DARIO

Dario® Smart Blood Pressure Monitor Gen 2

Owner's Manual

Model: 1217-05

Ver 1.0

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Thank you for choosing the Dario® Smart Blood Pressure Monitor Gen 2.

The Dario® Smart Monitor 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. For your convenience, the monitor also has an American Heart Association (AHA) blood pressure classification level indicator on the LCD.

Indications for Use

The Dario® blood pressure monitoring system is intended for measuring blood pressure and heart rate in adults with an arm circumference ranging from 8¾″-16½″ (22 cm to 42 cm). It is intended for adult indoor use only.

Disclaimers

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 functions other than obtaining a blood pressure measurement. This device does NOT serve as a cure for any symptom or disease. The data measured is for reference only. Always consult your healthcare provider to have the results interpreted.

Supported Devices and Operating Systems

The Dario® Smart Monitor works with Android 8 & above and with iOS 13 & above. You can find the most updated list of supported system here:
https://mydario.com/support/getting-started/

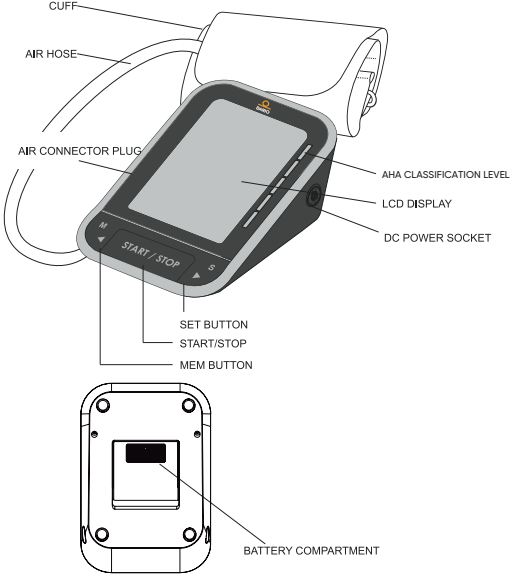
Help and Warranty

For help follow the link below:
www.mydario.com/support/getting-started
For Warranty information follow the link below:
https://mydario.com/return-policy/

What's in the box

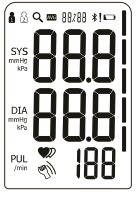
- Blood pressure monitor
- Pressure cuff (22cm–24cm)
- Owner's manual
- Batteries
- Travel bag
- Quick Guide

Blood Pressure Monitor Description



Display

Blood pressure level indicator (according to American Heart Association (AHA) level classification)



- Hypertensive crisis (HT crisis)
- High BP (stage2)
- High BP (stage1)
- Elevated
- Normal

SYMBOL	DESCRIPTION	EXPLANATION
SYS.	Systolic blood pressure	High blood pressure
DIA.	Diastolic blood pressure	Low blood pressure
PUL/min	Pulse display	Pulse in beats per minute
	Memory	Indicate it is in the memory mode and which group of memory it is.
	Motion indicator	Motion may result in an inaccurate measurement
kPa	kPa	Measurement Unit of the blood pressure (1kPa=7.5mmHg)
mmHg	mmHg	Measurement Unit of the blood pressure (1mmHg=0.133kPa)
	Low battery	Batteries are low and need to be replaced
	Irregular heartbeat	Blood pressure monitor is detecting an irregular heartbeat during measurement.
	Blood pressure level indicator	Indicate the blood pressure level
88/88	Current Time	Year/Month/Day, Hour : Minute
	Heartbeat	Blood pressure monitor is detecting a heartbeat during measurement.
1	User 1	Start measurement,save and transmit the measuring results for User 1
2	User 2	Start measurement and save measuring results for User 2. Note: User 2 cannot transmit the results to the App.
	Bluetooth icon	The bluetooth icon blinks when the bluetooth is working
AVG	Average value	The average value of blood pressure
!	Bluetooth connection	It blinks when the bluetooth connection fails or the data is not sent.

