KANOX

Arm-Type Fully Automatic Digital Blood Pressure Monitor

User Manual

Model: LK-2202

KANOX

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Manufactured for:

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If assistance is needed when setting up, using or maintaining the product, or reporting an unexpected operation or event, please send us an email at info@kanoxmed.com

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Safety Notice

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Thank you for purchasing the LK-2202 Blood Pressure Monitor. The unit was built using reliable circuitry and durable materials. The unit will provide years of satisfactory use if used properly.

Measure blood pressure(systolic and diastolic)and pulse rate of adults and adolescents age 12 through 21years of age. All functions can be used safely, and all values can be read in one LCD DISPLAY. Measurement position is on adult upper arm only. The PATIENT is an intended OPERATOR.

Blood pressure measurement determined with this device are equivalent to those obtained by a trained observer using the cuff/ stethoscope auscultation method, within limits prescribed by the Recognized Consensus Standard (IEC 81060-2-30) for electronic sphygmomanometers.

Precautions to Ensure Safe, Reliable Operation:

1. Do not drop the unit. Protect it from sudden jars or shocks.
2. Do not insert foreign objects into any openings.
3. Do not attempt to disassemble the unit.
4. Do not crush the pressure cuff.
5. If the unit has been stored at temperatures below 0 C°, leave it in a warm place for about 15 minutes before using it. Otherwise, the cuff may not inflate properly.
6. If the unit has been stored at temperatures above 40 C°, leave it in a cool place for about 15 minutes before using it. Otherwise, the cuff may not inflate properly.
7. Do not store the unit in direct sunlight, high humidity or dust.
8. To avoid any possibility of accidental strangulation, keep this unit away from children and do not drape tubing around your neck.
9. Ensure that children do not use the instrument unsupervised; some parts are small enough to be swallowed.
10. Some may get skin irritation due to the cuff taking frequent readings for the day, but this irritation typically goes away on its own after the cuff is removed.

Safety Notice

Important Instructions Before Use:

1. Do not confuse self-monitoring with self-diagnosis. Blood pressure measurements should only be interpreted by a health professional who is familiar with your medical history.
2. Contact your physician if test results regularly indicate abnormal readings.
3. If you are taking medication, consult with your physician to determine the most appropriate time to measure your blood pressure. NEVER change prescribed medication without first consulting with your physician.
4. Individuals with serious circulation problems may experience discomfort. Consult your physician before use.
5. For persons with irregular or unstable circulation resulting from diabetes, liver disease, arteriosclerosis or other medical conditions, there may be variations in blood pressure values measured at the wrist versus at the upper arm. Monitoring the trends in your blood pressure taken at either the arm or the wrist is nevertheless useful and important.
6. People suffering from vascular constriction, liver disorders or diabetes, people with cardiac pacemakers or a weak pulse, and women who are pregnant should consult their physician before measuring their blood pressure themselves. Different values may be obtained due to their condition.
7. People suffering from arrhythmias such as atrial or ventricular premature beats or atrial fibrillation only use this blood pressure monitor in consultation with your doctor. In some instances, the oscillometric measurement method can produce incorrect readings.
8. Too frequent measurements can cause injury to the patient due to blood flow interference.
9. The cuff should not be applied over a wound as this can cause further harm.
10. DO NOT attach the cuff to a limb undergoing IV infusions or any other intravascular access, therapy or an arterio-venous (A-V) shunt. The cuff inflation can temporarily block blood flow, potentially causing harm to the patient.
11. The cuff should not be placed on the arm on the side of a mastectomy. In the case of a double mastectomy, use the side of the least dominant arm.
12. Pressurization of the cuff can temporarily cause loss of function of simultaneously used monitoring equipment on the same limb
13. A compressed or kinked connection hose may cause continuous cuff pressure resulting in blood flow interference and potential injury to the patient.
14. Check that operation of the unit does not result in prolonged impairment of the circulation of the patient.
15. The product is designed for its intended use only. Do not misuse it in any way.
16. The product is not intended for infants or individuals who cannot express their intentions.
17. Prolonged over-inflation of the bladder may cause ecchymoma of your arm.
18. Do not disassemble the unit or arm cuff. Do not attempt to repair.
19. Use only the approved arm cuff for this unit. The use of other arm cuffs may result in incorrect measurement results.

