

MODEL KD-5904**Fully Automatic Arm Cuff Blood Pressure Monitor**

(ELECTRONIC SPHYGMOMANOMETER)

OPERATION GUIDE

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IMPORTANT INFORMATION

NORMAL BLOOD PRESSURE FLUCTUATION

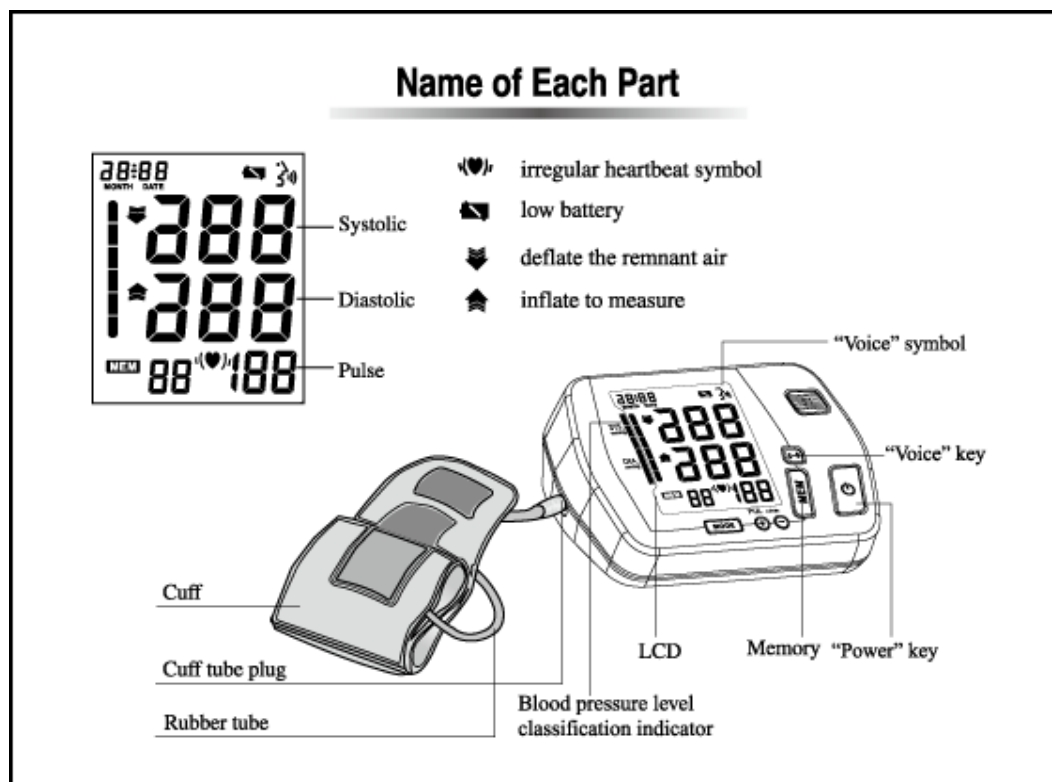
All physical activity, excitement, stress, eating, drinking, smoking, body posture and many other activities or factors (including taking a blood pressure measurement) will influence blood pressure value. Because of this, it is mostly unusual to obtain identical multiple blood pressure readings.

Blood pressure fluctuates continually ---- day and night. The highest value usually appears in the daytime and lowest one usually at midnight. Typically, the value begins to increase at around 3:00AM, and reaches to highest level in the daytime while most people are awake and active.

Considering the above information, it is recommended that you measure your blood pressure at approximately the same time each day.

Too frequent measurements may cause injury due to blood flow interference, please always relax a minimum of 1 to 1.5 minutes between measurements to allow the blood circulation in your arm to recover. It is rare that you obtain identical blood pressure readings each time.

CONTENTS AND DISPLAY INDICATORS



INTENDED USE

Fully Automatic Electronic Sphygmomanometer is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm.

CONTRAINDICATION





It is inappropriate for people with serious arrhythmia to use this Electronic Sphygmomanometer.

PRODUCT DESCRIPTION

Using Oscillometric methodology and silicon integrated pressure sensor technology; blood pressure and heart rate are measured automatically and non-invasively. The LCD display visually shows blood pressure, heart pulse rate measurements and irregular heartbeat (if any). The most recent 60 measurements are stored in the memory with date and time. The voice announces each displayed blood pressure, heart pulse rate measurements and irregular heartbeat (if any). The Electronic Sphygmomanometer corresponds to the below standards: IEC 60601-1:2005/EN 60601-1:2006/AC:2010 (Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance), IEC60601-1-2:2007/EN 60601-1-2:2007 /AC:2010 (Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests), EN 1060-1: 1995 + A1: 2002 + A2: 2009 (Non-invasive sphygmomanometers - Part 1: General requirements), EN 1060-3: 1997 + A1: 2005 + A2: 2009 (Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems), ANSI/AAMI SP-10:2002+A1:2003+A2:2006.





