



# Dario<sup>®</sup> Smart Blood Pressure Monitor (Cellular)

User Manual



# Table of Contents

Indications for Use.....	3
Measurement Principle.....	3
Supported devices and operating systems.....	4
Help and Warranty.....	4
What's in the box.....	4
<b>INTRODUCTION</b> .....	5
Blood Pressure monitor description .....	8
Display and Symbols.....	9
<b>GETTING STARTED</b> .....	11
Downloading the Dario App .....	11
Setting up your Dario Smart Blood Pressure Monitor (Cellular).....	12
Setting up a cellular connection .....	14
Pair your Dario Dario Smart Blood Pressure Monitor (Cellular) and the Dario App.....	16
First time measurement.....	17
How to measure.....	18
Maintenance.....	22
Troubleshooting .....	24
FAQ: All about blood pressure.....	25
Device Specifications.....	28
<b>SAFETY</b> .....	29
Safety Information.....	29
FCC statement.....	30
EMC guidance.....	31
Specifications for 2G/4G.....	34

# Thank you for choosing the Dario Smart Blood Pressure Monitor (Cellular)

The Dario Smart Blood Pressure Monitor (Cellular) allows you to monitor your blood pressure from the comfort of your home or office. Track your trends to get a better overview of your condition. Store all your readings in the Dario App and get alerts you can easily share with your doctor regarding potential health complications.

## Indications for Use

This Blood Pressure Monitor is intended for use in measuring blood pressure and pulse rate in patients with arm circumferences from 16 to 36 cm ( $6\frac{1}{3}$  to  $14\frac{1}{5}$  inch), 22 to 42cm ( $8\frac{3}{4}$  to  $16\frac{1}{2}$  inch), 22 to 45cm ( $8\frac{3}{4}$  to  $17\frac{3}{4}$  inch) or 40 to 52cm ( $15\frac{3}{4}$  to  $20\frac{1}{2}$  inch).

Cuff model AC1636-01, arm circumference range is 16~36cm ( $6\frac{1}{3}$  to  $14\frac{1}{5}$  inch), which is intended for children older than 3 years old or adults without conditions of diabetes, pregnancy, or pre-eclampsia.

Cuff model AC2245-021, arm circumference range is 22–45 cm ( $8\frac{3}{4}$  to  $17\frac{3}{4}$  in), which is intended for the adult population or those with conditions such as diabetes, pregnancy, or pre-eclampsia.

Cuff model AC2242-41 and cuff model AC4052-04, arm circumference range are 22-42cm ( $8\frac{3}{4}$  to  $16\frac{1}{2}$  inch) and 40-52cm ( $15\frac{3}{4}$  to  $20\frac{1}{2}$  inch) respectively, which are intended for adults without conditions of diabetes, pregnancy, or pre-eclampsia.

It is intended indoor use only.

## Measurement Principle

This product uses the Oscillometric Measuring method to detect blood pressure. Before every measurement, the unit establishes a “zero pressure” equivalent to the atmospheric pressure. Then it starts inflating the arm cuff, meanwhile, the unit detects pressure oscillations generated by beat-to-beat pulsatile, which is used to determine the systolic and diastolic pressure, and also pulse rate.

## Supported devices and operating systems

The Dario Smart Blood Pressure Monitor (Cellular) works with Android 9 & above and with iOS 13 & above. You can find the most updated list of supported systems here:

<https://mydario.com/support/getting-started/>

## Help and Warranty

For help follow the link below:

[www.mydario.com/support/getting-started](http://www.mydario.com/support/getting-started)

For Warranty information follow the link below:

<https://mydario.com/return-policy/>

## What's in the box

- Blood pressure monitor
- Pressure cuff (8¾ - 17¾ inch)  
(Other cuff sizes listed in this manual are compatible with the device but not included in this package.)
- Owner's manual
- Quick starter guide
- Batteries

