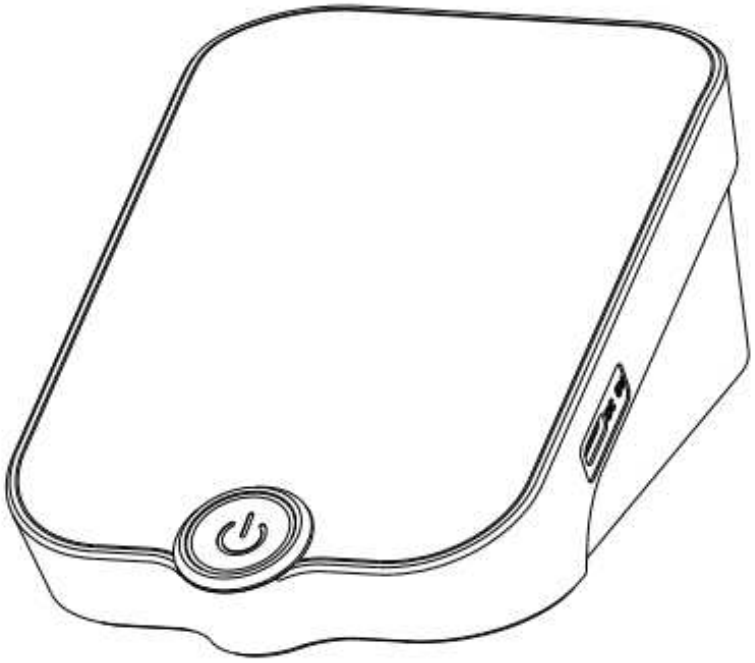
Arm Blood Pressure Monitor
Instruction Manual



Model: AES-U373

Version:1.0

Date modified: 2022-03-22

Please read this instruction manual carefully before use

CE 0123

Table of Contents

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
- 4×AAA batteries
- 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 adult 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 who over the age of 12.
Contraindications: no.

3. Product information

Product name: Arm Blood Pressure Monitor , Product model: AES-U373 ,
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 Email: infor@alicn-med.com

Authorized European Representative

Company name: CMC Medical Devices & Drugs S.L.
Address: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Web: www.cmcmedicaldevices.com
Tel: +34951214054 Email: Info@cmcmedicaldevices.com

4. Classification

(1) Internally powered equipment;
(2) Type BF applied part;
(3) IP classification: IP21;
(4) Disinfection of 70% 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 from 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.
- Please do not continue to use the cuff if you are allergic to it.
- Please use our company's matching cuff, if you use other parts or materials may not be able to boot or reduce safety.
- If non-manufacturer supplied parts are used, errors in measurement results may be caused.
- Please check whether the battery is leaking before use, if it leaks, do not use it.
- Please check whether the power adapter is in good condition before use. If it is damaged, please replace with a new one.
- Do not remove the power adapter during the measurement when using the power adapter to supply power.

5.2 General precautions

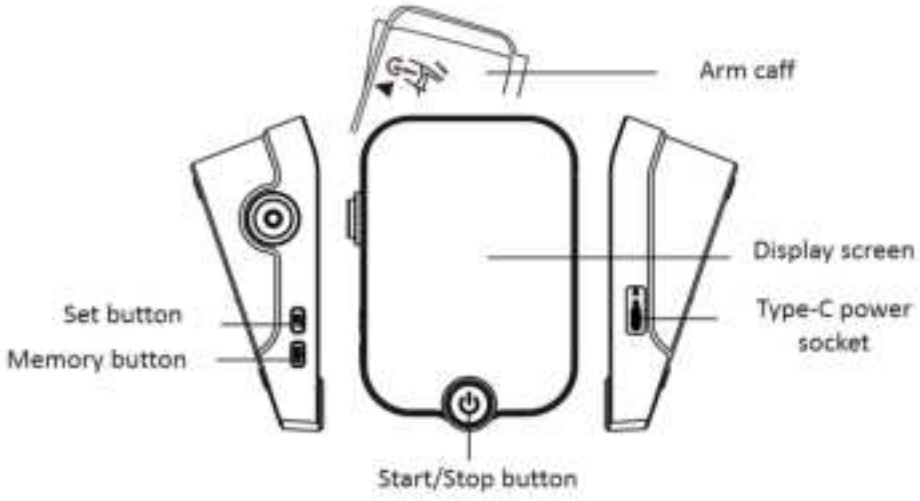
- Do not forcibly crease the arm cuff or the air tube excessively.
- Do not press the air tube while taking a measurement.
- Do not drop the monitor or subject device to strong shocks or vibrations.
- Do not inflate the arm cuff when it is not wrapped around your arm.
- Do not use the device outside 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

