

Upper Arm Electronic **Blood Pressure Monitor** 

Model:U80EH



# **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 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

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

CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC.

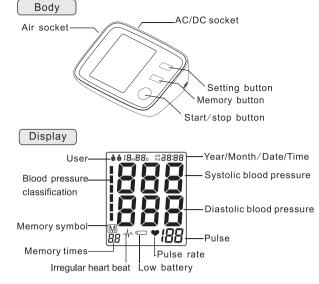
DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary

Direct current

Follow instructions for use

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#### **Product structure**



Cuff size and connection

The accessories cuff is L 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 (Only provided cuff can be used, can not change to any other branded cuff.)

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#### Setting mode

· 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. User setting

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



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



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### Proper use of the unit

#### Fitting the cuff

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

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

cuff by affixing the velcro

That you can fit 2 fingers between the cuff and your upper arm. Any piece of clothing restricts the arm

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

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### 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

A 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

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

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### **Battery installation**

#### Battery installation

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 in the proper direction

#### Low battery and replacement

When power on, the low battery symbol 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

### **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 incinerate the battery.

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



4. 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



Pre-measurement

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### Proper use of the unit

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

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

symbol • on the display starts to flash.

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

### 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

Memory-recall of measurements itor automatically stores 2x90 sets measurement value when more than 90 sets each user

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.

# 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 use

▲ Intelligent inflation will reduce the uncomfortable feeling by 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

▲ 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 measure the systolic pressure, diastolic pressure and pulse rate through upper arm. They are expect used into the home and hospital, intended for over 12 years old adult using.

### **Safety Information**

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

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

### **M** WARNING:

Do not dispose of electrical appliances as unsorted municipal waste, use separate collection facilities. are disposed of in landfills or dumps, hazardous

Internally powered equipment;

I. Not category AP / APG equipment;

The user must check that the equipment functions safely and

 $\Delta$ Do not mix the old and new batteries.

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

Contact you local government for information regarding the collection systems available. If electrical appliances substances can leak into the groundwater and get into the food chain, damaging your health and well-being.

### Classification

2. Type BF applied part;

3. Protection against ingress of water or Particulate matter: IP21;

5. Mode of operation: Continuous operation;

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

### **Battery installation**

### Adapter usage (option)

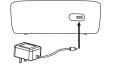
1. When optional AC adapter should comply with the requirement of IEC 60601-1:2005. Furthermore all configurations shall comply with ments for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3Ed, of IEC 60601-1, respectively), Anybody connecting additional equipment to medical electrical 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 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 polarities 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

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5. To remove the AC adapter, disconnect the adapter

Adapter technical features: Output voltage: Type-C 5V

Max. output current: At least 600 mA



Proper use of the unit

#### Relax for about five to ten minutes prior to the measurement Avoid eating, drinking alcohol, smoking, exercising and bathing for 30 minutes before taking a measurement. All these factors will influence the measurement result

- Remove any garment that fits closely to your upper arm
- Always measure on the same arm(normally left)
- Take measurement regularly at the same time of every day, as blood pressure changes even during the day.

Common factors of wrong measurement

- All efforts by the patient to support their arm can increase blood pressure
- measurement. Use a cushion for support if necessary.

• Only use clinically approved cuffs!

• A loose cuff or a exposed bladder causes 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 12/25

3). When the device detects the signal, the heart

4). When the measurement has been completed.

a period of 3 minutes, the device switches off itself in

measurements value, the oldest record will be replaced by the latest

# About blood pressure

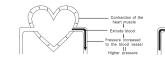


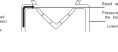
If you are sure that you want to permanently remove all stored memories. Press the button SET for 7 times until CL appears when power off, press the START/STOP button, CL will flash for 3 times to clear all the memories. After this press button MEM, M and "no" will be shown on the

### About blood pressure

Blood pressure is the pressure exerted the arteries The systolic blood pressure value represents the blood pressure

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





· When use AC adapter, the power of battery won't be consumed.

#### How to set

Press button SET when power off , the screen will display 🐧 or 🦓 , press



Continue to above step, the screen will display and flash 20XX, the last



### Measuring procedure:

1). Press the START/STOP button, all symbols appear on

the systolic, diastolic and pulse rate will appear on the display.

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

Read memory record
Press the button MEM when power off, the latest 3 times average value



### Memory -clear of measurements

display which mean that no memory in store.

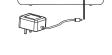
Systolic blood pressure Diastolic blood pressure



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plug from the outlet first and then disconnect the cord from the unit's socket



 Make sure you are in a comfortable, relax position and do not activate any of the muscles in the measurement arm during

• If the arm artery lies lower or higher than the heart, a false reading will be obtained.