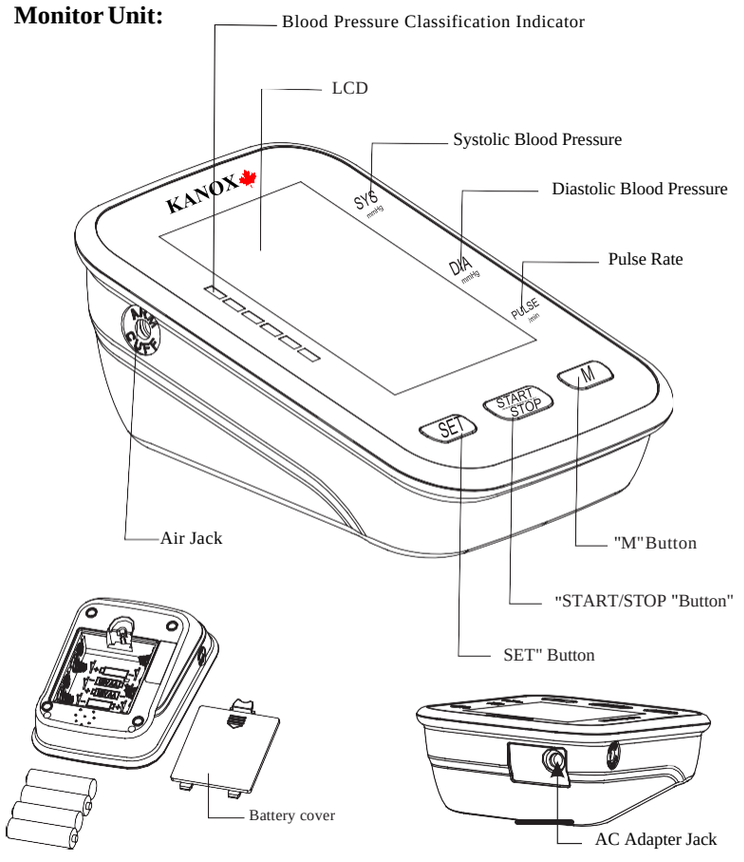
Safety Notice

20. The system might produce incorrect readings if stored or used outside the manufacturer's specified temperature and humidity ranges. Make sure to keep the blood pressure monitor outside of the reach of children, pets and pests.
21. Please do not use the device near strong electrical or electromagnetic fields generated by cell phones or other devices; they may cause incorrect readings and interference or become an interference source to the device.
22. Do not mix new and old batteries simultaneously.
23. Replace all batteries when Low Battery Indicator " " appears on the screen. Replace batteries at the same time.
24. Do not mix battery types. Long-life alkaline batteries are recommended.
25. Remove batteries from a device when not in operation for more than 3 months.
26. Dispose of batteries properly; observe local laws and regulations.
27. Only use a recommended AC adaptor double-insulated complying with EN 60601-1 and EN 60601-1-2. An unauthorized adapter may cause fire and electric shock.
28. Advises the operator that the instruction manual must be consulted.
29. Do not use the device in moving vehicles such as patient transport (ambulances or helicopters) as this may influence measurement accuracies.
30. It contains small parts that may cause a choking hazard if swallowed by infants.
31. Please align each battery's polarities with the + ve and - ve signs imprinted on the battery housing when you replace them.

WARNING SIGNS AND SYMBOLS USED	
	Keep Dry
	Keep out of Sunlight
	Type BF Equipment
	Instructions For Use MUST be Consulted
	Discard the used product to the recycling collection point according to local regulations

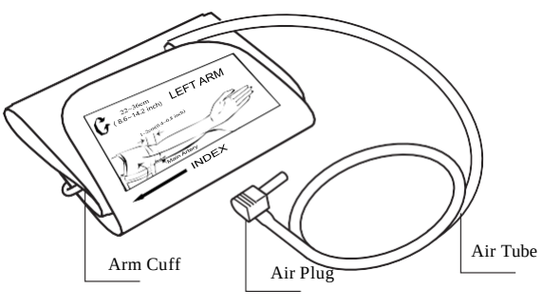
Unit Illustration

Monitor Unit:



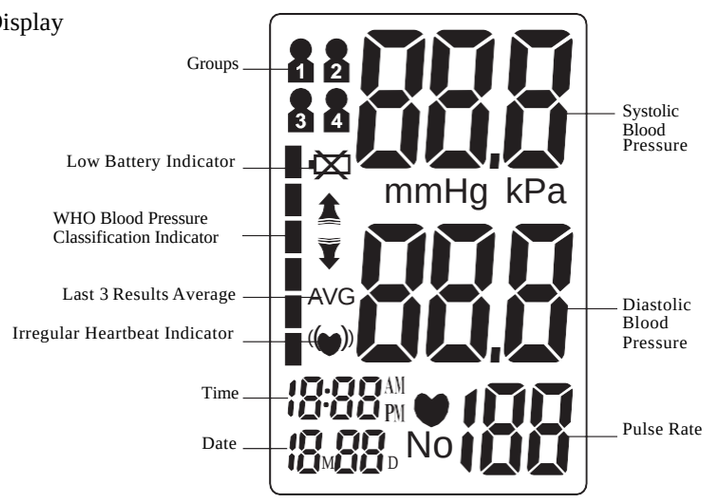
Unit Illustration

Arm Cuff Large size cuff (fits arm circumference: 22.0 cm -42.0 cm).



