

Upper Arm Electronic **Blood Pressure Monitor**

Model:U80EH



Instruction Manual

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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 manual

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 and its use.

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 EC REP Authorized Representative in the European Community

SN Specifies serial number

(€_{0.22} CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC.

DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately

for special treatment is necessary. === Direct current

Safety Information

Safety Information

to blood flow interference.

on the side of a mastectomy.

from ilnesses.

allow the accumulated blood to flow away.

and result in harmful injury to the PATIENT.

flowing unsmooth and wrong measurement data.

Follow instructions for use

⚠ CAUTION: Consult accompanying documents

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Safety Information

♠ Do not use the equipment where flammable gas(such as anesthetic gas,oxygen or hydrogen)or flammable liquid(such as ⚠ Do not touch the output of AC adapter and the patient

simultaneously ⚠ Do not touch the live end of battery and the patient simultane-

ously when change the batteries

▲ WARNING:

Do not dispose of electrical appliances as unsorted municipal waste, use separate collection facillities. 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

- 1. Internally powered equipment;
- 2. Type BF applied part; 3. Protection against ingress of water or Particulate matter: IP21;

Product structure

Body

Air socket

Display

- 4. Not category AP / APG equipment;
- 5. Mode of operation: Continuous operation.
- 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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Start/Stop button

Irregular heart beat

The accessories cuff is M size, for upper-arm circumference 22-32cm

Insert the connector with cuff tube into the hole which is on the left

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Year/Month/Date/Time

Battery installation

Adapter usage(option)

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, respective-ly). 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 over the above mentioned requirements.If in doubt, consult your local representative or the technical service

1. When optional AC adapter should comply with the requirement of IEC

2. This device is double insulated and protected against short circuit and overload by a primary thermal fuse. Make sure to take the batteries out of the compartment before using the mains part. Equipment class 2. 3. When using AC power, to avoid possible damage to the monitor, use only the exclusive AC adapter that can be purchased from authorized dealers. 4.Insert the adapter plug into the hole on the backside of the unit as

5. Insert the other side of the adapter into the outlet with 100-240V. 6.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:6V±5%

Output current:At least 600 mA Output plug polarity: <+> inner

External diameter: 5. 5mm 0.1 mm Internal diameter: 2.1 mm 0.1 mm

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Proper use of the unit

the accumulated blood to flow away.

·Only use clinically approved cuffs!

can lead to false reading.

Proper use of the unit

minutes before taking a measurement.

pressure changes even during the day.

Common factors of wrong measurement

·Relax for about five to ten minutes prior to the measurement Avoid

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

·All efforts by the patient to support their arm can increase blood

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

·With repeated measurements.blood accumulates in the arm which

Consecutive blood pressure measurements should be repeated after

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1 minute pause or after the arm has been held up in order to allow

·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.

eating, drinking alcohol, smoking, exercising and bathing for 30

All these factors will influence the measurement result.

·Always measure on the same arm(normally left)

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

Measurement

Pre-measurement

will be obtained.

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 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 tube

If it is not possible to fit the cuff to your left arm, it can also be placed

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 blood pressure

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

The automatic blood pressure monitor intended to measurement the systolic pressure, diastolic pressure and pulse rate through upper arm. They are expect used into the home and hospital, intended for over than 12 years old adult using.

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⚠ Those who have arrhythmia, diabetes, blood circulation or apoplexy problem, please use under the physician's instruction. ▲ 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. ▲ Please place on a high place where children can't be touched.

▲ 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 equipment.

⚠ The cuff hose around neck may cause the suffocation. ⚠ The swallowing of samll park like packing bag,battery,battery cover and 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 work.

⚠ 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.

⚠ Replace the new batteries if the unit display a low battery symbol. ⚠ 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

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⚠ Consecutive blood pressure measurements should be repeated

⚠ If the arm circumference size is beyond the measuring range of

⚠ Don't kink the connection tube during use, otherwise the cuff

△ Too frequent measurements can cause injury to the PATIENT due

△ Don't apply CUFF over a wound, it can cause further injury to the

women, patients with implanted, electronical devices, patients with

therapy or arterio-venous shunt or people who received a mastecto-

pre-eclampsia, premature ventricular beats, atrial fibrillation,

peripheral, arterial disease and patients undergoing intravascular

my. Please consult your doctor prior to using the unit if you suffer

⚠ When using this device, please pay attention to the following

circulation of the patient, thus cause harmful injury to the patient:

connection tubing kinking too frequent :the application of the cuff

therapy, or an arterio-venous (A-V) shunt, is present; inflating the cuff

⚠ Do not inflate the cuff on the same limb which other monitoring

ME equipment is applied around simultaneously, because this could

⚠ Please check that operation of the device does not result in

and its pressurization on any arm where intravascular access or

situation which may interrupt blood flow and influence blood

The device is not suitable for use on neonatal patients, pregnant

pressure may continuously increase which can prevent blood flow

after 1 minute pause or after the arm has been held up in order to

CUFF, it can't be measured and used, then it will cause the blood

Battery installation

Cuff size and connection

side of the device as picture.

