

Automatic Upper Arm Blood Pressure Monitor

Model BP2/BP2A

User Manual



English | Deutsch | Italiano | Español | Français

User Manual

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1. The Basics

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observing this manual is a prerequisite for proper product performance and correct operations, which ensures patient and operator safety.

1.1 Safety

Warnings and Tips

- Before using the device, please ensure that you have read this manual thoroughly and fully understand the corresponding precautions and risks.
- This device has been designed for practical use but is not a substitute for visiting the doctor.
- The data and results displayed on the device are for reference only and cannot be directly used for diagnostic interpretation or treatment.
- We recommend not using this device if you have a pacemaker or other implanted devices. Follow your doctor's advice, if applicable.
- Do not use this device with a defibrillator.
- Do not use this device during an MRI exam.
- Do not use the device in a combustible environment (i.e., oxygen-enriched environment).
- Never submerge the device in water or other liquids. Do not clean the device with acetone or other volatile solutions.
- Do not drop this device or subject it to strong impacts.

- Do not place this device in pressure vessels or gas sterilization devices.
- Do not dismantle the device because this could cause damage or malfunctions or impede device operations.
- This device is not intended for use by people (including children) with restricted physical, sensory, or mental acumen or a lack of experience and/or a lack of knowledge unless they are supervised by someone responsible for their safety, or they receive instructions from this person on how to use the device. Children should be supervised around the device to ensure they do not play with it.
- Do not allow the electrodes to come into contact with other conductive parts (including the ground).
- Do not use the device on anyone with sensitive skin or allergies.
- Do not store the device in the following locations: locations in which the device is exposed to direct sunlight, high temperatures or levels of moisture, or heavy contamination; locations near sources of water or fire; or locations that are subject to strong electromagnetic influences.
- Do not swing the device with the strap, which may result in injury.
- This device displays changes in heart beat, blood oxygenation, etc. which may have varying causes. These may be harmless, but may also be triggered by illnesses or diseases of differing degrees of severity. Please consult a medical specialist if you believe you may have an illness or disease.
- Vital sign measurements, such as those taken with this device, cannot identify all diseases. Regardless of the measurements taken using this device, you should

consult your doctor immediately if you experience symptoms that could indicate a serious disease.

- Do not self-diagnose or self-medicate based on this device without consulting your doctor. In particular, do not start taking any new medication or change the type and/or dosage of any existing medication without prior approval.
- This device is not a substitute for a medical examination for your heart or other organ functions, or for medical electrocardiogram recordings, which require more complex measurements.
- It is not possible to use this device to diagnose illnesses or diseases. This is exclusively the responsibility of your doctor.
- We recommend that you record the ECG curves and other measurements and provide them to your doctor if required.
- Clean the device and cuffs with a dry, soft cloth or a cloth moistened with water and a neutral detergent. Never use alcohol, benzene, thinners, or other harsh chemicals to clean the device or cuffs.
- Avoid tightly folding the cuffs or wrapping the hoses for long periods, to avoid shortening the component use period.
- The device and cuffs are not water-resistant. Keep rain, sweat and water from getting on the device and cuffs.
- Measurements may be distorted if the device is used close to televisions, microwave ovens, mobiles phones, X-rays, or other devices with strong electrical fields.
- Do not modify the device. It may cause damage to the device.
- To measure blood pressure, the arm must be squeezed by the cuff hard enough to temporarily stop blood flow

through the artery. This may cause pain, numbness, or a temporary red mark on the arm. This condition will appear especially when measurements are repeatedly taken. Any pain, numbness, or red marks will disappear with time.

- Do not apply the cuff on an arm with another electronic medical device. The equipment may not function properly.
- People who have a severe circulatory deficiency in their arm must consult a doctor before using the device, to avoid medical problems.
- Do not self-diagnose the measurement results and start treatment on your own. Always consult your doctor to evaluate the results and subsequent treatment.
- Do not apply the cuff on an arm with an unhealed wound.
- Do not apply the cuff on an arm receiving an intravenous drip or blood transfusion. It may cause injury or accidents.
- Do not use the device where flammable gases, such as anesthetic gases are present. It may cause an explosion.
- Do not use the device in highly concentrated oxygen environments, such as a high-pressure oxygen chamber or an oxygen tent. It may cause a fire or explosion.