# INTRODUCTION

## Precaution

- Blood Pressure Monitor is intended to be operated by adults, including medical staff and lay persons. Adult patients could also be intended users or operators.
- This device is intended for indoor, home use and is not intended for self-use in public areas.
- This device is portable, but it is not intended for use during patient transport.
- This device is not suitable for continuous monitoring during medical emergencies or operations.
- This device is intended for non-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the arm, or for any purpose other than obtaining a blood pressure measurement.
- This device is for adults. Do not use this device on neonates or infants.
- Consult with your physician before using this monitor if you suffer from the following conditions: common arrhythmias such as premature ventricular beats or atrial fibrillation; peripheral arterial disease, implantation with electrical devices; undergoing intravascular therapy; arteriovenous shunt or mastectomy. Please note that any of these conditions may affect measurement readings, in addition to patient motion, trembling or shivering.
- If you are taking medication, consult your physician to determine the proper time to measure your blood pressure.
- This device may be used only for the intended use described in this manual, the manufacturer shall have no liability for any incidental, consequential, or special damages caused by misuse or abuse.
- Please use the device under the environment which is provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.
- The device may require up to 30 minutes to warm up / cool down from the minimum/ maximum storage temperature before it is ready for use.
- Do not wash the cuff in a washing machine or dishwasher!
- The device contains sensitive electronic components. To avoid measurement errors, avoid taking blood pressure measurements near a strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
- Wireless communication equipment, such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies may cause interference that may affect the accuracy of measurements. A minimum distance of 1 foot (30 cm) should be kept from such devices during a measurement.

## Caution

- Do not attempt to repair the unit yourself if it malfunctions. Only have repairs carried out by authorized service centers.
- It is recommended that the performance should be checked after repair, maintenance, and every two years of use, by retesting the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50 mmHg and 200 mmHg). Please contact manufacturer or distributor for authorized service personnel.
- Store your device, cuff and adapter in a clean and dry place, protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on it.
- Make sure the rubber tube of the cuff is not squeezed, stretched, or kinked during storage.
- Dispose of accessories, detachable parts, and the device according to the local guidelines.

## Warning

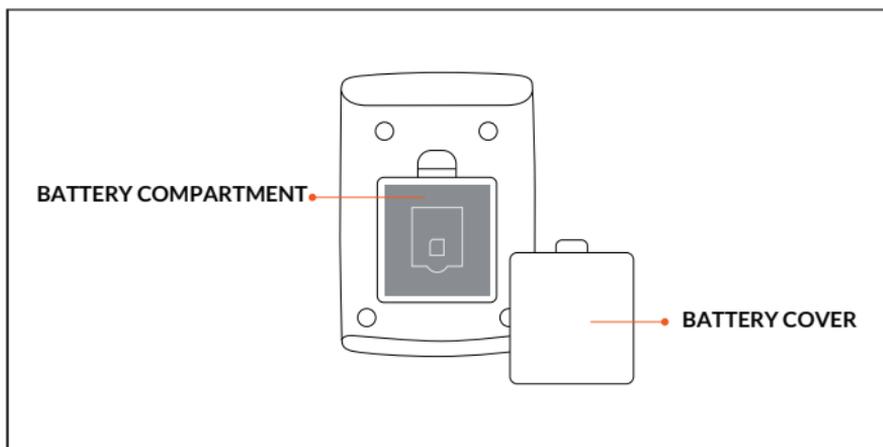
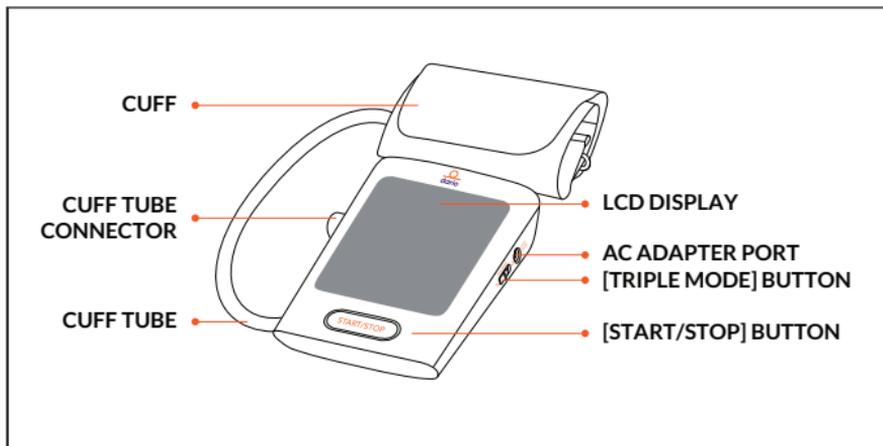
- DO NOT self-diagnose the measurement results and start treatment by yourself. The measurement results given by this device are not a diagnosis. ALWAYS consult your doctor for evaluation of the results and treatment.
- DO NOT adjust medication based on readings from this blood pressure monitor. Take medication as prescribed by your physician. ONLY a physician is qualified to diagnose and treat high blood pressure.
- DO NOT apply the cuff on an arm that has an intravenous drip or a blood transfusion attached.
- DO NOT kink, fold, stretch, compress, or otherwise deform the tube during measuring, as the cuff pressure might continuously increase, which could prevent blood flow and result in injury.
- Taking blood pressure measurements too frequently could disrupt blood circulation and cause injuries.
- DO NOT apply cuff to areas on patient where skin is delicate or damaged. Check cuff site frequently for irritation.
- DO NOT place the cuff on the arm of a person whose arteries or veins are undergoing medical treatment, i.e. intra-vascular access or intra-vascular therapy or an arteriovenous (A-V) shunt, which could disrupt blood circulation and cause injuries.
- DO NOT place the cuff on the arm on the same side of a mastectomy (especially when lymph nodes have been removed). It is recommended to take measurements on the unaffected side.
- DO NOT wrap the cuff on the same arm to which another monitoring device is applied. One or both devices could temporarily stop functioning if you try to use them at the same time.

