

Upper Arm Electronic Blood Pressure Monitor

USER MANUAL

Please read this guide thoroughly before using the product.



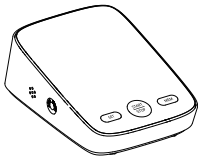
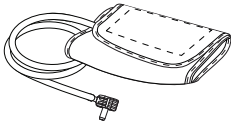
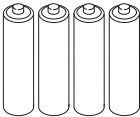
Model: FC-BP121



DARTWOOD

a WASSERSTEIN brand

In the Box

 1x blood pressure monitor	 1x arm cuff
 4x AAA batteries	

Intended Use

- Intended for blood pressure and pulse rate measurement in adults.
- Identifies irregular heartbeats, provides warning signal.
- For home use only.

Safety Information

Important Safety Notices

To ensure proper usage of the product, it is important to follow the basic safety measures and precautions outlined below:

- Before using the unit, it is essential to thoroughly read all the information provided in the instruction manual and any additional literature included in the box.
- Please consult your physician for specific information regarding your blood pressure. Engaging in self-diagnosis and treatment based solely on measurement results can be hazardous. Always adhere to the instructions provided by your healthcare provider.
- Please ensure that you operate the unit solely for its intended purpose and avoid using it for any other applications. The unit is designed specifically for measuring blood pressure and pulse rate in adult individuals, and it is not recommended for use with newborns or infants, either at home or in a medical center.
- To prevent incorrect operation of the unit, avoid using mobile phones or other devices that emit electromagnetic fields in close proximity to the unit.
- To ensure accurate readings, please refrain from using the unit in areas with high levels of radiation.
- Do not disassemble or attempt to repair the unit or its components. Do not use the equipment in areas where flammable gases (such as anesthetic gas, oxygen, or hydrogen) or flammable liquids (such as alcohol) are present.
- It is important to note that excessive frequency in measurements can potentially interfere with the blood flow, leading to possible injury to the patient.

- It is advised not to place the cuff over a wound as doing so may worsen the injury.
- Please be mindful of the potentially harmful effects caused by continuous cuff pressure due to tangling of the connection tubing, which can interfere with blood flow and result in injury to the patient.
- The adapter must meet the following conditions as per the requirements: the output voltage should be DC 5V, the current should be 1000mA, and it must comply with IEC 60601-1 and IEC 60601-1-11 standards. Additionally, it must provide two MOPP (Means of Patient Protection) insulation between the AC input and DC output.
- Please ensure that the battery is installed correctly.
- When the battery power is depleted, please replace it with four new batteries.
- If the battery has not been used for over three months, it is advisable to remove the battery. Prolonged inactivity may lead to issues such as leakage, overheating, rupture, and potential damage to the blood pressure monitor body.

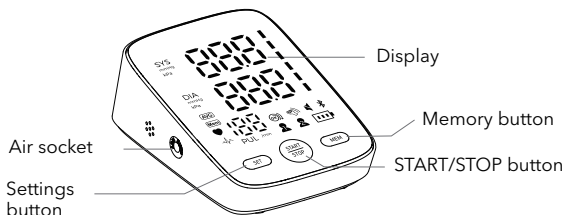
Warnings and Safety Precautions

- When applying the cuff and exerting pressure on any limb that has vascular access, therapy, or an arteriovenous (A-V) shunt, exercise caution. Temporary interference with blood flow in such cases can potentially lead to injury to the patient.
- When applying the cuff and exerting pressure on the arm, specifically on the side of the brachial artery, please take care and follow proper procedures.

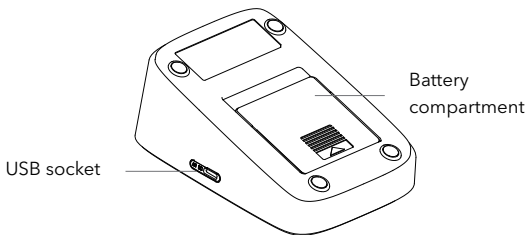
- The pressurization of the cuff may temporarily interfere with the functioning of other monitoring medical equipment simultaneously used on the same limb.
- It is important to check, such as through observation of the relevant limb, that the operation of the automated blood pressure monitor does not lead to prolonged impairment of the patient's blood circulation.
- If the user's arm becomes uncomfortable under pressure from an over-inflated cuff, please loosen the cuff or remove the batteries immediately.
- Please avoid touching the patient and the battery output simultaneously during the measurement process as this may interfere with the reading.
- Do not use lure connectors. If lure lock connectors are utilized in the tubing construction, there is a risk of accidental connection to vascular fluid systems, potentially leading to the introduction of air into a blood vessel.
- Portable RF communications equipment, including peripherals such as antenna cables and external antennas, must be kept at a minimum distance of 30 cm (12 inches) from any part of the Blood Pressure Monitor, including cables specified by the manufacturer. Failure to do so may result in a degradation of the performance of the equipment.
- Ensure that the Blood Pressure Monitor is kept out of reach of children and animals.
- There is a risk of accidental ingestion of small disassemblable parts, such as batteries.

