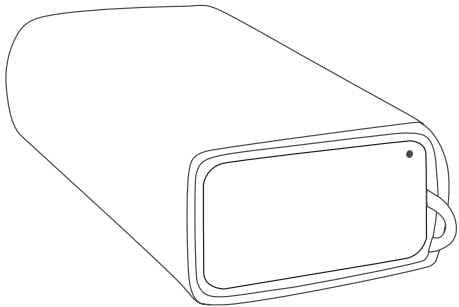

QARDIOARM

THE SMART BLOOD PRESSURE MONITOR
YOU WILL ACTUALLY USE

User Manual

FR Guide d'utilisation - DE Bedienungsanleitung - IT Guida Utente - ES Guia del Usuario - PT Guia do Usuário
DA Brugsvejledning - NL Gebruikershandleiding - NO Brukerveiledning - SV Bruksanvisning - PL Instrukcja Obsługi
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QARDIOARM: THE SMART BLOOD PRESSURE MONITOR

QardioArm is a clinically validated, portable blood pressure monitor. QardioArm is the smart way to measure and track your systolic and diastolic blood pressure and heart rate. This device was developed in collaboration with physicians and clinical tests were conducted to prove its measurement accuracy.

Qardio offers a better way of tracking heart health that fits effortlessly into your life. Our devices are powerful and smart, have a beautiful design with a delightful user experience so you can use them anytime, anywhere.

With its ease of use and accuracy, QardioArm is ideal for monitoring your blood pressure in your home, office or wherever is convenient for you.

Please read through these instructions carefully so you understand all functions and safety information. We want you to be happy with your QardioArm. If you have any questions, problems or suggestions, please contact Qardio's Customer Service at *support.getqardio.com*, or visit our website *www.getqardio.com* for more information.

INTENDED USE

QardioArm is a fully automatic, non-invasive, wireless blood pressure monitor. QardioArm is a blood pressure measurement system intended to measure the systolic and diastolic blood pressures and pulse rate of an adult individual. QardioArm utilizes an inflatable cuff that is wrapped around the upper arm. This device is not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated. The cuff circumference is limited to 8.7in -14.6in (22cm-37cm).

IMPORTANT SAFETY INFORMATION

Please read the User Manual carefully before using the QardioArm blood pressure monitor. In the case of pregnancy, arrhythmia or arteriosclerosis, consult your doctor before use.

PACKAGE CONTENTS

- QardioArm blood pressure monitor
- Four AAA alkaline batteries, already pre-installed in the QardioArm
- User Manual
- Quick Guide

REQUIREMENTS

QardioArm requires a device with:

- Bluetooth 4.0
- iOS 7.0 or later
- Android 4.4 “KitKat” (or later)

And works with:

- iPhone, iPod, iPad and Apple Watch
- Android Phones and Tablets

In order to use your QardioArm blood pressure monitor, you must download the free Qardio App from the Apple App Store or Google Play, or go to *www.getqardio.com*

USING QARDIOARM FOR THE FIRST TIME

1. Download the free Qardio App: On your mobile phone or tablet go to *www.getqardio.com* and when prompted, download the app. Alternatively, go on the iTunes App Store or Google Play.
2. Open the Qardio App on your phone or tablet. If requested, you should enable Bluetooth on your device. You can enable Bluetooth under the Settings menu on your smartphone or tablet.
3. Create a new user login, or login with your existing user name and password. Follow the on-screen instructions to register and set up your personal account.
4. Fit the QardioArm on the upper arm.
5. With the Qardio App open, touch your device to the QardioArm to perform the pairing of your QardioArm with your phone or tablet. When prompted, accept the pairing request.
6. On the Qardio App, press the green START button to initiate the blood pressure measurement. Blood pressure can be affected by the position of the cuff and your physiological condition. It is very important that the cuff is correctly placed. Please read the "Detailed Instructions On Correct Cuff Placement" and the "Checklist For Measuring Your Blood Pressure Correctly and Accurately" section on the User Manual with particular care.

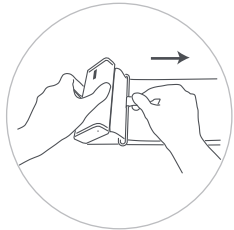
The blood pressure measurement can be stopped at any time by pressing the Cancel button on the Qardio App.

HOW TO TURN ON/OFF THE QARDIOARM

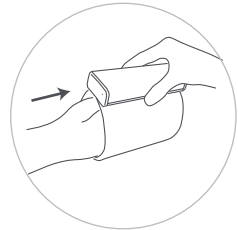
The QardioArm has a small magnet inside the cuff. The device turns itself on when you unwrap the cuff and it turns off when you wrap the cuff back up. When left unwrapped, QardioArm will turn itself off after a few minutes automatically to preserve battery life. To check if your device is switching on, look for the short blink of a green light on the side of the device when opening the cuff. Always store the QardioArm with the cuff wrapped around the device.