SPECIFICATIONS

1. Product name: Blood Pressure Monitor
2. Model: KD-5904
3. Classification: Internally powered, Type BF applied part, IPX0, No AP or APG, Continuous operation
4. Machine size: 145mm×104mm×55mm
5. Cuff circumference: 22cm-30cm, 30cm-42cm(Optional), 42cm-48cm(Optional)
6. Weight: about 300g (exclude batteries)
7. Measuring method: Oscillometric method, automatic inflation and measurement
8. Memory volume: 60 times with time and date stamp
9. Power source: DC:6V  600mA, batteries: 4 x 1.5V  SIZE AA
10. Measurement range:
 - Cuff pressure: 0-300mmHg
 - Systolic: 60-260mmHg
 - Diastolic: 40-199mmHg
 - Pulse rate: 40-180 beats/minute
11. Accuracy:
 - Pressure: ±3mmHg
 - Pulse rate: ±5%
12. Environmental temperature for operation: 5°C ~ 40°C (41°F ~ 104°F)
13. Environmental humidity for operation: ≤90%RH
14. Environmental temperature for storage and transport: -20°C ~ 55°C (-4°F ~ 131°F)
15. Environmental humidity for storage and transport: ≤90%RH
16. Environmental pressure: 80KPa-105KPa
17. Battery life: Approx. 360 times
18. All components belonging to the pressure measuring system, including accessories: Pump, Valve, LCD, Cuff and Sensor.

Note: These specifications are subject to change without notice.

NOTICE

1. Read all of the information in the operation guide and any other literature in the box before operating the unit.
2. Stay quiet, calm and rest for 5 minutes before blood pressure measurement.
3. The cuff should be placed at the same level as your heart.
4. During measurement, neither speak nor move your body and arm.
5. Measuring on same arm for each measurement.
6. Please always relax at least 1 or 1.5 minutes between measurements to allow the blood circulation in your arm to recover. Prolonged over-inflation (cuff pressure exceed 300 mmHg or maintained above 15 mmHg for longer than 3 minutes) of the bladder may cause ecchymoma of your arm.
7. Consult your physician if you have any doubt about below cases:

- 1) The application of the cuff over a wound or inflammation diseases;
 - 2) The application of the cuff on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present;
 - 3) The application of the cuff on the arm on the side of a mastectomy;
 - 4) Simultaneously used with other monitoring medical equipments on the same limb;
 - 5) Need to check the blood circulation of the user.
8.  This Electronic Sphygmomanometers is designed for adults and should never be used on infants or young children. Consult your physician or other health care professionals before use on older children.
 9. Do not use this unit in a moving vehicle, This may result in erroneous measurement.
 10. Blood pressure measurements determined by this monitor are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method, within the limits prescribed by the American National Standard Institute, Electronic or automated sphygmomanometers.
 11. Information regarding potential electromagnetic or other interference between the blood pressure monitor and other devices together with advice regarding avoidance of such interference please see part ELECTROMAGNETIC COMPATIBILITY INFORMATION.
 12. If Irregular Heartbeat (IHB) brought by common arrhythmias is detected in the procedure of blood pressure measurement, a signal of  will be displayed. Under this condition, the Electronic Sphygmomanometers can keep function, but the results may not be accurate, it's suggested that you consult with your physician for accurate assessment. There are 2 conditions under which the signal of IHB will be displayed:
 - 1) The coefficient of variation (CV) of pulse period >25%.
 - 2) The difference of adjacent pulse period $\geq 0.14s$, and the number of such pulse takes more than 53 percentage of the total number of pulse.
 13. Please do not use the cuff other than supplied by the manufacturer, otherwise it may bring biocompatible hazard and might result in measurement error.
 14.  The monitor might not meet its performance specifications or cause safety hazard if stored or used outside the specified temperature and humidity ranges in specifications.
 15.  Please do not share the cuff with other infective person to avoid cross-infection.
 16. Medical AC adapter which output is DC 6.0V 600mA and complied with IEC 60601-1/EN 60601-1/UL 60601-1 and IEC 60601-1-2/EN 60601-1-2/UL 60601-1-2 is suitable for this monitor. Please note that the monitor jack size: hole $\Phi 5.5mm$, center pin $\Phi 2.0mm$. Please pay attention to polarity.
 17. This blood pressure monitor is verified by auscultatory method. It is recommended that you check annex B of ANSI/AAMI SP-10:2002+A1:2003+A2:2006 for details of verification method if you need.
 18. 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.