2. Introduction

2.1 Intended Use

The product is intended to be used for measuring, displaying, reviewing, and storing ECG and blood pressure variations in the home or healthcare facilities.

ECG and Blood pressure variation is intended for use with adult.

The data and results provided by this device are for precheck screening purposes only and cannot be directly used for diagnosis or treatments.

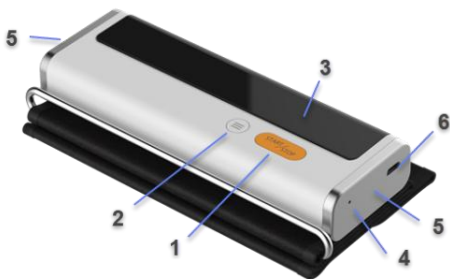
Product Features

Model	Blood Pressure Measurement	ECG Measurement
BP2	√	√
BP2A	√	

2.2 Contraindications

- This device is contraindicated for use in ambulatory environments.
- This device is contraindicated for use on aircraft.

2.3 About the Product

























1. Start/Stop button
 - Power On/Off
 - Press to Start/Stop measuring blood pressure.
2. Function button
 - Press to start the ECG measurement.
 - Press and hold for 2 seconds to review historical data.
3. Display screen
4. LED indicator
 - Blue light is on: the battery is charging.
 - Blue light is off: the battery is fully charged.
5. ECG electrodes
Press and hold them while taking ECG measurements.
6. Cable connector
Connect with the charging cable.

2.4 Unpacking

Main Unit; Charging Cable; User Manual; Quick Guide

2.5 Symbols

Symbol	Description
	Manufacturer
	Date of manufacture
SN	Serial number
	Indicates a medical device that is not to be disposed of as unsorted municipal waste.
	Follow Instructions for Use.
	Type BF Applied Part
	No alarm system
	MRI unsafe. Presents hazards in all MR environments as device contains strongly ferromagnetic materials.
IP22	Resistant to liquid ingress
	CE marking
	Authorized representative in the European community
	UKCA marking
	Authorized Representative in the United Kingdom

	<p>This product complies with the rules and regulations of the Federal Communication Commission.</p>
	<p>Non-ionizing radiation</p>
	<p>Our products and packaging can be recycled, don't throw them away! Find where to drop them off on the www.quefairedemesdechets.fr site (Only applicable for French market).</p>
	<p>Heartbeat symbol</p>
	<p>Battery symbol</p>
	<p>Bluetooth symbol</p>
	<p>Data transmission symbol</p>
	<p>ECG waveform</p>
	<p>ECG measurement progress bar</p>
	<p>Press to display next record</p>
	<p>Press to return to home screen</p>
<p>13/50</p>	<p>Current record / Total records</p>

Poor Signal	Low signal amplitude or noise
Check connection	Lead off when ECG is measuring
Regular ECG	The recorded ECG satisfies a common regular pattern.
Irregular ECG	The recorded ECG is erratic. It may be caused by heart issues or other conditions.

3. Using the Monitor

3.1 Charging the Battery

Use the USB cable to charge the monitor. Connect the USB cable to a USB charger or to the PC. It takes 2 hours to fully charge. When the battery is fully charged, the indicator will be off.

The monitor works on very low power consumption, and a full charge usually lasts for months. A battery symbol, which indicates the battery status is displayed on the screen.

Note: The device cannot be used while charging.

3.2 Blood Pressure Measurement

3.2.1 Before Taking Measurements

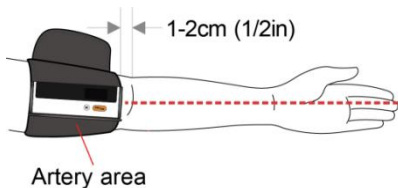
To help ensure accurate measurements, follow these directions:

- Rest for at least 5 minutes before taking measurements.
- Stress raises blood pressure. Avoid taking measurements when stressed.