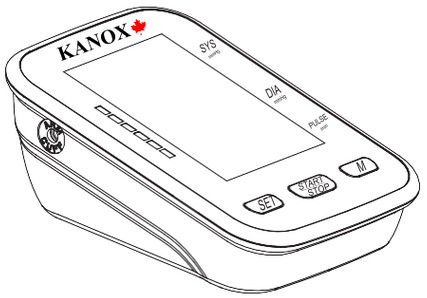
If air is leaking from the arm cuff, replace the arm cuff with a new one. It is generally recommended to have the cuff replaced timely to ensure correct functioning and accuracy. Please consult your local authorized distributor or dealer.

Display



Unit Illustration

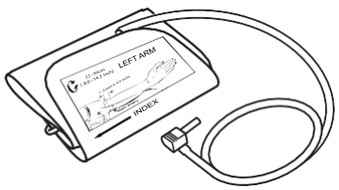
Contents



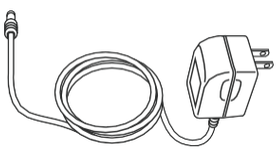
1.Monitor Unit

2.Owner's Manual

4.Storage Bag



3.Arm Cuff



5. 2MOPPMedical AC Adapter (DC6.0 V, 600mA)
(recommended, not provided)

Important Testing Guidelines

1. Avoid eating, exercising, and bathing for 30 minutes before testing.
2. Sit in a calm environment for at least 5 minutes before testing.
3. Do not stand while testing. Sit in a relaxed position while keeping your arm level with your heart.
4. Avoid speaking or moving body parts while testing.
5. While testing, avoid substantial electromagnetic interference such as microwave ovens and cell phones.
6. Wait 3 minutes or longer before re-testing.
7. Try to measure your blood pressure at the same time each day for consistency.
8. Test comparisons should only be made when the monitor is used on the same arm, in the same position and at the same time of day.
9. This blood pressure monitor is not recommended for people with severe arrhythmia.
10. Do not use this blood pressure monitor if the device is damaged.

Any blood pressure recording can be affected by the following factors:

1. The position of the subject, his or her physiologic condition;
2. The performance and accuracy of the device;
3. Cuff size: too small cuff (bladder) will produce a higher blood pressure value than usual, too big cuff (bladder) will deliver a lower blood pressure value;
4. Measuring position does not keep level with your heart;
5. Speaking or moving body parts while testing;
6. Not relaxing for about 5 minutes before taking the measurement.

Quick Start

1. Install batteries. (See Figure A)
2. Insert cuff air plug into the left side of the monitor unit. (See Figure B)

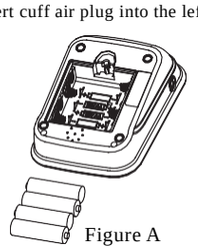


Figure A

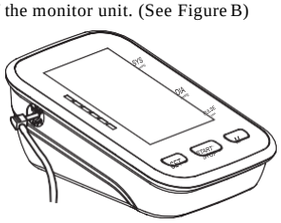


Figure B

3. Remove thick clothing from the armarea.
4. Rest for several minutes before testing. Sit down in a quiet place comfortably, back and arm support on a desk or table, with your legs uncrossed, your arm resting on a firm and your feet flat on the floor. (See Figure C)

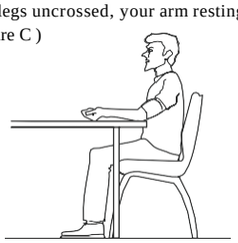


Figure C

5. Apply the cuff to your left arm and middle of the cuff at the level of your heart. The cuff's bottom should be placed approximately 1-2cm (½") above the elbow joint. (See Figures D&E)

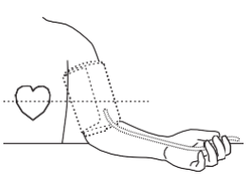


Figure D

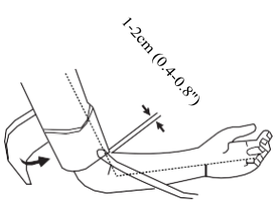


Figure E

6. Press the "START/STOP" button to starttesting.

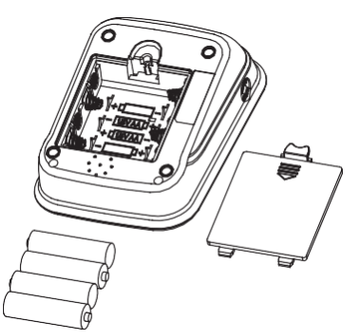
Unit Operation

Battery Installation

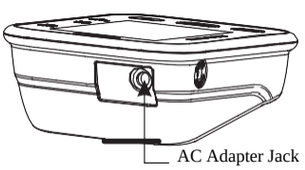
Slide battery cover off as indicated by the arrow.

