




Safety Information

1. General usage
- Do not adjust medication based on measurement values from this blood pressure monitor. Take medication as prescribed by your physician. Only a physician is qualified to diagnose and treat High Blood Pressure.
  - The monitor is not intended to be a diagnostic device.
  - Consult your physician before using the device for any of the following conditions: common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, age, pregnancy, pre-eclampsia, renal diseases.
  - Note that PATIENT movement, trembling, shivering may affect the measurement.
  - Do not use the device on the injured arm or the arm under medical treatment, as this can cause further injury.
  - Do not apply the arm cuff on the arm while on an intravenous drip or blood transfusion.
  - Prolonged over-inflation of the monitor will result in harmful injury to the patient.
  - Too frequent measurements can cause injury due to blood flow interference.
  - Consult your physician before using the device on the arm with an arterio-venous (A-V) shunt.
  - Do not use the device with other medical electrical (ME) equipment simultaneously.
  - Do not use the device in the area of HF surgical equipment, MRI, or CT scanner, or in an oxygen rich environment.
  - Please ask your doctor about your normal blood pressure before taking the measurement by yourself.
  - If the cuff causes any discomfort, please turn off the equipment by pressing the SET button.
  - If the arm cuff doesn't deflate automatically after the equipment has pressurized to 300mmHg (40kPa), please press the SET button to stop inflation and take off the cuff.
  - This product applies only for adults. Please keep the unit out of reach of children.
  - The device complies with RF specifications when the device is used at 0mm from your body.
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Trouble Shooting

PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display is dim or will not light up.	Battery is exhausted.	Recharge the battery.
Low battery		Battery is low.	Recharge the battery.
Error message	“Err 1”	Arm cuff deflates too fast or the pulse signal is too weak.	Apply the cuff correctly and repeat measurement.
	“Err 2”	Disrupted by portable and mobile RF communications equipment.	Repeat the measurement and make sure there is no any portable and mobile RF communications equipment around.
	“Err 3”	Incorrect measurement result.	Repeat measurement.
	“Err P”	Arm cuff fails to inflate.	Apply the cuff correctly and repeat measurement.
	“Err H”	Inflating pressure is too high.	Repeat measurement in proper way.

Electromagnetic Compatibility

The ME EQUIPMENT or ME SYSTEM is suitable for home or hospital environment. **Warning:** Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high. **Warning:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

- This monitor is calibrated at the time it was manufactured, if the monitor is used according to the instruction, periodic recalibration is not required. If it is inaccurate often, please contact Smart Meter Customer Service Mon-Fri, 9am - 5pm ET at 1-844-445-8267.
  - Do not disassemble, repair, or remodel the main unit or the cuff of the blood pressure monitor by yourself. If necessary, contact Smart Meter Customer Service.
  - The user must check that the equipment functions safely and see that it is in proper working condition before being used.
  - If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the blood pressure monitor.
  - Please do not continue to use the cuff if you are allergic to it.
  - Please only use the arm cuff that was supplied with your iBloodPressure Plus.
  - If non-manufacturer supplied parts are used, errors in measurement results may be caused.
  - Please check whether the battery is leaking before use, if it leaks, do not use it.
  - Please check whether the power adapter is in good condition before use. If it is damaged, please replace with a new one.
  - Do not remove the power adapter during the measurement when using the power adapter to supply power.
  - The operator shall not touch output of AC adapter and the patient simultaneously.
  - The Type-C power socket used for charging needs to be securely isolated from the power grid, such as the security isolation adapter or power source with IEC60950 or IEC62368 or iec60601-1, the power adapter and product constitute the medical system when charging, and the risk of leakage of current should be paid attention to.
  - Changes or modifications to this product not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
2. General precautions
- Do not forcibly crease the arm cuff or the air tube excessively.
  - Do not press the air tube while taking a measurement.
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**If any:** a list of all cables and maximum lengths of cables (if applicable), transducers, and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE). **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). **Warning:** When the device is affected by EM DISTURBANCES, the data measured may fluctuate and may not be accurate, please measure in another environment to ensure its accuracy.  Warning: The device should not enter the MRI scanner room. Patients with MR Unsafe devices should not be scanned. 1. All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life. 2. Guidance and manufacturer's declaration -electromagnetic emissions and Immunity.

Guidance and manufacturer’s declaration – electromagnetic emission	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/flicker emissions IEC 61000-3-3	Applied

- Do not drop the monitor or subject the device to strong shocks or vibrations.
- Do not inflate the arm cuff when it is not wrapped around your arm.
- Do not use the device outside the specified environment. It may cause an inaccurate reading.
- Dispose of the device, components and optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution.

