yuwell



YE650ARS

Electronic Blood Pressure Monitor

User's Manual

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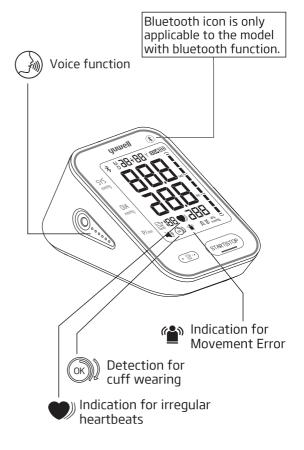
YY-BPM0088D-01(A/0)



Please read the user's manual closely before using!

Contents

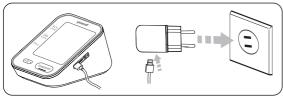
Before using
Product features 01
Operation guide 02
Product structure and parts 04
Cautions06
Important notes
Battery charging11
Time and date setting
Voice volume and unit setting14
Measuring method
Using method of cuff
Measuring posture
Start measuring
Blood pressure range indicator 21
Memory function 22
Auxiliary measuring function24
Static mode
Common problems
Common questions of blood Pressure measurement 27
Common fault and trouble shooting 30
Alarm system 32
Maintenance 33
Features and technical parameters34
Electromagnetic compatibility information37



This device uses the oscillometric method of blood pressure measurement. Please follow the steps as shown below.

Power-on

Connect the power source for charging as shown below.



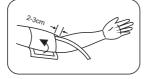
Except the power adapter supplied by the manufacturer as spare parts, using any unspecified accessories or power adapter may cause increasing emission or decreasing immunity of the instrument.

Measurement

1. Using method of cuff

Wearing the cuff and make the lower edge 2~3cm above the elbow, keep the air tube inside of the arm. (Please turn to page 15 for details.)





2. Measuring posture

Sit straightly, keep the center of cuff and heart at the same level. (Please turn to page 17 for details.)



3. Start measuring

Sit still for 5 minutes and then press the [START|STOP] button to measure. (Please turn to page 18 for details.)

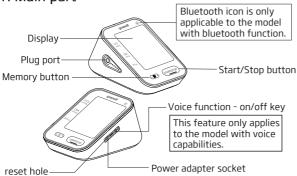
Check the records

Press the [] button to check the measuring records. This monitor can display the average measurement and store 60 records. (Please turn to page 22 for details.)

Product structure and parts

Product structure and parts

1. Main part



2. Cuff

There are 6 types of cuff provided by yuwell. Please subject to the received type.

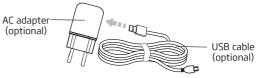


Model	YE-61MC	YE-61LC	YE-62MC	YE-62LC	YE-63MC	YE-63LC
Charac-	c- Without hard support With hard supp				d cupport	
teristic	Fabric: 210	T polyester	Fabric: 250	D polyester		a support
The range of arm circumfe-rence	22cm - 32cm	22cm - 45cm	22cm - 32cm	22cm - 45cm	22cm - 32cm	22cm - 45cm

Please select a suitable size cuff according to the arm circumference. Out of the given value can lead to inaccurate results of measurements.

Marning: Please use cuff made by Yuwell, otherwise the measurement results will be inaccurate.

3. AC adapter and USB cable



AC adapter

INPUT: 100-240V~

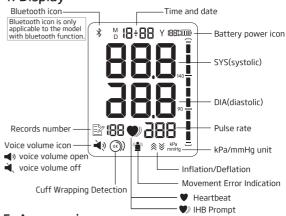
50/60Hz 0.35A MAX

OUTPUT: 5V==1000mA

MFR: WEIHAI HITAI ELECTRONICS Co.,LTD.

US Model: HT-C38B-0510WW

4. Display



5. Accessories

User's manual、Warranty card、USB cable

-05-

Pay attention with the symbols shown here to prevent harm or damage to the user.