- Warning: Please check (for example, by observation of the limb concerned) that the operation of the device does not result in prolonged impairment of patient blood circulation.
- Warning: On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, loosen and remove the cuff immediately. Prolonged high pressure applied to the arm (cuff pressure >300 mmHg or constant pressure > 15 mmHg for more than 3 minutes) might lead to bruising and discolored skin.
- DO NOT use this device with high-frequency (HF) surgical equipment at the same time.
- This device is not used in conjunction with oxygen rich environments, not intended for use with flammable anaesthetics, not intended for use in conjunction with flammable agents.
- Excessive cuff tube lengths could cause strangulation if you don't manage them properly.
- DO NOT touch output of the batteries/adaptor and the user simultaneously.
- The power cord is considered the disconnect device for isolating this equipment from supply mains. DO NOT position the equipment so that it is difficult to reach or disconnect.
- DO NOT use this device if you are allergic to polyester, nylon, or plastic.
- Only use accessories approved by manufacturer. Using unapproved accessories might cause damage to the unit and injure users.
- If you experience discomfort during a measurement, such as pain in the arm or other complaints, press the Power button immediately to release the air from the cuff.
- DO NOT use the device while under maintenance, or being serviced.
- Sensor degradation or looseness may reduce performance of device or cause other problems.
- The air tube poses a risk of strangulation. Furthermore, the small parts of product and batteries present a choking hazard if swallowed. They should therefore always be kept away from infants/children.

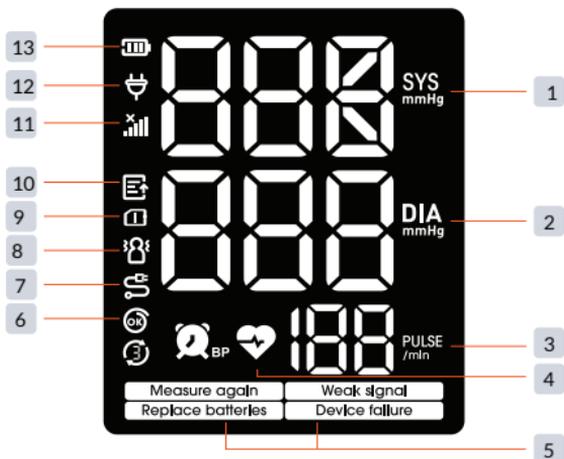
## Notice

- You can use this device to take your own measurement, no third-party operator is required.
- At the request of authorized service personnel, circuit diagrams, component part lists, descriptions, and calibration procedures will be made available by the manufacturer or distributor.
- The expected lifetime of the cuff may vary by the frequency of washing, skin condition, and storage state.
- Please report any serious incident related to this device to the manufacturer or distributor, and to the competent authority in your country.

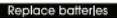
## Blood pressure monitor description



## Display and Symbols



SYMBOL	EXPLANATION	
1	Systolic blood pressure reading	
2	Diastolic blood pressure reading	
3	Pulse display	
4		Irregular pulse rate symbol Appears when detected during a measurement.
5	Warning messages	
6		Cuff wearing detection icon will appear if the cuff is worn incorrectly (not wrapped tight enough, wrapped too tight, if there is an air leak, etc.)

