

GENERAL PRECAUTIONS

This section informs you of potential hazards which may harm your Dario™ system or cause it to not function properly:

Avoid using any system parts with broken seals or expired “use by” 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 Dario™ should only be done in temperatures between 10°C - 45°C (50°F - 113°F). Test results may not be correct if the room temperature is outside this range.
- Changes or modifications to the Dario™ system not expressly approved by LabStyle Innovations™ Ltd. will void your warranty and could cause you harm.
- Avoid testing with your Dario™ system in altitudes higher than 11,155 feet (3,400 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 or use meter or test strips in high humidity, such as a bathroom or kitchen.
- 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 biohazardous and can potentially transmit infectious diseases, even after you have performed cleaning and disinfection.

ADDITIONAL INFORMATION

For your safety, please observe the following recommendations when monitoring your blood glucose using the Dario™ system:

- It is always a good idea to have a back-up testing method available. Failure to test could cause a delay in treatment decisions and lead to a serious medical condition. Examples of back-up testing methods include a back-up glucose meter device or testing by a laboratory. Ask your healthcare provider about other possible back-up methods.
- It is recommended that you periodically compare the test results from your Dario™ BGMS with another laboratory test system that is well-maintained and

monitored by your healthcare provider.

- Do not change your treatment based on a single result that does not match how you feel or if you believe that your test result could be incorrect.
- Never make significant changes to your diabetes control program or ignore physical symptoms without consulting with your healthcare professional.

CHAPTER 2 – DARIO™ SYSTEM OVERVIEW AND FEATURES

This section provides an overview of the Dario™ system components and how it is set up for the first time.

YOUR DARIO™ SYSTEM AT A GLANCE

Dario™ is a cloud-based, diabetes management solution that includes novel software applications combined with the stylish, 'all-in-one', compact, Dario™ Smart Meter (all in one: lancing device, strip cartridge and mini meter). Together with a smart mobile device Dario™ is the absolute Diabetes Management Solution, allowing one to monitor and gain insights with the information needed to manage blood sugars in one's pocket every step of the way.

The Dario™ Personalized Smart Meter Dario aims at providing the precise combination of Tools, Knowledge and Motivation through a compact, personalized pocket-sized, all-in-one glucose meter. Patients can check their blood glucose with a tiny sample of 0.3 µl of their blood and get answers within 6 seconds, the same way they check everything else in life - on their mobile device.

Dario connects to smart mobile devices via an easy-to-use mobile app that provides real-time and actionable information so that your patients always know exactly where they stand and what to do next. Dario logs and tracks their glucose levels, and helps them know how food intake and exercise are affecting their diabetes. Dario also alerts you, the caregiver, when your patients need special attention.

Dario™ Components

Your Dario™ system components are described in the table below.



Component	Description
Glucose meter A Dario™ Meter B Dario™ meter release panel	The miniature glucose meter has: <ul style="list-style-type: none"> · An audio connector that is plugged into the headphone socket of the smart mobile device · A strip port for insertion of the test strip. The glucose meter receives its power from the mobile device and 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.
Lancing Device and Cover C Orange cover D Disposable lancet E Lancet release button F Lancet loader G Depth selector 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. Lancets are changed for each use. Puncture depth may be adjusted, by removing the cover and moving the depth selection dial. The cover is then put back on for use. The lancing device is activated by sliding it with two fingers until it clicks and then pressing the release button. Instructions on using the lancing device are included in Testing your Blood Glucose Level on page 18
H Test Strip Cartridge	Test strip are sold separately in packages of 25, 50, and 100 test strips. Each test strip cartridge holds 25 strips. The cartridge snaps into the modular Dario™ housing.
Test Strip	The Dario™ test strip is the only strip which may be 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	Dario™ uses a 30G lancet. The lancet is replaced by removing the orange lancing device cover, pulling out the used lancet and replacing it with a sterile one.



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

DARIO™ WELCOME KIT CONTENTS



Once you remove the tamper-proof sealed exterior packaging, you will find a white package. If the tamper-proof seal is missing, it is recommended that you return this Dario™ System to where you purchased it, as it has been opened.

As soon as you receive your Dario™ System Welcome Kit:

1. Carefully unpack the kit and verify that it contains the following parts:
 - Dario™ System including Lancing Device and built in Blood Glucose Meter
 - Sterile Lancets (25 lancets)
 - Documentation: User Instructions for Use and a Quick User Guide.
2. If anything is missing, please contact customer support at www.mydario.com/support/contact/.
3. Test strips and Lancets are available in your local pharmacies. For additional information please contact your local representative (www.mydario.com/support/contact/).
4. Additional Dario™ accessories (i.e. Control Solution) can be ordered via your local representatives or the Dario™ App.

For details on the products availability please refer to section Supplies and Accessories

GETTING STARTED WITH DARIO™

Your Dario™ meter works seamlessly with your smart mobile device. Simply download the Dario™ application on your 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, so you can stay in control of your health.