\triangle	Caution			
☆	Type BF applied part			
₿	Follow instructions for	r use		
***	Manufacturer			
M	Date of manufacture			
X	Recover waste electrical and electronic equipment			
<u> </u>	Keep Upright Fragile			
Ť	Keep Dry			
IP20	IP Classification			
	Class II Device			
UDI	Indicates a carrier that contains unique device identifier information			
===	DC Current	\sim	AC Current	
LOT	Batch code			
SN	Serial Number			
MD	Indicates the item is a medical device			
MR	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR(magnetic resonance) environment.			

Statement: The device is a medical device.

1. Intended purpose

This product is intended to measure the blood pressure and pulse rate of adult who is more than 12 years old at household or medical center (not suitable for neonate, pregnancy or pre-eclampsia).

2. Attention items

Pay attention to the following points when measuring, otherwise it may cause damage or incorrect results.

- Sit still for 5 minutes before measuring to ensure quiet and stable mode.
- Do not take the measurement within 1 hour of eating, smoking, drinking wine or coffee (black tea).
- Do not measure while standing, walking, lying down or having body pressed.
- Do not take the measurement after sports or bath.
- Do not speak, move, shake arm or bend fingers while measuring.
- Do not take the measurement at extreme temperature condition or the varied severely environment.
- The incorrect measurements of the equipment may be caused by external interference, such as accelerating during transportation or transportation.
- Do not take the measurement in a moving vehicle.
- Do not measure continuously. (At least 2~3 minutes or more should be spared between two measurements.)

- Please start again if cannot measure.
- For patient of arrhythmia, arterial sclerosis, poor perfusion, diabetes, pergnancy, pre-eclampsia, renal diseases, patient motion, trembling, shivering, measuring results may not be accurate.
- Do not keep the cuff in the aerated state for a long time to avoid the injury to the patient.
- The patient is an intended operator, this monitor is used for adult whom more than 12 years old.
- Warning: The AC adapter cable and rubber air tube may cause accidental strangulation in infants.
- Warning: Do not swallow small parts that may cause choking hazard.
- The device must not be used with high frequency surgical equipments.
- Warning: Do not use the CUFF over a wound arm or being on an intravenous drip.
- Warning: Do not use the device if the arm where intravascular access or therapy, or an arterio-venous (A-V) shunt is present because of temporary interference with blood flow and could result in injury to the patient.
- Please pay attention to product storage to prevent damage caused by pets, pests or children.
- Operator can't touch the accessible part of adapter/main unit and patient at the same time.
- Warning: Do not use the cuff on the arm where the side of a mastectomy or lymph node clearance.
- Warning: Note that it will lose function of other monitor devices simutaneously on the same limb while cuff inflating.
- Warning: Do not allow frequent measurements the resulting restriction of the blood flow may cause injury.

- Avoid compression or bending of the cuff connection tubing while using the device. Otherwise the measurement results will be inaccurate.
- Warning: Do not tangle the connection tubing, because the continuous cuff pressure can affect blood flow interference, resulting harmful injury to the patient.
- According to the local laws and regulations to deal with device and battery.
- The patient operator could not touch the battery and DC socket. Or the operator could not touch the patient and the battery and DC socket at the same time.
- Please follow the battery requirement of manufacturer.
- Please report serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State.
- Please disconnect the plug of adapter with mains when you need to safely terminate operation of ME EQUIPMENT.
- When it is dirty in single patient daily use, clean the monitor with soft dry cloth. If it is necessary, please use wiped soft cloth with water before cleaning by soft cloth. Then clean the device with 75% alcohol.
- Please turn off the device and unplug the adapter before cleaning.
- Do not let the alcohol flow into the monitor and arm cuff.
- Do not interconnect this equipment to other equipment not described in the instructions for use.
- Note: Do not diagnose with the measurement, please follow doctor's instruction.

Important notes

 Note: Software version can be viewed in engineering mode by designated person. This mode is not accessible for regular users, and please conect the manufacturer for method to enter into the mode.

Statement: If the monitor has not been used and stored in the required temperature, altitude and humidity range, it may not conformance to specification.

About bluetooth transmission

- To ensure that the measurement results can be transmitted through Bluetooth, please keep the distance between the device and the mobile phone no more than 10 meters.
- If you want your blood pressure measurements to be sent to your phone via Bluetooth, get a phone that supports Android 5.0 and above or IOS 9.0 and above to download Yuwell HealthCare+.
- Note: This section applies only to the model with bluetooth function.

