Upper Arm Electronic **Blood Pressure Monitor**

Model: U85E



Instruction Manual

Safety Information

■ To assure the correct use of the product, basic safetymeasures 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

▲ WARNING: 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

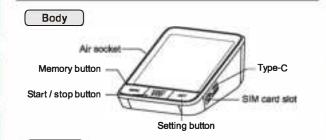
SN Specifies serial number

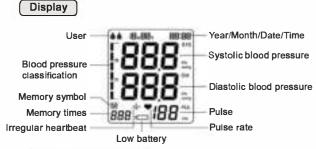
Authorized Representative in the European Community

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

Follow instructions for use

Product structure





Cuff size and connection

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 not change to any other branded cuff.)

- 10000 -

Setting mode

4. Insert the other side of the adapter into the outle

with 100-240V

5. To remove the AC adapter, disconnect the adapter plug from the outlet first and then disconnect the cord from the unit's socket

Adapter technical features: Output voltage: Type-C 5V±5% Max.output current: At least 600 mA



· 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.

How to set

1. Start to set, Unit setting:

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 nto the User setting mode



10

activate any of the muscles in the measurement arm during measurement. Use a cushion for support if necessary.

Only use clinically approved cuffs!

reading will be obtained.

Proper use of the unit

Measurement

Pre-measurement

• A loose cuff or a exposed bladder causes false reading.

Relax for about five to ten minutes prior to the measurement

• 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

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

for 30 minutes before taking a measurement. All these factors will influence the measurement resul

• 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

 With repeated measurements .blood accumulates in the arm which can lead to false reading.

Consecutive blood pressure measurements should be repeated after 1 minute pause or after the arm has been held up in order to allow the accumulated blood to flow away.

Table of Contents

Introduction	3
Safety Information	4
Product Structure	
Each part name	7
Battery installation	8
Setting mode	
How to set	10
Proper use of the unit	
Pre-measurement	13
Common factors	
of wrong measurement	13
Fitting the cuff	14
Measuring procedure	15
Discontinuing a measurement	15
Memory-recall of measurements	15
Read memory record	15
Memory-clear of measurements	16
Checking IMEI details	16
Signal Strength Indicator	17
About blood pressure	17
Exceptional situations	19
Care and maintenance	20
Specification	21
Warranty information	22
EMC Declaration	23
FCC Statement	27

2

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

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

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 suffocation

⚠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 ⚠Do not replace or remove the battery from device (in the case

of device with rechargeable lithium battery). ⚠Do not use a cellular phone near the unit. It may result in operational failure.

⚠Please avoid using in high radiant area in order to make your measuring data correctly.

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

The device is equipped with 1pc 3.7V 1000mAh rechargeable lithium battery.

On not replace or remove the battery from device.

LOW battery and charge

When power on, the low battery symbol will be displayed once the device starts. Plug in the device using the included USB cable to charge. Take the USB cable and connect it to the charger (charge connector) or to your USB port on your computer or power bank. Connect the end of

the round tip to the USB socket of device Noted: the lithium battery could be used for about 70 times when charge is full. Charge time is 4-6 hours.



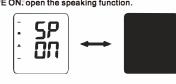
During charging when power off, the LCD will shows the blood pressure bars on the left side from one bar to six bars in a continuous loop. And unmoved 6 bars along with the battery symbol will be displayed once battery is full, as picture shown.



Setting mode

2. Speaking setting

Continute to above step, the screen will display SPEOFF or SPEON, 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. Remark: SPE OFF: close the speaking function. SPE ON. open the speaking function.



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



4. Alarm clock Setting

The screen will display the alarm time Settings XX:XX and alarm 1(there are three alarms by default). Press THE MEM key to adjust the time and press the SET key to confirm. After that, the device automatically switches to the alarm switch setting screen and displays "OF" (the alarm is disabled by default). You can press the MEM key to turn the alarm on or off.



Proper use of the unit

Fitting the cuff

1) Put the cuff on a table flatly with the velcro side down. Pass the end of the cuff through the netal 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 cuff on the inner side of the arm.

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

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, it can also be placed on the right However, all measurements should be made using the same arm.

Proper use of the unit

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

olsplay.

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

4. When the measurement has been completed,

uploading, and automatically shute down after 5 seconds

symbol on the display starts to flash.

the systolic, diastolic and pulse rate will

appear on the display

corner of LCD (as Pic 1).

Measuring Procedure:



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118

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After the cuff has been appropriately positioned, the

Note: The symbol $\mbox{\rlap/--}\hspace{-0.04cm}/\hspace{-0.04cm}/\hspace{-0.04cm}$ will be displyed along with the reading if the irregular heartbeat

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

If Err is displayed (as Pic 2), the upload failed. Upload failure displays Er5 (as Pic 3).

indicating that no SIM card is detected. LCD displays nd (as Pic 4) after successful

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.

▲ 2x90 sets memory function,each measurement result will be 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.

3

Safety Information

⚠ Do not use the equipment where flammable gas (such as anesthetic gas, oxygen or hydrogen) or flammable liquid (such as alcohol) are present.



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;

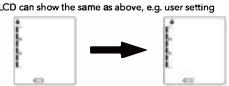
3. Protection against ingress of water or Particulate matter:IP21; 1. Not category AP / APG equipment;

5. Mode of operation: Intermittent operation; The user must check that the equipment functions safely and

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

Battery installation

If the device under setting mode and battery charging in the same time, LCD can show the same as above, e.g. user setting



M WARNING:

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

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 the refore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your 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 polaritles 3. Insert the adapter plug into the hole on the packside of the unit as picture

Setting mode

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 2022 to 2099 Press button SET when you confirm

6. 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 MFM, the digit will keep changing from 01 to 31. Press button SET when you confirm the date, then it will enter into

7. 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.