Your data is saved under your username on your smart mobile devices and on the Dario™ cloud, with easy access through the Dario™ application and also My Dario™ website.

So let's get started!

ASSEMBLING THE DARIO™ FOR THE FIRST TIME

Setting up the Dario™ for the first time includes the following steps described in this section:

- Inserting a test strip cartridge (see [“Inserting the Test Strip Cartridge” on page 10](#))
- Inserting a lancet (see [“Inserting a Lancet” on page 11](#))
- Setting lancet depth (optional) (see [“Setting Lancet Depth \(Optional\)” on page 12](#))
- Downloading the Dario™ application to your smart mobile device (see [“Downloading & Installing the Dario™ Application” on page 13](#))
- Setting up the Dario™ application on your smart mobile device using the Dario™ app instructions or the instructions provided on the Dario™ website.



Both ends of the housing have covers that are removable. The lancet cover is orange with the small opening. Please 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:

Remove the carbon paper from the device and open the white cover

1. Remove the new test strip cartridge from its pouch.
2. Hold the test strip cartridge with the side that opens, facing up (as shown below).



3. Insert the cartridge into the housing until it snaps into place.

4. Replace the housing cover by sliding it into place until it clicks.



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

Inserting a Lancet

❖ To insert a lancet:

1. Remove the Lancet Device Cover (the Orange cap) from the Dario™ housing.



2. Remove a new lancet from the packaging.

3. Insert a sterile lancet as far as it will go and make sure it is firmly set.



4. Carefully twist off the lancet cap. Make sure not to bend the lancet while removing the cap.

Setting Lancet Depth (Optional)

The depth of the lancet, as it punctures the skin of your fingertip, can be adjusted by moving the lever between the numbers one to four (printed on the dial). One (1) is the shallowest depth and (4) is the deepest. It is recommended to start with your lancet depth set to level one and adjust the level 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.



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



THE DARIO™ APPLICATION

The Dario™ is compatible on both iOS and Android operating systems. For full list of compatible devices please refer to www.mydario.com/supprt/getting-started.

Your Dario™ meter is operated via the app displayed on the screen of your smart mobile device. The mobile device receives information from the glucose meter, displays and stores it. The app also provides a step-by-step Quick Guide for operating the system. Additionally, you can find more instructional videos on the Dario™ Application at www.mydario.com/support/getting-started.

Instructions for downloading the app are provided in the next section.

Downloading & Installing the Dario™ Application

You can download and install the Dario™ app to your smart mobile device using the Apple App Store or Google Play. The app is downloaded and installed the same way as other Apps on your smart mobile device. The Dario™ app is free of charge and is customized for your smart mobile device.



Downloading the app from the App Store 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 on your device, please refer to the support materials for the device.

❖ To download the Dario™ App:

1. Turn on your smart mobile device and launch the App Store app. Alternately, for quicker access, you can use an app that scans codes to scan the following code.



2. Search for the Dario™ app by LabStyle Innovations™ Ltd (Health & Fitness category) and tap on the Dario™ icon.
3. Tap Free and then tap Install.
4. Enter your password information as required in your device.

The application downloads. Once installed, the orange Dario™ icon appears on your smart mobile device home screen.



The Dario™ app needs to be installed once for each of your smart mobile devices.



Updates may be downloaded periodically from the App Store/Google Play.

Creating Your Account & Personalizing Your Settings

❖ To setup your Dario™ App:

1. After installing the Dario™ app on your mobile device, click on the orange Dario™ icon . The icon appears on your mobile device Home screen.

The Dario™ screen appears.

2. Select Get Started to register as a Dario™ user. You can connect with Facebook or alternatively sign up by inputting your name, phone number, email, and password. You must also confirm your Password.
3. Continue by following the instructions on the screen to sign up.



Your password must have at least seven characters, an upper case letter, a lower case letter and a number.



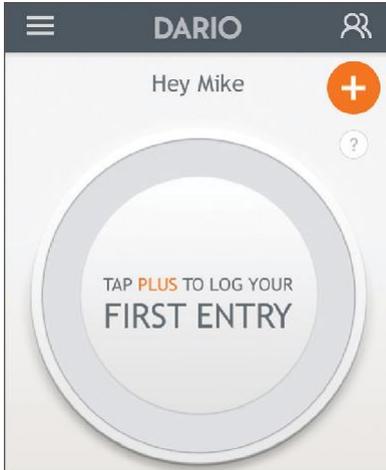
Your e-mail address and password will be used for future login to the app and to the Dario™ web-portal.



If you already have a Dario™ account, you may skip this section by tapping Log in at the bottom of the screen.

4. Press Create Account when done.

The First Entry screen appears.



You can edit your e-mail address and password and set the Dario™ app language and region by going to the menu and then selecting **SETTINGS > ACCOUNT SETTINGS**.