Tips!

Please take attention that changes or modification not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

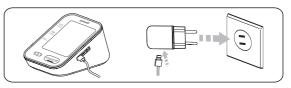
This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: ① This device may not cause harmful interference, and ② This device must accept any interference received, including interference that may cause undesired operation.

This product is powered by lithium battery. Please make sure the battery is sufficient when using the product.

- ▶ The " ☐ " icon appearing and showing 25% or less mean the battery is low and needs to be charged.
- ▶ The " : icon appearing and showing 5% or less mean the battery is running out. Please charge before using.

Power-on

 Connect the power source for charging as shown below.



- 2. The " " icon flashs during charging, and the " " icon stops flashing when the battery is fully charged.
- 3. Please unplug the power adapter after charging.

Note: Do not measure blood pressure when charging, so as not to cause abnormal measurement.

Note: Please charge the device in a position where it is easy to disconnect from supply mains.

Tips!

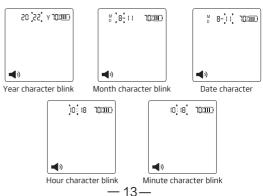
Please use only the authorized Yuwell AC Adapter (output DC 5V 1A) to charge, and you can contact the local dealer for consultation about the relevant information.

- On not place equipment with lithium batteries near the fire source.
- O Do not remove and replace the battery or squeeze the battery with hard objects.
- Please charge the device in time when the battery is low.
- In order to extend the service life of lithium battery, it is recommended to maintain more than half of the power.
- When the equipment is not used for a long time (more than 6 months), it is easy to cause the passivation of the electrode material and lead to the decline of the battery performance. It is recommended to make it frequently.
- Please dispose of waste batteries in accordance with local environmental protection regulations.
- Warning: Do not replace the battery without authorization. Replacement of the battery by untrained personnel may result in overtemperature, fire, or explosion.

Time and date setting

The monitor will store the measuring results automatically by the management system. It is necessary to reset time and date after charging and starting up again. Please operate as following steps. (For example: setting the date as 2022-08-11 and time as 10:18)

- 1. In standby mode, press the [START|STOP] button and the [] button for more than 3 seconds till the year's number starts flashing.
- 2. Press the () button to advance by increments of one year.
- 3. After setting the year, press the [START|STOP] button to switch to the month setting, indicating that the month's number starts flashing.
- 4. Using the same way to set the month, day, hour, and minute in turn.



Voice volume setting

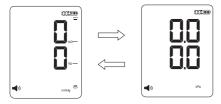
After finishing the time and date setting, press the [START|STOP] button to enter the voice volume setting. The size of the sound ranges from 01 to 04. Press the [] to choose the sound which you need.

Tips!

When the voice function key is in a state of shut, there is without voice broadcast function.

Unit setting

After finishing the voice volume setting, press the [START|STOP] button to enter the unit setting. Press the [START|STOP] button to choose unit between mmHg and kPa. Press [] to finish setting.



After finishing unit setting, press the [START|STOP] button to shut down.

Tips!

Either of the upper-arms can be measured. Do not measure other parts of the body.

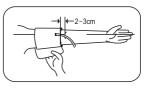
Cuff connecting

Connect the air connector of the cuff to the socket which on the left side of the monitor.



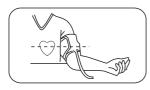
Using method of cuff

▶ Wind the cuff around the upper arm. (as shown in the picture) Keep the lower edge of the cuff at the position above 2-3cm to the elbow joint and keep the air inlet which insert to the cuff at the inner side of arm.



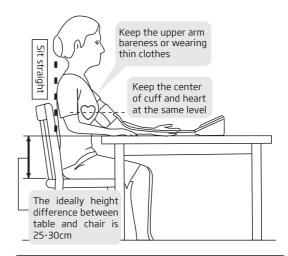
▶ Stick the cuff tightly.

Note: The cuff should be wearing comfortably, avoiding too tight or loose.



Sit straight and flat the arm on table with palm up, also keep the center of cuff and heart at the same level. Also please ensure the air tube not twisted.