SYMBOL		EXPLANATION
7		<b>Cuff abnormal icon</b> Appears when the air connector plug is not properly plugged in .
8		<b>Excessive body motion detector icon</b> Appears when talking, moving, or shaking of the arm with the cuff on is detected during a measurement. <b>NOTE:</b> The measured blood pressure reading may not be accurate when this symbol is displayed with the reading.
9		<b>SIM card error icon</b> Appears when the SIM card is abnormal or the SIM is not properly plugged in.
10		<b>Data pending to transmit icon</b> Appears when the data transmission failed. Up to 500 measurements can be temporarily saved on the device and sent to your account when the Cellular internet is available.
11		<b>Signal indication icon</b> Indicates no cellular coverage or cellular connection error.
12		<b>Adapter Insert Indicator</b> Appears when the power is supplied from the adapter.
13		<b>Battery Indicator</b> Indicates the current battery level.
		<b>Low battery symbol</b> Indicate the battery is too low when appears with 

## GETTING STARTED

The Dario Smart Blood Pressure Monitor (Cellular) automatically uploads your data to your Dario App via a cellular network. Make sure that you have the latest version of the Dario App installed on your smartphone.

### Downloading the Dario App

1. Go to the App Store or Google Play and search for DarioHealth. Download the Dario App.



For quicker access you can scan the QR code.



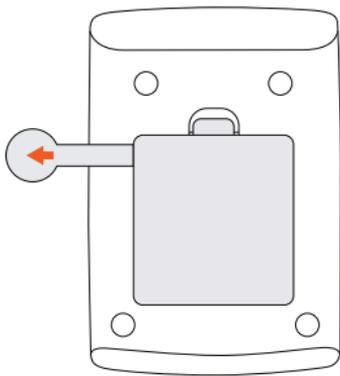
2. Open the Dario App. 
3. If you have an existing account, log in.
4. If not, tap Sign Up and follow the instructions.

# Setting up your Dario Smart Blood Pressure Monitor (Cellular)

## Installing and replacing the batteries

1. If this is your first time using the device:

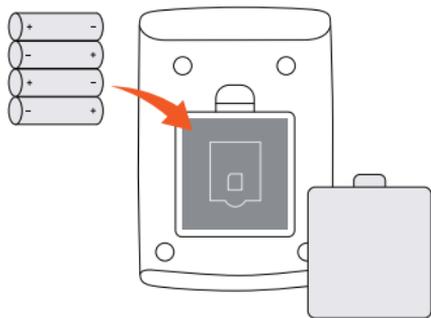
Pull and remove the plastic insulating strip before first use. The batteries are already installed.



2. Replace the batteries whenever the following happens:

- **Replace batteries**  are displayed
- The display dims
- The display does not light up

To replace the batteries, open the battery compartment cover located on the back of the monitor. Insert 4 AA batteries into the battery compartment and close the cover.

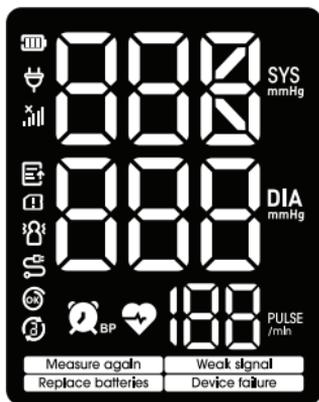


- Do not mix new and used batteries, or different types of batteries.
- Remove the batteries if the device will not be used for an extended period.
- Do not heat, deform, or dispose of the batteries in fire.
- Do not dispose of batteries with household waste.
- Contact your local authority for information on proper battery recycling.

3. Make sure that the Triple Mode button next to the AC adapter port is set to "1"

## Setting up a cellular connection

When you remove the plastic insulation strip or insert new batteries into the device, the LCD will display the following screen for about 5 seconds before turning off automatically.



After the device turns off, it will automatically search for and connect to the mobile network. If the connection fails, the monitor will stop searching and enter standby mode.

A possible reason for connection failure is an unstable cellular network. Try again in a location with a stronger signal. You can check the network strength on your smartphone.

Still can't connect?