12









80

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

80



About blood pressure

Memory-recall ofmeasurements

This blood pressure monitor automatically stores 2x90 sets measurements value, the oldest record will be replaced by the latest measurement value when there are more

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 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 18 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

After long pressing the MEM button for 5 seconds in the shutdown state, a bouncing bar "-" will appear in the upper right comer of the screen for about 2 seconds, and then the IMEI number of the device will be displayed on the screen. Press the



unit by yourse f!

Exceptional Situation

Error indicators

■The	■The following symbol will appear on the display when measuring abnormal.					
Syr	Symbol Cause		Correction			
_	E- !	Weak signal or pressure change suddenly	Wrap the cuff properly.			
"			Remeasure with correct way.			
E	E-3	External strong disturbance	When near cell phone or other high radiant device, the measurement will be failed			
-			Keep quite and no chatting when measure			
	E-3	It appears error during the process of inflating	Wrap the cuff properly.			
E			Make sure that the air plug Is properly inserted in the unit			
			Remeasure			
E	E-5 Abnormal blood pressure		Repeat the measurement after relax for 30 mins, if get unusual readings for 3 times, please contact your doctor			
	_	Low battery	Connect the USB cable and charger to charge the battery.			

Trouble removal

Problem	Check	Cause and solutions	
No power	Check the battery power	Charge the battery	
	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	
0.411	Whether the cuff wrap too loose	Wrap the cuff tightly	
Cuff leak	Whether the cuff broken	Change a new cuff	
▲ Please contact the	distributor if you can't solve the	problem, do not disassemble the	

19

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 from the upper arm.
- 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
- 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.

22

EMC Declaration

Immunity Test	IEC 60601-1-2 Test level	Compliance level	
Electrostatic discharge (ESD)	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV	±8 kV contact ±2 kV, ±4 kV, ±8 kV	
IEC 61000-4-2	air	±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 At0°, 45°, 90°, 135°, 180°, 225°, 270° and 315 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 250 cycle (50Hz	
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 amateu 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	

25

Upper Arm Electronic Biood Pressure Monitor

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Shenzhen Urion Technology Co.,Ltd.
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ECREF Eu representative Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany Tel:+49-40-2513175





Rev.00

About blood pressure

Signal StrengthIndIcator

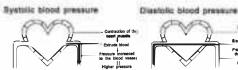
H means signal is strong. L means signal is weak. These marks will appear after finishing measurement and start to upload data.



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



Care and maintenance

Care for the main unit and blood pressure monitor cuff Keep the unit in the storage case when

Clean the unit with soft dry cloth Do not use any abrasive or volatile

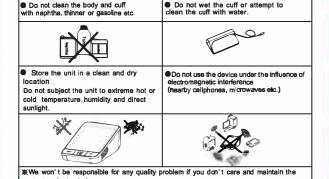
Never immerse the unit or any

 Make sure the monitor is off prior to cleaning, a mixture of disti 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 moisture from the cloth to avoid any dripping or potential oversaturation of the

Wipe all surfaces of the blood pressure monitor cuff thoroughly, making sure to clean the inside and outside of the cuff. Be cautious 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 position and allow the cuff to airdry.

Maintenace



20

EMC Declaration

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

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 TYPÉ 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).

23

EMC Declaration

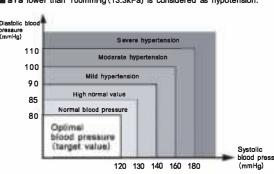
Guld	ance and	manufactur	er's declaration -	electromagn	etic im	munit	у
Radiated RF IEC61000- 4-3 (Test	Test Freque ncy (MHz)	Band (MHz)	Servica	Modulatio n		Dist ance (m)	IMMUNI TY TEST LEVEL (V/m)
specificatio ns for ENCLOSU	385	380 - 390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27
RE PORT IMMUNITY to RF	450	430 - 470	GMRS 460, FRS460	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	GSM 800/800, TETRA 800, Pulse i0 iDEN 820, modulation CDMA850, 18 Hz				
	870 930			Pulse modulation	2	0.3	28
			LTE Band 5				
	1720	1700 – 1990	GSM 1800; CDMA 1900:				
	1845		GSM 1900; DECT;				
	1970		LTE Band 1, 3, 4, 25; UMTS				
	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 – 5800		Pulse modulation 217 Hz	0,2	0.3	9
	5500						
	5785						

26

About blood pressure

■According to the blood pressure classification by the WHO/ISH. ■ SYS lower than 100mmHg (13.3kPa) is considered as hypotension.

17



Blood pressure type



Specification

roduct es instructed

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	
00	Pressure	3 digits display of mmHg	
.CD ndication	Pulse	3 digits display	
Traiou ii o Tr	symbol	Memory/Heartbeat/Low battery	
Memory function	2x90 sets memory of measure ment values		
Power source	1pc 3.7V 1000mAh rechargeable lithium battery in 3 minutes		
Automatic power off			
Main unit weight	Approx.273g(bat	tteries not included)	
Main unit size	130mm*95mm*4	17mm	
vaın unıt lifetime	10,000 times und	ler normal use	
Battery life	Could be used for	r about 70 times when charge is full	
Accessories	Cuff, instruction manual, lithium battery, USB cable		
Operating	Temperature	5°C~40°C	
environment	Humldity	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 bum or rain during transportation		
Expected service life	Five years		
Software version	UA1.0		

21

EMC Declaration

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 - electromagnetic emissions					
Compliance					
Group 1					
Class B					
Class A					
Compliance					

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 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 Exposure Information and Statement

This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

This device complies with RF radiation exposure limits set forth for an uncontrolled environment, this device should be installed and operated with minimum distance 6.5cm between the radiator and your body.