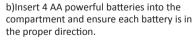
(Only provided cuff can be used,

use. The cuff is treated as the applied part.

can not change to any other branded cuff.)

Battery installation

Remove the battery cover from the battery compartment insert the battery. a)Remove the battery cover as picture



Low battery and replacement

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 time.

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. 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 1to 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 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.



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.



Proper use of the unit

Measuring procedure:

After the cuff has been appropriately positioned, the measurement can begin: 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

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

5). The measurement readings remain on the display until you switch off the device. If no button is pressed

for a period of 3 minutes, the device switches off itself in order to save the power.

heartbeat is detected during the measurement. 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

measurements value, the oldest record will be replaced by the latest measurement value when more than 90 sets each user.

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prolonged impairment of patient blood circulation.

cause temporary loss of function of those.

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·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.user setting

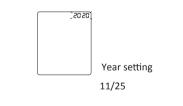
Setting mode

Press button SET when power off, the screen will display norm , press button MEM, it will be changed between and and and press button SET when you confirm the user, then it will enter into the year setting mode



2.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.



on the right. However, all measurements should be made using the same arm

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150

6 10M 180 8:00

1 18

Note: The symbol 4 will be displayed along with the reading if the irregular

pressure automatically. Memory-recall of measurements This blood pressure monitor automatically stores 2×90 sets

About blood pressure

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

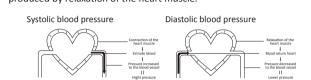


Memory -clear of measurements

If you are sure that you want to permanently remove all stored memories. Press the button SET for 7 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.

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

- Keep the unit in the storage case when no use. Clean the unit with soft dry cloth.
- Do not use any abrasive or volatile cleaners.
- Never immerse the unit or any component in water.



 Make sure the monitor is off prior to cleaning, a mixture of distilled water and 10 percent bleach could be used.

- Using a spray bottle, moisten a soft cloth towel with the bleach or detergent mix until i potential oversaturation of the cuff.
- Wipe all surfaces of the blood pressure monitor cuff thoroughly, making sure to clear 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 bloo pressure cuff. Lay the cuff flat in an unrolled position and allow the cuff to air dry.



Maintenace	
● Do not clean the body and cuff with naphtha, thinner or gasoline etc.	Do not wet the cuff or attempt to clean the cuff with water.
The second secon	

Store the unit in a clean and dry location.Do not subject the unit to extreme hot or Remove the batteries if the unit will not be used in 3 months or longer. cold temperature, humidity and direct

₩ We won' t be responsible for any quality problem if you don't care and maintain the product as

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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. $\textbf{Warning:} \ \mathsf{Don't} \ \mathsf{near} \ \mathsf{active} \ \mathsf{HF} \ \mathsf{surgical} \ \mathsf{equipment} \ \mathsf{and} \ \mathsf{the} \ \mathsf{RF} \ \mathsf{shielded} \ \mathsf{room} \ \mathsf{of}$

an ME system for magnetic resonance imaging, where the intensity of $\ensuremath{\mathsf{EM}}$ 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 $% \left(1\right) =\left(1\right) \left(1\right$ 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 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).

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EMC Declaration

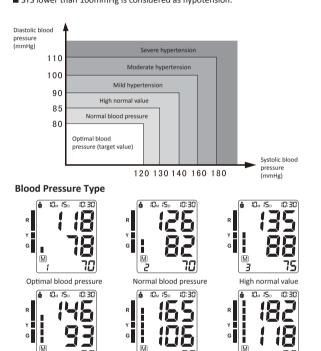
Tabe 3

Radiated RF	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation (W)	Distance (m)	IMMUNIT TEST LEVE (V/m)
(Test	385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1,8	0.3	27
for ENCLOSURE	450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
PORT IMMUNITY to RF wireless	710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
communications equipment)	810 870	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850,	Pulse modulation 18 Hz	2	0.3	28
	930 1720	1700 – 1990	LTE Band 5 GSM 1800; CDMA 1900;	Pulse modulation	2	0.3	28
	1845		GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	217 Hz			
	2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5240 5500	5100 - 5800	WLAN 802.11 a/n	Pulse 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 is considered as hypotension.