Before you measure: Important information

- The device shouldn't be used on:
  - Infants
  - Pregnant women
  - Anyone with electronic implants, pre-eclampsia, premature ventricular beats, atrial fibrillation, or peripheral arterial disease
  - Anyone undergoing intravascular therapy or who has an arterio-venous shunt
  - Anyone who had a mastectomy
  - Anyone allergic to polyester, nylon, or plastic
  - The device is not suitable for measuring the blood pressure of children. Ask your doctor before using it on older children.

  Note: Contact your health care provider for information about using this device if you suffer from any other illness.

GETTING STARTED

The Dario® Smart Monitor automatically uploads your data to your Dario App via a Bluetooth® 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.

Download on the App Store

GET IT ON Google Play

For quicker access you can scan the QR code.

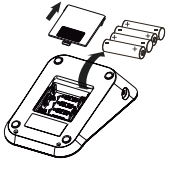
2. Open the Dario® App.
3. If you have an existing account, log in.
4. If not, tap Sign Up and follow the instructions.

Setting up your Dario® Smart Monitor

Installing and replacing the batteries

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

   Open the battery compartment cover located on the back of the monitor. Insert 4 AAA alkaline batteries into the battery compartment and close the cover.



2. Replace the batteries whenever the following happens:

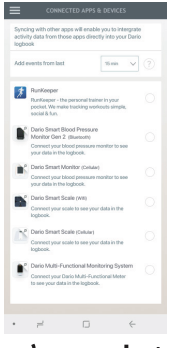
- Lo+ is displayed
- The display dims
- The display does not light up

Pair your Dario® Smart Monitor and the Dario App

If you do not have the Dario® App installed on your smartphone, follow the **Getting Started** instructions on pg. 8.

It's important to pair your Smart Monitor with your Dario App before first time use.

1. On the Dario® App, go to Menu.
2. Select SETTINGS.
3. Open the CONNECTED APPS & DEVICES screen.
4. Select Dario® Smart Blood Pressure Monitor Gen 2.
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, exercise, 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.

Prepare your monitor

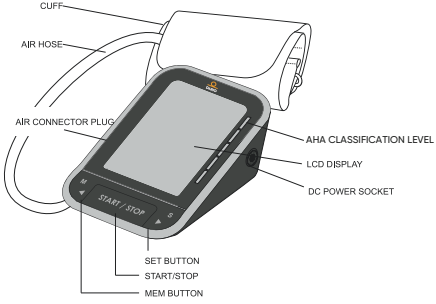
- Do not use the monitor if it is damaged. Using a damaged unit can cause serious injury and can result in incorrect measurements.
- Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, and walkie-talkies, can affect the monitor and should be kept at least 40 inches (1 meter) away from it.

Warnings

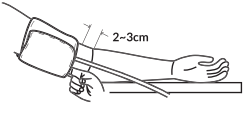
- Do not twist the connection tube during use. This can cause the cuff pressure to inflate continuously, which can prevent blood flow and result in serious injury.
- Do not apply the cuff over a wound as it may cause injury.
- Do not inflate the cuff on an arm that is already using another medical electrical monitoring device, as this could cause the monitoring equipment to stop working temporarily.
- Keep the monitor out of the reach of infants, young children, and pets, to avoid inhalation or swallowing of small parts.

How to measure

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

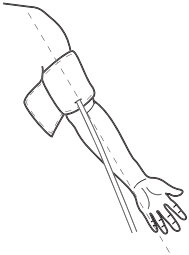


2. Open the cuff and orient the cuff so that the tube exits towards the hand.
3. Place your arm through the cuff loop, with your palm facing up. Position the cuff's edge about an inch (2–3 cm) above the elbow.



4. Align the Φ marker (located to the right of the tube exit) with the center of your arm.

5. Tighten the cuff evenly around your arm by pulling on the end. Make sure the Φ marker stays aligned with the center of your arm.