Introduction to Components

Main unit (front)

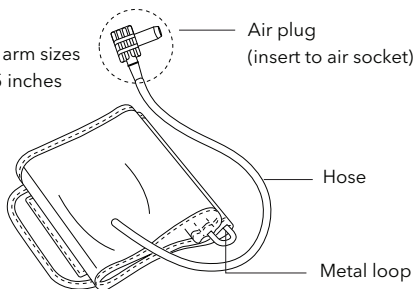


(Back)

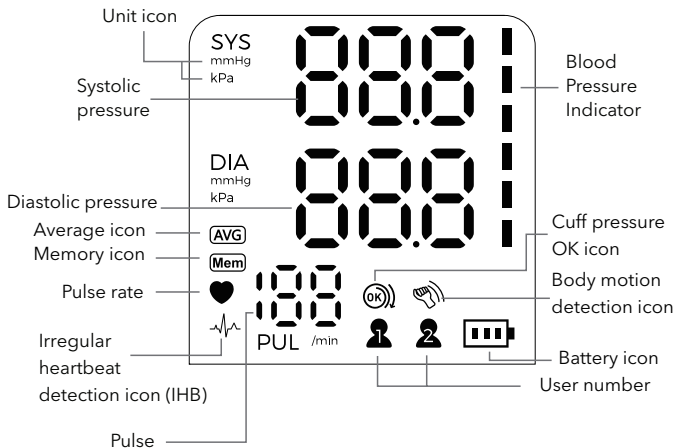


Arm cuff

The cuff fits upper arm sizes between 8.7 - 16.5 inches (22cm - 42cm)



Display



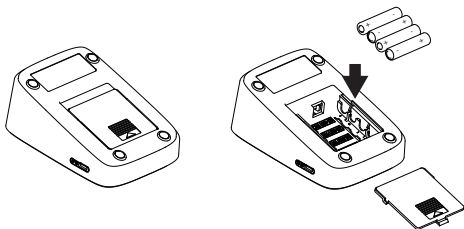
Battery Handling and Usage Guidelines

- Ensure correct alignment of battery polarities when inserting them.
- Use only 4 AAA alkaline or manganese batteries with this monitor.
Do not use any other types of batteries.
- Do not mix new and used batteries together.
- Do not mix different brands of batteries together.
- If the blood pressure monitor will not be used for an extended period, please remove the batteries.
- Do not use batteries past their expiration date.
- Regularly inspect the batteries to ensure they are in good working condition.

Before Use

Install the batteries

1. To access the battery compartment, remove the battery cover.
2. Install four AAA-size batteries, ensuring that the + (positive) and - (negative) polarities align with the corresponding markings.
3. Securely replace the battery cover.

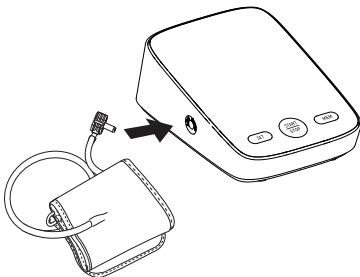


Note: If the low battery symbol appears on the display, promptly replace the batteries.

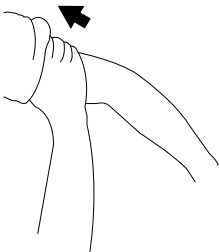


Applying the arm cuff

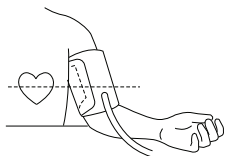
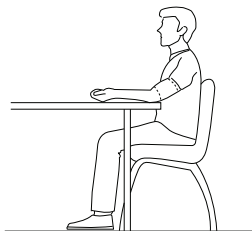
1. Ensure the air plug is properly inserted into the main unit.