Setting Your Personal and Diabetes Profiles

❖ To set your personal profile:

1. Tap the Menu icon  on the top left corner and selecting **SETTINGS > PERSONAL SETTINGS**.
2. Tap the pencil on the upper right corner to edit the information.
3. Enter your Gender, Weight, Height and Date of Birth. It is also possible to upload a photo from your device by tapping **UPLOAD PHOTO**.
4. Press **DONE**.

❖ To set your diabetes profile:

1. Tap the Menu icon  on the top left corner and selecting **Hey > DIABETES PROFILE**.

2. Tap the pencil on the upper right corner to edit the information.
3. Select your preferred Carbs measurement unit
4. We advise you to continue setting your Diabetes Profile, following the app instructions. Completing your profile will allow full app functionality.



You can do the Walkthrough at any time by tapping the  icon.
Select HELP&INFO > APP WALKTHROUGH.



CHAPTER 3 – CHECKING YOUR DARIO™ GLUCOSE METER

This section 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 does not match the way 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 a meter and test strip.

CONTROL SOLUTION

The Control Solution confirms that the meter and test strips are performing as expected. A drop of control solution is placed on a test strip (using a piece of paper). Compare the results on the meter with the values displayed on the test strip cartridge.

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

- Avoid contact with the eye. Contact your healthcare professional immediately if solution is swallowed, injected, or applied to the eye.
- Dye in control solution may stain skin, clothing, or surfaces.
- Store the control solution between 8°C-30°C (46°F-86°F). Keep away from direct sunlight, fluorescent light, and heat. Do not freeze.
- Once you open a new bottle of control solution, mark the opening date on the bottle.
- Make sure that your control solution has not expired. Check the expiration date on the bottle.
- Make sure that your control solution was not opened more than 3 months ago.
- Keep the control solution away from children.
- Shake the control solution well before using.
- Wipe the container tip clean after use and be sure to close the container tightly after each use.

- No reconstitution or dilution of the control solution is necessary.

Control Solution Test Principle

Dario™ Glucose Control Solution contains a known amount of glucose that reacts with chemicals on the Dario™ test strip.

When applying a drop of control solution to the test strip, following the same procedure that is used for whole blood, 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. Obtaining a single result within the expected range is sufficient to verify system performance. A result outside the range printed on the Test Strip cartridge label may indicate the system is not performing correctly.



This control solution is not for use as a cleaning solution.

Chemical Composition

Dario™ Glucose Control Solution is an aqueous solution, which contains D-glucose as the reactive ingredient in the approximate concentration.

- Buffer 75mM
- Polyvinylpyrrolidone 5%
- Polyvinyl alcohol 5%
- SDS 0.1%
- Preservative 0.1%

CHECKING YOUR DARIO™ GLUCOSE METER

The following steps are required to perform a control solution test.

Removing the Glucose Meter from the Housing

Before performing a control solution test, it is necessary to remove the glucose meter from the housing.

The glucose meter is stored in the housing when not in use.



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 three (3) minutes, as it can get warm and can affect accuracy.

❖ 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. *The meter will pop up.*



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



Do not plug the Dario™ meter into any device other than a compatible smart mobile device audio socket. The list of compatible smart mobile devices is provided on 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, please go to [Inserting the Test Strip Cartridge on page 11](#).

- ❖ 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).



2. Snap open the case by pushing up the edge.
3. Remove a test strip from the cartridge.



4. Snap the case closed immediately and replace the cartridge cover by pushing it into place until it clicks.



It is recommended to use the test strip immediately after removing it from the cartridge. It is recommended *not* to 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.

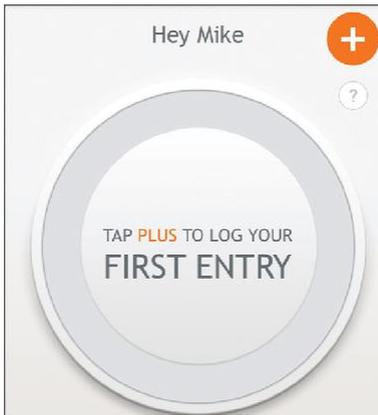


- Do not touch the yellow testing site when handling the test strip.
- Do not use a damaged test strip.

Performing a Control Test

❖ To perform a control test.

1. Tap the Dario™ icon on your smart mobile device to launch the Dario™ application.



2. Insert your meter into the audio plug of your smart mobile device.



the Dario™ meter direction (logo facing up)



the screen notification changes

A Connecting... message appears, followed by INSERT A NEW STRIP.



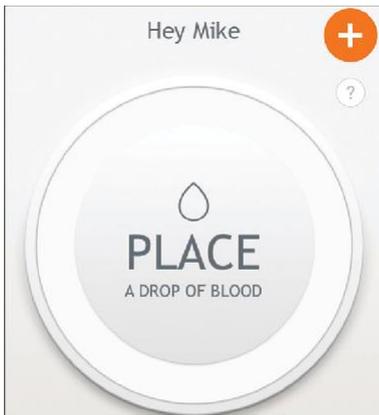
Verify that the meter is inserted as far as it can go into the socket of the smart mobile device.

