QARDIO

QardioArm A100

A Smarter Read on Blood Pressure

User Guide

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QardioArm: Welcome to a smarter read on blood pressure!

Your new QardioArm blood pressure monitor is a reliable medical device for taking measurements on the upper arm. This device was developed in collaboration with physicians and clinical tests were carried out prove its measurement accuracy.

Every day, we at Qardio put our passion and effort into bringing you products of superior quality, design and technology that can change your life for the better.

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 on www.getqardio.com/support, or visit our website www.getqardio.com, for more information.

Track your revolution with Qardio.

Intended Use

QardioArm is a fully automatic, non-invasive wireless blood pressure monitor. QardioArm is a blood pressure measurement system intended to measure the diastolic and systolic 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 22cm-37cm (8.7in -14.6in).

Important safety information

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

Package contents

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

Requirements

The QardioArm blood pressure monitor requires iOS 7.0 or later, and an iOS device with Bluetooth 4.0. These include: iPhone 4S, iPhone 5 or later, iPad 4th generation or later, iPad mini, iPod Touch 5th generation or later.

In order to use your QardioArm blood pressure monitor, you have to install the Qardio app available for free on the Apple App Store, or on www.getqardio.com.

Using QardioArm for the first time

1. Download the Qardio app: On your mobile phone or tablet go to www.getqardio.com and when prompted, download the app. Alternatively,go on the Apple App Store. The Qardio app is available for free.

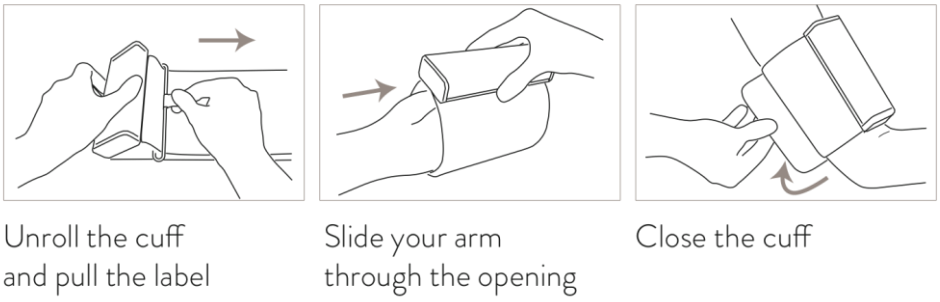
2. Open the Qardio app on your phone or tablet. If requested, you should enable Bluetooth on your device, You can enable Bluetooth under the *Settings* menu on your smartphone or tablet

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 Qardio Arm on the upper arm
5. With the Qardio app open, touch your device on the QardioArm to perform the pairing of your QardioArm with your phone or tablet. You should accept the pairing request.
6. On the Qardio app, press the green START button to initiate the blood pressure measurment. Blood pressure can be affected by the position of the cuff and your physiologic 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 reliably* sections of this User Guide with particular care.

Detailed instructions on correct cuff placement

1. Ideally, remove close-fitting garments from the upper arm, or ensure that rolling the sleeve up does not cause constriction. If you are unable to remove or roll-up your shirtsleeve, then ensure it remains flat under the cuff.
2. Always ensure that the cuff fits correctly, verifying the markings on the cuff. You should fit the cuff closely, but not too tight.
3. Make sure that the cuff is positioned 2cm (0.8in) above the elbow. The QardioArm must be positioned over the artery that runs down the inner side of the arm. The Qardio logo should be on the bottom, towards your hand. Support your arm so it is relaxed, and ensure that the QardioArm is at the same height as your heart. Your arm should lightly bend while taking the measurement.