- Remove any tight-fitting clothing from your arm.
- A single measurement does not provide an accurate indication of your true blood pressure. You need to take and record several results over a period of time.
- Try to measure your blood pressure at the same time each day to maintain consistency.

3.2.2 Applying the Arm Cuff

1. Wrap the cuff around the upper arm, about 1 to 2 cm above the elbow joint, as shown.
2. Place the cuff directly against the skin, as clothing may cause a faint pulse and result in measurement errors.
3. Constriction of the upper arm, caused by rolling up a shirtsleeve, may prevent accurate readings.
4. Confirm that the artery position mark is lined up with the artery.



Note: Keep the host wear position aligned with the middle finger.

3.2.3 Sitting Correctly

To take measurements, you need to be relaxed and comfortably seated. Sit in a chair with your legs uncrossed and your feet flat on the floor. Place your arm on a table, so that the cuff is level with your heart.



3.2.4 Measuring Blood Pressure

1. Power on the blood pressure monitor.
2. Press the Start/Stop button to start taking blood pressure measurements.
4. The monitor will automatically deflate the cuff slowly while taking measurements. A typical measurement takes about 30s.
4. The readings will be displayed when the measurement is finished.

You can press Start/Stop button again to stop the blood pressure measurement.

Note: While taking measurements, you should remain still and not squeeze the cuff.

3.2.5 After Taking Measurements

The monitor will automatically release the gas in the cuff once finished taking measurements.

Press the button to turn the power off after taking measurements. Remove the cuff.

Note: The device has an automatic power shut-off function, which turns off the power automatically 2 minutes after taking measurements.

3.3 Recording ECG

3.3.1 Before Taking Measurements

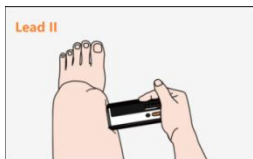
To help ensure accurate measurements, follow these

directions:

- Before using the ECG function, pay attention to the following points to obtain precise measurements.
- The ECG electrode must be positioned directly against the skin.
- If your skin or hands are dry, moisten them using a damp cloth before taking measurements.
- If the ECG electrodes are dirty, remove the dirt using a soft cloth or cotton swap dampened with disinfection alcohol.
- While taking measurements, do not touch your body with the hand with which you are taking measurements.
- Please note that there must be no skin to skin contact between your right and left hand. Otherwise, the measurements cannot be taken correctly.
- Stay still while taking measurements, do not speak and hold the device still. Movements of any kind will falsify measurements.
- If possible, take measurements when sitting and not when standing.
- Follow the text and voice guides on your phone to finish taking measurements.

3.3.2. Recording ECG without the Cable

There are four methods to record ECG without the cable.



A. Right hand to left Leg



B. Hand to hand



C. Right hand to abdomen



D. Right hand to chest

To start an ECG Recording:

1. Put your right palm on the right side electrodes of the monitor.
2. Place the left side electrodes to the body position that you desired to measure.
3. Once the body parts are placed on the electrodes, press the **Function** button to start EKG recording.
4. Wait for 30 seconds, the result readings will be displayed.

To start recording ECG again, press the **Start/Stop** button to return to the Home screen, then press the **Function** button.

Note:

- The recording must take at least 30 seconds to complete, and to be analyzed by the detectors
- You can get different signal amplitudes from different methods. Use Lead II mode if the signal is too low in Lead I mode.

3.3.3. Turn on/off Heartbeat Sound

The buzzer beeps when a heartbeat is detected while recording ECG. You can turn on/off the heartbeat sound on the App.

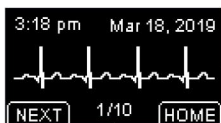
3.4 Reviewing History Records

You can review the history results and replay the recorded ECG waveform on the History screen.

Hold the **Function** button for 2 seconds to enter the History screen. The last measurement results will be displayed by default



For ECG recordings, the Heart Rate will be displayed first and then replayed over the 30-second ECG waveform.



To view the next records, press the **NEXT** button.