Wrong measurement postures

- ▶ Do not bend down or body bend forward.
- ▶ Do not sit with legs crossed, feet should flat on the floor.
- ▶ Do not sit on a sofa. (Belly pressure may increase the blood pressure.)
- ▶ Do not put the arm on the low table. (May increase the blood pressure.)
- Do not lie down.

Don't eat, smoke, drink, take bath or do any highintensity sport within an hour before measuring. Measurements shall be taken at the same time every day.

Sit still for 5 minutes before the measurement

1. Measurement

All icons on screen appear for 1 sec after pressing the [START|STOP] button, then disappear. After hat the deflation icon " > " flashes which means the system is in zero testing. Several seconds later the inflation icon " > " flashes which means the zero testing is finished. Then inflation starts.



Full screen display state

The monitor starts measuring automatically after inflation finished, and the heart icon " \P " starts to flicker. The air escape valve automatically exhausts slowly, and the pressure value drops continuously.

Please relax as much as possible and not talk or move during the measurement procedure.

2. Measurement finished

After measurement, the monitor will show the SYS, DIA and pulse rate, then daflate the air automatically.



Three color backlight prompt function

1. Blue backlight prompt

When the SYS is lower than 140mmHg and the DIA is lower than 90mmHg, the LCD displays blue backlight.

2. Yellow backlight prompt

When the following measurement results appear, the LCD displays yellow backlight.

- ① The SYS is lower than 140mmHg, and the DIA is not only higher than 89mmHg but also lower than 110mmHg.
- ② The SYS is higher than 139mmHg and lower than 180mmHg, and the DIA is lower than 110mmHg.

3. Orange red backlight prompt

The SYS is higher than 179mmHg, or DIA is higher than 109mmHg, the LCD displays orange red backlight.

3. Take off the cuff

4. Shut down

Press the [START|STOP] button to shut down. Also it will power off automatically in 3 minutes without any operation.

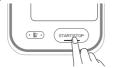
5. Power off

Unplug the adapter to safely disconnect it from mains.

Do not position the device to make it difficult for safely disconnection from supply mains.

Emergency stop during measurement

If the measurement need stopping for uncomfortableness or other reasons, please press the <code>[START|STOP]</code> button, the measurement will stop immediately and air releases fast. Take off the cuff manually if the <code>[START|STOP]</code> button is not working.



Warning: Upper limit pressure of air inflation is 300mmHg/40.0kPa. Don't keep the inflated state for a long time to avoid damage.

- ▶ If the SYS is higher than 139mmHg or DIA higher than 89mmHg means having high blood pressure, please contact with doctor for advice.
- ▶ If unexpected readings are obtained, please measure again or consult your doctor
- ▶ The blood pressure range indicator can show the blood pressure intuitively.



Tips!

- ▶ The time interval between two measurements should be at least 2~3 minutes or longer.
- ▶ Estimate the blood pressure condition according to the BP classification table, and consult the doctor.

Tips!

The monitor will store the measurement data automatically (including blood pressure and pulse), and the upper limit of records is 60. Press the [] button to check the measurement data.

1. Press the [] button for the records

A. Press the [🖹] button to show the average value of the latest 3 times measurement.

B. Repress the [] button to display the 1st group of memory, the serial number is displayed as "01" to "60". "01" is the latest group and the "60" is the earliest one.



The average value



The 1st group of memory

Tips!

The 60th data may be replaced by the 59th when the memory capacity is full.

- C. Read the recorded data by pressing the [] button as the sequence: "01", "02""60" (max). Then return to the 1st. Holding the [] button to search the data quickly.
- D. Press the [START|STOP] button to shut off the monitor.

2. Delete the recorded data

Press the both [START|STOP] button and [] button until the display shown as the following picture, which means the recorded data is cleared. Press the [START|STOP] button to turn off the monitor after deleting.



Note: This operation will delete all the recorded data.

Detection for cuff wearing

The icon " ()" appears when the cuff is wrapped correctly, and the icon " () " appears when the cuff is wrapped loosely or tightly.

Indication for Movement Error

The product can automatic detection of the body during the measurement of the wrong movement and give the icon " "" r prompt . If the icon " "" appears during the measurement, measure it again.

