Arm Blood Pressure Monitor



Instruction Manual

Safety Information

■ To assure the correct use of the product, basic safety measures should always be followed including the warning and the caution listed in the instruction

The following symbols may appear in this manual, on the label on the device or on it's accessories. Some of the symbols represent standards and compliances associated with the device

MARNING: This alert identifies hazards that may cause serious personal injury or death.

⚠ CAUTION: This alert identifies hazards that may cause minor personal injury, product damage, or property damage

Type BF applied part

Manufacturer

SN Specifies serial number

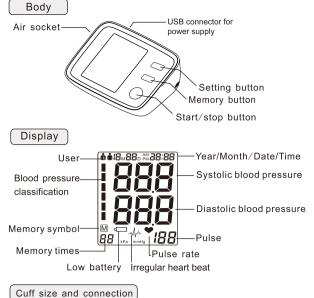
EC REP Authorized Representative in the European Community **C** € ₀123 CE Mark: conforms to essential requirements of the

DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary

Direct current

Follow instructions for use

Product structure



The accessories cuff is universal size for upper-arm circumference 22-42 cm use. The cuff is treated as the applied part

Insert the connector with cuff tube into the hole which is on the left side of the device as picture

(Only provided cuff can be used, can no change to any other branded cuff.)

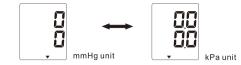
Setting mode

· When use AC adapter, the power of battery won't be consumed. · When suddenly stop during measurement (like the plug off from the outlet by carelessness), it must be reinserted the plug into the unit, and restart the measurement.

1. Start to set, Unit setting:

into the User setting mode

Press the SET button when power off, 0 or 0.0 will be displayed, then the setting begin.
Continute to above step, the unit will be changed when press the MEM button each time. Press the SET button to confirm the unit, then it will enter

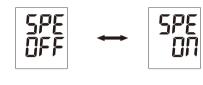


2. Speaking setting

Continute to above step, the screen will display SPE OFF or SPE ON, press the MEM button and it will change between SPE OFF and SPE ON, press the SET button to confirm the option. Following this, the device will enter into the User setting mode.

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SPE OFF: close the speaking function. SPE ON: open the speaking function.



up in order to allow the accumulated blood to flow away.

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FCC Statement ----- 27

Safety Information

⚠ Those who have arrhythmia, diabetes, blood circulation or apoplexy problem, please use under the physician's

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

A Please place on a high place where children can't be touched

A No modification of this equipment is allowed.

⚠ Do not modify this equipment without authorization of the

⚠ If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of

⚠ The cuff hose around neck may cause the suffocation.

The swallowing of small part like packaging bag, battery, battery cover and so on may cause the suffocati

⚠ Please don't use a dilution agent, alcohol or petrol to clean the unit. Please don't hit heavily or fall down the product from a high place. Use the right cuff, otherwise it can not

⚠ Never leave any low battery in the battery compartment since they may leak and cause damage to the unit.

⚠Please take off the battery if you won't use in 3 months. AReplace the new batteries if the unit display a low battery

Battery installation

SIM card installation

Remove the battery cover from the battery compartment, the SIM card slot is on the right side (as picture shown).

Insert SIM card into the slot in accordance with direction

"" and chip side down.

Battery installation

in the proper direction.

Remove the battery cover from the battery compartment, insert the battery,

a) Remove the battery cover as picture

b) Insert 4 AA powerful batteries into the compartment and ensure each battery is

Low battery and replacement

When power on, the low battery symbol \(\square \) will display once the unit start to work, and you must replace with new batteries, otherwise the unit can't work.

Battery type and replacement Please use 4pcs AA identical 1.5V alkaline batteries.

Do not use the batteries beyond their expiry date. Please remove the batteries if you do not need to use for long

▲ WARNING:

Dispose of the battery in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery

Setting mode

3. User setting

Continue to above step, the screen will display 📩 or 🙇 , press button MEM ,it will be changed between and a , press button SET when you confirm the user, then it will enter into the year setting mode



4. Year setting

Continue to above step, the screen will display and flash 20XX, the last digit of the year will increase 1 when press button MEM each time, you could choose from 2020 to 2099. Press button SET when you confirm the year, then it will enter into the month and date setting mode



Proper use of the unit

Proper use of the unit

blood pressure

reading will be obtained.