To exit the History screen, press the **HOME** button.

3.5 Connecting with the App

App name: ViHealth

iOS: App Store

Android: Google Play



The monitor has built-in Bluetooth wireless connectivity, which enables exporting measurement records to mobile phones and tablets running iOS or Android.

Hold the function button and Start/Stop button simultaneously to enable Bluetooth and start pairing it to your smart device.

4.Troubleshooting

Problem	Possible Cause	Solution
No power. No display appears on the device.	Battery is depleted	Recharge the battery
Blood pressure readings appear too high or too low	Blood pressure varies constantly. Many factors including stress, time of day, and/or how you apply the arm cuff, may affect your blood pressure.	Hold still for a moment and try again
Error 1 Apply the arm cuff tighter.	Arm cuff is applied too loosely	Tighten the arm cuff and try again.
Error 2 Do not move or talk, remain still.	Moving or talking while taking measurements, and the pressure of the cuff is interfered with.	Remain still and do not talk while taking measurements
Error 3 Remove any clothing interfering with the cuff.	The signal is poor while measuring blood pressure.	Take blood pressure on a bare arm.
Error x (x>4) Contact customer	The device has malfunctioned.	Contact customer service.

service.		
Check the connection	The ECG cable is off, or the body parts are not placed on the electrodes closely enough.	Check the ECG cable, or place the electrodes closer to your body part.
ECG waveform drifts	The pressure exerted on the electrode is not stable or too much.	Hold the device stably and gently.
	Hand or body may be moving.	Try to keep perfectly still and test again.
The ECG waveform amplitude is small	The measurement method you chose is not suitable for you.	Change another lead and try again.

5. Maintenance

5.1 Maintenance

To protect your monitor from damage, store the monitor and the components in a clean, safe location.

Caution: DO NOT disassemble or attempt to repair this monitor or other components. This may cause inaccurate blood pressure readings and/or EKG recordings.

5.2 Cleaning

- Do not use any abrasive or volatile cleaners.
- Use a soft dry cloth or a soft cloth moistened with mild (neutral) detergent to clean your monitor and the arm cuff and then wipe them with a dry cloth.
- When electrodes are dirty, use a soft cloth or cotton swab moistened with an alcohol-based sanitizer to

clean the electrodes.

- Do not use gasoline, thinners, or similar solvents to clean your monitor and arm cuff or other components.

5.3 Storage

Keep your monitor and other components in the storage case when not in use.

- Store your monitor and other components in a clean, safe location.
- Do not store your monitor and other components in locations exposed to extreme temperatures, humidity, direct sunlight, dust, or corrosive vapors, such as bleach.

6. Specifications

Classifications		
EC Directive	MDD, 93/42/EEC	
	RED, 2014/53/EU	
	ROHS 2.0, 2011/65/EU	
Degree of protection against electrical shock	Type BF	
Environmental		
Item	Operating	Storage
Temperature	5 to 40°C	-25 to 70°C
Relative humidity (non-condensing)	10% to 95%	10% to 95%
Barometric	700 to 1060 hPa	700 to 1060 hPa
Degree of dust & water resistance	IP22	

Drop test	1.0 m
Physical	
Size (main unit)	135mm(L)×45mm(W)×20mm(H)
Weight (main unit)	240 g
Cuff size	Adult cuff: 22-42cm Small adult cuff (optional): 17-22cm Adult cuff (optional): 22-32cm
Wireless connectivity	Built-in Bluetooth 4.0 BLE
Power Supply	
Charge input	USB Type-C, DC 5V
Battery type	Rechargeable lithium-polymer battery
Battery run time	500 measurements
Charge time	2 hours
Blood Pressure Measurements	
Technology	Oscillometric Method
Pressure measurement range	0 – 300mmHg
Pressure measurement accuracy	±3mmHg
Pulse rate range	40 to 200 /min
Pulse rate accuracy	±2 /min
Clinical accuracy	Meet IEC80601-2-30
ECG Recording	
Lead type	Integrated ECG electrodes
Lead set	Lead I, Lead II, Chest Lead
ECG length	30s

Heart rate range	30 - 250/min
Heart rate accuracy	± 2 /min or $\pm 2\%$, whichever is greater
Storage	
Blood pressure records	50
ECG records	10
Bluetooth RF	
Frequency range	2.402 – 2.480 GHz
Max RF power	-10 dBm

7. Electromagnetic Compatibility

The device meets the requirements of EN 60601-1-2.