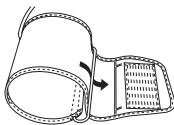
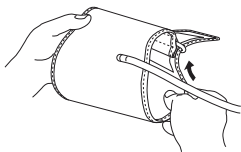
2. Before applying the cuff, remove any clothing from your upper arm, allowing the cuff to make direct contact with the skin.



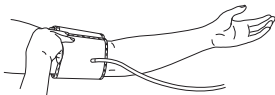
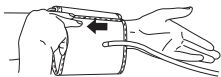
3. Sit in a chair with your feet flat on the floor. Position your arm on a table, the cuff should be level with your heart.



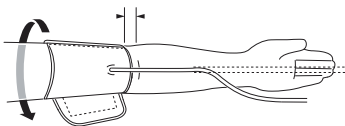
4. Thread the hose through the metal loop and ensure that the hose extends outward.



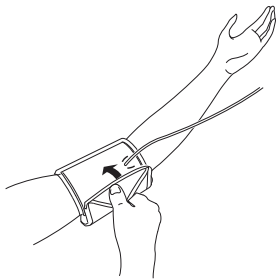
5. Slide your arm through the loop and pull the cuff up to the position of your upper arm



6. The hose should run down the inside of your arm along the main arteries. Position the bottom of the cuff approximately 0.8-1.2 inches (2~3cm) above your elbow.



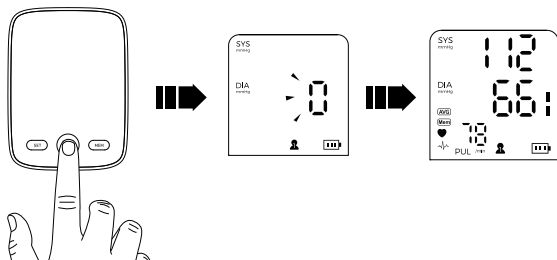
7. Wrap the cuff tightly around your upper arm using the Velcro strip. Ensure that there is a space of 1-2 fingers between your arm and the cuff.



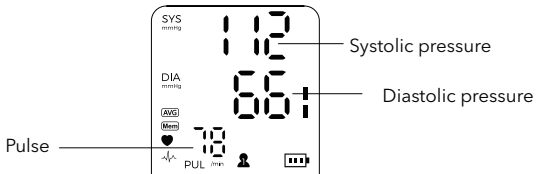
8. Relax your arm and keep your palm facing upward. Let your fingers naturally curve. Turn on the unit and start the measurement.

Taking the Measurement

1. Press 'START/STOP' to begin. All symbols will display, and the cuff will inflate automatically for measurement.



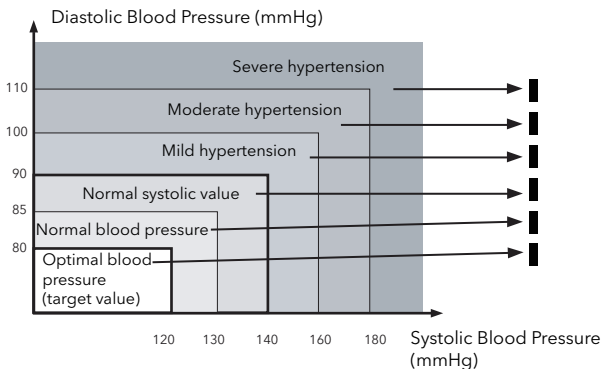
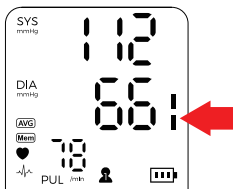
2. After measurement, blood pressure and pulse rate will be displayed and stored in memory. Cuff deflates automatically.



*  icon signals irregular heartbeat during measurement.

Blood Pressure Indicator

After each measurement, the LED display shows your position on the WHO Blood Pressure Indicator bar. See below.

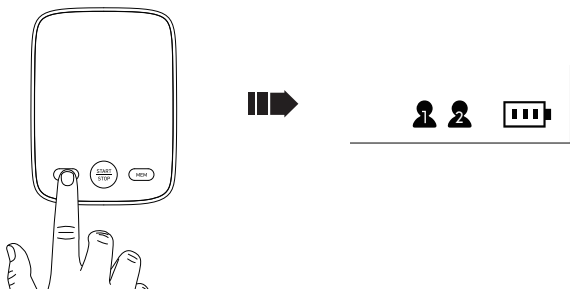


(Source: Journal of Hypertension
1999, Vol 17 No.2)