SETUP AND OPERATING PROCEDURES


1. BATTERY LOADING

- a. Open battery cover at the back of the monitor.
- b. Load four “AA” size batteries. Please pay attention to polarity.
- c. Close the battery cover.

When LCD shows battery symbol , replace all batteries with new ones.

Rechargeable batteries are not suitable for this monitor.

Remove the batteries if the monitor will not be used for a month or more to avoid relevant damage of battery leakage.

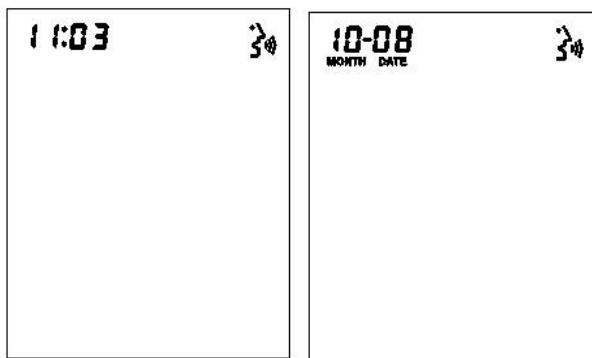
 Avoid the battery fluid to get in your eyes. If it should get in your eyes, immediately rinse with plenty of clean water and contact a physician.



— The monitor, the batteries and the cuff, must be disposed of according to local regulations at the end of their usage.

2. Clock Mode

Once you install the battery, with two “beep”, the LCD will display the time and date by turns.



3. CLOCK AND DATE ADJUSTMENT

- a. When the monitor is turned off, hold on the buttons “Mode” for 3 seconds and the number of the year will blink on and off on the LCD display. In this mode, when the button “Mode” is pressed and released, the day of the month will blink. Press and release the button “Mode” again and the month will blink, Press and release the button “Mode” again and the hours will blink, Press and release the button “Mode” again and the minutes will blink.



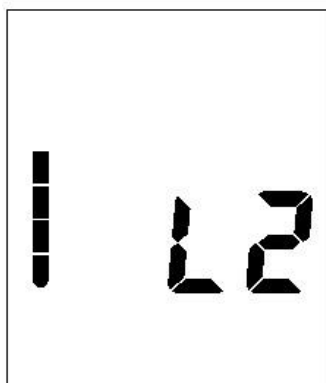
- b. When the year, month, day, hours or minutes that you wish to set is blinking, each time that you press and release the button “+” the displayed number will increase by one and button “-“ decrease by one. By holding down the button “+” / “-“ the displayed number will continue to increase/decrease. Once you set the correct year, press and release the button “Mode”. Then repeat this process to set the month, day, hour, and minutes.
- c. Note that the hours are displayed as 1 through 24 rather than 1AM through 12 Noon and 1PM through 12 Midnight.
- d. After setting the minutes, when you press and release the button “Mode”, you exit the time and date adjusting mode and the numbers on the LCD display will no longer blink.
- e. When batteries are replaced, the time and date must be reset.

4. VOICE SETTING

- a. Voice processor language selection: When the monitor is in Clock Mode, press and hold down the button “MEM” until “L1” appears on the LCD display and the voice announces corresponding Language. If you continue to hold the button “MEM” down, other language will announced and the corresponding language code will appear on the LCD display. When the language of choice appears and is announced, release the button “MEM”.



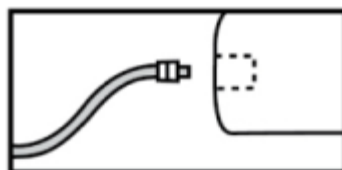
- b. Voice volume setting: Once you have selected a language, again press and hold down the button “MEM”. A line of dashes will appear on the left side of the LCD display and as each new dash appears the monitor will sound a chime. The amount of dashes that appear and the louder the chime sounds, the louder the voice volume is set. Release the button “MEM” when the volume is set at the loudness that you desire. Once you have set the volume, the monitor will exit the language and volume adjustment mode.



- c. You can active/inactive the voice by press the Voice key during most state. When the LCD is displaying the result, re-active the voice can make the monitor speak once again.