Indication for irregular heartbeats

the icon "" flashes if irregular pulse signal is detected during measurement, and it indicates that the measurement is abnormal and need to be remeasured. If the icon "" appears during multiple measurements, consult your doctor.

This function is mainly for professional personnel to enter the static mode to test the monitor through standard pressure gauge.

Warning: Normal users don't need to know this function and also do not operate. The company will not take any responsibility for damage caused by this operation.

System restores

The screen will show all of icons after pressing the [START|STOP] button. After that, the screen will show the "\$\overline{x}" icon which means the system is in restore testing. Several seconds later, the "\$\overline{x}" icon disappears and the air pump starts inflating at the same time, which indicates the test ended. Then press the [START|STOP] button to stop inflating and take out the batteries to enter the next step.

Note: It must restore the system before entering the static mode, otherwise it may cause inaccurate results.

Entering the static mode

Press the [] button and hold. At the same time, poke the reset hole and release it. When you hear a click, release the [] button. Then the screen will show the pressure value " ", the time and date, mmHg. Now the system has restored and entered the static mode. Now can take the static test.

Common question of blood pressure measurement

Note:When the measured pressure exceeds 300mmHg during static test, pressure value and "HI" are displayed, indicating the measurement result exceeds the rated range and may be inaccurate.



Tips!

- ▶ After entering the static mode, if the screen still doesn't show " ☐ ", please operate again as the system restore. Please contact with the local distributor if it still does not work.
- ▶ The monitor will automatically power off if there is no operation in 4 minutes.

Method of verifying calibration

- ▶ The verification system is determined by applying a adapter to the pressure line and attaching a reference standard.
- ► Enter into the static mode, read the device and the reference gauge simultaneously, the error of 3mmHg is normal by reducing the pressure from 300mmHg to zero at a rate of 3mmHg/s ± 1mmHg/s.
- If the error out of 3mmHg, please contact the manufacturer for calibration.

1. What is blood pressure?

Blood pressure is the force exerted by blood against the walls of the arteries. Systolic pressure occurs when the heart contracts. Diastolic pressure occurs when the heart expands. Blood pressure is measured in millimetres of mercury (mmHg). One's natural blood pressure is represented by the fundamental pressure, which is measured first thing in the morning while one is still at rest and before eating.

2. What is Hypertension and how is it controlled? Hypertension, an abnormally high arterial blood pressure, if left unattended can cause many health problems including stroke and heart attack. Hypertension can be controlled by altering lifestyle, avoiding stress, and with medication under a doctor's supervision. To prevent Hypertension or keep it under control: Do not smoke, exercise regularly, reduce salt and fat intake, have regular physical checkups, maintain proper weight.

3. Why measure Blood Pressure at home?

Blood pressure measured at a clinic or doctor's office may cause apprehension and can produce an elevated reading, 25~30mmHg higher than that measured at home. Home measurement reduces the effects of outside influences on blood pressure readings, supplements the doctor's readings and provides a more accurate, complete blood pressure history.

Common question of blood pressure measurement

4. WHO Blood Pressure Classification? Standards to assess high blood pressure, without regard to age, have been established by the world Health Organization (WHO), as shown below:

Range	Systolic pressure kPa/mmHg	Diastolic pressure kPa/mmHg	Counter measures
Ortho-arteriotony	12.0~18.5kPa 90~139mmHg	8.0~11.9kPa 60~89mmHg	Self check
Mild hypertension	18.7~21.2kPa 140~159mmHf	12.0~13.2kPa 90~99mmHg	Consult dr.
Medium hypertension	21.3~23.9kPa 160~179mmHg	13.3~14.5kPa 100~109mmHg	Consult dr.
Severe hypertension	≥24.0kPa ≥180mmHg	≽14.7kPa ≽110mmHg	Danger! Go to hospital as soon as possible

Note: There is no definition about hypopiesia, and generally SYS (systolic pressure) less than 90mmHg or DIA (diastolic pressure) less than 60mmHg is called hypotension.

