

制作工艺:

封面:157g铜版纸, 过哑胶, 彩色;

(logo色号: CMYK: 100/ 40/ 0/ 0)

内页: 80g书写纸, 黑白

胶装

尺寸/公差: 95*140mm/ ± 1 mm

此页不印刷



LEPU MEDICAL

Blood Pressure Monitor

Model BP2A

User Manual

English | Deutsch | Italiano | Español | Français

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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 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 pressure, 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.
- It is not possible to use this device to diagnose illnesses or diseases. This is exclusively the responsibility of your doctor.
- 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

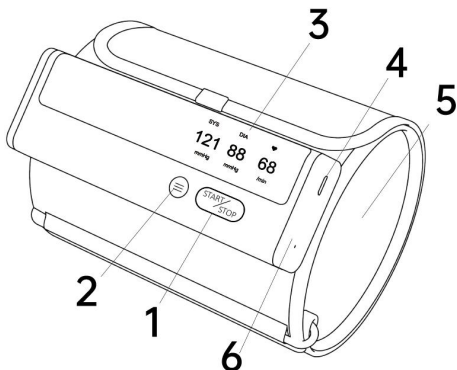
The product is intended to be used for measuring, displaying, reviewing, and storing blood pressure variations in the home or healthcare facilities.

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

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 review historical data.

3.Display screen

4.Cable connector

Connect with the charging cable.

5.Arm Cuff













6.LED indicator










- Blue light is on: the battery is charging.
- Blue light is off: the battery is fully charged.

2.4 Unpacking

Main Unit; Charging Cable; User Manual; Quick Guide

2.5 Symbols

Symbol	Description
	Manufacturer
	Date of manufacture
	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
	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
	This product complies with the rules and regulations of the Federal

	Communication Commission.
IC	This device contains licence-exempt transmitter(s)/ receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s).
	Non-ionizing radiation
	This product complies with verpackG.
	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).
	Heartbeat symbol
	Battery symbol
	Bluetooth symbol
	Data transmission symbol
	Press to display next record
	Press to return to home screen
13/50	Current record / Total records

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:

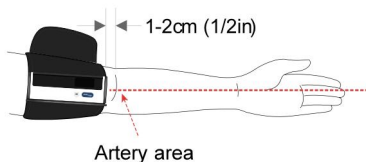
- Rest for at least 5 minutes before taking measurements.
- Stress raises blood pressure. Avoid taking measurements when stressed.
- Remove any tight-fitting clothing from your arm.
- A single measurement does not provide an accurate indication of your true blood pressure. You need to take and record 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.

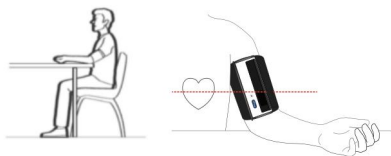
3. Constriction of the upper arm, caused by rolling up a shirtsleeve, may prevent accurate readings.
4. Confirm that the artery position mark is lined up with the artery.



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.
3. 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 Reviewing History Records

You can review the history results on the History screen.

Press the **Function** button to enter the History screen. The last measurement results will be displayed by default.



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

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

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 service.	The device has malfunctioned.	Contact customer service.

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.

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.
- 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.

5.4 Disposal



Batteries and electronic instruments must be disposed of in accordance with the locally applicable regulations, not with domestic waste.

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 45°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
Wireless connectivity	Built-in Bluetooth 4.0 BLE
Power Supply	
Charge input	USB Type-C, DC 5V
Battery type	Li-ion rechargeable
Battery run time	500 measurements
Charge time	2 hours
Blood Pressure Measurements	
Technology	Oscillometric Method
Pressure measurement range	0 – 300mmHg
Pressure measurement accuracy	±3mmHg or 2%, whichever is greater
Pulse rate range	40 to 200 /bpm
Pulse rate accuracy	±2 /bpm
Clinical accuracy	Meet IEC 80601-2-30
Storage	
Blood pressure records	50
Bluetooth RF	
Frequency range	2.402 – 2.480 GHz

Max RF power	-10 dBm
Durable period	
Useful life	5 years
Note: The useful life here is calculated from the first use, not including storage time, not the shelf life!	

7. FCC Statement

FCC Warning:

FCC ID: 2AD XK-8621

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

This device complies with part 15 of the FCC Rules. 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.

Note: 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.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

8. IC Caution

IC ID: 29845-B001

This device contains licence-exempt transmitter(s)/ receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

- (1) This device may not cause interference.
- (2) This device must accept any interference, including interference that may cause undesired operation of the device.

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

9. 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	Group 1	The Blood Pressure Monitor uses RF

CISPR 11		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	$\pm 2\text{kV}$ for power supply lines 100kHz repetition frequency $\pm 1\text{kV}$ for input/output lines	N/A	--
Surge IEC 61000-4-5	$\pm 0.5\text{kV}$, $\pm 1\text{kV}$ 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 (30% dip in U_T) for 25/30 cycles at 0° 0% U_T (100% dip in U_T) for 250/300 cycles at 0°	N/A	--
Power frequency (50/60 HZ)	30 A/m, 50/60Hz	30 A/m, 50/60Hz	Power frequency magnetic fields should be at

magnetic field IEC 61000-4-8			levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and Declaration - Electromagnetic Immunity			
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.			
Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC61000-4-6	3Vrms 150kHz to 80 MHz 6Vrms 150 kHz to 80 MHz outside ISM bands	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distances: $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$
Radiated RF IEC61000-4-3	10V/m 80MHz to 2.7 GHz	10 V/m	

$$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$$

80MHz to 800MHz

$$d = \left[\frac{7}{E_1} \right] \sqrt{P}$$

800MHz to 2.7GHz

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).

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:



Note 1: At 80 MHz to 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.

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.

- 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.
- 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.
- 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 $d = [\frac{3.5}{V_1}] \sqrt{P}$	80MHz to 800MHz $d = [\frac{3.5}{E_1}] \sqrt{P}$	800MHz to 2.7GHz $d = [\frac{7}{E_1}] \sqrt{P}$
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.

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