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

1). Put the cuff on a table flatly with the velcro  $\,$ 

the tube points in the direction of the lower arm

cuff on the inner side of the arm 4). Tighten the free end of the cuff and close the

5). The cuff should be snug on your upper arm so







# ■According to the blood pressure classification by the WHO/ISH. ■ SYS lower than 100mmHg (13.3kPa) is considered as hypotension. 110 Moderate hypertensio 100 Mild hyperten olood pressure (target value) 120 130 140 160 180 ■ Blood pressure type 70

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Warranty information

Specification

Measurement range

Accuracy

Memory func

Upper arm

Pressure

In 3 minutes

umidity

Pulse

~299 mmHg

40~199 pulses/mi

±5% of reading

3 digits display

4pcs AA alkaline battery (not included) or DC, 6V

15%~93%RH

Air pressure: 86kPa-106kPa Temperature: -20°C~55°C , Humidity: 10%~93%RH avoid crash, sun burn or rain during transportation.

86kPa~106kPa

Approx. 219g (batteries not included)

3 digits display of mmHg

Memory/Heartbeat/Low battery

Storage enviror

- 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.
- $\hfill\blacksquare$  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 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
- 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

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# **EMC Declaration**

**EMC Declaration** 

disturbances for the excepted service life.

1.All necessary instructions for maintaining BASIC SAFETY and

2. Guidance and manufacturer's declaration -electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions

Compliance

Group 1

Class A

Compliance

ESSENTIAL PERFORMANCE with regard to electromagnetic

Technical description

and Immunity

Emissions test

RF emissions CISPR 11

RF emissions CISPR 11

Voltage fluctuations/ flicker emissions

Harmonic emissions

IEC 61000-3-2

IEC 61000-3-3

Tabe 1

Guidance and manuf	facturer's declaration - electror	nagnetic Immunity
Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD)	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contactv ±2 kV, ±4 kV, ±8 kV, ±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% 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% 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 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

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NOTE UT is the a.c. mians voltage prior to application of the test level.

# Symbol Cause

**Exceptional Situation** 

About blood pressure

## Error indicators

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

Correction

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•		
E- :	Weak signal or pressure change	Wrap the cuff properly.
E . (	suddenly	Remeasure with correct way.
E-2	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	E-3 It appears error during the process of inflating	Wrap the cuff properly.
		Make sure that the air plug is properly inserted in the unit.
		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.

Problem	Check	Cause and solutions		
No power	Check the battery power	Replace new one		
NO POWEI	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	hether move the arm when inflate Keep the body peaceful			
Err and stop working	Check if chatting when measured	Keep quite when measure		
Cuff leak	Whether the cuff wrap too loose	Wrap the cuff tightly		
Cuil 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!				
dilit by yourson.				

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### Care and maintenance

Care for the main unit and blood pressure monitor cuff

Clean the unit with soft dry cloth



o not use any abrasive or volatile Never immerse the unit or any

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

 Using a spray bottle, moisten a soft cloth towel with the bleach of tergent mix until it is fully saturated. Squeeze any excess moisturum the cloth to avoid any dripping or potential oversaturation of the Wipe all surfaces of the blood pressure monitor cuff tho

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

\*We won't be responsible for any quality problem if you don't care and maintain the

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# **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.

 $\textbf{Warning:} \ \mathsf{Don't} \ \mathsf{near} \ \mathsf{active} \ \mathsf{HF} \ \mathsf{surgical} \ \mathsf{equipment} \ \mathsf{and} \ \mathsf{the} \ \mathsf{RF} \ \mathsf{shielded} \ \mathsf{room} \ \mathsf{of} \ \mathsf{an} \ \mathsf{ME}$ system for magnetic resonance imaging, where the intensity of EM disturbances is

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

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 ORGANIZA-TION 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

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 DISTUR-BANCES (the defined term "ESSENTIAL PERFORMANCE" need not be used).

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**EMC Declaration** 

Guida	nce and	manufacti	urer's declaration	- electrom	agnetic	Immu	nity
Radiated RF	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation (W)	Distance (m)	IMMUNITY TEST LEVEI (V/m)
(Test specifications	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	810	800 – 960	GSM 800/900, TETRA 800.	Pulse	2	0.3	28
equipment)	870		iDEN 820,	modulation 18 Hz			
	930		CDMA 850, LTE Band 5				
	1720	1700 – 1990	GSM 1800; CDMA 1900;	Pulse modulation	2	0.3	28
	1845		GSM 1900; DECT;	217 Hz			
	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	WLAN 802.11	Pulse	0.2	0.3	9
	5500		a/n	modulation 217 Hz			
	5785			2.7112			

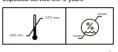


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