Arm Blood Pressure Monitor
Instruction Manual

Model: AES-U212

Version:1.1

Date modified: 2023-05-10

Please read this instruction manual carefully before use

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1. Introduction

Thank you for purchasing the Arm Blood Pressure Monitor. The blood pressure monitor uses the oscillometric method of blood pressure measurement. This means the monitor detects your blood's movement through your brachial artery and converts the movements into a digital reading. An oscillometric monitor does not need a stethoscope so the monitor is simple to use.

The Blood Pressure Monitor comes with the following components:

- Monitor
- Arm Cuff
- Instruction Manual

Please read this instruction manual thoroughly before using the unit.

Please keep for future reference.

For specific information about your own blood pressure, please consult your doctor.

2. Indications for Use

The Arm Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of person via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm. It can be used at medical facilities or at home. The intended upper arm circumference is 22-42cm. Suitable for adults and adolescents who over the age of 12.

3. Product information

Product name: Arm Blood Pressure Monitor , Product model: AES-U212 ,

Software version: A.01.00.00

Standard: The product is made under the IEC 80601-2-30.

Manufacturer

Company name: Alicn Medical Shenzhen, Inc

Address: Room 410, Building A, 3rd Sub-park, Leibo Zhongcheng Life Science Park, No. 22 Jinxiu East Road, Pingshan District, 518118 Shenzhen, Guangdong, PEOPLE'S REPUBLIC OF CHINA

Web: www.alicn-med.com Tel: +86 755 26501548 Fax: +86 755 26504849

4. Classification

(1) Internally powered equipment;
(2) Type BF applied part;
(3) IP classification: IP21;
(4) Disinfection of 75% medical alcohol;
(5) Not Category AP / APG equipment;
(6) Mode of operation: continuous operation.

5. Safety Information

5.1 General usage

- Do not adjust medication based on measurement values from this blood pressure monitor. Take medication as prescribed by your physician. Only a physician is qualified to diagnose and treat High Blood Pressure.
- The monitor is not intended to be a diagnostic device.
- Consult your physician before using the device for any of the following conditions: common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, age, pregnancy, pre-eclampsia, renal diseases.
- Note that PATIENT motion, trembling, shivering may affect the measurement value.
- Do not use the device on the injured arm or the arm under medical treatment, as this can cause further injury.
- Do not apply the arm cuff on the arm while on an intravenous drip or blood transfusion.
- Prolonged over-inflation of the monitor will result in harmful injury to the patient.
- Too frequent measurements can cause injury due to blood flow interference.
- Consult your physician before using the device on the arm with an arterio-venous (A-V) shunt.
- Do not use the device with other medical electrical (ME) equipment simultaneously.
- Do not use the device in the area of HF surgical equipment, MRI, or CT scanner, or in an oxygen rich environment.
- Please ask your doctor about your normal blood pressure for right direction before taking the measurement by yourself.
- If the cuff causes any discomfort, please turn off the equipment by pressing the START/STOP button.
- If the arm cuff doesn’t inflate automatically after the equipment has pressurized to 300mmHg (40kPa), please take off the cuff.
- This product applies only for adults. Please keep the unit out of reach of children.
- The device complies with RF specifications when the device used at 0mm form your body.
- This monitor is calibrated at the time of manufactured, if the monitor is used according to the instruction, periodic recalibration is not required. If it is inaccuracy often, please contact your retailer or customer services.
- Do not disassemble, repair, or remodel the main unit or the cuff of the blood pressure monitor by yourself. If necessary, contact your retailer or customer services.
- The user must check that the equipment functions safely and see that it is in proper working condition before being used.
- If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
- The patient can use and maintain the device as an operator.