5. CONNECTING THE CUFF TO THE MONITOR

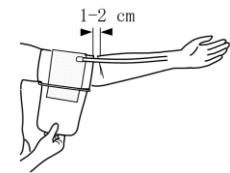
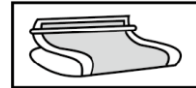
Connect the cuff to the monitor by placing the rubber tube plug into the cuff socket on the monitor. Make certain that the plug is completely inserted so that there will be no air leakage during blood pressure measurements.



Avoid compression or restriction of the connection tubing during measurement, which may cause inflation error, or harmful injury due to continuous cuff pressure.

6. APPLYING THE CUFF

- Pulling the cuff end through the medial loop (the cuff is packaged like this already), turn it outward (away from your body) and tighten it and close the Velcro fastener.
- Place the cuff around a bare arm 1-2cm above the elbow joint.
- While seated, place palm upside in front of you on a flat surface such as a desk or table. Position the air tube in the middle of your arm in line with your middle finger.
- The cuff should fit comfortably, yet snugly around your arm. You should be able to insert one finger between your arm and the cuff.



Note:

- Please refer to the cuff circumference range in “SPECIFICATIONS” to make sure that the appropriate cuff is used.
- Measuring on same arm each time.
- Do not move your arm, body, or the monitor and do not move the rubber tube during measurement.
- Stay quite, calm for 5 minutes before blood pressure measurement.
- Please keep the cuff clean. If the cuff becomes dirty, remove it from the monitor and clear it by hand in a mild detergent, then rinse it thoroughly in cold water. Never dry the cuff in clothes dryer or iron it. Clean the cuff after the usage of every 200 times is recommended.

7. BODY POSTURE DURING MEASUREMENT

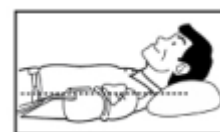
Sitting Comfortably Measurement

- Be seated with your feet flat on the floor, and don't cross your legs.
- Place palm upside in front of you on a flat surface such as a desk or table
- The middle of the cuff should be at the level of the right atrium of the heart.



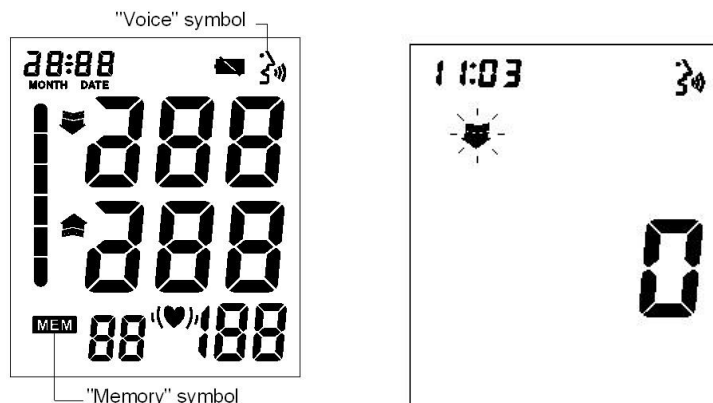
Lying Down Measurement

- Lie on your back.
- Place your arm straight along your side with your palm upside.
- The cuff should be placed at the same level as your heart.



8. TAKING YOUR BLOOD PRESSURE READING

- a. With the cuff wrapped around your arm and your body in a comfortable position, press and release the button “START”. You will hear a beep and the LCD display will first verify itself, then it will set itself to read all zeros.



See the picture. You can check the LCD display according to the picture. Please contact the service center if segment is missing.



If the monitor has previous blood pressure measurements in the memory, the LCD will momentarily display the most recent measurement reading.



- b. If the voice function is on, the monitor will speak out measurement tips and then state.

- c. The monitor will pump up the cuff; then release the air pressure from the cuff; then show the measurement on the LCD display. If the voice feature is activated, it will announce the blood pressure, heart pulse rate measurements and irregular heartbeat (if any) and it will state the classification of the measurements according to the standards of the World Health Organization (WHO)

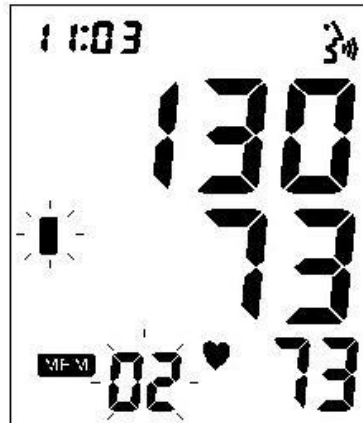


- d. The monitor power will turn-off automatically after 1 minute of non-use. Alternatively, you can press and hold the button "START" to manually turn off the monitor.