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 to the left

You are instructed to place a drop of blood on the test strip.



5. Shake the control solution container and apply a drop of control solution to a piece of paper.
6. Hold the paper and move it so that the solution touches the tip of the yellow window of the strip.
7. **Important:** Verify that enough control solution is applied to fill the window so

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

When the meter detects that the solution was applied, the “Measuring...” message appears. The orange rotating in the circle indicates that the test is in progress.



8. The test result appears on the screen after six (6)seconds. Read your result and look at the test strip .

The glucose test result is automatically saved to memory. The result appears on the screen and is automatically saved to memory.



It is possible to delete this control test from memory, if desired.
For more information, refer to the Dario™ Application User Guide at www.mydario.com.

9. When the test is done, remove the test strip.
10. Compare the results on the meter with the values displayed on the test strip cartridge.
11. If the results are:
 - within the acceptable range, then your meter is ready for use.
 - outside of the acceptable range, perform the test again. If the problem recurs, contact customer support at www.mydario.com.
12. Disconnect the meter from your smart mobile device.
13. Wipe the tip of the control solution container clean and tightly seal the container.



The Dario™ Glucose Control Solution ranges printed on the test strip cartridge label are intended for the Dario™ test strip cartridge only.



The glucose concentrations in these solutions, when measured by systems other than Dario™ Glucose Monitoring System, 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™ Glucose Monitoring System to test your blood if your control solution result falls outside of the acceptable range.

14. Place the meter back into the housing:

- a. Hold the meter at an angle with the part that connects to the smart mobile device facing away from the ridged orange panel.
- b. Push the meter into the housing at an angle and then push downwards until the meter clicks into place.



CHAPTER 4 – TESTING YOUR BLOOD GLUCOSE LEVEL

The glucose meter in Dario™ measures the amount of glucose in your blood. Once placing a small drop of blood from your fingertip onto the test strip, the result will be displayed in six (6) seconds.

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 in order to prevent an incorrect result or improper treatment.



Do not put any fluid into the test strip port.

Once you start your Dario™ app, follow the prompts on the screen.

BLOOD GLUCOSE TESTING PRECAUTIONS



The meter, test strips, and control solutions are only 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.



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



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

Incorrect test results can cause the wrong therapy recommendation to be made and may lead to serious adverse health effects. Therefore, please follow these instructions carefully.

Test Strip Precautions

- Only use Dario™ test strips. Using other test strips with this 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.

- 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 keep the test strips dry.
- Be sure to check the “Use by” date on the test strip cartridge. Do not use the test strips after that date.
- Be sure to write down the date the strips were first opened. Check the date when using the strips. If the date surpasses the shelf life after first opening, do not use the strips from this cartridge.
- 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 2°C (36°F) or above 32°C (90°F).
- Do not refrigerate your open test strip cartridges. Do not put them in a freezer.
- Do not expose your test strips to direct sunlight, moisture or humidity, which can damage your test strips and lead to inaccurate results.
- 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 material on the test strip.
- It is recommended to use the test strip immediately after removing it from the cartridge. It is recommended *not* to 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 anything else. These items 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 falsely high results. For more information, refer to the test strip package insert. If you are taking medication or dietary supplements, consult you

healthcare professional.



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, diabetic ketoacidosis). Certain health conditions, such as serious illness and dehydration, can cause falsely high test results in glucose meters. If you are very sick or think you are dehydrated, or are urinating frequently, call your doctor immediately.



Dirty or wet hands could affect your results. Alcohol can affect test results.

INTERPRETING THE RESULTS

If the displayed test result reflects the way you feel, continue as instructed by your doctor.



If the test result does not reflect the way you feel, please check your Dario™ system by running a control solution check ([Performing a Control Test on page 21](#)). Repeat the blood glucose test afterward. If your blood glucose result still doesn't match how you feel and you have followed the instructions provided here, follow your healthcare provider's instructions.



Do not change your treatment based on a single result that does not match 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™ BGMS should not be the only information you use to make decisions about your health. Always consult a health care professional to interpret and understand the measurement results.

MEASUREMENT RANGE

Your meter measures blood glucose results in the range of 0.5-33.3 mmol/L. Results that are outside of this range should be reviewed according to the procedure below.

- If your test result is lower than 0.5 mmol/L, "LOW!" is displayed instead of a result.



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

- If the result is higher than 33.3 mmol/L, “HIGH!” is displayed instead of a result.
- If your blood glucose test results in a LOW or HIGH message, repeat the blood glucose test following all of the instructions provided in [“Step Four - Testing Your Blood Glucose” on page 33](#).
- If your blood glucose test results in a LOW or HIGH message a second time, follow the protocol established by your health care professional or contact your healthcare provider immediately.
- Please note that the exact blood glucose reading that constitutes a HIGH or LOW reading depends on many factors, including individual differences, and the time since your last meal.