Warnings and Tips

- Using accessories other than those specified in this manual may result in increased electromagnetic emissions or decreased electromagnetic immunity for the device.
- The device or its components should not be used adjacent to or stacked with other equipment.
- The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
- Other devices may interfere with this device even though they meet CISPR requirements.
- When the inputted signal is below the minimum amplitude provided in the technical specifications, erroneous measurements could result.

- Portable and mobile communication equipment may affect device performance.
- Other devices that have RF transmitters or sources may affect this device (e.g. cell phones, PDAs, and PCs with wireless functionality).


Guidance and Declaration - Electromagnetic Emissions		
The Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Blood Pressure Monitor should assure that it is used in such an environment.		
Emission tests	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The 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.
RF emissions CISPR 11	Class B	The 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.
Harmonic emissions IEC61000-3-2	N/A	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	N/A	

Guidance and Declaration - Electromagnetic Immunity
The Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Blood Pressure Monitor should assure that it is used in such an environment.

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	± 8kV contact ±2kV, ±4kV, ±8kV, ±15kV 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	± 2kV for power supply lines 100kHz repetition frequency ± 1kV for input/output lines	N/A	--
Surge IEC 61000-4-5	± 0.5kV, ±1kV differential mode line-line	N/A	--
Voltage dips, short Interruptions and Voltage variations on power supply input lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T (100% dip in U_T) for 1 cycle at 0° 70% U_T	N/A	--

	<p>(30% dip in U_T) for 25/30 cycles at 0°</p> <p>0% U_T (100% dip in U_T) for 250/300 cycles at 0°</p>		
<p>Power frequency (50/60 Hz) magnetic field IEC 61000-4-8</p>	<p>30 A/m, 50/60Hz</p>	<p>30 A/m, 50/60Hz</p>	<p>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</p>
<p>Note: U_T is the AC mains voltage prior to application of the test level.</p>			

Guidance and Declaration - Electromagnetic Immunity			
<p>The Blood Pressure Monitor is intended for use in the specified electromagnetic environment. The customer or the user of the Blood Pressure Monitor should assure that it is used in such an environment as described below.</p>			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
<p>Conducted RF IEC61000 -4-6</p>	<p>3Vrms 150kHz to 80 MHz 6Vrms 150 kHz to 80 MHz outside ISM bands</p>	<p>N/A</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation</p>

<p>Radiated RF IEC61000 -4-3</p>	<p>10V/m 80MHz to 2.7 GHz</p>	<p>10 V/m</p>	<p>distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distances:</p> $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$ <p>80MHz to 800MHz</p> $d = \left[\frac{7}{E_1} \right] \sqrt{P}$ <p>800MHz to 2.7GHz</p> <p>Where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a, should be less than the compliance level in each frequency range ^b. Interference may occur in the vicinity of equipment marked with the following symbol: </p>
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<p>Note 1: At 80 MHz to 800 MHz, the separation distance for the higher frequency range applies.</p>			
<p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>a The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.</p>			
<p>b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.</p>			
<p>c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Blood Pressure Monitor is used exceeds the applicable RF compliance level above, the Blood Pressure Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Blood Pressure Monitor.</p>			

- d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Blood Pressure Monitor

The Blood Pressure Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Blood Pressure Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Blood Pressure Monitor as recommended below, according to the maximum output power of the communications equipment.

Rated max. output power of transmitter (W)	Separation distance according to frequency of the transmitter (m)		
	150kHz to 80MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80MHz to 800MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800MHz to 2.7GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.37	0.12	0.23
1	1.17	0.35	0.70
10	3.70	1.11	2.22
100	11.70	3.50	7.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations.

Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.