Install 4 new AA alkaline batteries according to polarity.

Close battery cover.



AC Adapter jack is on the backside of the monitor. A medical AC adapter (DC 6.0 V,600mA) can be used with the device (recommended, not provided). The adapter connect pin should be positive inside and negative outside with a 2.1mm coaxial joint.
Do not use another type of AC adapter as it may harm the unit.



AC Adapter Jack

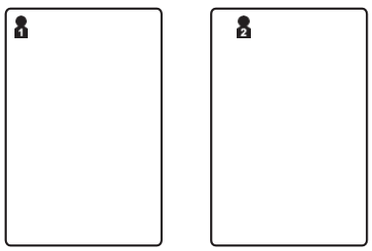
Note: Power supply is specified as part of ME EQUIPMENT.

System Settings

With power off, press the "SET" button to activate System Settings. The Memory Group icon flashes.

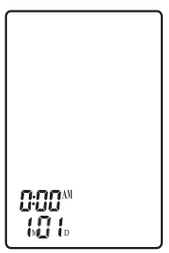
1. Select Memory Group :

While in the System Setting mode, you may accumulate test results into 2 different groups. This allows multiple users to save individual test results (up to 60 memories per group.) Press the "M" button to choose a group setting. Test results will automatically be stored in each selected group.



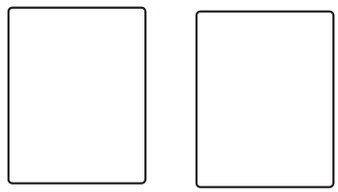
2. Time /Date Setting

Press the "SET" button again to set the Time/Date mode. Set the month first by adjusting the "M" button. Press the "SET" button again to confirm the current month. Continue setting the day, hour and minute in the same way. Every time the "SET" button is pressed, it will lock in your selection and continue in succession (month, day, hour, minute.)



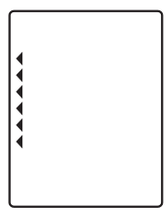
3. Voice Setting:

Press the "SET" button to enter voice setting mode—set voice format ON or OFF by pressing the "M" button.



4. Volume Setting:

Press the "SET" button to enter volume setting mode. Set the voice volume by adjusting the "M" button. There are six volume levels.



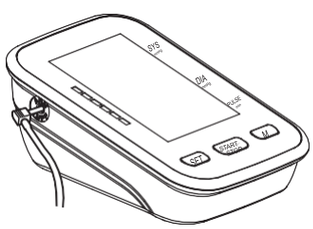
5. Saved Settings:

While in any setting mode, press the "START/STOP" button to turn the unit off. All information will be saved.

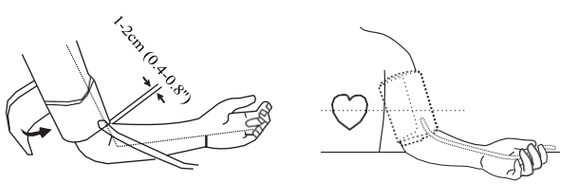
Note: If the unit is left on and not in use for 3 minutes, it will automatically save all information and shut off.

Applying the Arm Cuff:

1. Firmly insert air plug into the opening located on the left side of the monitor unit.



2. Insert the cuff's end underneath the cuff's metal ring, with the sticky nylon section facing outward.
3. Fasten cuff about 1-2cm (0.4-0.8") above the elbow joint. For best results, apply the cuff to a bare arm and keep it level with your heart while testing, as seen below.

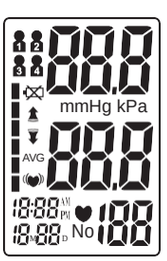


Note: Do not insert air plug into the opening located on the right side of the monitor. This opening is designed for an optional power supply only.

Testing

1. Power On:

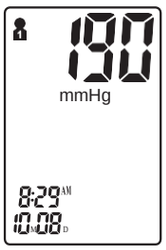
Press and hold the "START/STOP" button to turn on the unit. The LCD screen will appear for one second as the unit performs a quick diagnosis. A voice tone will indicate when the unit is ready for testing.



Note: The unit will not function if residual air from the previous testing is present in the cuff. The LCD will flash " " until pressure is stabilized.

2. Pressurization:

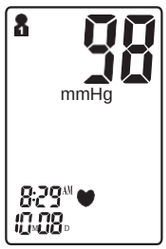
The unit will automatically inflate to the proper pressure value and stop inflating. During this time, please keep quiet.