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™ may also lead to implausible test results which don’t match the way you feel. These include:

- 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 allowed time.
- Test strips were stored incorrectly.
- Testing was done in a humid environment (for humidity specifications, refer to [Technical Specifications on page 45](#)).
- Your glucose meter has been dropped.



If your meter has been dropped and you are receiving error messages or implausible results, contact customer support.



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

STEP ONE - INSERTING A NEW LANCET INTO THE LANCING DEVICE



Use a new sterile lancet in your lancing device every time you test your blood glucose to prevent infection.

❖ To insert a lancet:

1. Remove the Lancet Device Cover from the Dario™ Housing.



The lancet cover is the orange cover.



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



Dispose of used lancet in a safe manner so as not to cause accidental injury.



3. Remove a new lancet from the packaging.



Do not use the lancet if the cap is missing or damaged. Please contact customer support at www.mydario.com.

4. Insert a sterile lancet and make sure that it is firmly in place.



- It is recommended to use LabStyle Innovation™ (30G).
- If the lancet does not click into place or the lancet holder does not hold the lancet properly, insert another sterile lancet.
- If the problem persists, it may be necessary to replace your Dario™ housing. Contact Customer Support at www.mydario.com.



5. Carefully twist off the lancet cap as shown above. Make sure not to bend the lancet needle.
6. If necessary, set the depth of the lancing device. For additional information, see [Setting Lancet Depth \(Optional\) on page 12](#).
7. Replace the lancing device cover by sliding it into place until it clicks. Be careful not to touch or bend the lancet.

STEP TWO - REMOVING THE GLUCOSE METER FROM THE HOUSING

Before starting the testing procedure, you should remove the meter from the housing.

The meter is stored in the housing when not in use.

❖ 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 arrow direction.
The meter will pop up.



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



Do not plug the Dario™ meter into any device other than a compatible smart mobile device audio socket. The list of compatible smart mobile devices is provided on www.mydario.com/supprt/getting-started.



Tap the Dario™ icon on your smart mobile device to launch the Dario™ application before you connect the Dario™ meter.

4. Insert your meter into the audio plug of your smart mobile device. Verify that the meter is inserted as far as it can go into the socket of the smart mobile device.

A Connecting... message appears, followed by INSERT A NEW STRIP.



the Dario™ meter
direction (logo facing up)



the screen notification
changes

STEP THREE- REMOVE 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, please go to [Inserting the Test Strip Cartridge on page 10](#).

1. Wash your hands with warm soapy water and dry thoroughly. If you use alcohol wipes to cleanse fingers, make sure the area is completely dry before lancing finger.
2. Remove the Cartridge Cover of the Dario™ housing by pushing it outwards until it comes off (use the removal indication lines).



3. Open the lid by pushing up the edge.



4. Remove a test strip from the cartridge.



5. Close both the lid and cartridge cover.



If the cover does not close properly, the cartridge may not have been inserted 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. *You are instructed to place a drop of blood on the test strip.*



Verify the test strip direction as shown to the left



STEP FOUR - TESTING YOUR BLOOD GLUCOSE

Testing Information and Guidelines

- The meter requires only a small drop of blood, about the size of a sugar grain (0.3µL) at least, to perform the test. For best results, select a puncture site along the side of a fingertip.
- While applying blood to the test strip you should verify that enough blood is applied to fill the window so that it turns completely red.
- Testing blood from sites other than the fingertip may give inaccurate results.
- If too little blood is applied to the test strip, an alert informs you that your sample size is too small and you should try again with a new strip.
- If a test strip error occurs, perform another test with a new test strip.
- Blood glucose results are automatically saved to memory. The results remain on

the screen for 15 minutes.

- If an error message or symbol appears on the screen, refer to [Chapter 6 – Troubleshooting on page 40](#) for additional information.
- Dirty or wet hands could affect your 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 three (3) minutes, as it can get warm and can affect accuracy.*



To prevent malfunction of the meter, keep the test strip port free of blood, moisture, dirt, or dust.

Performing a Glucose Test

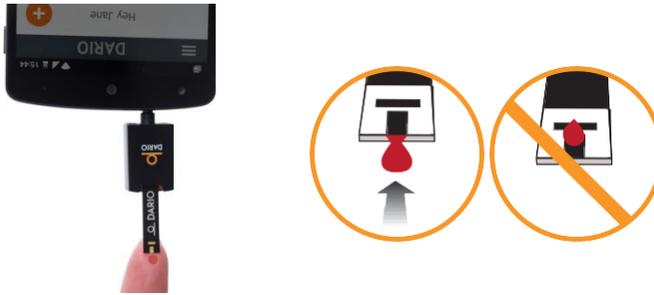
1. Set the lancing device for activation by sliding it with two fingers as far as it goes.



2. Place the fingertip orange lancing device cover to the side of your and press the release button to prick your finger



3. Apply a drop of blood to the tip of the yellow window of the test strip. Capillary action will pull the blood into the strip.