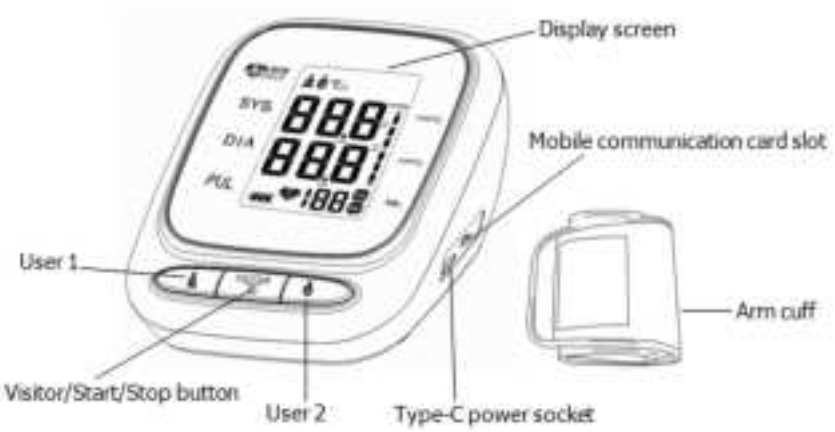
5.2 General precautions

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

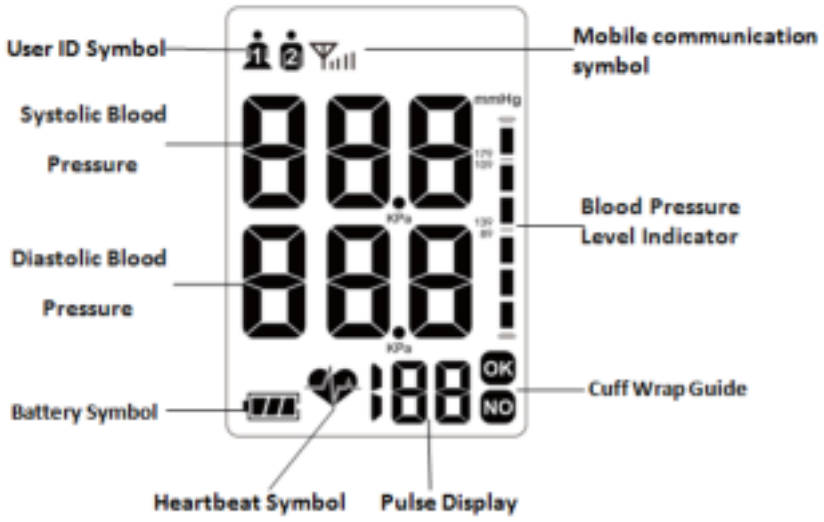
6. Explanation of Marks or Symbols

	Follow instructions for use
	Type-BF applied part.
	**Caution:** Consult accompanying documents.
	Disposal: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.
	Transport package shall be kept away from rain.
	Transport package shall not be exposed to sunlight.
	Indicates correct upright position of the transport package.
	Contents of the transport package are fragile therefore it shall be handled with care.
	Indicates temperature limits within which the transport package shall be stored and handled.
	Lot number
	Production date
	The device should not be used after the end of the shown or the day
	Manufacturer
IP21	Protected against solid foreign objects of 12.5mm ⌀ and greater. Protection against vertically falling water drops.

7. Unit Description



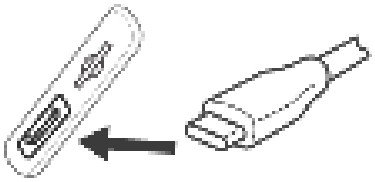
8. Display



9. Charging the Battery

The blood pressure monitor comes with a rechargeable Li-ion battery inside. Use Type-C USB cable to charge the monitor. will appear on the screen when the monitor needs to be charged.

1. Insert one end of the USB charging cable into the Type-C power socket on the side of the monitor.
2. Insert the other end of the USB charging cable into a DC 5V, 1A adapter outlet or a powered USB outlet.
3. When the blood pressure level indicator is full grid display, means that the battery is fully charged.