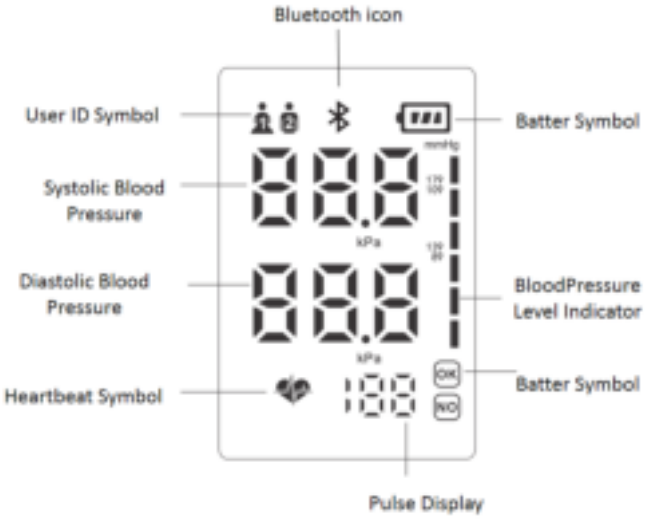
	Follow instructions for use
	Type-BF applied part.
	**Caution:** Consult accompanying documents.
	Disposal: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.
	Transport package shall be kept away from rain.
	Transport package 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	Lot number
	Product number
	The device should not be used after the end of the shown or the day
	Manufacturer
EC REP	Authorized Representative in the European Community
CE	CE mark: indicates that the device complies with the EU 2017/745
IP21	Protected against solid foreign objects of 12.5mm ∅ and greater. Protection against vertically falling water drops.
MD	Medical Device
	Non-ionizing electromagnetic radiation.

7. Unit Description

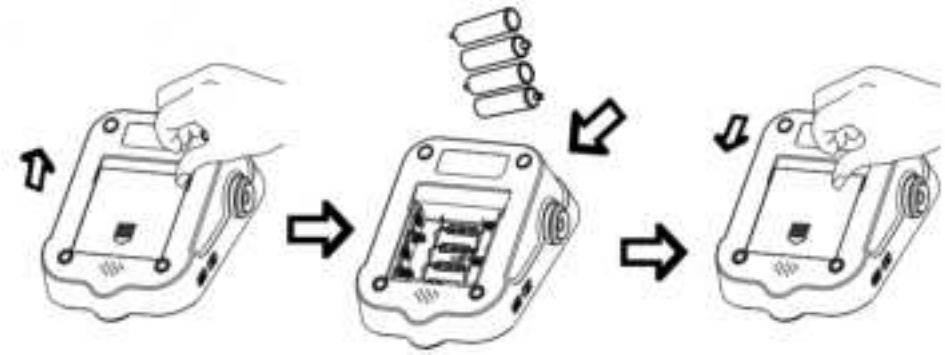


8. Display



9. Battery Installation

1. Remove the battery cover by pushing it in the direction of the arrow.
2. Install 4×AAA batteries and make sure the poles are in the right direction.
3. Replace the battery cover.



Note:

- When the symbol of low battery " ▭ " is flashing, please replace new batteries immediately. After that, the date and time need to be reset.
- If the blood pressure monitor will not be used for a long time, please remove the batteries.
- Do not mix different type of batteries.
- Do not mix new and old batteries together.
- Do not store the batteries in places of the high temperature or humidity or under direct sunlight. Be sure not to expose the batteries to condensation, rain or frozen condition.
- If battery fluid should get in your eyes, immediately rinse with plenty of clean water and contact a physician immediately.
- When dealing with disused batteries, please refer to the relevant laws and environment regulations.
- Do not use batteries after their expiration date.

- To ensure the battery performance, please stored the device (battery) in the dry and cool indoor environment.
- Please stop using when you find the battery was bulging or leaks, replace new batteries immediately.

10. Setting the User, Voice and Unit

Turn off the unit.
Step1: press and hold the SET button for about 3 seconds, when the User ID symbol which is on the top of the screen is flashing, means enter the user setting mode.
Step2: press the MEM button, chose user 1 or user 2
Step3: press the SET button to confirm the setting, and enter the next parameter setting.

Repeat the above step2 and step3 to set the voice, “ON” for sound mode, “OFF” for silent mode.

Repeat the above step2 and step3 to set the unit. “ON” for kPa, “OFF” for mmHg.

After finish all setting, the equipment will turn off automatically.

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.

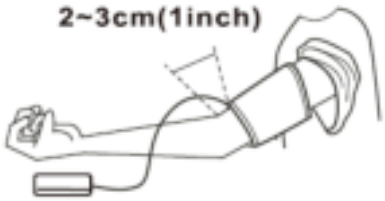
12. Applying the Arm Cuff

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.