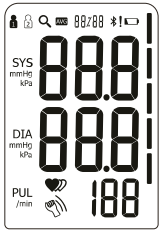


6. Wrap the end of the cuff over your arm to secure it in place. Do not make it too tight – leave room for a finger to fit between the cuff and your arm.
7. Place your arm on a table with your palm facing up. The cuff should be at the same height as your heart. Sit up straight and rest your feet flat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

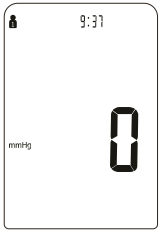
8. When the monitor is off, press the “START/STOP” button to turn it on.

9. The screens below will appear as you measure:

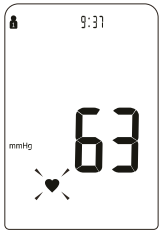
1. LCD display



2. Start screen

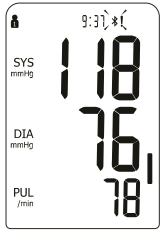


3. Measurement screen



4. Results screen

10. After you measure, the monitor will automatically transmit your data. The blinking symbol on the LCD indicates that data is being transmitted. Make sure that the Dario® App is up and running for the synchronization to work.



11. If the data transmission fails, the monitor will turn off automatically. If the data transmission succeeds, the will stop blinking and the monitor will turn off after a few seconds.

    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.

Troubleshooting

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

PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display will not light up.	Batteries are exhausted.	Replace with new batteries
		Batteries are inserted incorrectly.	Insert the batteries correctly
Low batteries	Display is dim or show	Batteries are low.	Replace with new batteries
Error message	E 01 shows	The cuff is not secure.	Refasten the cuff and then measure again.
	E 02 shows	The monitor detected motion,talking or the pluse is too poor while measuring.	Relax for a moment and then measure again.
	E 03 shows	The measurement process does not detect the pulse signal.	Loosen the clothing on the arm and then measure again.
	E 04 shows	The treatment of the measurement failed.	Relax for a moment and then measure again.
	EExx,shows on the display.	A calibration error occurred.	Retake the measurement. If the problem persists, contact the retailer or our customer service department for further assistance.Refer to the warranty for contact information and return instructions.
Warning message	“out ” shows	Out of measurement range	The measurement result is out of the measurement range (SYS:60mmHg to 230mmHg; or DIA: 40mmHg to 130mmHg;or Pulse: 40-199 pulse/minute)

Care & maintenance

- The service life of the cuff can be affected by the frequency of washing, skin condition, and storage state. The typical service life is 10,000 measurements.
- Do not subject the monitor to shaking or strong shocks, such as dropping on the floor.
- Avoid dust and extreme hot or cold temperatures. Storage conditions: (-20°C to +60°C). A relative humidity range of ≤ 93%, non-condensing, at a water vapour pressure up to 50hPa -4°F to +140°F.
- Do not use wet cloths to remove dirt and do not wash the cuff.
- When not in use, store the device in a dry room and protect it against extreme moisture, heat, lint, dust, and direct sunlight.

Note: The typical service life is 10000 times.

If you have any problems setting up or using your Smart Monitor, please contact the Dario Customer Service Department.

Monday to Friday
9:00 AM – 9:00 PM EST
1-800-895-5921
https://mydario.com/support/getting-started/

FAQ: All about blood pressure

What are systolic pressure and diastolic pressure?

Blood pressure is written as two numbers. The top (systolic) number is the pressure when the heart beats. The bottom (diastolic) number is the pressure when the heart rests between beats.

What is the standard blood pressure classification?

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

This chart reflects blood pressure categories defined by American Heart Association.

Blood Pressure Category	Systolic mmHg (upper#)		Diastolic mmHg (lower#)
Normal	less than 120	and	less than 80
Elevated	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

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.

What is the Irregular Heartbeat Detector?