3. To power off, press "START/STOP". The device will also automatically turn off after three minutes of inactivity.

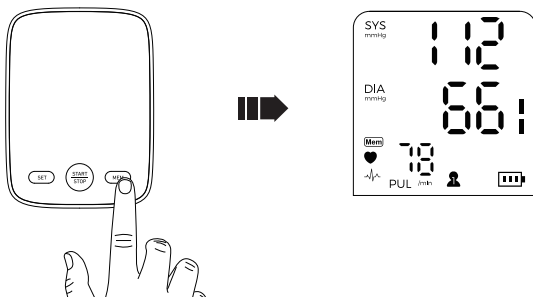
Switch User

To switch users, power off the unit, then press setting button to toggle between "1" and "2". Confirm by pressing "START/STOP".

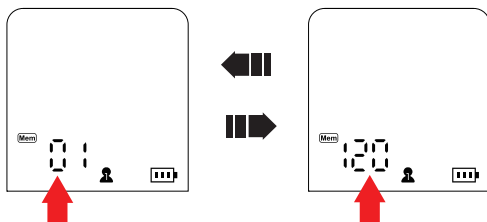


Memory Function Overview

1. To view the average of the last 3 measurements, power off and press memory button. Display will show the average.

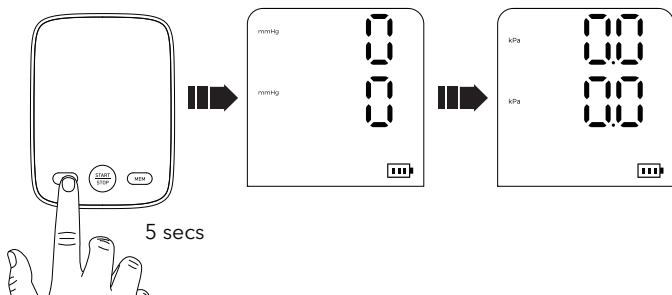


2. Press memory button again to access records.
3. Display shows "01" for latest record.
4. Use memory button to navigate through records.



Change the Measurement Unit

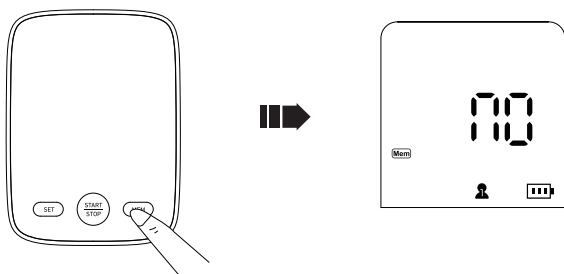
1. Change unit (kPa or mmHg) by holding setting button for 5s when off.
2. Display flashes for unit setting.
3. Press memory button to choose unit.
4. Confirm with "START/STOP".



Clearing the Memory

Note: Ensure you want to delete all records.

Switch user, then hold the memory button 10s. "NO" displays when all records are deleted.



Cleaning/Disinfecting and Maintenance

For optimal performance and protection:

1. Clean monitor and cuff after use.
2. Avoid abrasive cleaners.
3. Never submerge in water.
4. Wipe with a soft, damp cloth.
5. Disinfect cuff with 75% alcohol cotton.
6. Follow manual instructions; use authorized parts.

Storage and Maintenance

1. Store unit in a dry place; do not fold cuff tightly.
2. Shield from extreme temps, humidity, sunlight.
3. Avoid dropping; protect from impacts.
4. If unused for 3 months, replace batteries.
5. Follow instructions, use authorized parts.

Tips

- For consistent readings, use the same arm.
- If significant difference, consult physician for future measurements.

Error Codes

Symbol	Cause	Correction
	Inflation error.	Adjust cuff, reinflate.
	Measurement failure.	Remain still and keep arm steady.
		Remeasure following correct procedure.
		Ensure tube is not compressed.
		Keep body still during measurement.
	Low battery power.	Replace worn batteries with new ones.
	Irregular heartbeat detected.	Remove cuff, wait 2-3 minutes, then retake measurement. If error persists, consult physician for guidance.
	Movement detected.	Result may be inaccurate due to movement. Retake measurement for accuracy.

IEC 60601-1-2:2014/AMD1:2020 Medical electrical equipment (ME EQUIPMENT) and medical electrical systems (ME SYSTEMS) identification, marking and documents for Class B product.

Instructions for Use

This ME EQUIPMENT / ME SYSTEM device is designed to be appropriate and safe for use in home healthcare environments

WARNING: Keep device a safe distance from active high-frequency (HF) surgical equipment and the radio frequency (RF) shielded room of an ME system for magnetic resonance imaging, as the intensity of electromagnetic disturbances is high.