DETAILED INSTRUCTIONS FOR CORRECT CUFF PLACEMENT

1. Ideally, remove close-fitting garments from upper arm. If you roll up your sleeve, ensure it does not cause constriction of the blood flow in your upper arm.
2. Unroll the cuff of your QardioArm, and pull the tab to open the cuff loop. (As indicated in drawing 1.)
3. Insert your arm inside the cuff loop. (As indicated in drawing 2.)
4. Pull the cuff to close it around your arm. You should fit the cuff closely, but not too tight so you can insert a finger between your arm and the cuff. (As indicated in drawing 3.)
5. Make sure that the cuff is positioned about 1 inch or 2 cm above the elbow, and your QardioArm is positioned on the inner side of the arm, over the artery. The Qardio logo should be on the bottom, towards your hand.
6. Support your arm so it is relaxed, and ensure that the QardioArm is at the same height as your heart. Your arm should remain slightly bent while taking the measurement.



1. Unroll the cuff and pull the tab

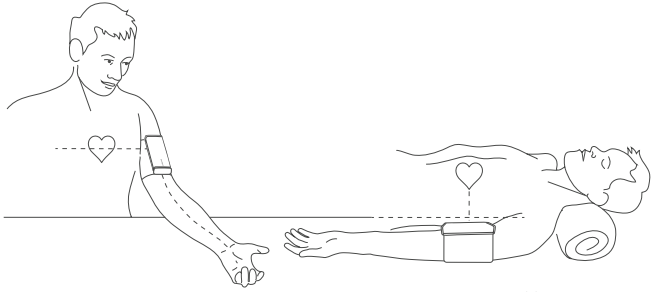


2. Insert your arm through the cuff loop

3. Close the cuff

BODY POSTURE DURING BLOOD PRESSURE MEASUREMENT

Note: Blood pressure can be affected by the position of the cuff and your physiological condition.



Sitting During Measurement:

1. Be seated with your feet flat on the floor without crossing your legs.
2. Place your hand, palm-side up, in front of you on a flat surface such as a desk or a table.
3. The middle of the cuff should be at the same level as your heart.

Lying Down During Measurement:

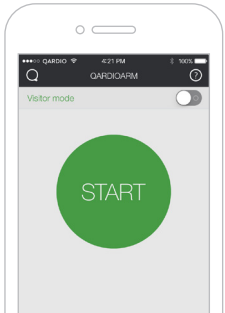
1. Lie on your back.
2. Straighten your arm alongside your body with your palm facing up.
3. The cuff should be placed at the same level as your heart.

DETAILED INSTRUCTIONS ON TAKING A BLOOD PRESSURE MEASUREMENT

Taking a blood pressure measurement with the QardioArm is easy and is done in a few simple steps:

1. Open the Qardio App on your iOS or Android device.
2. Unwrap the cuff from around the QardioArm to switch on the device and pull the tab to open the cuff loop.
3. Fit the QardioArm cuff around your upper arm. You can review the instructions for proper cuff placement at any point.
4. Press the green START button on the Qardio App to start measuring.

   The cuff will inflate automatically. Relax, do not move and do not tense your arm muscle until the measurement result is displayed. Breathe normally and do not talk.



When the correct pressure is reached, the inflation stops and the pressure gradually decreases. If the required pressure was not reached, the device will automatically inflate additional air into the cuff.

5. The result, comprising of the systolic and the diastolic blood pressure and the pulse rate, is displayed on the Qardio App.
6. When the device has finished measuring, remove the cuff and wrap it around the QardioArm to switch off the device.

   If the cuff is left unwrapped, in a few minutes QardioArm switches off automatically. In this case, you will have to wrap the cuff around the QardioArm and re-open it to switch on the device.

CHECKLIST FOR MEASURING YOUR BLOOD PRESSURE CORRECTLY AND ACCURATELY

- ✓ Avoid eating, smoking or any activity immediately before taking the measurement.
- ✓ Sit down and relax for a few minutes before taking the measurement.
- ✓ Always measure the same arm (normally left, or as instructed by your doctor).
- ✓ Ideally, remove close-fitting garments from upper arm. If you roll up your sleeve, ensure it does not cause constriction of the blood flow in your upper arm. Do not place the cuff over thick clothes.
- ✓ You should fit the cuff closely, but not too tight so you can insert a finger between your arm and the cuff.
- ✓ Make sure that the cuff is positioned about 1 inch or 2 cm above the elbow, and your QardioArm is positioned on the inner side of the arm, over the artery.
- ✓ The Qardio logo should be on the bottom, towards your hand.
- ✓ Support your arm so it is relaxed and ensure the QardioArm is at the same level as your heart. Your arm should remain slightly bent while taking the measurement.
- ✓ The blood pressure measurement can be stopped at any time by pressing the Cancel button on the Qardio App.