Only use clinically approved cuffs!

which can lead to false reading

• Relax for about five to ten minutes prior to the measurement

All these factors will influence the measurement result.

• Remove any garment that fits closely to your upper arm.

• Take measurement regularly at the same time of every day, as

• All efforts by the patient to support their arm can increase

• Make sure you are in a comfortable, relax position and do not

activate any of the muscles in the measurement arm during

measurement. Use a cushion for support if necessary

A loose cuff or a exposed bladder causes false reading

Consecutive blood pressure measurements should be

• With repeated measurements ,blood accumulates in the arm

repeated after 1 minute pause or after the arm has been held

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• If the arm artery lies lower or higher than the heart, a false

for 30 minutes before taking a measurement

Always measure on the same arm(normally left)

blood pressure changes even during the day.

Common factors of wrong measurement

Avoid eating, drinking alcohol, smoking, exercising and bathing

Fitting the cuff

1). Put the cuff on a table flatly with the velcro side down. Pass the end of the cuff through the metal loop so that a circle is formed. The velcro closer will now be facing outwards (ignore this step if the cuff has already been prepared)

2). Push the cuff over the left upper arm so that the tube points in the direction of the lower arm.

3). Wrap the cuff on the arm as illustrated. Make certain that the lower edge of the cuff lies approximately 2 to 3 cm above the elbow and the rubber tube leaves the

4). Tighten the free end of the cuff and close the cuff by affixing the velcro.

cuff on the inner side of the arm.

5). The cuff should be snug on your upper arm so That you can fit 2 fingers between the cuff and your upper arm. Any piece of clothing restricts the arm which must be taken off.

6). Secure the cuff with the velcro closer in such a way that it lies comfortably and not too tight. Lay your arm on a table (palm upwards) so that the cuff is at the same height as the heart. Do not bend the

If it is not possible to fit the cuff to your left arm can also be placed on the right. However, all measurements should be made using the same arm

150

6 ID..20: ***8:00

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1 18

End

Introduction

▲ Your new digital 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

▲ Intelligent inflation will reduce the uncomfortable feeling by incorrect inflation, and shorten the measurement time, prolong the cuff's usage lifetime.

displayed on the screen, and automatically stored. This unit has blood classification index, could easy to check your classification index, could easy to check your

▲ Please read the manual carefully before you use the unit, and keep the manual well after using.

CONTRAINDICATION

This product can't be used in patients who is with severe heart insufficiency to avoid suffocation and death.

This product is not suitable for infants and children.

INTENDED USE

This automatic blood pressure monitor intends to measure the systolic pressure, diastolic pressure and pulse rate through upper arm. It's expected to be used at home or in the hospital, intended for people over 12 years old.

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Safety Information

⚠Do not mix the old and new batteries.

⚠ Do not use a cellular phone near the unit. It may result in

⚠ Please avoid using in high radiant area in order to make your measuring data correctly. ⚠ Do not use the equipment where flammable gas (such as

anesthetic gas, oxygen or hydrogen) or flammable liquid (such as alcohol) are present.

▲ WARNING:

Do not dispose of electrical appliances as unsorted municipal waste, use separate collection facilities. Contact you local government for information regarding the collection systems available. If electrical appliances are disposed of in landfills or dumps, hazardous substances can leak into the groundwater and get into the food chain, damaging your health and well-being.

Classification

Internally powered equipment;

- 2. Type BF applied part:
- 3. Protection against ingress of water or Particulate matter:IP21;
- 4. Not category AP / APG equipment
- 5. Mode of operation: Continuous operation:
- A The user must check that the equipment functions safely and

see that it is in proper working condition before being used.

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Battery installation

Adapter usage (option)

1. When optional AC adapter should comply with the requirement of IEC 60601-1:2005. Furthermore all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3Ed. of IEC 60601-1, respectively). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority local representative or the technical service department.