⚠ **Note**:

- Charging may take 3-4 hours.
- Every 2 months (or when battery life is significantly shorter), fully charge the monitor and then allow the battery to drain until the monitor shuts off. This will optimize battery performance.
- Battery life depends on frequency and time of use. If battery life is unusually reduced, please contact Customer Support.
- In extreme conditions, the battery may leak corrosive fluid. If this comes into contact with eyes or skin, rinse immediately with water and seek medical attention.
- Only use a Type-C USB charging cable to charge the monitor, do not insert the adapter when using the product.

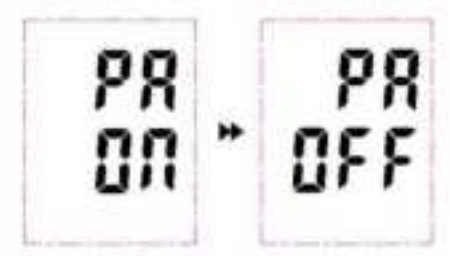
Adapter use

1. The optional AC adapter should be complied with the requirements of IEC 60601-1, and all configurations should meet the requirements of the medical electrical system. Please note that local laws take precedence over the above requirements. If any doubt, please consult your local representative or technical service department.
2. When using AC power, select the power cord of the Type-C jack, and plug it into the power jack.
3. To remove the AC adapter, first unplug the adapter from the outlet and then disconnect the power cord from the device outlet.

Adapter parameter requirements:
Output voltage: DC 5V
Maximum output current: at least 1A
Type-C socket

10. Setting the Measurement Unit

In shutdown mode, press and hold the “ VISITOR ⏻ ”button for about 10 seconds, unit symbol “PA” appears. Then press the user “ 2 ” button to change between ON and OFF, ON for kPa, OFF for mmHg, press user “ 1 ” button to confirm and power off the device.



11. Precautions for Measurement

To ensure a reliable reading follow these recommendations:

- Avoid eating, drinking alcohol, smoking, exercising, and bathing 30 minutes before taking a measurement. Rest for at least 5 minutes before taking the measurement.
- Stress raises blood pressure. Avoid taking measurements during stressful times.
- Use the same arm when repeat the measurement, and if it is your first time to measure your blood pressure, measure both of your arms.
- Remove tight-fitting clothing from your arm.
- Sit on a chair with your feet flat on the floor. Rest your arm on table so that the cuff is at the same level as your heart.
- Please sit down and be quiet, do not talk and move your body during the measurement.
- Patients with arrhythmia and atherosclerosis should not measure by themselves if there is no medical staff there.
- Avoid any electromagnetic interference or noise interference during measurement.
- Keep a record of your blood pressure and pulse readings for your physician. A single measurement does not provide an accurate indication of your true blood pressure. You need to take and record several readings over a period of time. Try to measure your blood pressure at the same time each day for consistency.

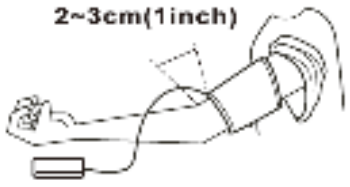
12. Applying the Arm Cuff

1. Make sure the air plug is securely inserted in the main unit.

2. Remove tight-fitting or thick clothing from your upper arm. Do not wear any accessories, please bare upper arm or wear a thin shirt for measurement.

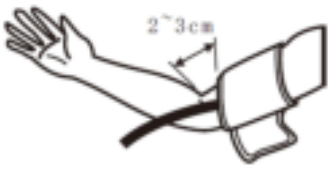
3. Apply the cuff to your left upper arm.