Note: Pressurization will gradually subside and ultimately stop when the cuff is not correctly applied to the arm. If this occurs, press the "START/STOP" button to turn the unit off.

3. Testing:

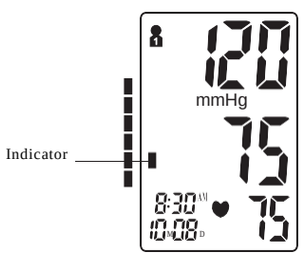
After cuff inflation, air will slowly subside, as indicated by the corresponding cuff pressure value. A flashing "♥" will appear simultaneously on-screen, signalling heartbeat detection.



Note: Keep relaxed during testing. Avoid speaking or moving body parts.

4. Result Display:

The screen will display measurements for systolic and diastolic blood pressure with a voice broadcast. An indicator representing the current measurement will appear next to the corresponding WHO Classification.



Note: Refer to Page 23~24 for detail WHO Blood Pressure Classification Information.

Irregular Heartbeat Indicator:

If the monitor detects an irregular heart rhythm two or more times during the measuring process, the Irregular Heartbeat Symbol" ((♥)) "appears on the screen along with measurement results. Irregular heartbeat rhythm is defined as a rhythm that is either 25% slower or faster than the average rhythm detected while measuring systolic blood pressure and diastolic blood pressure. Consult your physician if the Irregular Heartbeat Symbol " ((♥)) "frequently appears with your test results.

5. Deleting/Storing Test Results:

User may delete their current test result due to unfavourable testing conditions or for any other reason. To delete the last test result, press the "SET" button after the result is displayed. If the result is not deleted, it will automatically store by date within the previously configured Memory Group.

Note: Be sure the appropriate Memory Group selection is made before testing.

If the number of tests surpasses the allotted 60 memories per group, the most recent tests will appear first, thus eliminating the oldest readings.

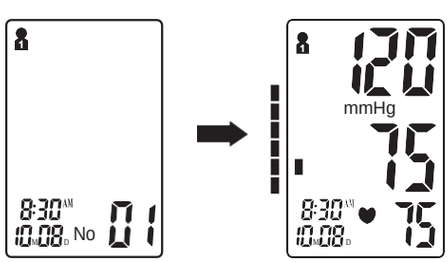
Power Off

The "START/STOP" button can be pressed to turn off the unit in any mode. The unit can turn off the power itself after about 3 minutes without operation in any mode.

Safety Precaution: If the pressure in the arm cuff becomes too extreme while testing, press the 'START/STOP" button to turn the power off. The cuff pressure will rapidly dissipate once the unit is off.

Memory Check:

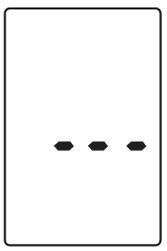
With power off, you may check past test results by using the "M" button. The most recent test result and the oldest test result in memory can be viewed by pressing and holding the "M" button upon activating test results. You can press the "M" button to scroll through all test results stored in memory.



Note: Previous test results will only be displayed from the most recently used memory group. To check previous test results in other memory groups, you must first select the desired group, then turn the monitor off.
(See "Select Memory Group" on Page 10.)

Memory Deletion

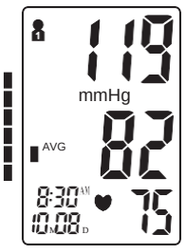
Memory for a selected group may be deleted while in Memory Check mode. Press and hold the "SET" button for approximately 3 seconds to delete all memory records from the selected group with voice broadcast "Memory Clear" and then transfer them into testing mode. Press the "START/STOP" button to turn the unit off.



Note: Memory cannot be recovered once it has been deleted.

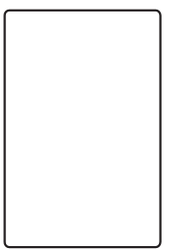
Last 3 Tests Average

With power off, press the "M" button to activate the screen display. After the unit performs a self-diagnosis, the screen will display the average test results from the last 3 readings of the last group used. The "AVG "symbol will appear along with the corresponding WHO Blood Pressure Indicator. The Memory Check mode can be accessed by pressing the "M" button. To check the average results from other groups, select the desired group first before activating the "M" button in the off position. (See "Select Memory Group" on Page 10.)



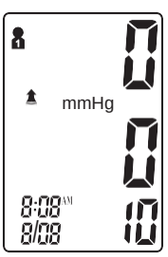
Low Battery Indicator

The unit will broadcast "Low Battery" when battery life is depleting, and it is unable to inflate cuff for testing. The "⊠" appears simultaneously for approximately 5 seconds before shutting off. Replace batteries at this time. No memory loss will occur throughout this process.



Static Pressure Measurement

In an "off" state, press and hold the "START/STOP" button and install the batteries. Until the LCD screen is full, release the "START/STOP" button.
When the LCD screen displays the double zero, the blood pressure meter is in a static state. The software version is displayed at the heart rate.