THE TRAFFIC LIGHT INDICATOR

The blood pressure measurement screen shows you the range within which the indicated blood pressure value lies. Depending on the values detected, the bar is colored in green (optimum value), yellow (high value), orange (very high value), or red (dangerously high value). The classification corresponds to the 4 ranges in the table as defined by the international guidelines (ESH, AHA, JSH), as described in “How to Evaluate Your Blood Pressure”.

SELECTING MULTIPLE MEASUREMENT AVERAGING

Blood pressure constantly fluctuates so a result determined by multiple measurements is more reliable and accurate than one produced by a single measurement.

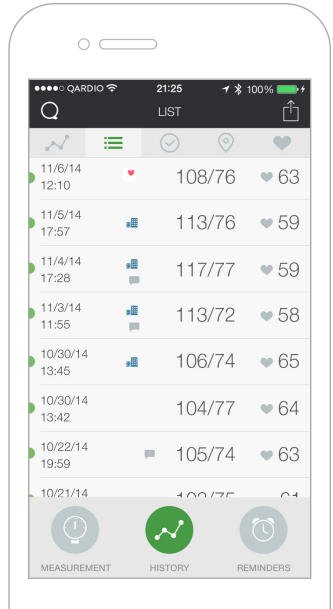
To activate the Multiple Measurement Averaging, which is also useful in case of pulse irregularity, press the Q menu button (on the top left of the screen), then press the Settings button.

On the Settings screen you can select the number of measurements and the pause between measurements (which is set at 30 seconds by default).

When the Multiple Measurement Averaging feature is on, the individual results during the measurement are not displayed. Your blood pressure will only be displayed after all measurements are taken. A countdown indicates the remaining time between measurements. Do not remove the cuff between measurements.

VISUALIZING YOUR HISTORICAL BLOOD PRESSURE DATA

Press the History button on the Blood Pressure page to see your historical blood pressure and heart rate data in a table or chart format.



IMPORTANT FACTS ABOUT BLOOD PRESSURE AND SELF-MEASUREMENT

QardioArm measures your blood pressure. Blood pressure is the pressure of the blood flowing in the arteries generated by the pumping of the heart. Two values, the systolic (upper) value and the diastolic (lower) value, are always measured.

QardioArm also measures your pulse rate. Pulse rate is the number of times the heart beats in a minute.

High blood pressure, especially when permanent or recurrent, can negatively affect your health and must be treated by your doctor.

Always discuss your measurement readings with your doctor and tell him/her if you have noticed anything unusual or if you feel unwell. Never rely on a single blood pressure reading.

There are several potential causes of high blood pressure. Your doctor will explain them in more detail and offer treatment where appropriate. Besides medication, weight loss and exercise can also help to lower your blood pressure.

You should never alter the dosage of any medications prescribed by your doctor.

Blood pressure is subject to wide fluctuations throughout the day, depending on various potential factors, including physical exertion and physical condition. You should routinely take your measurements in quiet conditions when you feel relaxed. Ideally, you should take two readings every time (both in the morning and in the evening) or as prescribed by your doctor.

Deviations between measurements taken by your doctor or in the pharmacy and those taken at home are quite normal, as these situations are completely different.

It is recommended to have at least 30 seconds in between measurements.

If you are pregnant, consult your healthcare provider before use. Monitor your blood pressure regularly throughout pregnancy as it can change drastically during this time.

When you detect unusually high readings during pregnancy, you should measure again after at least four hours. If the reading is still too high, consult your doctor or obstetrician.

Physical activity including eating, drinking, and smoking as well as excitement, stress, and many other factors can influence blood pressure results.

HOW TO EVALUATE YOUR BLOOD PRESSURE

The World Health Organization (WHO) has created the following guide for assessing high blood pressure (without regard to age or gender). It is important to note that various factors (e.g. diabetes, obesity, smoking, etc.) also need to be considered. Consult with your physician for an accurate assessment and diagnosis of your health condition.

BLOOD PRESSURE CLASSIFICATION CHART	Systolic BP mmHg	Diastolic BP mmHg	COLOR INDICATOR
Optimal	< 120	< 80	Green
Normal	120 - 129	80 - 84	Green
High-Normal	130 - 139	85 - 89	Yellow
Grade 1 Hypertension	140 - 159	90 - 99	Yellow
Grade 2 Hypertension	160 - 179	100 - 109	Red
Grade 3 Hypertension	> 180	> 100	Red

WHO/ISH Definitions and Classifications of Blood Pressure Levels
Source: Chalmers J et al. WHO-ISH Hypertension Guidelines Committee. 1999 World Health Organization - International Society of Hypertension Guidelines for the Management of Hypertension. J Hypertens, 1999, 17:151-185

This chart is not intended to provide a basis for any type of diagnosis or emergency assessment; this chart only depicts different classifications of blood pressure. Consult your physician for an interpretation and diagnosis based on your personal blood pressure results.