4. Do not wrap the cuff too tight, the bottom of the cuff should be about 2-3cm above your elbow.



5. After wrap the cuff, put the air tube on the inside of your arm and make it aligned with the middle finger.

6. If it's not convenient to measure with left arm, please measure with your right arm follow the instructions as below.



13. Correct Measurement Posture

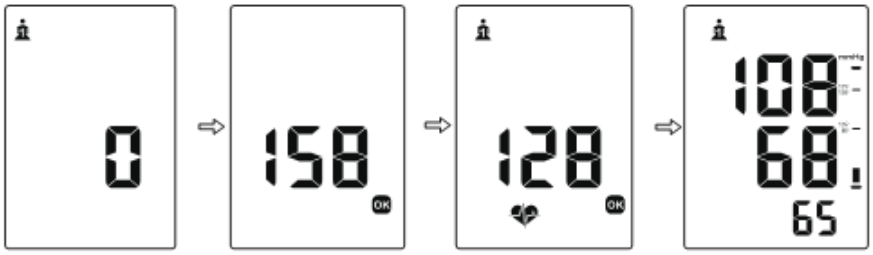
1. Correct posture: sit on a chair as shown in the figure below with your feet flat on the floor. Place your arm on the table so the cuff is level with your heart. Relax yourself for the measurement.

2. Keep quiet during the measurement. Do not shake, talk or eat to avoid inaccuracy.
3. Since blood pressure can vary from time to time throughout the day, please take measurements at the same time every day to ensure reliability.

14. Taking A Measurement

1. Press the " VISITOR ⏻ " or user " 1 " or user " 2 " button, the monitor will full display and start the measurement. It will automatically check whether the arm cuff is applied correctly during the measurement process. When the cuff is applied correctly, is displayed, otherwise is displayed, need to reapply the arm cuff. During the inflation process, the monitor also detects the pulse rate, please do not move until the entire measurement process is completed. As the cuff deflates, decreasing numbers appear on the display, the Heartbeat Symbol ( ) flashes at the same time. When the measurement is complete, the arm cuff deflates automatically, the blood pressure value and pulse rate appear on the display. The difference between the three buttons for measurement is that the blood

pressure values measured by pressing the user " " or user " " button will be uploaded and saved in the background server in the corresponding account for health management. When the measurement data is uploaded, the wireless communication symbol " " flashes and then lights up. But the results of blood pressure measured by pressing the " VISITOR " button are only displayed on the monitor, and will not be uploaded to the background server.



2. In very rare cases, higher pressure inflation may be required. At this point, the monitor will automatically re-inflate to about 40mmHg higher than the initial inflation, and then re-measure, without affecting the measured value.

3. After finish the measurement, the blood pressure value and pulse rate will display on the screen. Press the " VISITOR " button to turn the monitor off. Or the monitor will automatically switch off after about two minutes of inactivity.

15. Care and Maintenance

15.1 Cleaning the monitor and cuff

Make sure the monitor is off prior to cleaning, it can be sterilized with 75% medical alcohol on the soft towel or cotton sliver.
Clean the monitor with a soft dry cloth. Do not use any abrasive or volatile cleaners.
Use a soft moistened cloth and soap to clean the arm cuff, do not wash it in water.
Never immerse the monitor or any of the components in water.

15.2 Maintaining the monitor and cuff

Keep the monitor and cuff in the storage box when not in use.
Do not forcefully bend the arm cuff or air tube. Do not fold tightly.
Do not press the START/STOP button before wear the cuff properly.
Do not disassemble or attempt to refit the unit or components.
Do not subject the monitor to strong shocks, such as dropping the unit on the floor.
Protect the unit from contamination and dust and direct sunlight.
If the unit will not be used for a long time, please remove all the batteries.

16. Guarantee

One-year warranty is available from purchasing date, excluding user-caused failures listed below:

(1) Failure resulted from unauthorized disassemble and modification.

(2) Failure resulted from unexpected drop during application or transportation.

(3) Failure resulted from not following the instructions in User's Manual.