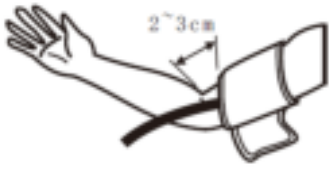
3. Apply the cuff to your left upper arm.

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



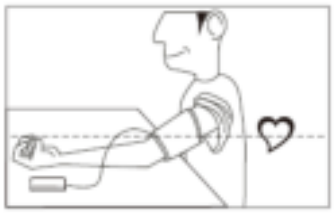
5. After wrap the cuff, put the air tube on the inside of your arm and make it aligned with the middle finger.

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

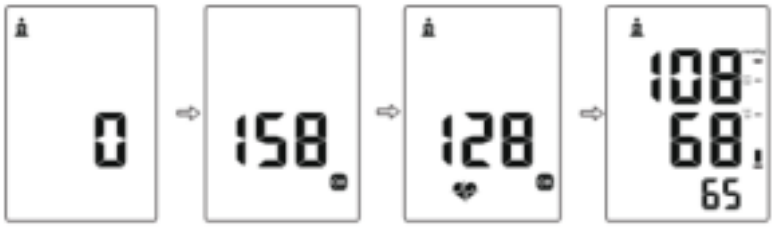
1. Correct posture: sit on a chair as shown in the figure below with your feet flat on the floor. Place your arm on the table so the cuff is level with your heart. Relax yourself for the measurement.



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 START/STOP button, the monitor will reset to zero and start the measurement, it detects the pulse rate during inflation, please do not move until the entire measurement process is completed.
2. 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 and pulse rate appear on the display.
3. It will automatically check whether the arm cuff is applied correctly during the measurement process. When the cuff is applied correctly, OK is displayed, otherwise NO is displayed, need to reapply the arm cuff. 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.



4. When the measurement is complete, the blood pressure and pulse rate will be saved automatically. Press the START/STOP button to turn the monitor off. Or the monitor will automatically switch off after two minutes of inactivity.
5. Unplug the cuff joint from the blood pressure monitor, and gently not forcefully fold the air tube into the cuff.

15. Viewing Memory Values

The monitor automatically stores up to 90 sets of measurement values for each user.
Turn off the unit.
Step1: press the MEM button, average of the last three sets of measurement values displays first on the screen.

Step2: press the MEM button to view each measurement value.

16. Deleting Memory Values

In shutdown mode, press and hold the MEM button, after about 3 seconds press the SET button at the same time, “ ” appears on the display, means all the memories have been deleted.

17. Bluetooth connection

The Bluetooth function (Bluetooth version: BLE5.0) will be automatically turned on when the monitor is power on. The external receiver can search and connect to the monitor. The bluetooth symbol “” lights up when connect successful. After measurement, the monitor will send the measurements to the receiver.

18. Care and Maintenance

18.1 Cleaning the monitor and cuff

Make sure the monitor is off prior to cleaning, it can be sterilized with 70% 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.

18.2 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.

19.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.

20.Error Messages

Error messages	Problem	Solution
	Low batteries	Please replace new batteries
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	Please repeat the measurement and make sure there is no any portable and mobile RF communications equipment
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

21.Technical Specifications

Name	Arm Blood Pressure Monitor
Model	AES-U373
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
Memories recall	90 measurement recalls each user
Dimensions	133mm×97mm×56mm
Weight	About 196g (without batteries)
Power supply	DC 6.0V, 4×AAA batteries；
Type-C power supply	DC5V, 1A
Switch off	Automatically turn off after 60 seconds
Included in delivery	4×AAA batteries, user manual, cuff
Cuff size is suitable for arm size	About 22cm between 42cm
Product life	5 years or 10000 measurements under normal use
Battery life	Approximately 1000 measurements (using new batteries)
Adapter	Input:100-240VAC,50/60Hz 0.5A(MAX) output:5V⎓1A which should be applied to IEC60601-1 and IEC60601-1-2

22.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.

23.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.

24.Electromagnetic Compatibility

Instructions for use

The ME EQUIPMENT or ME SYSTEM is suitable for home or hospital environment.

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

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

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-U111), 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	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	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,	Pulse modulation 18 Hz	2	0.3	28
	870						
	930						

			iDEN 820, CDMA 850, LTE Band 5				
	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, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0.3	9
	5500						
	5785						

25.FCC Warning

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.

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

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.

FCC RF Radiation Exposure Statement:

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. This equipment complies with RF radiation exposure limits set forth for an uncontrolled environment.

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