Contact Dario Customer Support

Monday to Friday

9:00 AM - 8:00 PM EST

1-833-914-3798

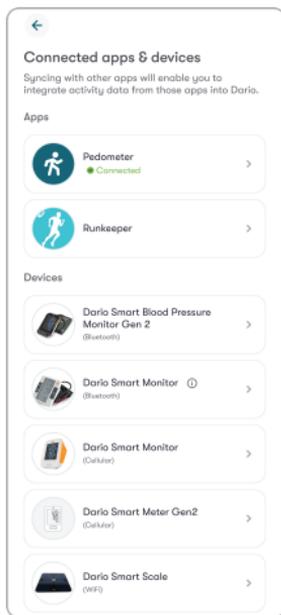
<https://mydario.com/support/getting-started/>

**Note:**

To see the correct time and date for your measurements in your app logbook, the Dario Smart Blood Pressure Monitor (Cellular) must be connected to the cellular network. This happens automatically the first time you turn it on or when you replace the batteries.

## Pair your Dario Smart Blood Pressure Monitor (Cellular) and the Dario App

1. On the Dario App, go to Menu.
2. Select SETTINGS.
3. Open the CONNECTED APPS & DEVICES screen.
4. Select Dario Smart Monitor Gen2 (Cellular).
5. Follow the app instructions for pairing your monitor with the app.



**Congratulations! You're ready to start measuring.**

# First time measurement

## Get ready

- Do not measure within 30 minutes of eating, drinking, smoking, exercising, or bathing. If possible, relax and rest for at least 5 minutes before taking a measurement.
- Avoid taking measurements when stressed.
- Avoid taking measurements in a noisy or cold environment.
- Remove tight-fitting clothing from your upper arm.
- Sit on a chair with your feet flat on the floor. Rest your arm on a table so that the cuff is at the same level as your heart.
- Remain still and do not move your fingers or talk during measurement.

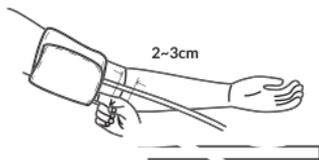
**Note:** A single measurement may not provide an accurate indication of your true blood pressure. Try to measure your blood pressure at the same time each day for consistency.

# How to measure

1. Plug the connector on the cuff tube into the monitor.

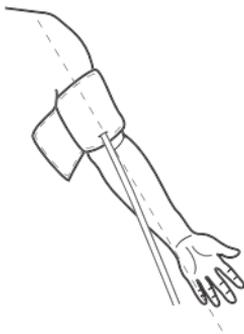


2. Roll or push up your sleeve to expose the skin. Make sure your sleeve is not too tight.
3. Open the cuff and orient the cuff so that the tube exits towards the hand.
4. Place your arm through the cuff loop, with your palm facing up. Position the cuff's edge about an inch (2-3 cm) above the elbow.



5. Align the cuff tube with the center of your arm.

6. Tighten the cuff evenly around your arm by pulling on the end. Make sure the cuff tube stays aligned with the center of your arm.



7. Wrap the end of the cuff over your arm to secure it in place. Do not make it too tight – leave room for a finger to fit between the cuff and your arm.
8. Place your arm on a table with your palm facing up. The cuff should be at the same height as your heart. Sit up straight and rest your feet flat on the ground.



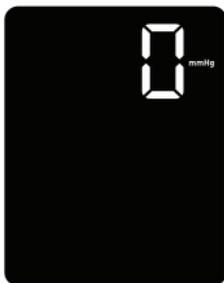
9. When the monitor is off, press the “START/STOP” button to turn it on.

10. The screens below will appear as you measure:

1. LCD display



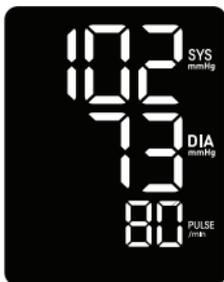
2. Start screen



3. Measurement screen



4. Results screen



11. After you measure, the monitor will transmit your data. The blinking symbol “The image shows a black LCD screen with white digital readouts. At the top left, there is a small signal strength icon consisting of four vertical bars of increasing height. The screen displays three rows of data: the top row shows '102' followed by 'SYS' and 'mmHg'; the middle row shows '93' followed by 'DIA' and 'mmHg'; and the bottom row shows '80' followed by 'PULSE' and '/min'.