Note: Please consult a health care professional for interpretation of pressure measurements.

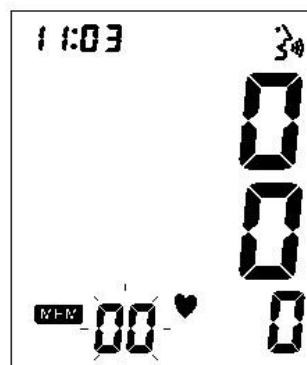
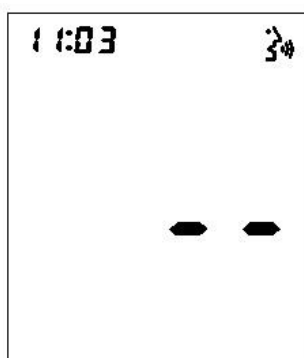
9. DISPLAYING STORED RESULTS

- a. When the monitor is turned off (the time and date remain displayed), press and release the button "MEM". The LCD display will show the number of measurements in the memory; then the average of the last three measurements will be displayed. After few seconds, the most recent measurement will be displayed. If more than one measurement is in the memory, press and release the button "MEM" again and the second most recent measurement will be displayed. Repeat this process to view each measurement stored in the memory.
- b. If the voice function is on, the voice will announce each measurement and irregular heartbeat (if any) in the memory when the measurement is shown on the LCD display. The voice will also state how each measurement is classified according to WHO (World Health Organization).
- c. After reading the measurements in the memory, press and release the button "MEM" when display the last memory or press and release the button "START", the monitor will power off. When in the memory reading mode, the monitor will power-off automatically after 1 minutes of non-use.



10. DELETING MEASUREMENTS FROM THE MEMORY

When in the memory reading mode, pressing and holding the button “MEM” for 3 seconds will delete all measurements from the memory once the monitor sounds three “beeps”. After the “beeps” the LCD display will show two dashes unless you release the button “MEM”, then the LCD display will show that no measurements are in the memory.



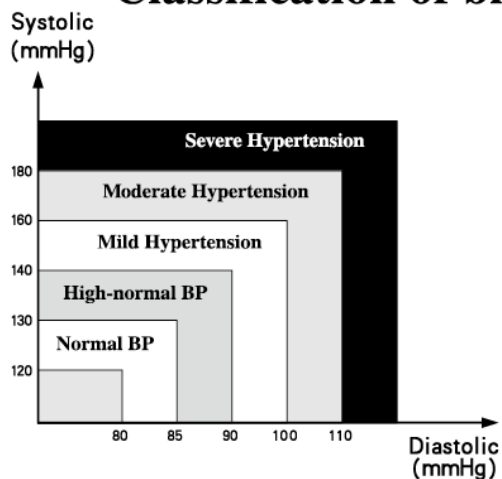
11. TURNING THE MONITOR POWER OFF

The monitor power will turn-off automatically after 1 minute of non-use after measurement displaying and storing. Alternatively, you can press the button “START” to manually turn off the monitor.

12. ASSESSING HIGH BLOOD PRESSURE FOR ADULTS

The following guidelines for assessing high blood pressure (without regard to age or gender) have been established by the World Health Organization (WHO). Please note that other factors (e.g. diabetes, obesity, smoking, etc.) need to be taken into consideration. Consult with your physician for accurate assessment, and never change your treatment by yourself.

Classification of blood pressure for adults



BLOOD PRESSURE CLASSIFICATION	SBP mmHg	DBP mmHg	COLOR INDICATOR
Optimal	<120	<80	GREEN
Normal	120-129	80-84	GREEN
High-Normal	130-139	85-89	GREEN
Grade 1 Hypertension	140-159	90-99	YELLOW
Grade 2 Hypertension	160-179	100-109	ORANGE
Grade 3 Hypertension	≥ 180	≥ 110	RED

WHO/ISH Definitions and Classification of Blood Pressure Levels




Note: It is not intended to provide a basis of any type of rush toward emergency conditions/diagnosis based on the color scheme and that the color scheme is meant only to discriminate between the different levels of blood pressure.