WARNING: Avoid using this equipment adjacent to or stacked with other equipment, as it may lead to improper operation. If such use is necessary, carefully monitor both this equipment and the other equipment to ensure they are operating normally.

WARNING: Using accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment may lead to increased electromagnetic emissions or reduced electromagnetic immunity, potentially causing improper operation. Please adhere to the manufacturer's recommendations to ensure proper functionality and safety.

Warning: Portable RF communications equipment, including peripherals such as antenna cables and external antennas, should not be used closer than 12 inches to any part of the Upper Arm Electronic Blood Pressure Monitor (FC-BP121), including cables specified by the manufacturer. Failing to adhere to this distance may lead to a degradation of the performance of this equipment.

If applicable, the Responsible Organization must provide a comprehensive list of all cables and their maximum lengths, transducers, and other replaceable ACCESSORIES that have the potential to affect the compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). These ACCESSORIES can be specified either generically (e.g., shielded cable, load impedance) or specifically (e.g., by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE). It is crucial to ensure that the replacement of these components does not compromise the compliance of the medical equipment or system with the relevant emission and immunity standards.

If any: the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term "ESSENTIAL PERFORMANCE" need not be used).

Technical Description

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

Table 1

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

Table 2

Guidance and manufacturer's declaration - electromagnetic immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Electrical fast transient/burst IEC 61000-4-4	Power supply lines: ± 2 kV 100 kHz repetition frequency	Power supply lines: ± 2 kV 100 kHz repetition frequency
Surge IEC 61000-4-5	line(s) to line(s): ± 1 kV.	line(s) to line(s): ± 1 kV.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle	0% 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1 kHz
Radiated RF IEC61000-4-3	10 V/m 80 MHz - 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz - 2,7 GHz 80 % AM at 1 kHz
Proximity magnetic fields IEC 61000-4-39	30 kHz: 8A/m 134.2 kHz: 65A/m 13.56 MHz: 7.5A/m	30 kHz: 8A/m 134.2 kHz: 65A/m 13.56 MHz: 7.5A/m
NOTE UT is the a.c. mains voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic immunity								
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power(W)	Distance (m)	IEC 60601-1-2 Test level (V/m)	Compliance level (V/m)
	385	380-390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27	27
	450	430-470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28	28
	710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0.3	9	9
	745							
	780							
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28
	870							
	930							
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28	28
	1845							
	1970							

	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	28
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0.3	9	9
	5500							
	5785							

Table 4

Guidance and manufacturer's declaration - electromagnetic Immunity		
Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz	CW	8
134,2 kHz	Pulse modulation ^a 2,1 kHz	65 ^b
13,56 MHz	Pulse modulation ^a 50 kHz	7,5 ^b
a) b)	The carrier shall be modulated using a 50% duty cycle square wave signal. r.m.s., before modulation is applied.	

Troubleshooting

Problem	Possible solution
No power	Replace all the worn batteries with new ones.
No display appears on the display screen	Check the battery installation for proper placement of the batteries' polarities.
Measurement values appear too high or too low	Please try again later in the day. If the measurements are the same, contact your physician for further guidance and evaluation.

Symbols and Explanation

	Refer to instruction manual/booklet			
	MANUFACTURER		SERIAL NUMBER	
	Date of manufacture			
	Type BF applied part			
	The marking of electrical and electronics devices according to Directive 2002/96/EC. The device accessories and the packaging have to be disposed of as waste correctly at the end of its service life. Please follow Local Laws or Regulations for disposal.			

Specifications

Model:	FC-BP121
Display:	LED digital display
Method:	Oscillometric
Range	
Pressure:	0~299mmHg (0 kPa -39.9 kPa)
Pulse:	40~180 beats/min
Accuracy of the cuff	
Static pressure:	Within ± 3 mmHg
Pulse rate:	Within $\pm 5\%$
Resolution:	1mmHg (0.1 kPa)
Power supply:	USB Type C (DC5V1A) 4 x AAA batteries included
Storage and transport conditions:	-4~131 °F / 0%~95%RH
Operating conditions:	50~104°F / 15%~85%RH
Product weight:	11.52oz (excluding batteries)
Product size:	5.0 x 3.8 x 2.0in
Memory storage:	2 users x 120 sets
Cuff size:	8.7 - 16.5in (22-42cm)

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