**Please note:** If you experience discomfort during measurements, such as pain in your arm or anything else, press the “START/STOP” button to release the air immediately from the cuff.

Loosen the cuff and remove it from your arm.

# Maintenance

In order to get the best performance, please follow the instructions below.

## 1. Cleaning Process:

**Step 1:** Before cleaning the monitor, make sure that the monitor is switched off and not connected to any AC power line.

**Step 2:** Clean the cuff with a soft cloth dampened with the soapy water until no visible contaminants remain.

**Step 3:** Rinse the cuff and wipe off the cleaning solution with a fresh cloth or towel, dampened with tap water after cleaning until no visible cleaning agent remains.

**Step 4:** Wipe off with a dry cloth to remove residual moisture.

**Step 5:** Air dry the cuff thoroughly after cleaning.

## **2. Disinfection Process (Clean the monitor before disinfection):**

**Step 1:** Before disinfecting the monitor, make sure that the monitor is switched off and disconnected from the power line.

**Step 2:** Disinfect the cuff with a soft cloth dampened with the 70% isopropanol for about 10 minutes.

**Step 3:** Rinse the cuff and wipe off the disinfection solution with a fresh cloth or towel, dampened with tap water after disinfecting until no visible disinfection agent remains.

**Step 4:** Wipe off with a dry cloth to remove residual moisture.

**Step 5:** Air dry the cuff thoroughly after disinfecting.

### **Suggestion:**

Frequency of Cleaning and Disinfection:

For single patient multiple use, it's recommended to clean the device surface once a month or whenever it's necessary.

# Troubleshooting

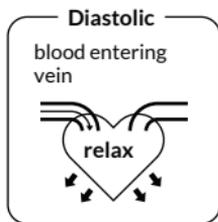
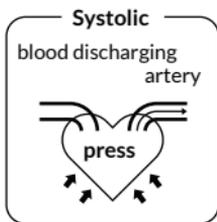
Having a problem with your Smart Monitor? Check the list below for common issues and what to do about them.

DISPLAY	ISSUE	SOLUTION
 Replace batteries	Display will not light up or shows the icon on screen	Check that the batteries/AC were inserted correctly. If the batteries were inserted correctly and you still see this message, you may need to replace them.
	The cuff is not secure or inflation is abnormal	Refasten the cuff and measure again
	The cuff tube connector plug is not properly plugged	Plug the cuff tube connector correctly and measure again
 Measure again	Movement detected during measurement	Relax for a moment and then measure again
 Measure again	No pulse detected	Loosen the clothing on your arm. Relax for a moment and then measure again
 Measure again	Out of measurement range	Relax for a moment. Refasten the cuff and then measure again. If the problem persists, contact your healthcare provider
	Server communication failure	Use the device at a location where you get strong cellular signal with your mobile phone. If the issue persists, contact customer support.
 Weak signal	Cellular Connection failure	Use the device at a location where you get strong cellular signal with your mobile phone. If the issue persists, contact customer support.
	SIM card is not detected	Turn the monitor OFF and ON again. If the issue persists, contact customer support.
	Hardware error	Retake the measurement. If the issue persists, contact customer support.

# FAQ: All about blood pressure

## What are systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cycle, which is called systolic pressure. When the ventricles relax, the blood pressure reaches its minimum value in the cycle, which is called diastolic pressure.



## What is the standard blood pressure classification?

The chart below is the standard blood pressure classification published by American Heart Association (AHA).

Blood Pressure Category	Systolic mmHg (upper#)		Diastolic mmHg (lower#)
Normal	Less than 120	and	Less than 80
Prehypertension	120-129	and	Less than 80
High Blood Pressure (Hypertension) Stage 1	130-139	or	80-89
High Blood Pressure (Hypertension) Stage 2	140 or higher	or	90 or higher
Hypertensive Crisis (Consult your doctor immediately)	Higher than 180	and/or	Higher than 120

**CAUTION**

Only a physician can tell your normal BP range. Please contact a physician if your measuring result falls out of the range. Please note that only a physician can tell whether your blood pressure value has reached a dangerous point.

## **Why does my blood pressure fluctuate throughout the day?**

Individual blood pressure varies throughout the day. This can be due to weather, emotion, exercise, and more. It is also affected by the way you tighten your cuff and your measurement position, so please take measurements under the same conditions whenever possible. Certain medications can also affect your measurements.