2. When using AC power, to avoid possible damage to the monitor, use only the exclusive AC adapter that can be purchased from authorized dealers Other adapters may vary in output voltage and polarities

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3. Insert the adapter plug into the hole on the

backside of the unit as picture. 4. Insert, the other side of the adapter into the outlet

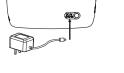
5. To remove the AC adapter, disconnect the adapter

plug from the outlet first and then disconnect the cord

from the unit's socket.

Output voltage: 6V ± 5% Max. output current: At least 600mA Output plug polarity: <+> inner External diameter: 5.5 mm 0.1mm Internal diameter: 2.1mm 0.1mm

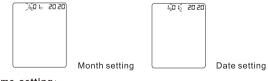
Adapter technical features:



Setting mode

5. Month and date setting

Continue to above step, the screen will display xxMxxD and xxxx, and keep flashing on month , the digit will increase 1 when press button MEM each time, you could choose from 1 to 12. Press button SET when you confirm the month, then it will set the date. Same as the month setting each time you press button $\ensuremath{\mathsf{MEM}}$, the digit will keep changing from 01 to 31. Press button SET when you confirm the date, then it will enter into the time setting mode



6. Time setting

Continue to above step, the screen will display xxMxxD and xx:xx, and keep flashing on the digits of hour, the digit will increase 1 when press button MEM each time, you could choose from 0 to 23. Press button SET when you confirm the hour, then the digits of minute start to flash, same as the hour setting, each time you press button MEM the digits will keep changing from 00 to 59. Press button SET when you confirm the minute, then the total setting mode is completed.



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Pre-measurement

Proper use of the unit

Measuring Procedure: After the cuff has been appropriately positioned, the

measurement can begin as follows 1.Press the START/STOP button, all symbols appear on the display, then the pump begins to inflate the cuff, the rising pressure in the cuff is shown on the display.

2. After the suitable pressure has been reached, the

pump stops and the pressure gradually falls. The cuff pressure is displayed. In case that the inflation is not sufficient, the device automatically re-inflates to a higher pressure.

3. When the device detects the signal, the heart

symbol on the display starts to flash. 4. When the measurement has been completed the systolic, diastolic and pulse rate will appear on the display. Remark: Once finish the measurement, the

device it will upload the dada to the background server automatically with showing two rotating signal bar in the top right corner of LCD (as Pic 1). After uploading the data successfully, the LCD will show End (as Pic 2) and then the device switches off immediately. If fail to upload the data, LCD will display Err

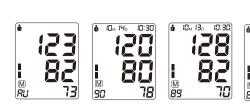
Note:The symbol 🦟 will be displayed along with the reading if the irregular heartbeat is detected during the meas Discontinuing a measurement

If it is necessary to interrupt a blood pressure measurement for any reason (eg. the patient feels unwell) the START/STOP button can be pressed at any time. The device immediately decrease the cuff pressure automatically.

Memory-recall of measurements
This blood pressure monitor automatically stores 2x90 sets measurements value, the oldest record will be replaced by the lates: neasurement value when more than 90 sets each user

Read memory record
Press the button MEM when power off, the latest 3 times average value will be shown, press the button MEM again, the last measurement value will be shown, as well as subsequent measurements can be display one

after the other by pressing the button MEM each time.



Memory -clear of measurements

If you are sure that you want to permanently remove all stored memories. Press the button SET for 9 times until CL appears when power off, press the START/STOP button ,CL will flash for 3 times to clear all the memories. After this press button MEM, M and "no" will be shown on the display which mean that no memory in store

Check IMEI details:

Hold and press the MEM button for 3 seconds when power off, released the button and wait for 5 seconds, then the LCD will display the device IMEI number. And press the START/STOP



Exceptional Situation

Error indicators

■The following symbol will appear on the display when measuring abnormal

Symbol	Cause	Correction		
E- 1	Weak signal or pressure change	Wrap the cuff properly.		
suddenly		Remeasure with correct way.		
E-2	External strong	When near cell phone or other high radiant device , the measurement will be failed.		
	disturbance	Keep quite and no chatting when measure.		
	It appears error	Wrap the cuff properly.		
E-3	during the process of inserte	Make sure that the air plug is properly inserted in the unit.		
		Remeasure.		
E-S	Abnormal blood pressure	Repeat the measurement after relax for 30 mins , if get unusual readings for 3 times, please contact your doctor.		
	Low battery	Replace all the worn batteries with new ones.		