Important: Verify that enough blood is applied to fill the window so that it turns red. Do *not* put blood on top of the test strip.

When the meter detects that blood has been applied the “Measuring...” message appears. The border of the circle is gradually filled with orange, indicating that the test is in progress.



6. Remove your finger from the strip once the message appears.



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

4. The test result appears on the screen after approximately six (6) seconds. Read your result.

The glucose test result is automatically saved to memory. If for some reason you do not see a result, go to your Logbook.



If a phone call is received during a measurement, the test will be stopped and will not be saved. A message test strip is used will appear on the result screen.

5. When the test is done, remove the test strip. Dispose of the test strip in accordance with instructions provided by your healthcare professional for bio-hazardous waste.
6. Remove the lancet from the lancing device (see [page 29](#)). Dispose of the used lancet according to local guidelines.

When the test strip is removed from the glucose meter, the message “Please insert new test strip” appears.

7. You may continue to input data into your Dario™ application.
8. Return the meter to the housing as described in the next section.

STEP FIVE - 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 a angle with the part that connects to the smart mobile device 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 LIMITATIONS

Normal endogenous (within body) natural levels of uric acid, ascorbate (vitamin C), bilirubin, triglycerides, and hemoglobin do not interfere with your blood glucose results. Elevated levels of these compounds in your blood may, however, interfere with the accuracy of your blood glucose results obtained with the Dario™ System. The system should not be used if blood levels of these compounds exceed the limitations detailed in the table below.

Compound	Limitation
Ascorbic acid	> 4 mg/dL
Uric acid	> 5 mg/ dL
Acetaminophen	> 6 mg/dL
Total bilirubin	> 35 mg/dL
Triglycerides	> 810 mg/ dL

The drugs L-dopa, dopamine, methyl-dopa, acetaminophen, and ibuprofen will not interfere with Dario™ system blood glucose results when taken at therapeutic concentrations.

Patients undergoing oxygen therapy may yield false results.

PERFORMANCE ANALYSIS

User performance study was conducted with 193 people with Diabetes using Dario™ and three Dario™ test strips lots. Results were compared to YSI® analyzer. The table below compares the accuracy of the two methods. Acceptance criteria in ISO15197:2013 are Ninety-five percent (95%) of the measured glucose values shall fall within either ± 0.83 mmol/L of the average measured values of the reference measurement procedure at glucose concentrations < 5.5 mmol/L or within $\pm 15\%$ at glucose concentrations ≥ 5.5 mmol/L.

Accuracy: Dario™ BGMS					
for glucose concentrations <5.5 mmol/L			for glucose concentrations ≥ 5.5 mmol/L		
Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L	Within ± 5 %	Within ± 10 %	Within ± 15 %
23 / 45 (51.1%)	39 / 45 (86.7%)	45 / 45 (100.0%)	65 / 148 (43.9%)	113 / 148 (76.4%)	142 / 148 (95.9%)

Dario™ BGMS was tested on 210 people using capillary blood samples and three Dario™ test strips lots. Results were compared to YSI® analyzer. The table below provides summary of the intermediate precision.

Intermediate Precision: Dario™ BGMS			
Glucose Concentration range	1.67-2.78	5.33-8	15.55-23.33
Average, mmol/L	2.69	5.77	16.42
Standard Deviation, mmol/L	0.129	0.17	0.4
Coefficient of Variation, %	4.8	2.9	2.4
Max	3.16	6.33	17.78
Min	2.33	5.39	15.55
Max-Min	0.83	0.99	2.22

CHAPTER 5 – CLEANING AND MAINTENANCE

This section provides cleaning and disinfecting information for your meter.

Since you are the only person operating your personal Dario it is recommended that you disinfect the device once a week. If a care taker is assisting you with blood glucose testing or they disinfect the device, they should wear gloves to protect themselves when handling the meter.

CLEANING AND DISINFECTING

The outer surfaces may be cleaned when you feel that your Dario™ is visibly dirty. It is advised to disinfect your Dario™ once a week to avoid transmitting bloodborne pathogens.

Wipe the Dario™ Blood Glucose Monitoring System with disinfecting, germicidal wipes (GermiCide3 by GERMIPHENE)

1. Before disinfecting your Dario™ take out the test strips cartridge from the device.
2. Before you clean and disinfect your Dario™ pre-clean the outside with a disinfecting wipe.
3. With a new disinfecting wipe, disinfect your Dario™, using the GermiCide3 wipes. In addition, follow the instructions on the disinfecting wipe container label for safe handling of the wipes.
4. Wipe each side of your Dario™, with moderate pressure 3 times using the following method:
 - a. Wipe the Dario™ up and down 5 times
 - b. Wipe the Dario™ left and right 5 times
 - c. Avoid getting disinfectant inside the test strip port
5. After 3 minutes of contact time, let air dry

You should wash your hands thoroughly with soap and water after handling the Dario™.