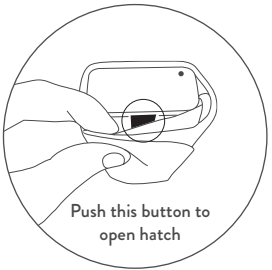
REPLACING THE BATTERIES

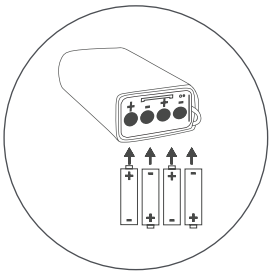
When the batteries are approximately 25% full the battery symbol will appear on the Qardio App blood pressure measurement screen. Although the QardioArm will continue to measure reliably, you should obtain replacement batteries.

If the empty battery symbol appears on the Qardio App, your QardioArm batteries are depleted and it's time to replace them. You cannot take any further measurements and must replace the batteries.

You should replace all four AAA alkaline batteries at the same time.

Use 4 new, long-life 1.5V, size AAA batteries. Do not use batteries beyond their expiration date, and do not use rechargeable batteries.





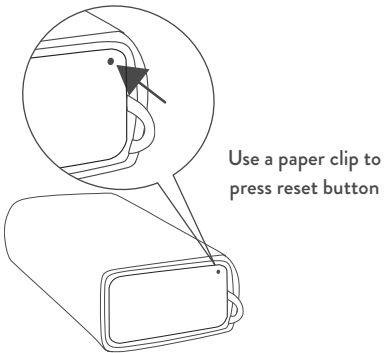
To Replace Batteries:

1. Release the battery compartment hatch by pressing the button under the cuff as shown in the drawing.
2. Replace all four AAA alkaline batteries with new ones, ensuring that the polarities are correctly aligned: the + (positive) and – (negative) polarities should match the polarities indicated on the AAA alkaline batteries compartment.
3. Put the battery compartment hatch back in place, pushing until it clicks in place.
4. You will see a green light shining through the battery compartment hatch.

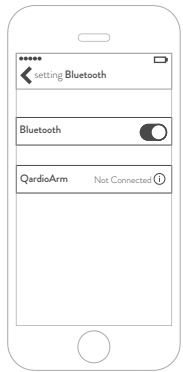
RESETTING THE PAIRING ON iOS

In order to reset the pairing, unwrap the cuff from around the QardioArm to switch on the device and use a paper clip to press the button on the pinhole on the battery compartment hatch. You should see a green light shining through.

If necessary, go into the Settings of your phone or tablet, select the QardioArm and select “Forget this device”.

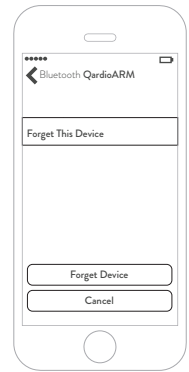


Use a paper clip to press reset button



Step 1

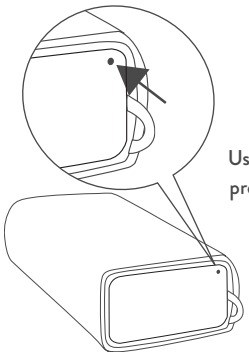
Step 2



Step 3

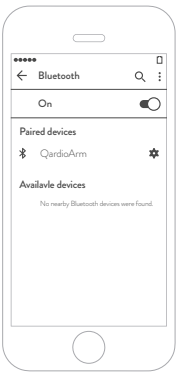
RESETTING THE PAIRING ON ANDROID

In order to reset the pairing, unwrap the cuff from around the QardioArm to switch on the device and use a paper clip to press the button on the pinhole on the battery compartment hatch. You should see a green light shining through.

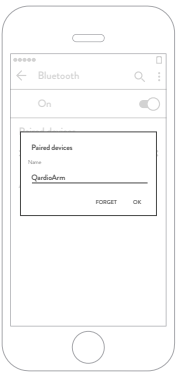


Use a paper clip to press reset button

If necessary, go into the Settings of your phone or tablet, select the QardioArm and select “Forget this device”.



Step 1



Step 2

ACCURACY TESTING AND MAINTENANCE

QardioArm comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in the "Technical Specifications" section.

If you can't fix the problem using the trouble shooting instructions, please contact Qardio customer service at *support.getqardio.com*.

We recommend the QardioArm be tested for accuracy every 2 years or after mechanical impact (e.g. being dropped). Please contact Qardio customer service at *support.getqardio.com* to arrange the test.

⚠ CONTRAINDICATIONS

It is not recommended for people with serious arrhythmia to use this blood pressure monitor.