Tips for operation

Reading may be inaccurate if they are taken under the following circumstances:

Less than 1 hour after eating or drinking.

Immediate measurement after tea, coffee, smoking.

Less than 20 minutes after taking a bath.

When talking or moving your fingers.

In a very cold environment.

When you want to discharge urine.

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	38 kV contact 32 kV, 34 kV, 38 kV, 315 kV air	38 kV contact 32 kV, 34 kV, 38 kV, 315 kV air
Electrical fast transient/burst IEC 61000-4-4	Power supply lines: 32 kV input/output lines: 31 kV	N/A
Surge IEC 61000-4-5	line(s) to line(s): 31 kV. line(s) to earth: 32 kV. 100 kHz repetition frequency	N/A
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	N/A
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	N/A
Radiated RF IEC61000-4-3	10 V/m 80 MHz ~ 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz ~ 2.7 GHz 80% AM at 1 kHz
NOTE U <sub>i</sub> is the a.c. mains voltage prior to application of the test level.		

Care and Maintenance

1. Cleaning the monitor and cuff  
Make sure the monitor is off prior to cleaning.  
The monitor can be sterilized using 70% medical alcohol on a soft towel or cotton ball.  
Clean the monitor with a soft dry cloth.  
Do not use any abrasive or volatile cleaners.  
Use a soft moistened cloth and soap to clean the arm cuff, do not immerse in water.  
Never immerse the monitor or any of the components in water.

2. Maintaining the monitor and arm cuff  
Keep the monitor and arm cuff in the storage box when not in use.  
Do not forcefully bend the arm cuff or air tube. Do not fold tightly.  
Do not press the USER buttons and start a measurement before the arm cuff is properly applied.  
Do not disassemble or attempt to refit the device or components.  
Do not subject the monitor to strong shocks, such as dropping the device on the floor.  
Protect the device from contamination and dust and direct sunlight.  
If the device will not be used for a long time, please fully charge the device.

Standard blood pressure classification

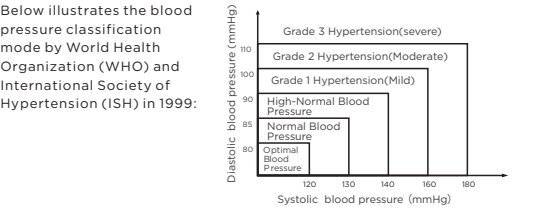


Table 3

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	Modulation (W)	Distance (m)
	385	380 - 390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3
	450	380 - 390	GMR5 460, FRS 460	FM 35 kHz deviation 1kHz sine	2	0.3
	710	704-787	LTE Band 13	Pulse modulation 217 Hz	0,2	0.3
	810	800-960	GSM 800/900, TETRA 800, GSM 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3
	870	800-960				
	930					
	1720		GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3
	1845	1700-1990				
	1970					
	2450	2400-2570	Bluetooth, WLAN, 802.11 a/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0.3
	5500					
	5785					

Blood Pressure(mmHg)\Level	Optimal	Normal	High-normal	Mild	Moderate	Severe
SYS	<120	<130	130~139	140~159	160~179	≥180
DIA	<80	<85	85~89	90~99	100~109	≥110

CAUTION ⚠

Only a physician can tell you your normal blood pressure range and the point at which you are at risk. Consult your physician to obtain these values. If the measurements taken with these products fall outside the range, consult your physician immediately.

Common Q&A on Blood Pressure

Q1: Why does my blood pressure fluctuate throughout the day?  
1. Individual blood pressure varies throughout the day, it is also affected by the way you apply your arm cuff and your measurement position, so please take the measurement under the same conditions, when possible.  
2. Medications may affect blood pressure readings.  
3. Wait at least 4 – 5 minutes between measurements.

Q2: Why is the blood pressure I get from the hospital different when I test at home?  
Blood pressure varies throughout the day and can be affected by many environmental factors, like stress, weather, exercise, etc. When you measure your blood pressure at home, ensure:  
1. that the arm cuff is applied properly.  
2. that the cuff is not too tight or too loose.  
3. that you are not feeling anxious.

Q3: Will my results be different if I measure my blood pressure on my right arm?  
It is recommended that you use your left arm for measurements but it is okay to use your right arm if you need to. Measuring on your right arm may cause your readings to vary. We suggest measuring on the same arm every time.

Disposal



Do not dispose of electrical appliances as unsorted municipal waste, use separate collection facilities. Contact you local government for information regarding the collection systems available. If electrical appliances are disposed of in landfills or dumps, hazardous substances can leak into the groundwater and get into the food chain, damaging your health and well-being.

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