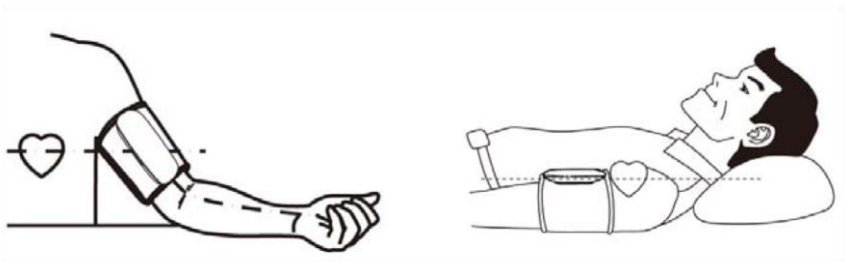
Body Posture

Sitting Comfortably During Measurement

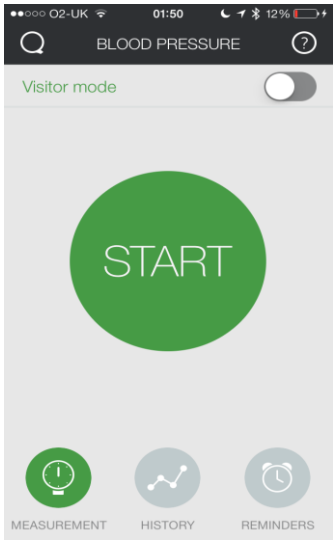
1. Be seated with your feet flat on the floor without crossing your legs.
2. Place your hand, palm-side up, in front of you on a flat surface such as a desk or a table.
3. The middle of the cuff should be at the level of the right atrium of your heart.

Lying Down During Measurement

1. Lie on your back.
2. Place your arm straight along your side with your hand palm-side up.
3. The cuff should be placed at the same level as your heart.



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



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 device.
2. Unwrap the cuff from around the QardioArm to switch on the device.
3. Fit the QardioArm cuff around your upper arm. You can review the instructions to do so at any point.
4. Press the green START button on the Qardio App Blood Pressure measurement screen to start measuring.
5. The cuff will now inflate automatically. Relax, do not move and do not tense your arm muscles until the measurement result is displayed. Breathe normally and do not talk.
6. When the correct pressure is reached, the inflation stops and the pressure gradually decrease. If the required pressure was not reached, the device will automatically inflate additional air into the cuff.
7. The result, comprising the systolic and the diastolic blood pressure and the pulse rate, is displayed on the Qardio App.
8. When the device has finished measuring, remove the cuff and wrap it around the QardioArm to switch it off automatically.

Checklist for measuring your blood pressure correctly and reliably

- ✓ Avoid activity, eating or smoking immediately before the measurement.
- ✓ Sit down and relax for a few minutes before the measurement.
- ✓ Always measure on the same arm (normally left, or as instructed by your doctor).
- ✓ Ideally, remove close-fitting garments from the upper arm, or ensure that rolling the sleeve up does not cause constriction. If you are unable to remove or roll-up your shirtsleeve, then ensure it remains flat under the cuff.
- ✓ Always ensure that the cuff fits correctly, verifying the markings on the cuff. You should fit the cuff closely, but not too tight.
- ✓ Make sure that the cuff is positioned 2cm (0.8in) above the elbow. The QardioArm must be positioned over the artery that runs down the inner side of the arm. The Qardio logo should be on bottom, towards your hand.
- ✓ Support your arm so it is relaxed, and ensure that the QardioArm is at the same height as your heart. Your arm should lightly bend while taking the measurement.

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 values), yellow (high values), orange (very high values), or red (dangerously high values). 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 measurements averaging

Because blood pressure constantly fluctuates, a result determined with multiple measurements is more reliable than one produced by a single measurement.

There is a break of 30 seconds between the measurements. A count down indicates the remaining time.The individual results are not displayed. Your blood pressure will only be displayed after all measurements are taken. Do not remove the cuff between measurements.

Visualizing your historical blood pressure data

Press the History button on the Blood Pressure page to visualize 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 feel unsure. 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 lowering your blood pressure.

You should never alter the dosages 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 condition. You should routinely take your measurements in quiet conditions when you feel relaxed. Ideally, you should take two readings every time (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.

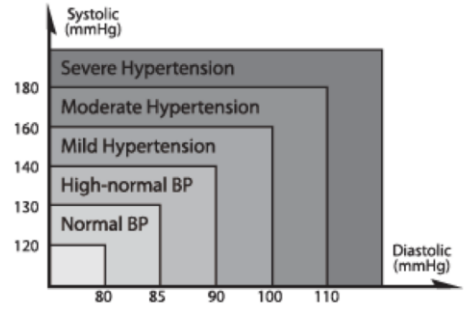
If you are pregnant, consult your healthcare provider before use. Monitor your blood pressure regularly throughout pregnancy as it can change drastically during this time. When you detect unusual high readings during pregnancy, you should measure again after at least four hours. If the reading is still too high, consult your doctor or obstetrician.