An irregular heartbeat (IHB) is detected when a heartbeat rhythm varies while the device is measuring systolic pressure and diastolic pressure. During each measurement,

the Dario® Smart Monitor will keep a record of all the pulse intervals and calculate the average value of them. If there are two or more pulse intervals and the difference between each interval and the average is more than the average value of ±25%, or there are four or more pulse intervals and the difference between each interval and the average is more than the average value of ±15%, then the irregular heartbeat symbol will appear on the display with the measurement result.

The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heartbeat was detected during measurement. If the symbol appears often, we recommend you seek medical advice. Please note that the device does not replace a cardiac examination but serves to detect pulse irregularities at an early stage.

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.

Device Specification

Power supply	Battery powered mode: 6VDC 4×AAA alkaline batteries AC adaptor powered mode:6V⎓1A(not included) (Please only use the recommended AC adapter).
Display mode	Digital LCD V.A.100mm×68mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0mmHg~299mmHg(0kPa ~ 39.9kPa) Measurement pressure: SYS: 60mmHg~230mmHg (8.0kPa~30.7kPa) DIA: 40mmHg~130mmHg (5.3kPa~17.3kPa) Pulse value: (40-199)beat/minute
Accuracy	Pressure: 5°C-40°C within±3mmHg(0.4kPa) Pulse value:±5%
Normal working condition	A temperature range of :+5°C to +40°C A relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa An atmospheric pressure range of : 700 hPa to 1060 hPa
Storage & transportation condition	Temperature:-20°C to +60°C A relative humidity range of ≤ 93%, non-condensing, at a water vapour pressure up to 50hPa
Measurement perimeter of the upper arm	About 22cm~42cm
Weight	Approx.282g(Excluding the dry cells and cuff)
External dimensions	Approx.154mm×106mm×57.1mm
Attachment	4×AAA alkaline batteries,user manual,Quick guide, Travel bag
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP21 It means the device could protected against solid foreign objects of 12.5mm and greater, and protect against vertically falling water drops.
Device Classification	Battery Powered Mode: Internally Powered ME Equipment AC Adaptor Powered Mode: Class II ME Equipment.
Software Version	A01

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

	Symbol for “THE OPERATION GUIDE MUST BE READ”		Symbol for “TYPE BF APPLIED PARTS”
	Caution: These notes must be observed to prevent any damage to the device.		Symbol for “ENVIRONMENT PROTECTION - Electrical waste products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice”
	Symbol for “MANUFACTURER”		
	Symbol for “SERIAL NUMBER”		
	Symbol for “DIRECT CURRENT”		Symbol for “Recycle”
	Symbol for “MANUFACTURE DATE”		For indoor use only
F1	T1A/250V Φ3.6*10CCC		Symbol for “Class II Equipment”

Note: The typical service life is 10000 times.

FCC Statement

Contains FCC ID: OU9TMB1585BS

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 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.
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 30 cm (12 inches) to any part of the equipment LS802-GP, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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, ±4kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4kV, ±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 ±1 kV signal input/output 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 ±0.5 kV, ±1 kV,±2 kV common mode
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 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced 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_T is the a.c. mains 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 communica-tions equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
	385	380-390	TETRA 400	Pulse modulation b) 18Hz	1.8	0.3	27
	450	430-470	GMRS 460 , FRS 460	FM c) ± 5kHz deviation 1kHz sine	2	0.3	28
	710	704-787	LTE Band 13, 17	Pulse modulation b) 217Hz	0.2	0.3	9
	745						
	780						
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18Hz	2	0.3	28
	870						
	930						
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation b) 217Hz	2	0.3	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
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
	5500						
	5785						

Still need help?
Contact Dario Customer Support
Monday to Friday
9:00 AM – 9:00 PM EST
1-800-895-5921
https://mydario.com/support/getting-started

Distributed by DarioHealth Corp
18 W 18th St, New York, NY 10011
Toll Free:1-800-895-5921 (Mon to Fri / 9AM to 9PM EST)
For assistance outside of these hours,
please contact your healthcare professional