13. TROUBLESHOOTING

PROBLEM	POSSIBLE CAUSE	SOLUTION
LCD Display shows battery symbol	Batteries are low	Install new batteries
LCD Display shows "EE 0"	Pressure system unstable before measurement.	Re-test taking care to not move your arm or the blood pressure monitor
LCD Display shows "EE 1"	Systolic pressure detect fail	Measurement again
LCD Display shows "EE 2"	Diastolic pressure detect fail	Measurement again
LCD Display shows "EE 3"	Pneumatic system blocked or cuff is too tight during inflation	Tighten cuff correctly and refer to "CUFF Connecting"
LCD Display shows "EE 4"	Pneumatic system leakage or cuff is too loose during inflation	Tighten cuff correctly and refer to "CUFF Connecting"
LCD Display shows "EE 5"	Inflation above 300mmHg	Re-test taking care to not move your arm or the blood pressure monitor
LCD Display shows "EE 6"	Over 3 minutes while pressure above 15 mmHg	Press the button "START"
LCD Display shows "EE 7"	EEPROM access error	Please contact the factory
LCD Display shows "EE 8"	Device parameter check error	Please contact the factory
LCD Display shows "EE 9"	MCU self-verify error	Please contact the factory
LCD Display shows "EE A"	Span error	Please contact the factory
LCD Display shows "EE b"	EEPROM backup error	Please contact the factory

BPM no response when you press button. BPM hang	Incorrect operation	Take out batteries for 5 min at least, and then reinstall all batteries.
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MAINTENANCE

1.  Do not drop this monitor or subject it to strong impact.
2.  Avoid high temperature and solarization. Do not immerse the monitor in water as this will result in damage to the monitor.
3. If this monitor is stored near freezing, allow it to acclimate to room temperature before use.
4.  Do not attempt to disassemble this monitor.
5. If you do not use the monitor for a long time, please remove the batteries.
6. It is recommended the performance should be checked every 2 years or after repair. Please contact the service center.
7. Clean the monitor with a dry, soft cloth or a soft cloth squeezed well after moistened with water, diluted disinfectant alcohol, or diluted detergent.
8. No component can be maintained by user in the monitor. The circuit diagrams, component part lists, descriptions, calibration instructions, or other information which will assist the user's appropriately qualified technical personnel to repair those parts of equipment which are designated repairably can be supplied .
9. The monitor can maintain the safety and performance characteristics for a minimum of 10,000 measurements or three years, and the cuff integrity is maintained after 1,000 open–close cycles of the closure.
10. It is recommended the cuff should be disinfected 2 times every week if needed (For example, in hospital or in clinique). Wipe the inner side (the side contacts skin) of the cuff by a soft cloth squeezed after moistened with Ethyl alcohol (75-90%), then dry the cuff by airing

EXPLANATION OF SYMBOLS ON UNIT



Symbol for "THE OPERATION GUIDE MUST BE READ" (The sign background colour: blue. The sign graphical symbol: white)



Symbol for "WARNING"



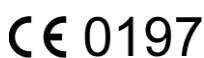
Symbol for "TYPE BF APPLIED PARTS" (The cuff is type BF applied part)



Symbol for "ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local Authority or retailer for recycling advice".



Symbol for "MANUFACTURER"



Symbol for "COMPILES WITH MDD93/42/EEC REQUIREMENTS"



Symbol for "DATE OF MANUFACTURE"



Symbol for "EUROPEAN REPRESENTATION"

SN Symbol for "SERIAL NUMBER"



Symbol for "KEEP DRY"

WARRANTY INFORMATION

Only charge the cost of components and transport.

SERVICE CENTER



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ELECTROMAGNETIC COMPATIBILITY INFORMATION

Table 1

For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture's declaration - electromagnetic emissions		
The KD-5904 is intended for use in the electromagnetic environment specified below. The customer or the user of the KD-5904 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The KD-5904 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The KD-5904 is suitable for use in all establishments other than domestic 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	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2

For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration - electromagnetic immunity			
The KD-5904 is intended for use in the electromagnetic environment specified below. The customer or the user of the KD-5904 should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3

For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration - electromagnetic immunity			
The KD-5904 is intended for use in the electromagnetic environment specified below. The customer or the user of the KD-5904 should assure that it is used in such an environment.			
IMMUNITY test	IEC 60601test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the KD-5904, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:


Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 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 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 and 800 MHz, 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.			
<p>a 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 KD-5904 is used exceeds the applicable RF compliance level above, the KD-5904 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the KD-5904.</p> <p>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Table 4
For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the KD-5904
The KD-5904 is intended for use in an electromagnetic environment in which radiated RF

disturbances are controlled. The customer or the user of the KD-5904 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the KD-5904 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined 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.