Trouble removal

Problem	Check	Cause and solutions
No nower	Check the battery power	Replace new one
No power	Check the polarity position	Installation for proper placement of the batteries polarities
	Whether the plug insert	Insert into the air socket tightly
No inflation	Whether the plug broken or leak	Change a new cuff
Err and stop working	Whether move the arm when inflate	Keep the body peaceful
Err and stop working	Check if chatting when measured	Keep quite when measure
	Whether the cuff wrap too loose	Wrap the cuff tightly
Cuff leak	Whether the cuff broken	Change a new cuff

Warranty information

Statement

- The intended use: the unit is intended to be used by adults at home or medical center to measure blood pressure and pulse rate
- The unit satisfies the requirements of EN ISO 81060-1 Part 1 Noninvasive sphygmomanometers, EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers. IEC80601-2-30 Part 2 Non-invasive sphygmomanometers.
- Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method, within the limits prescribed by the American National Standard, manual, electronic, or automated sphygmomanometers
- The risk of patient and user can be lowered to acceptable level.

Warranty Information

- The unit is guaranteed to be free of defects in workmanship and materials under normal use for a period of Five Years from the date listed on the purchase record.
- For repair under this warranty. Our authorized service agent must be advised of the fault with the period of the warranty. This warranty covers parts and labor only under normal operations. Any defect resulting from natural causes, eg. flood, hurricane etc, is not within this guarantee. This guaranty does not cover damage incurred By use of the unit not in accordance with the instructions, accidental damage, or being tampered with or serviced by unauthorized service
- Monitor subjected to misuse, abuse, and neglect of these manual content, non-instructional purposes; unauthorized repair or modifications will be excluded from this warranty.
- ⚠ The device requires no calibration
- ⚠ The device is not repairable and contains no user serviceable parts.

EMC Declaration

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 k\ ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Power supply lines: ±2 kV 100 kHz repetition frequency	Power supply lines ±2 kV 100 kHz repetition frequency
Surge IEC 61000-4-5	line(s) to line(s): ±0.5kV ±1 kV.	line(s) to line(s): ±0.5kV ±1 kV.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 250 cycle (50Hz)	0% 0.5 cycle At 0°, 45 °, 90 °, 135 °, 180 °, 225 °, 270 ° and 315 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 250 cycle (50H;
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 amate 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 GH: 80 % AM at 1 kH;

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Arm Blood Pressure Monitor

Shenzhen Urion Technology Co.,Ltd.
Floor 4-6th of Building D , Jiale Science&Technology Industrial Zone, No.3 , ChuangWei Road ,Heshuikou Community,MaTian Street,GuangMing New District, 518106 ShenZhen, PEOPLE'S REPUBLIC OF CHINA

Manufactured for:Telli Health LLC 66 West Flagler Street - Suite 900, Miami, FL, 33130 USA



REV.01

About blood pressure

Signal Strength Indicator:

H means signal is strong, L means signal is weak, _ means there is no signal. These marks will appear after finishing measurement and start to upload data.





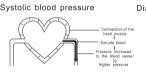


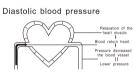
About blood pressure

Blood pressure is the pressure exerted the arteries.

The systolic blood pressure value represents the blood pressure produced by contraction of the heart muscle

The diastolic blood pressure value represents the blood pressure produced by relaxation of the heart muscle.





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Care and maintenance

Care for the main unit and blood pressure monitor cuff

Clean the unit with soft dry cloth

- Do not use any abrasive or volatile
- Never immerse the unit or any nponent in water.
- Make sure the monitor is off prior to cleaning, a mixture of distillent water and 10 percent bleach could be used.
- Using a spray bottle, moisten a soft cloth towel with the bleach or detergent mix until it is fully saturated. Squeeze any excess moistur from the cloth to avoid any dripping or potential oversaturation of the Wipe all surfaces of the blood pressure monitor cuff the
- naking sure to clean the inside and outside of the cuff. Be cautiou
- not to get any moisture in the main unit.