⚠ CAUTIONS

Self-diagnosis of measurement results and self-treatment are potentially dangerous. You should always consult your doctor.

People with severe blood flow problems, or blood disorders, should consult a doctor before using the blood pressure monitor as cuff inflation might cause internal bleeding.

Complicating factors such as common arrhythmias, ventricular premature beats, atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, age, pregnancy, preeclampsia or renal disease can affect the performance of the automated sphygmomanometer and/or its blood pressure reading.

If you suffer from an irregular heartbeat, measurements taken with this device should be evaluated with your doctor.

This device may only be used for the purposes described in this User Manual. The manufacturer cannot be held liable for damage or injury caused by incorrect use. Always follow the operating procedures described in this User Manual to measure your blood pressure accurately and safely.

As QardioArm contains magnets, please consult your implantable pacemaker, defibrillator or other device before use. As a general rule, maintain a minimum distance of 6 inches or 15 cm between QardioArm and your implanted devices, or more if so specified by the manufacturer of your implanted device.

⚠ GENERAL USAGE, SAFETY AND PRECAUTIONS, CLEANING

- Do not use the QardioArm blood pressure monitor for any purpose other than measuring blood pressure.
- Do not take a measurement immediately after eating, smoking, drinking alcohol, bathing or exercising.
- Do not use the QardioArm blood pressure monitor while operating a mechanical vehicle or in a moving vehicle (e.g. during air travel)
- Do not leave the QardioArm blood pressure monitor unattended around children or persons who cannot express their consent to use.
- Do not inflate the arm cuff when it is not wrapped around your arm.
- Do not wrap the cuff inside-out.
- Do not apply strong shocks and vibrations to the QardioArm blood pressure monitor, as this may result in damage to the device.
- Do not drop the QardioArm blood pressure monitor.
- Do not expose the cuff and/or the QardioArm blood pressure monitor to temperatures outside the storage or operating range.
- Do not expose the cuff and/or the QardioArm blood pressure monitor to direct sunlight for extensive periods of time.
- Do not expose the arm cuff and/or the QardioArm blood pressure monitor to water, liquids or moisture.
- Do not expose the arm cuff and/or the QardioArm blood pressure monitor to dust or particles.

- Do not disassemble the QardioArm blood pressure monitor.
- Do not use an alcohol-based or solvent agent to clean the device. Clean the device only with a soft, dry cloth. Clean the cuff carefully with a damp cloth and soap. Do not submerge any part of the QardioArm in water at any time.

AAA ALKALINE BATTERY USAGE AND STORAGE

- If AAA alkaline battery fluid should get on your skin or clothing, immediately rinse thoroughly with plenty of clean water.
- Use only four AAA alkaline batteries with the QardioArm blood pressure monitor. Do not use any other types of AAA batteries, and do not use any type of rechargeable batteries.
- When replacing batteries, insert the four AAA alkaline batteries with their polarities aligned as indicated on the QardioArm blood pressure monitor.
- Immediately replace the AAA alkaline batteries when they are depleted.
- Always replace all four AAA alkaline batteries at the same time: do not use new and old AAA alkaline batteries together.
- If the QardioArm blood pressure monitor will not be used for a long period of time, the batteries should be removed.
- Store the device and the components in a clean, dry and safe location.

IRREGULAR HEART BEAT MESSAGE

If irregular heartbeat is detected during the measurement procedure, a message will be displayed. Repeat the measurement after one hour. If irregular heart beat is detected several times in a day or week, we recommend you discuss this with your doctor.

Under this condition, the wireless blood pressure monitor can keep functioning, but the results may be inaccurate. There are 2 conditions under which the signal of irregular heart beat will be displayed:

1. The coefficient of variation (CV) of pulse period >25%.
2. The difference between adjacent pulse periods ≥0.14s and the number of such pulses constitutes more than 53 percent of the total number of pulses.

CUSTOMER SERVICE CONTACT

Qardio customer service contact is available at *support.getqardio.com*.

LIMITED WARRANTY

This device is covered by a three-year limited warranty from the date of purchase. The cuff has a functional warranty (bladder tightness) for two years or one thousand (1000) measurements (whichever comes sooner), while batteries and other wearing parts are not covered by the limited warranty.

The limited warranty is valid only on presentation of the purchase receipt confirming date of purchase. Opening or altering the device invalidates the limited warranty.

The guarantee does not cover damage caused by improper handling, discharged batteries, accidents or non-compliance with the operating instructions and normal wearing of parts.

If a defect arises during the warranty period, Qardio, at its option and to the extent permitted by law will (1) repair the product at no charge, using new parts or parts that are equivalent to new in performance and reliability, (2) exchange the product with a functionally equivalent product that is new or equivalent to new in performance and reliability, or (3) refund the original purchase price. This warranty excludes damage resulting from abuse, accident, modifications or other causes that are not defects in materials and workmanship.