Physical activity including eating, drinking, and smoking as well as excitement, stress, and many other factors 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.

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 blood pressure results.



BLOOD PRESSURE CLASSIFICATION	SBP mmHg	DBP mmHg	COLOR INDICATOR
Optimal	<120	<80	GREEN
Normal	120-129	80-84	GREEN
High-normal	130-139	85-89	GREEN
Grade 1 Hypertension	140-159	90-99	YELLOW
Grade 2 Hypertension	160-179	100-109	ORANGE
Grade 3 Hypertension	≥180	≥100	RED

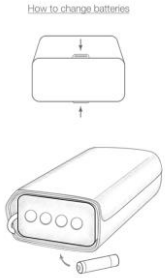
WHO/ISH Definitions and Classification of Blood Pressure Levels

Replacing the AAA alkaline batteries

When the batteries are approximately 75% empty 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.

To replace batteries:



1. Release the batteries compartment hatch by pressing the button under the cuff as shown in the drawing.
2. Replace all four AAA alkaline cells 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 batteries compartment hatch back in place, pushing until it clicks in place.
4. You will see a green light shining through the batteries compartment hatch.

Resetting the pairing

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 in the Settings of your phone or tablet, select the QardioArm and select forget device.

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 problems using the troubleshooting instructions, please contact Qardio customer service on www.getqardio.com

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

Contraindication

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

Caution

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

QardioArm is not suitable for checking the frequency of heart pacemakers.

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 measurement immediately after bathing, drinking alcohol, smoking, exercising or eating.
- 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 particulate.
- Improper continuous pressure of cuff or too frequent measurements may interfere with blood flow , and result harmful injury to the users. Especially, cuff's inflating pressure on the patients who have intravascular access or therapy, or an arterio-venous (A-V) shunt, or same side of mastectomy will have danger on injury.

- Improper continuous pressurization from cuff's inflation on the same limb will cause loss of function of device.
- Do not apply the cuff over the users' arm bearing a wound or medical treatment and so on, as this can cause further influence on the therapy.
- When cuff inflation, always check the device will not result in prolonged impairment of the circulation of the blood on users.
- Do not disassemble the QardioArm blood pressure monitor.
- Do not use an alcoholic-based or solvent agent to clean the device. Clean the device only with a soft, dry cloth. Clean the cuff carefully with a humid cloth and soap. Do not submerse any part of the QardioArm in water at any time.

AAA alkaline cells usage, storage

If AAA alkaline batteries fluid should get on your skin or clothing, immediately and thoroughly rinse 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.

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

Error messages and troubleshooting

Problem	Cause	Remedy
START button is gray, not green	QardioArm is not connected to your smartphone or tablet.	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. 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 are 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.
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 fit to the arm. 2) Replace the batteries if necessary. Repeat the measurement. If the problem occurs again, please contact customer service.
Abnormal result	The measuring signals are inaccurate and no result can therefore be displayed. This could be due to cuff not fully	1) Read through instructions for performing reliable measurements. Re-position the cuff and repeat the measurement keeping your arm still and without talking. If the problem occurs again, please contact

	deflated before measurement, noise interference, user talking, user movements, cuff not correctly fastened, cuff broken, pump or valve failure, pressure overflow, or user special characteristics.	customer service. 2) If user has special characteristics, please contact your physician.
Batteries depleted	Battery level is too low.	Replace batteries according to instructions. If the problem occurs again, please contact customer service..
Irregular heart beat	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, the IHB symbol 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. Batteries 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 cells polarities, and correct, if required. 3) Replace the AAA alkaline cells.
Each measurement has significantly different results.	Under normal measuring circumstance, 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 status 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.
The cuff does not fit	The cuff circumference is limited to 22cm-37cm (measured by close fitting in the centre of the upper arm).	Contact Qardio customer service.

Customer service contact

Qardio customer service is available on www.getqardio.com.

Guarantee

This device is covered by a three-year guarantee from the date of purchase. The guarantee is valid only on presentation of the purchase receipt confirming date of purchase.

Batteries and wearing parts are not included.

Opening or altering the device invalidates the guarantee.

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

The cuff has a functional guarantee (bladder tightness) for two years.