If you have any questions about cleaning and disinfecting your Dario™ contact Customer Support at support@mydario.com

Do not:

- Get any moisture in the test strip.

- Spray any cleaning solution directly onto the glucose meter or the lancing device
- Submerge any part of the Dario™ 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:



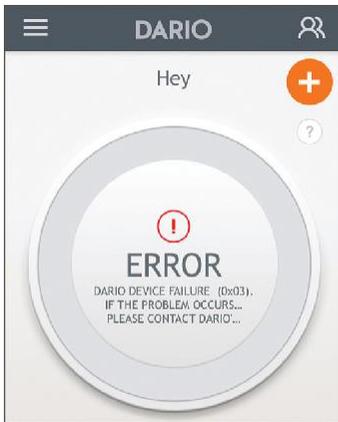
If the device becomes wet, wipe off all moisture and allow sufficient time for drying before using.

CHAPTER 6 – TROUBLESHOOTING

In this chapter you will find information about all the symbols and error messages which may be displayed on the Dario™ app. To ensure safe and accurate use of Dario™, please pay attention to all symbols and messages when you use the system. They provide you with important information.

If you still have questions after reading this chapter, contact customer support at www.mydario.com.

An error message can appear as a popup or as a message within the main circle.



TROUBLESHOOTING

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

Message Content	Possible Cause / Recommended Action
to reconnect your Dario. If the problem recurs, some adjustments might be required. Check the following settings on your device:	<p>Smart device volume setting inappropriately.</p> <p>Follow the instructions on the app to adjust the settings in your mobile device:</p> <ol style="list-style-type: none"> 1. Make sure that Mono Audio is set to off: <ul style="list-style-type: none"> · Verify that Mono Audio is set to off. 2. Adjust the audio balance: <ul style="list-style-type: none"> · The audio volume balance must be set in the middle between L and R. 3. Make sure that your Ringer and Alerts volume is set to the maximum: 4. Allow Dario™ to use your microphone: 5. Make sure that your music volume is set to the maximum
Insufficient blood detected, try again with a new strip	<p>Not enough blood on the strip.</p> <p>Repeat the measurement with a new strip.</p>
The Strip is used, please insert a new strip	<p>A strip was used more than once.</p> <p>Perform a new measurement with a new strip</p>

Message Content	Possible Cause / Recommended Action
High! Measure with a new strip, if recurs contact your physician Immediately	<p>High glucose level.</p> <p>Measurement result is above 33.3 mmol/L. Repeat the measurement with a new strip. If this recurs, contact your physician Immediately. If your measurement results are inconsistent with the way you feel, contact customer support at www.mydario.com.</p>
Temperature out of range. Move to an area between 10-45°C (50°-113°F), wait 30 minutes and try again	<p>The meter was left in an extreme temperature environment.</p> <p>Move to a cooler or warmer area, wait at least 30 minutes and repeat the measurement with a new strip.</p>
Dario™ device failure (0x00). If the problem occurs again, please contact Dario™'s customer support	<p>Communication failure.</p> <p>Contact customer support at www.mydario.com/support.</p>
Dario™ device failure (0x01). If the problem occurs again, please contact Dario™'s customer support	<p>Firmware software failure.</p> <p>Contact customer support at www.mydario.com/support.</p>
Dario™ device failure (0x02). If the problem occurs again, please contact Dario™'s customer support	<p>Voltage Failure</p> <p>Contact customer support at www.mydario.com/support.</p>
Unknown device, please connect Dario™	<p>Another device is inserted into the smart mobile device's audio connector.</p> <ul style="list-style-type: none"> · If another device is connected to the earphone plug, disconnect it in order to connect Dario™. You can still use the Dario™ app if another device is connected. · If you received this message while the Dario™ meter is connected, disconnect and reconnect the meter. If this message still appears, contact customer support at www.mydario.com/support.
Hypo warning	<p>Hypoglycemia event occurred</p> <p>You received a measurement result lower than defined in the hypo warning section under Blood Glucose Thresholds in your Diabetes Profile. Contact your physician immediately.</p>

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 strip or meter is defective.

- Repeat the measurement, using a new test strip.
- Check the meter with control solution (see [Checking the Glucose Meter on page 18](#)). If the result is not okay, contact customer support at www.mydario.com/support. If the result is okay, test with a new test strip.

Cannot pierce skin with lancet.

- The needle depth may be incorrect. Adjust the lancet depth lever to a different depth level.
- The lancet needle may be bent. Replace the lancet.
- 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. Contact customer support at www.mydario.com/support.

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.

Lancing Device does not operate correctly.

The lancing device spring or handle may be faulty. Make sure that you set the lancing device for activation by sliding it with two fingers until it clicks (see [page 33](#)). Then you can press the button to puncture your skin.

Lancet Depth Indicator lever is stuck.

The indicator lever may be faulty. Replace the Dario™ housing. Contact customer support at www.mydario.com/support.