Other than the consumer law rights to which you are entitled, all warranties, conditions and other terms not set out in this warranty document are excluded from the limited warranty. Some countries do not allow limitations on how long such warranties, conditions and/or implied terms may last, so the limitations described above may not apply to you.

In no event shall Qardio be liable for (a) any losses that were not caused by our breach of this limited warranty; (b) losses relating to any business of yours, loss of profits, loss of data or loss of opportunity. The provisions of this limited warranty shall not apply to any other liability, except those that cannot be limited or excluded as a matter of law. Depending on where you live, some of the above limitations or exclusions may not apply to you. To obtain warranty service, contact Qardio at www.getqardio.com.

ERROR MESSAGES AND TROUBLESHOOTING

PROBLEM	CAUSE	REMEDY
START button is gray, not green.	QardioArm is not connected to your smartphone or tablet.	Possible solutions: 1) Close the QardioArm cuff and reopen it again. 2) Ensure that Bluetooth is enabled on your phone or tablet and the QardioArm is nearby your phone or tablet. 3) Replace the batteries of the QardioArm. 4) Reset the pairing.
Measurement could not be performed.	During the measurement, error signals were auto-detected by the device, or the pulse signals on the cuff were too weak.	Re-position the cuff and repeat the measurement keeping your arm still and without talking. Check the marks on the cuff and the instructional videos on the Qardio App to verify you are positioning the QardioArm correctly. If the problem occurs again, please contact customer service.

PROBLEM	CAUSE	REMEDY
No pressure in the cuff.	An adequate pressure cannot be generated in the cuff. A leak may have occurred.	1) Check that the cuff is correctly positioned and fits on the arm. 2) Replace the batteries, if necessary. Repeat the measurement. If the problem occurs again, contact customer service.
Abnormal result.	The measuring signals are inaccurate therefore no result can be displayed. This could be due to the cuff not being fully deflated before measurement, noise interference, user talking, user movements, cuff not correctly fastened, cuff broken, pump or valve failure, pressure overflow, or other special characteristics of the user.	1) Read through the instructions for performing reliable measurements. Reposition the cuff and repeat the measurement while keeping your arm still and without talking. If the problem occurs again, please contact customer service. 2) If user has special conditions, please contact your physician.

PROBLEM	CAUSE	REMEDY
Irregular heartbeat.	Pulse irregularity was detected during measurement and the blood pressure measurement might not be fully reliable.	Repeat the measurement after one hour. If irregular heart beat is detected several times in a day or week, we recommend you to discuss this with your doctor. If irregular heartbeat is detected during the measurement procedure, a message will be displayed. Under this condition, the wireless blood pressure monitor can keep functioning, but the results may be inaccurate. Please consult your physician for accurate assessment.
Though the batteries are installed, the START button on the Qardio App is still gray.	Batteries are not inserted correctly. Battery level is too low.	1) Close the device and wait five seconds. Unwrap the cuff from around the QardioArm and try again. 2) Check the AAA alkaline batteries polarities and correct, if required. 3) Replace the AAA alkaline batteries.

PROBLEM	CAUSE	REMEDY
Each measurement has significantly different results.	Under normal measuring circumstances, the reading at home is different from that of the clinics. The variation is due to the different environments. The blood pressure is changing according to the physiological or psychological conditions of your body.	1) Relax for a few minutes before each measurement. Try to measure your blood pressure at consistent times and locations. Discuss your blood pressure values with your physician. 2) If the problem occurs again, please contact customer service at *support.getqardio.com*.
Batteries depleted.	Battery level is too low.	Replace the batteries according to the instructions. If the problem occurs again, please contact customer service at *support.getqardio.com*.
The cuff does not fit.	The cuff circumference is limited to 8.7 in - 14.6 in (22cm - 37cm) and is measured by a close fitting around the center of the upper arm.	Please contact customer service at *support.getqardio.com*.

QARDIOARM TECHNICAL SPECIFICATIONS

Weight	0.68 lb (310g) including batteries.
Cuff Size	8.7 in – 14.6 in diameter (22 cm – 37 cm diameter)
Dimensions	5.5 x 2.7 x 1.5 in (140 x 68 x 38 mm) when closed.
Measurement	Oscillometric method with automatic inflation and controlled pressure release valve.
Measurement Range	40~250 mmHg for blood pressure. 40~200 beats/minute for pulse.
Technical Measurement Precision	Accuracy ±3mmHg or ±2% of readout value for blood pressure. ±5% of readout for pulse.
Measurement Resolution	1mmHg for blood pressure. 1 beat/min for pulse.
Power Source	4 x 1.5V Batteries; size AAA, supplied.
Operating Conditions	50~104F (10~40C) temperature, 15~90% relative maximum humidity, atmospheric pressure 86Kpa~106kpa, maximum altitude: 2000m.
Operating Range	At a barrier-free space, the maximum range of detection between your QardioArm and the device is 10 meter.
Storage Conditions	-13~158F (-25~70C) temperature, 10~95% relative maximum humidity, atmospheric pressure 86Kpa~106kpa, maximum altitude: 2000m.
Works with	Requires a smart phone or tablet with Bluetooth 4.0, and iOS 7.0 (or later) or Android 4.4 "KitKat" (or later). The detailed list of compatible devices is available on getqardio.com/devices. Free Qardio App (available for download on the App Store or on Google Play).