Note: Only service personnel permitted to access this mode, the mode unavailable in regular use.

Troubleshooting

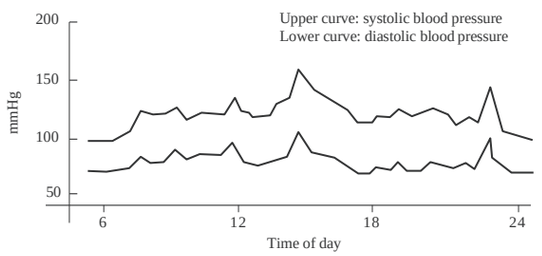
Problem	Possible Cause	Solution
Blood pressure results are not within typical range	Cuff is too tight or not properly positioned on the arm	Firmly reposition cuff approximately1-2cm (1/2") above the elbow joint (See Page 12)
	Inaccurate test results due to body movement or monitor movement	Sit in a relaxed position with arm placed near heart. Avoid speaking or moving body parts while testing. Make sure the monitor unit is placed in a stationary position throughout the testing period. (See Page 7)
"Err "displayed	Cuff fails to inflate properly	Make sure hose is properly fastened to cuff and monitor unit
	Improper operation	Read user manual carefully and re-test properly.
	Pressurization is over cuff rated pressure 300mmHg	Read user manual carefully and re-test properly.

Blood Pressure

Blood pressure is the force of blood pushing against the walls of arteries. It is typically measured in millimetres of mercury (mmHg.) Systolic blood pressure is the maximum force exerted against blood vessel walls each time the heartbeats. Diastolic blood pressure is the force exerted on blood vessels when the heart is resting between beats.

An individual's blood pressure frequently changes throughout the day. Excitement and tension can cause blood pressure to rise while drinking alcohol and bathing can lower blood pressure. Certain hormones like adrenaline (which your body releases under stress) can cause blood vessels to constrict, leading to a rise in blood pressure.

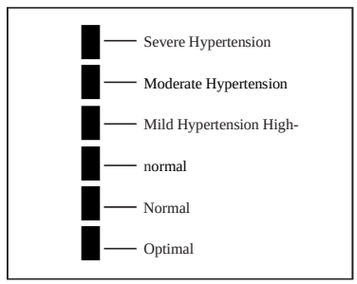
If these measuring numbers become too high, it means the heart is working harder than it should.

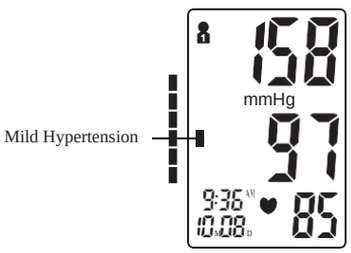


Example: fluctuation within a day (male, 35 years old)

WHO Blood Pressure Classification Indicator

The LK-2202 is equipped with a classification indicator based on established guidelines from the World Health Organization. The chart below (colour-coded on monitor unit) indicates test results.

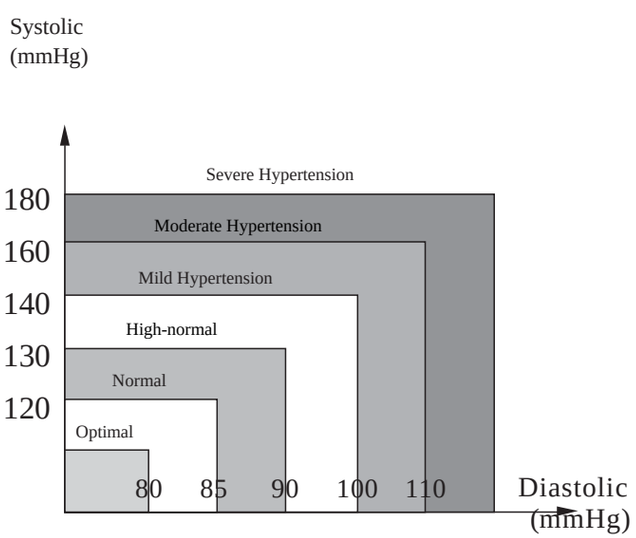




▮: Blood Pressure Classification Indicator

Health Reminder

Hypertension is a dangerous disease that can affect the quality of life. It can lead to many problems, including heart failure, kidney failure, and cerebral hemorrhaging. By maintaining a healthy lifestyle and visiting your physician regularly, hypertension and relative diseases are much easier to control when diagnosed in their early stages.



Note: Do not be alarmed if an abnormal reading occurs. A better indication of an individual's blood pressure occurs after 2-3 readings are taken at the same time each day over an extended period. Consult your physician if test results remain abnormal.