QardioArm Technical Specifications

1)	Weight: 350g (0.77 lb) including batteries
2)	Dimensions: 140 x 68 x 38 mm (5.5 x 2.7 x 1.5 in) when closed

3)	Measurement: Oscillometric method with automatic inflation and controlled pressure release valve.
4)	Measurement range: 40~250 mmHg for blood pressure, 40~200 beats/minute for pulse.
5)	Technical measuring precision:
	Cuff pressure Accuracy: ±3mmHg or ±2% of readout value for blood pressure. ±5% of readout for pulse.
6)	Measurement resolution: 1mmHg for blood pressure. 1 beat/min for pulse.
7)	Power source: 4 x 1.5V Batteries; size AAA, supplied.
8)	Operating conditions: 10~40C (50~104F) temperature, 15~90% relative maximum humidity, atmospheric pressure 86Kpa~106kpa, maximum altitude: 2000m.
9)	Storage and transport conditions: -25~70C (-13~158F) temperature, 10~95% relative maximum humidity, atmospheric pressure 86Kpa~106kpa, maximum altitude: 2000m.
10)	Compatibility: iPhone 4S or later, iPad 4th generation or later, iPad mini, iPod Touch 5th generation or later. Free companion app with iOS 7.0 or later.
11)	Product life : 5 years
12)	Clinical Test : In accordance with EN1060-4 :2004 & ANSI/AAMI/ISO 81060-2:2009

Specifications are subject to change without prior notice or any obligation on the parts of the manufacturer.

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 mared 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.

FCC/IC Caution:

1. This device complies with Part 15 of the FCC rules/ Industry Canada licence-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.

2. This Transmitter must not be colocated or operating in conjunction with any other antenna or transmitter.

3. Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

IMPORTANT NOTE : (For Portable Device Configuration)

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

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.

Industry Canada Caution:

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

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

(1) il ne doit pas produire de brouillage et

(2) l' utilisateur du dispositif doit étre prêt à accepter tout brouillage radioélectrique reçu, même si ce brouillage est susceptible de compromettre le fomctionnement du dispositif.

IC IMPORTANT NOTE : (For Portable Device Configuration)
IC Radiation Exposure Statement

This device has been evaluated and complied with IC RSS-102 RF exposure requirement.

Ce dispositif a ete evalue et respecte IC RSS-102 condition d'exposition aux RF.

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 potentialradio 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 Canada. pour réduire risque d'interférence aux autres utilisateurs, le type d'antenne et son gaindoivent être choisis de sorte que lapuissance isotrope rayonnée équivalente (PIRE) ne dépasse pas ce qui est nécessaire pour la réussite de communication.

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.

- Interference may occur in the vicinity of equipment marked with 
- 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 equipment.
- 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 that if adjacent or stacked use is necessary, which should be observed 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.

<table>
<tr><th colspan="3">Guidance and manufacturer’s declaration-electromagnetic emissions</th></tr>
<tr><td colspan="3">The Wireless Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Wireless Blood Pressure Monitor should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td>Compliance</td><td>Electromagnetic environment - guidance</td></tr>
<tr><td>CE emissions CISPR11</td><td>Group 1</td><td rowspan="2">The BP-801 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.</td></tr>
<tr><td>RE emissions CISPR11</td><td>Class B</td></tr>
</table>

Harmonic emissions IEC 61000-3-2	Not applicable	The BP-801 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	

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 Wireless Blood Pressure Monitor declaration- electromagnetic immunity				Declaration – electromagnetic immunity			
The Wireless Blood Pressure Monitor system is intended for use in the electromagnetic environment specified below. The customer or the user of the Wireless Blood Pressure Monitor system should assure that it is used in such an environment.				The Wireless Blood Pressure Monitor system is intended for use in the electromagnetic environment specified below. The customer or the user of the Wireless Blood Pressure Monitor system should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance	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 %.
Conducted RF IEC 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.	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.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	N/A		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	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

					UT) for 25 cycles -5 % UT (95 % dip in UT) for 5 sec		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	N/A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Manufactured for Qardio, Inc. 340 S Lemon Ave #1104F, Walnut, California 91789, USA.
www.getqardio.com


Type BF Applied Part (cuf

CE 0434


Read this manual before use.


WEEE

IP22 Ingress of water or particulate matter

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


YA HORNG ELECTRONIC CO., LTD.
No.35,Shalun,AndingDist.,Tainan,Taiwan

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2013

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User Guide v. 2.0.