17. Error Messages

Error messages	Problem	Solution
	Low battery	Recharge the battery
Err1	Arm cuff deflates too fast or the pulse signal is too weak	Apply the cuff correctly and repeat measurement
Err2	Disrupted by portable and mobile RF communications equipment	Repeat the measurement and make sure there is no any portable and mobile RF communications equipment around
Err3	Incorrect measurement result	Repeat measurement
Err P	Fails to inflate arm cuff	Apply the cuff correctly and repeat measurement
Err H	Inflating pressure is too high	Repeat measurement in proper way

18. Technical Specifications

Name	Arm Blood Pressure Monitor
Model	AES-U212
Measurement mode	Oscillography
Operating conditions	5℃-40°C, 15%-80%RH, 70-106kPa
Storage conditions	-20℃-+55℃, 15% -93% RH, 70-106kPa
Display range	0-290mmHg (0-39kPa)
Measurement range	Diastolic: 30-200mmHg Systolic: 60-255mmHg Pules: 40-199 pulses/min
Measurement accuracy	Pressure: ±3mmHg (±0.4kPa) Pules: ±5% of reading
Dimensions	137mm×114mm×70mm
Weight	About 286g
Power supply	3.7V, 1100mAh Li-ion battery
Type-C power supply	DC5V, 1A
Switch off	Automatically turn off after 60 seconds

Included in delivery	Monitor, arm cuff, user manual
Cuff size is suitable for arm size	About 22cm between 42cm
Product life	5 years or 10000 measurements under normal use
Adapter	Input:100-240VAC,50/60Hz 0.5A(MAX) output:5v ⎓ 1A which should be applied to IEC60601-1

19. Blood Pressure Classification for Adult

Blood pressure classification according to 2017 Guideline for the Prevention, Detection, Evaluation and Management of High Blood Pressure in Adults, there are four levels for blood pressure classification and two hypertensive crises: emergencies and urgencies as following:

BP classification	Systolic (mmHg)	Diastolic(mmHg)
Optimal blood pressure	＜120	and＜80
Normal blood pressure	120~129	80~84
High-normal blood pressure	130~139	or 85～89
Grade 1 hypertension (Mild)	140~159	or 90～99
Grade 2 hypertension (Moderate)	160~179	or 100～109
Grade 3 hypertension (Severe)	≥180	or≥110

Remark: Contact your physician for specific information about your blood pressure.
Self-diagnosis and treatment which use measured results may be dangerous. Follow the instructions of your physician or licensed healthcare provider.

20. Disposal

This marking shown on the product or its literature, indicates that it should not be disposed with other household wastes at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources.

The users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can take this item for environmentally safe recycling.

21. Electromagnetic Compatibility

Instructions for use

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments and so on.

Warning：Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

Warning： Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."

Warning：Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Arm Blood Pressure Monitor (AES-U212), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

If any：a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE).

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

Technical description

1.all necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the excepted service life.

2. Guidance and manufacturer's declaration -electromagnetic emissions and Immunity.

Table 1

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

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	**IEC 60601-1-2** **Test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Power supply lines：±2 kV input/output lines：±1 kV	Power supply lines：±2 kV
Surge IEC 61000-4-5	line(s) to line(s)：±1 kV. line(s) to earth：±2 kV. 100 kHz repetition frequency	line(s) to line(s)：±1 kV. 100 kHz repetition frequency
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle At 0º, 45 º, 90 º, 135 º, 180 º, 225 º, 270 º and 315 º 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle	0% 0.5 cycle At 0º, 45 º, 90 º, 135 º, 180 º, 225 º, 270 º and 315 º 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC61000-4-6	150KHz to 80MHz： 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	150KHz to 80MHz： 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE U_T is the a.c. mians voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity							
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	**Test Frequency** (MHz)	**Band** (MHz)	**Service**	**Modulation**	**Modulation** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL** (V/m)
	385	380 –390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27
	450	380 –390	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
	710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0.3	9
	745						
	780						
	810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
	870						
	930						
	1720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
	1845						
	1970						
	2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450,	Pulse modulation 217 Hz	2	0.3	28

			LTE Band 7				
	5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0.3	9
	5500						
	5785						

22.FCC Warning

FCC ID: 2AM8O-U212-2

15.19 Labeling requirements.

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.

15.21 Information to user.

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

15.105 Information to the user.

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.

This device complies with RF specifications when the device used at 2.5cm from the body.