Q: What is the difference between measuring blood pressure at home or at a professional healthcare clinic?

A: Blood pressure readings taken at home are now seen to give a more accurate account as they better reflect your daily life. Readings can be elevated when taken in a clinical or medical environment. This is known as White Coat Hypertension and may be caused by feeling anxious or nervous.

Note: Abnormal test results may be caused by:

1. Improper cuff placement
   Make sure the cuff is snug-not too tight or too loose.
   Make sure the bottom of the cuff is approximately 1-2cm (1/2") above the elbow joint.
2. Improper body position
   Make sure to keep your body in an upright position.
3. Feeling anxious or nervous
   Take 2-3 deep breaths, wait a few minutes and resume testing.

Q: What causes different readings?

A: Blood pressure varies throughout the course of a day. Many factors including diet, stress, cuff placement, etc., may affect an individual's blood pressure.

Q: Should I apply the cuff to the left or right arm? What is the difference?

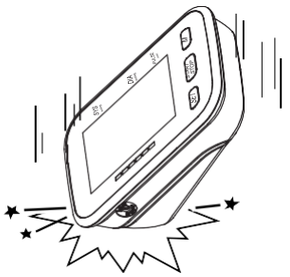
A: Either arm can be used when testing; however, when comparing results, the same arm should be used. Testing on your left arm may provide more accurate results as it is located closer to your heart.

Q: What is the best time of day for testing?

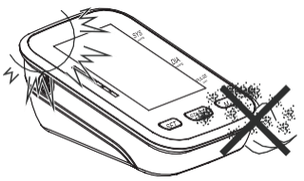
A: Morning time or any time you feel relaxed and stress-free.

Maintenance

1. Avoid dropping, slamming, or throwing the unit.



2. Avoid extreme temperatures. Do not expose the unit directly under sunlight.



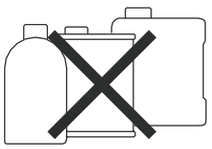
3. When cleaning the unit, use a soft fabric and lightly wipe with mild detergent.

Use a damp cloth to remove dirt and excess detergent.

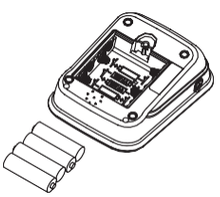
Maintenance

4. Cuff Cleaning and Disinfection:
   A) Spread the cuff (skin-contact surface) upwards onto a clean table. Use a damp clean cloth (water-based) to wipe the skin-contact surface with force.
   B) Soak the cloth clean with drinking water and wring it dry. Repeat A) with the damp cloth (water-based) for 3 times.
   C) Apply 70%-80% alcohol to a new cloth (or 75% alcohol cotton-ball), use it to wipe the skin-contact surface with force. Then soak the cloth with the alcohol again (or change a new 75% alcohol cotton-ball), repeat the disinfection procedure 3 times.
   D) When the disinfection towards the skin-contact surface is finished, wipe the non-skin-contact surface with a cloth (alcohol-based) or alcohol cotton-ball thoroughly for 3 times.
   E) Leave the cuff naturally dry, and then it is ready for reuse.
   Notice: Do not soak in water or splash water on it.

5. Do not use petrol, thinners or similar solvents.



6. Remove batteries when not in operation for an extended period.
7. Do not disassemble the product.



8. It is recommended to verify the unit's performance every 2 years.
9. The product's expected service life is approximately three years at 10 tests per day.
10. No service and maintenance while it is in use and maintenance only be performed by service personnel. Service and maintenance require parts. Repair and technical support will be provided.

Specifications

Product Description	Arm-type Fully Automatic Blood Pressure Monitor	
Model	LK-2202	
Display	LCD Digital Display Size: 84.1mm×55.1mm (3.31" x 2.17")	
Measurement Method	Oscillometric Method	
Measurement Range	Systolic Pressure	60mmHg～260mmHg
	Diastolic Pressure	30mmHg～200mmHg
	Pressure	0mmHg～300mmHg
	Pressure	±3mmHg or ±2% above 200mmHg
	Pulse	30 ~ 180 Beats/Minute
	Pulse	±5%
Pressurization	Automatic Pressurization	
Memory	120 Memories in Two Groups with Date and Time	
Function	Irregular Heartbeat Detection	
	WHO Classification Indicator	
	Last 3 Results Average	
	Low Battery Detection	
	Automatic Power-Off	
	Backlight	
	Voice	
Power Source	4 AA batteries or Medical AC Adapter(DC6.0V, 600mA) (recommended, not provided)	
Battery Life	Approximately 2 months at 3 tests per day	
Unit Weight	Approx.382g (13.47 oz.) (excluding battery)	
Unit Dimensions	Approx.148x100x56mm (5.83"x3.94"x2.21") （LxWxH）	
Cuff Circumference	Large cuff: Fits arm circumference 22-42 cm	
Operating Environment	Temperature	10℃ ~ 40℃ (50°F~104°F)
	Humidity	15%～93%RH
	Pressure	700hPa~1060hPa

Specifications

Storage Environment	Temperature:	-25℃~70℃ (-13°F~158°F)
	Humidity	≤93% RH
Classification:	Internal Powered Equipment,Type BF . Cuff is the Applied Part	
Ingress Protection Rating:	IP20, Indoor Use Only	
Battery Shelf life:	60 months	
Battery Storage Temperature:	-25℃~55℃ (-13°F~131°F)	

Specifications are subject to change without notice.