Specifications are subject to change without prior notice or any obligation on the parts of the manufacturer. Certain features may require purchase of separate services.

DISPOSAL

Actuation of European directives 2002/95/EC, 2002/96/EC and 2003/108/EC, for reduction in use of dangerous substances in the electric and electronic device and for garbage disposal. The symbol applied on the device or its packaging means that at the end of its useful life the product must not be disposed of with domestic waste.

At the end of devices useful life, the user must deliver it to the able collecting centers for electric and electronic garbage, or give back to the retailer when purchasing a new device. Disposing of the product separately prevents possible negative consequences for the environment and for health, deriving from inadequate disposal. It also allows the recovery of materials of which it's made up in order to obtain an important saving of energy and resources and to avoid negative effects to the environment and health. In case of abusive disposal of device by the user, will be applied administrative endorsements in compliance with current standard. The device and its parts is made with regard to disposal, as appropriate, in accordance with national or regional regulations.

CERTIFICATIONS

This device complies with the following normative documents:

COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices as amended by Directive 2007/47/EC

EN ISO 13485:2003 /AC: 2009: Medical devices - Quality management systems – Requirements for regulatory purposes (ISO 13485:2003) Reference to standards contd.

EN ISO14971:2012: Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)

IEC60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007); EN 60601-1:2006+AC (2010): Medical electrical equipment - Part 1: General requirements for basic safety and essential Performance

EN1060-3:1997+A1:2005+A2:2009: Non-invasive sphygmomanometers,Part 3: Supplementary requirements for electromechanical blood pressure measuring systems

EN1060-4:2004: Non-invasive sphygmomanometers. Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers

IEC/EN 60601-1-11: General requirements for basic safety and essential performance –Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC 80601-2-30:2009 (First Edition) for use in conjunction with IEC 60601-1:2005

EN 80601-2-30:2010/ ANSI/AAMI 80601-2-30:2009: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

EN300328 V1.7.1:2006: Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques;

Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive

EN301489-1-3 V1.9.2:2011 Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements

EN301489-1-17 V2.2.1:2012 Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements

EN60601-1-2:2007 /AC 2010: Medical electrical equipment: Part 1-2: General requirements for basic safety and essential performance-collateral standard electromagnetic compatibility

EN 55011Group 1 Class B:2009+A1:2010 : Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement

FCC part B 15B:2013 Electromagnetic Compatibility

FCC Rule Part: 15.247 Cat: DSS (Bluetooth) FCC Rule Part: 15.247 Cat: DTS (BT4.0)

EN ISO 10993-1:2009 Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)

ANSI/AAMI SP10:2002/A1 2003(R) 2008: Manual, electronic or automated sphygmomanometers

ANSI/AAMI/ISO 81060-2:2009 Non-invasive sphygmomanometers Part 2: Clinical validation of automated measurement type

FCC STATEMENT

Federal Communications Commission (FCC) Statement 15.21

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

15.105(b)

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.

A. This device complies with Part 15 of the FCC Rules/Industry Canada license-exempt RSS standard(s). Operation is subject to the following 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 of the device.

B. This device and its antenna(s) must not be co-located or operating in conjunction with any other antenna or transmitter

C. Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user authority to operate this equipment

IMPORTANT NOTE (for portable device configuration):

Federal Communication Commission (FCC) Radation Exposure Statement. This EUT is in compliance with SAR for general population/uncontrolled exposure limits in ANSI/IEEE C95.1-1999 and has been tested in accordance with the measurement methods and procedures specified in OET Bulletin 65 Supplement C.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de license. L'explotation est autorisée aux deux conditions suivantes:

1) il ne doit pas produire de brouillage et

2) L'utilizateur du dispositif doit être prêt à recepter tout brouillage radioélectrique reçu, même si se brouillage est susceptible de compromettre le fonctionnement du dispositif.

ICES-003. This Class B digital apparatus complies with Canadian ICES-003. Cet appareil numérique de la classe B est conforme à la norme NMB-003 du Canada.

FCC RF Radiation Exposure Statement:

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

IC Radiation Exposure Statement / IC Déclaration sur la radioexposition.