## **Why do I get different blood pressure readings at home compared to the hospital?**

A phenomenon known as “white coat syndrome” may cause blood pressure to increase in clinical settings.

## **Is the result the same if I measure on different arms?**

The monitor works for both arms, but there may be different results for different people. We suggest you measure on the same arm every time.

## Irregular Pulse Rate Detector

An irregular pulse rate will be detected if there is an irregular pulse rhythm while measuring systolic and diastolic blood pressure. When measurements were performed, the monitor will record all pulse intervals and calculate the average. If two or more pulse intervals were recorded, and the difference between each interval and the average is larger than  $\pm 25\%$  of the average; or if four or more pulse intervals were recorded, and the difference between each interval and the average is larger than  $\pm 15\%$  of the average value, the irregular pulse symbol will be displayed along with measurement results.



### CAUTION

The appearance of the IPR icon  indicates that a pulse irregularity consistent with an irregular pulse rate was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the irregular pulse rate detector results cannot be used directly for clinical judgement. Please seek medical advice from professionals before making any medical decisions.

# Device Specifications

<b>Power supply</b>	Battery powered mode: 6V DC 4x AA batteries AC Adaptor powered mode: 6V $\approx$ 1A (not included) (Please only use the recommended AC Adaptor). Type: BLJ06L060100P-U Input: 100-240V, 50-60Hz, 0.2A max Output: 6V $\approx$ 1A
<b>Display mode</b>	Digital LCD V.A. 3.1in*3.7in (79mm*93mm)
<b>Measurement mode</b>	Oscillographic testing mode
<b>Measurement range</b>	Rated cuff pressure: 0 mmHg ~ 299 mmHg (0 kPa ~ 39.9 kPa) Measurement pressure: SYS: 60 mmHg ~ 230 mmHg (8.0 kPa ~ 30.7 kPa) DIA: 40 mmHg ~ 130 mmHg (5.3 kPa ~ 17.3 kPa) Pulse value: (40-199) beat/minute
<b>Accuracy</b>	Pressure: 41°F-104°F (5°C-40°C) within $\pm$ 3mmHg (0.4kPa) Pulse value: $\pm$ 5% Clinical validation: Mean difference within $\pm$ 5mmHg; Standard deviation $\leq$ 8mmHg
<b>Normal working condition</b>	A temperature range of: +41°F to +104°F (+5°C to +40°C) A relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapor partial pressure greater than 5 kPa An atmospheric pressure range of: 70 kPa to 106 kPa
<b>Storage &amp; transportation condition</b>	Temperature: -4°F-140°F (-20°C to +60°C) A relative humidity range of $\leq$ 93%, non-condensing, at a water vapor pressure up to 5 kPa Atmospheric pressure: 50 kPa to 106 kPa
<b>Measurement perimeter of the upper arm</b>	About 8" $\frac{1}{2}$ "- 17" $\frac{3}{4}$ " (22cm-45cm)
<b>Weight</b>	Approx. 0.72lb (325g) (Excluding cuff and batteries)
<b>External dimensions</b>	Approx. 5.8in x 4in x 2in (148.3mm x 100.5mm x 52mm)
<b>Mode of operation</b>	Continuous operation
<b>Degree of protection</b>	Type BF applied part
<b>Protection against ingress of water</b>	IP21 It means the device could be protected against solid foreign objects of 12,5mm $\Phi$ and greater, and against vertically falling water drops.
<b>Device Classification</b>	Battery Powered Mode: Internally Powered ME Equipment AC Adaptor Powered Mode: Class II ME Equipment
<b>Software Version</b>	A01
<b>Types of use/reuse</b>	Single patient multiple use

**WARNING: No modification of this equipment is allowed.**

# SAFETY

## Safety Information

The signs below might be in the user manual, labeling or other components. They are standard usage requirements.

	Refer to instruction manual/booklet To signify that the instruction manual/ booklet must be read. Note: The background color of the symbol is blue.		Type BF applied part
	Consult instructions for use or consult electronic instructions for use		Serial Number
	Direct Current		Polarity of d.c. power connector
	Class II Equipment		For indoor use only
	Batch code		Manufacturer
	Date of manufacture		Temperature limit
	Atmospheric pressure limitation		Humidity limitation
	General symbol for recovery/recyclable		
	MR Unsafe To identify an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.		
	Caution Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.		
	The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.		