1. IEC 80601-2-30, medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers. (Cardiovascular)
2. ANSI/AAMI ISO 81060-2, non-invasive sphygmomanometers - part 2: clinical validation of automated measurement type. (Cardiovascular)
3. AAMI / ANSI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and, a2:2010/(r)2012 (consolidated text) medical electrical equipment -- part 1: general requirements for basic safety and essential performance
4. AAMI/ANSI/IEC 60601-1-2, Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests (General II (ES/EMC)).
5. IEC 60601-1-11, medical electrical equipment - part 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.

Correct Disposal of This Product
(Waste Electrical & Electronic Equipment)

This marking shown on the product indicates that it should not be disposed of with other household waste at the end of its life. To prevent potential harm to the environment or human health, please separate this product from different waste types and recycle it responsibly. When disposing of this type of product, contact the retailer where the product was purchased or contact your local government office for details regarding how this item can be disposed of in an environmentally safe recycling center.
Business users should contact their supplier and check the terms and conditions of the purchasing agreement. This product should not be mixed with other commercial wastes for disposal. This product is free of hazardous materials.

Warranty

The Blood Pressure Monitor is guaranteed for 3 years from the date of purchase. If the Blood Pressure Monitor does not function properly due to defective components or poor workmanship, we will repair or replace it freely. The warranty does not cover damages to your Blood Pressure Monitor due to improper handling. Please contact your local retailer for details.

Electromagnetic Compatibility Information

The device satisfies the EMC requirements of the international standard IEC 60601-1-2. The requirements are met under the conditions described in the table below. The device is an electrical medical product and is subject to special precautionary measures regarding EMC, which must be published in the instructions for use. Portable and mobile HF communications equipment can affect the device. In conjunction with non-approved accessories, the unit's use can negatively affect the device and alter the electromagnetic compatibility. The device should not be used directly adjacent to or between other electrical equipment.

Table 1

Guidance and declaration of manufacturer-electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment -guidance**
Radiated emission CISPR 11	Group 1, class B.	The device uses RF energy only for its internal function. Therefore, its emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted emission CISPR 11	Group 1, class B.	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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Compatibility Information

Table 2

Guidance and declaration of manufacturer-electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment -guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV,±4kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV,±4kV, ±8 kV, ±15 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 %.
Electrostatic transient/burst IEC 61000-4-4	± 2 kV , 100kHz, for AC power port	± 2 kV , 100kHz, for AC power port	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5kV, ±1kV (differential mode)	±0.5kV, ±1kV (differential mode)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m; 50Hz or 60Hz	30 A/m; 50Hz or 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Electromagnetic Compatibility Information

Table 3

Guidance and declaration of manufacturer-electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment -guidance**
Conducted RF IEC 61000-4-6	3V for 0.15-80MHz; 6V in ISM and amate-ur radio bands between0.15-80MHz	3V for 0.15-80MHz; 6V in ISM and amate-ur radio bands between0.15-80MHz	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.
Radiated RF IEC 61000-4-3	385MHz, 27V/m 450MHz, 28V/m 710MHz,745 MHZ,780MHz 9V/m 810MHz,870 MHZ,930MHz 28V/m 1720MHz,1845 MHZ,1970MHz 28V/m 2450MHz, 28V/m 5240MHz,5500 MHZ,5785MHz 9V/m	385MHz, 27V/m 450MHz, 28V/m 710MHz,745 MHZ,780MHz 9V/m 810MHz,870 MHZ,930MHz 28V/m 1720MHz,1845 MHZ,1970MHz 28V/m 2450MHz, 28V/m 5240MHz,5500 MHZ,5785MHz 9V/m	Recommended separation distance $d=[\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d=[\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.7 Ghz 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 metres (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. Interference may occur in the vicinity of equipment marked with the following symbol:

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the device		
The device is intended for use in an electromagnetic environment in which radiated therefore, disturbances are controlled. The customer or the device user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the communications equipment's maximum output power.		
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m	
	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.23
0.1	0.38	0.73
1	1.2	2.3
10	3.8	7.3
100	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in metres (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. NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		