This EUT is in compliance with SAR for general population-uncontrolled exposure limits in IC RSS-102 and has been tested in accordance with the measurement methods and procedures specified in IEEE 1528. This equipment should be installed and operated with minimum distance of 1.5cm between the ratiator and your body.

Cet appareil est conforme avec SAR pour la population générale/limites d'exposition abusive IC RSS-102 et a été testé en conformité avec les méthodes et procédures spécifiées dans la norme IEEE 1528 mesure. Cet équipement doit être installé et utilisé à une distance minimale de 1,5cm entre le radiateur et votre corps. La séparation de test SAR de la distance de 10mm pour hotspot.

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.
En vertu de la réglementation de l'Industrie du Canada, cet émetteur de radio ne peuvent fonctionner en utilisant une antenne d'un type et maximum (ou moins) gain approuvé pour l'émetteur par Industrie du Canada. Pour réduire le risque de brouillage aux autres utilisateurs, le type d'antenne et son gain doivent être choisis de sorte que la

puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas ce qui est nécessaire pour la réussite de comunication.

RF STATEMENT

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following section.

Interference may occur in the vicinity of equipment marked with the following symbol .

Portable and mobile RF communication equipment (e.g. cell phones) can affect Medical Electrical Equipment.The use of accessories and cables other than those specified may result in increased emissions or decreased immunity.

The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic quipment.

The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.

Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Any other accessories, transducers and cables may result in increased emissions or decreased immunity and EMC performance.

The device should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, it should be observed in order to verify normal operation in the configuration in which it will be used.

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following. Portable and mobile RF communication equipment (e.g. cell phones) can affect Medical Electrical Equipment. The use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the unit.

SHELF LIFE

The shelf life of your device is 5 years or for 10,000 measurements (conversion to usage: 2 people with 3 measurements a day that is approximately 5 years).

Guidance and manufacturer's declaration-electromagnetic emissions		
The QardioArm Blood Pressure Monitor system is intended for use in the electromagnetic environment specified below. The customer or the user of the QardioArm Blood Pressure Monitor system should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
CE emissions CISPR11	Group 1	The QardioArm Wireless Blood Pressure Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RE emissions CISPR11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	The QardioArm Wireless Blood Pressure Monitor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Not applicable	

Designed by and manufactured for Qardio, Inc. California, USA.
FOR US AND INTERNATIONAL

Type BF Applied Part (cuff)

FCC ID: 2ABF2-888ARM-1
IC: 11885A-888ARM01

Read this manual before use.

WEEE

CE 2460

YA HORNG ELECTRONIC CO., LTD.
Tainan, Taiwan
Factory: ATTEN ELECTRONIC (DONGGUAN) CO., LTD.
188 Industrial District, Ping Shan Administrative District,
Tang Shia Town, Dongguan, 190, CN, 518055

2017

US Importer Qardio, Inc. 340 S Lemon Ave #1104F,
Walnut, California 91789, USA.

EC REP Kahl Handelsvertretung
Add.: Isarstr.33 40699 Erkrath, Germany

Designed by and manufactured for Qardio, Inc. California, USA.
FOR CANADA

Type BF Applied Part (cuff)

FCC ID: 2ABF2-888ARM-1
IC: 11885A-888ARM01

Read this manual before use.

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2017

US Importer Qardio, Inc. 340 S Lemon Ave #1104F,
Walnut, California 91789, USA.

Declaration – electromagnetic emissions and immunity for equipment and systems that are not life-supporting and are specified for use only in a shielded location			
The QardioArm Wireless Blood Pressure Monitor system declaration-electromagnetic immunity			
The QardioArm Blood Pressure Monitor system is intended for use in the electromagnetic environment specified below. The customer or the user of the QardioArm Blood Pressure Monitor system should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RFIEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT or SYSTEM including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Interference may occur in the vicinity of equipment marked with the following symbol
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Declaration – electromagnetic immunity			
The QardioArm Blood Pressure Monitor system is intended for use in the electromagnetic environment specified below. The customer or the user of the QardioArm Blood Pressure Monitor system should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD)IEC 61000-4-2	6 kV contact 8 kV air	6 kV contact 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	2 kV for power supply lines 1 kV for input/output lines	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	1 kV differential mode 2 kV common mode	N/A	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	-5 % UT(95 % dip in UT) for 0.5 cycle -40 % UT(60 % dip in UT) for 5 cycles -70 % UT(30 % dip in UT) for 25 cycles -5 % UT(95 % dip in UT) for 5 sec	N/A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EQUIPMENT or SYSTEM requires continued operation during power mains interruptions, it is recommended that the EQUIPMENT or SYSTEM be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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Qardio products should be only used in conjunction with professional medical advice for diagnosis or treatment, and not as a substitute or replacement of it.

Patents assigned and pending.

Version 2.9.2 - Eng - 5005, 5012, 5029, 5036, 5043, 5050, 5067