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Specification

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	
maication	symbol	Memory/Heartbeat/Low battery	
Memory function	2x90 sets memory of measurement values		
Power source	4pcs AA alkaline battery DC.6V or AC adapter		
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 environment	Temperature	5°C~40°C	
	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		

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EMC Declaration

 ${\bf 1.AII\ necessary\ instructions\ for\ maintaining\ BASIC\ SAFETY\ and\ ESSENTIAL}$ PERFORMANCE with regard to electromagnetic disturbances for the excepted

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

Tabe 1

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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Technical description

Manufacturer
Shenzhen Urion Technology Co.,Ltd.
Floor 4-6th of Building D, Jiale Science&Technology Industrial
Zone, No.3, ChuangWel Road, Heshuikou Community, MaTian
Street, GuangMing New District, 518106 ShenZhen, PEOPLE'S
REPUBLIC OF CHINA
Tel:(86)-755-29231308 E-mail:urion@urion.com.cn
MADE IN CHINA

ECREP Eu representative Eu representative Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany Tel:+49-40-2513175 E-mail:shholding@hotmail.com

Software version: UA1.0 Expected service life: 5 year

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.	
E-1	suddenly	Remeasure with correct way.	
5-2	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	Make sure that the air plug is properly inserted in the unit.	
inflating	Remeasure.		
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	Replace all the worn batteries with new ones.	

Trouble removal

Problem	Check	Cause and solutions		
No power	Check the battery power	Replace new one		
No power	Check the polarity position	Installation for proper placement of the batteries polarities		
No inflation	Whether the plug insert			
THE HINGSON	Whether the plug broken or leak	Change a new cuff		
Err and stop	Whether move the arm when inflate	Keep the body peaceful		
working	Check if chatting when measured	Keep quite when measure		
Cuff leak	Whether the cuff wrap too loose	Wrap the cuff tightly		
Cull leak	Whether the cuff broken	Change a new cuff		
Please contact the distributor if you can't solve the problem, do not disassemble the unit by yourself!				
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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 wrist. ■ 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 device requires no calibration.

- The unit is guaranteed to be free of defects in workmanship and materials under normal use for a period of Two 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 agents.
- Monitor subjected to misuse, abuse, and neglect of these manual content,non-instructional purposes;unauthorized repair or modifications will be excluded from this warranty.

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⚠ 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)	±8 kV contact	±8 kV contactv ±2 kV,
IEC 61000-4-2	±2 kV, ±4 kV, ±8 kV, ±15 kV air	±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst	Power supply lines: ±2 kV	Power supply lines: ±2 kV
IEC 61000-4-4	100 kHz repetition frequency	100 kHz repetition frequence
Surge	line(s) to line(s): ±0.5kV ±1 kV	line(s) to line(s):
IEC 61000-4-5		±0.5kV ±1 kV
Voltage dips, short	0% 0.5 cycle At 0º, 45 º, 90 º,	0% 0.5 cycle At 0º, 45 º, 90 º,
interruptions and voltage	135 °, 180 °, 225 °, 270 ° and 315 °	135 º, 180 º, 225 º, 270 º
variations on power supply	0% 1 cycle And	and 315 º 0% 1 cycle And
input lines	70% 25/30 cycles Single phase:	70% 25/30 cycles Single
IEC 61000-4-11	at 0% 300 cycle	phase: at 0% 300 cycle
Power frequency magnetic	30 A/m	30 A/m
field IEC 61000-4-8	50Hz/60Hz	50Hz/60Hz
Conduced RF	150KHz to 80MHz:	150KHz to 80MHz:
IEC61000-4-6	3Vrms	3Vrms
	6Vrms (in ISM and amateur	6Vrms (in ISM and amateu
	radio bands)	radio bands)
	80% Am at 1kHz	80% Am at 1kHz
Radiated RF	10 V/m	10 V/m
IEC61000-4-3	80 MHz – 2,7 GHz	80 MHz – 2,7 GHz
	80 % AM at 1 kHz	80 % AM at 1 kHz
NOTE UT is the a.c. mians voltage		1

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