 Using a dry cloth, gently wipe away any excess moisture that may remain on the blood pressure cuff. Lay the cuff flat in an unrolled sition and allow the cuff to air dry.

Maintenace



EMC Declaration

IEC 60601-1-2: 2014 ME EQUIPMENT and ME SYSTEMS identification, marking and documents for Class B product 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

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 blood pressure monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could

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 PERFOR-MANCE is lost or degraded due to EM DISTURBANCES (the defined term "ESSENTIAL PERFORMANCE" need not be used).

EMC Declaration

Ta	ble	3	

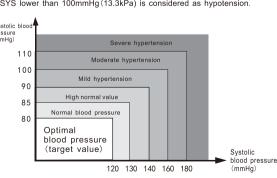
Guid	ance and	manufactur	er's declaration -	electromagn	etic Im	munit	У	
Radiated RF IEC61000- 4-3 (Test	Test Freque ncy (MHz)	Band (MHz)	Service	Modulatio n	Modul ation (W)	Dist ance (m)	IMMUN TY TEST LEVEL (V/m)	
specificatio ns for ENCLOSU	385	380 –390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27	
RE PORT IMMUNITY to RF	450	430 –470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28	
wireless communica tions	710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0.3	9	
equipment)	810	800 – 960 TETRA 80 iDEN 82 CDMA 85						
	870			Pulse modulation	2	0.3	28	
	930		CDMA 850, LTE Band 5	18 Hz				
	1720		GSM 1800;					
	1845	1700	1700 —	CDMA 1900; GSM 1900;	Pulse			
	1970	1990	DECT; LTE Band 1, 3, 4, 25; UMTS	modulation 217 Hz	2	0.3	28	
	2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	
	5240	5100 - 1		Pulse				
	5500		WLAN 802.11 a/n	modulation	0,2	0.3	9	
	5785			217 Hz				

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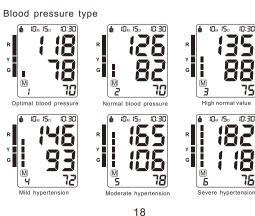
About blood pressure

■According to the blood pressure classification by the WHO/ISH

■ SYS lower than 100mmHg (13.3kPa) is considered as hypotension



■ Blood pressure type



Specification

Software version UA1.0

Description	Automatic upper arm blood pressure monitor		
Display	LCD digital display		
Measuring principle	Oscillometric method		
Measuring localization	Upper arm		
Measurement	Pressure	0~299mmHg	
range	Pulse	40~199 pulses/min	
Accuracy	Pressure	±3mmHg	
	Pulse	±5% of reading	
	Pressure	3 digits display of mmHg	
LCD indication	Pulse	3 digits display	
Indication	symbol	Memory/Heartbeat/Low battery	
Memory function	2x90 sets memory of measurement values		
Power source	4pcs AA alkaline battery		
Automatic power off	in 3 minutes		
Main unit weight	Approx.219g(batteries not included)		
Main unit size	132mm×100mm×45mm		
Main unit lifetime	10,000 times under normal use		
Battery life	Could be used for 300 times for normal condition		
Accessories	Cuff, instruction manual		
Operating	Temperature	5°C~40°C	
Operating environment	Humidity	15%~93%RH	
	Air pressure	86kPa~106kPa	
Storage environment	Air pressure:86kPa~106kPa; Temperature:-20°C-55°C; Humidity:10%~93%RH; avoid crash,sun burn or rain during transportation		
Expected service life	Five years		

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EMC Declaration

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

Guidance and manufacturer's declaration - electromagne 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	Compliance		

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FCC Statement

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 rates uses and can radiate radio frequency energy and, if no 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 Exposure Information and Statement

When carrying the product or using it while worn on your body, either use an approved accessory such as a holster or otherwise maintain a distance of 5 mm from the body to ensure compliance with RF exposure requirements. Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

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