Lancing Device release button does not work properly.

The lancing device is faulty. Replace the Dario™ housing. Contact customer support at www.mydario.com/support.

“Strip is used and should be replaced” message appears.

An incoming phone call during blood testing will result in this message appearing. It is recommended to set your smart mobile device to flight mode before performing a test.

Forgotten Dario™ password.

If you forget your password, tap on FORGOT PASSWORD in the LOG IN screen. An email with instructions for resetting your password will be sent to you.

My smart mobile device battery died.

If the battery of your smart mobile device is out of power, use a different device. Download the Dario™ application and login to your account.

CHAPTER 7 – TECHNICAL INFORMATION & SPECIFICATIONS

This section provides technical information on 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 smart mobile devices. For full list of compatible devices please refer to www.mydario.com/support/getting-started/

TECHNICAL SPECIFICATIONS

Meter Specifications	
Result Range	0.5-33.3 mmol/L
Calibration	Plasma-equivalent
Sample	Fresh capillary whole blood
Test Sample	0.3 microliter
Test Time	6 seconds
Assay Method	Glucose Oxidase Biosensor
Hematocrit Range	20% - 60%

Power Supply	Powerless
Glucose Units	mmol/L
Dimensions	104x211x11 mm (4.1x8.3x.4 in)
Weight	40 gram (1.4 oz)
Memory	Unlimited results Memory is limited to smart mobile device memory
Average	7-day, 14-day or 30-day averaging
Display	Dario™ application on a smart mobile device screen
Function	Hypo warning: Set by user.
Glucose Meter/Lancing Device	
Operational Temperature	10°C-45°C (50°F-113°F)
Storage Temperature	-40°C-85°C (-40°F-185°F)
Altitude	Up to 11,155feet (3,400 meters)
Test Strip	
Operational Temperature	10°C-45°C (50°F-113°F)
Storage Temperature Strip	2°C-32°C (36°F-90°F)
Operational Altitude	Up to 11,155feet (3,400 meters)



Do not store near solvents and ionizing radiation source.

COMPLIANCE WITH INTERNATIONAL STANDARDS

This meter meets the electromagnetic immunity requirements as per EN ISO 15197. The chosen basis for electrostatic discharge immunity testing was basic standard IEC 61000-4-2. In addition, it meets the electro-magnetic emissions requirements as per EN 61326. This meter complies with the applicable standards for Electromagnetic Compatibility; however it is not recommended that it be used in the presence of strong electromagnetic fields. When using this meter, keep away from sources of electromagnetic disturbances such as electric motors or radio transmitting equipment. This meter should not affect the normal operation of other devices. If this does occur, provide more distance between the meter and the affected device. Your meter is an electronic device. When disposing of your meter follow all local environmental regulations

DISPOSING OF YOUR METER

The product may come into contact with blood during measurement. Used products therefore carry a risk of infection.

Please dispose of used products according to the regulations applicable in your country. For information about correct disposal, please contact your local council or authority.

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

CHAPTER 8 – WARRANTY, REPAIRS SERVICE & SUPPLIES

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

REPAIR POLICY

When under warranty, repair and service must be performed by LabStyle innovations™ Ltd. When the LabStyle innovations™ warranty is not applicable, repairs may be performed by LabStyle innovations™ 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.

MANUFACTURERS ONE YEAR WARRANTY

It is important to LabStyle innovations™ Ltd. that you are completely satisfied with your Dario™ BGMS. LabStyle innovations™ Ltd. warrants 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 innovations™ 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™ BGMS 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.

SERVICE SUPPORT

Repairs of the Dario™ System under warranty must be made at authorized repair centers. If the device needs repair, contact LabStyle Innovations™ Ltd. customer support or your local distributor www.mydario.com/support.

If you need to ship the device, please pack the device and its accessories carefully to prevent shipping damage.

SUPPLIES AND ACCESSORIES

Dario™ BGMS supplies and accessories are available from LabStyle Innovations™ Ltd. or from your local distributor. For a list of distributors, please visit www.mydario.com.

Item	Catalog Number
System	1015-01
	Dario™ Welcome Kit
Test Strip Cartridge	1024-01
	Dario™ Test Strip (2 x 25)
	1105-01
	Dario™ Test Strip (1 x 25)
Lancet	1074-01
	Dario™ Test Strip (4 x 25)
Lancet	1018-01
	Dario™ Lancet (1 x 100)
Control Solution	1019-01
	Dario™ Lancet (1 x 25)
Control Solution	1054-01
	Dario™ Control Solution (2x1.25 ml)
Software	1022-01/1022-02
	Smart mobile device software application ver 2.x

CONTACT CUSTOMER SUPPORT:

You may contact customer support with any question or issue about Dario™ and its accessories anytime by emailing us support@mydario.com or on the website: www.mydario.com

If you have questions or need assistance outside the operational days and times, please contact your health care provider.

Life is easier
with Dario™ in your pocket