# FCC Statement

## FCC ID: OU9TMB2092-G

This device complies with Part 15 of the FCC Rules. Operation is subject to two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

**Caution!** Changes or modifications not expressly approved by DarioHealth shall cancel the warranty and any liability DarioHealth might have in connection with this device.

**NOTE:** This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

### FCC Radiation Exposure Statement:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator and your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

# EMC Guidance

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments.

## Essential performance:

Accuracy of measuring blood pressure and pulse rate (see Device Specifications section for measurement range and accuracy).

Warning: Do not use near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 12 in (30 cm) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment may occur.

## Technical description

1. All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the expected service life.
2. Guidance and manufacturer's declaration - electromagnetic emissions and Immunity

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations / flicker emissions IEC 61000-3-3	Comply

Table 2

Guidance and manufacturer's declaration – electromagnetic Immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV for power supply lines NA 100 kHz repetition frequency
Surge IEC61000-4-5	±0.5 kV, ±1 kV, differential mode ±0.5 kV, ±1 kV, ±2 kV common mode	±0.5 kV, ±1 kV differential mode N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT ; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% UT ; 1 cycle and 70% UT ; 25/30 cycles; Single phase: at 0°. 0% UT ; 250 / 300 cycle	0% UT ; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0% UT ; 1 cycle and 70% UT ; 25/30 cycles; Single phase: at 0°. 0% UT ; 250 / 300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz / 60 Hz	30 A/m 50 Hz / 60 Hz
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80% AM at 1 kHz
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz
NOTE U <sub>T</sub> is the a.c. main voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity								
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance level (V/m)
	385	380-390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27	27
	450	430-470	GMRS 460, FRS 460	FM c) $\pm 5$ kHz deviation 1 kHz sine	2	0.3	28	28
	710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9	9
	745							
	780							
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28
	870							
	930							
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation 217 Hz	2	0.3	28	28
	1845							
	1970							
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	28
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	2	0.3	9	9
	5500							
	5785							

# Specifications for 2G/4G

Specifications for 2G/4G			
E-MTC/GSM		2G	4G
	Supporting band :	GPRS/EGPRS: 850/1900	Cat-M1: B2/4/12/13/25
	Transmitted frequency range	824–849MHz, 1850–1910MHz	1850–1910MHz, 1710–1755MHz, 699–716MHz, 777–787MHz, 1850–1915MHz
	Transmitted power	850: 33±2dBm, 1900: 30±2dBm	20±2dBm
	Throughput	EGPRS:236.8-296Kbps GPRS: 85.6-107Kbps	375~1119 kbps
	Latency	< 500ms	≤ 21ms
	Jitter	< 500ms	≤ 21ms
	PER	< 10%	< 10%
	Data Integrity	Data shall be transmitted correctly and completely	
	Accessibility	Accessibility is high since 2G/4G is broadband	
	Signal Priority	Routine priority using 4G access standard	
<b>Remark:</b>			
1.The Quality of Service (QoS) is considered as KPIs here.			
2. For the Blood Pressure Monitor , the E-MTC is used to transmit the control data between the EUT and the controller, the manufacture considered 375~1119 kbps is a suitable throughput for the usage			
3.The PER of the wireless system is normally less than 1%, for Semi-anechoic chamber, we considered the PER cannot be greater than 10%.			
4. Use the wireless module which the EUT used as the test model,instead the EUT.			

## Warning

Failure to comply with the following warnings may cause cybersecurity issues.

DO NOT casually use the blood pressure monitor for others, as it may lead to leakage of personal measurement data.

DO NOT connect the blood pressure at places with poor network or wireless connectivity, as it may interrupt data upload and lead to deficient data.

## **Still need help?**

Contact Dario Customer Support

Monday to Friday

9AM to 8PM EST

**1-833-914-3798**

<https://mydario.com/support/getting-started>

For assistance outside of these hours,  
please contact your healthcare professional

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### **Manufactured by**

Guangdong Transtek Medical Electronics Co., Ltd.  
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528437 Zhongshan, Guangdong, China

**Manufacturer Model:** TMB-2092-G

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