Common question of blood pressure measurement

5. Blood pressure variations?

An individual's blood pressure varies greatly on a daily and seasonal basis. It may vary by 30 to 50 mmHg due to various conditions during the day. In hypertensive individuals variations are even more pronounced. Normally, the blood pressure rises while at work or play and falls to its lowest levels during sleep. So do not be overly concerned by the results of one measurement. Take measurements at the same time every day using the procedure described in this manual to get to know your normal blood pressure. Regular readings give a more comprehensive blood pressure history. Be sure to note date and time when recording your blood pressure. Consult doctor to interpret the blood pressure data.

6. When is the best time to measure blood pressure?

- ▶ After urination, before breakfast in the morning.
- ▶ Before sleeping at night.
- ▶ Before taking medicine.
- ▶ Please keep a stable body state and mind every time measuring. We suggest taking measurements at the same time every day.

-28-

Common fault and trouble shooting

Common fault	Solutions	
It doesn't work after pressing the [START STOP] button	Please try again after charging	
	Check the connection and winding of cuff	
Multiple occurrences of measuring failure, or measured value is low	Check if the cuff winded too tight or too loose. Take off your clothes if rolled too tight	
(or high)	Please ensure a quiet, relaxed body state. Deep breathing to relax yourself before measurement	
The monitor is in good condition, but the each measuring result are different	Please read the "blood pressure variations" carefully	
The value is different from that measured at a clinic or doctor's office	Write down the value every day, and consult a doctor	
Pump works, but the pressure doesn't rise	Check whether the cuff has connected well	

Common fault and trouble shooting

The table below shows the possible fault displaying icon, possible reason, and solutions.

. ,			
Wrong Fault cause		Solution	
	Unbale to measure pressure	Fasten cuff correctly before measurement	
Err4	The measurement results exceeds the measuring range of diastolic or systolic	Measure again please	
Err5	Pressurizing error	Check if there is air leakage from the cuff	
Err6	Pressurizing error caused by arm or body motion	Keep arm and body still and measure again	
Err7	Cuff is too lose or fall off	Fasten cuff tightly	
Err8	Pressure exceeds the maximum value (300mmHg)	Measure again please	
Showing the	Battery is low	Connect the power adapter for charging	
Showing the	Battery is running out	Connect the power adapter for charging	

Warning: If the situations cannot be solved or unexpected problem happens, please consult the local distributor.

consult the doctor.

When the determined blood pressure is outside the rated range, there is a visual alarm signal on the display screen. Please refer to below table for details.

Alarm indication	Display contents and causes	
SYS HI — 1	①When SYS display area shows " \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	
DIA sering P/rein 2	②When DIA display area shows " \(\mathbb{H} \) ", it indicates the measurement result of diastolic pressure exceeds 210mmHg.	
SYS LO - 1	①When SYS display area shows " L o ", it indicates the measurement result of systolic pressure is below 40mmHg.	
P/nin 2	②When DIA display area show " L n ", it indicates the measurement result of diastolic pressure is below 20mmHg.	
When the above alarm indication shows, please measure again or		

Note: If the alarm indication cannot be solved and the user feels uncomfortable, please consult the doctor as soon as possible.

Note: If the alarm indication cannot be solved or need to verify the functionality of the alarm system, please consult the manufacturer.

Please observe the following items to protect the device and ensure the accuracy of measurement.

- Please store the monitor and accessories properly after use.
- Do not place the monitor and accessories in high temperature, moisture, dust, or exposure to sunshine.
- The cuff contains an airbag inside, please care in applications, do not fold, pull or twist it.
- Warning: Do not disassemble or repair the device without authorization or modify the device without authorization.
- Do not service or maintain while the device is in use.
- Using soft dry cloth or soft cloth stained with little water to clean the device in the case of single people use it, but do not let the water flow into the monitor and cuff.
- Using soft cloth stained with 75% ethanol to clean the device in the case of many people use it, but do not let the ethanol flow into the monitor and cuff.
- Don't cleaning the device when it is connected to the AC mains supply.
- Manufacture will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service person to repair those parts of the device that are designated by the manufacture as repairable by service person.
- Degraded sensors can degrade performance.

Tips!

We advice to calibrate the monitor according to local laws and regulations (at least once a year).

Features and technical Parameters

Features and technical Parameters

1. Features

Detection for cuff wearing Indication for irregular heartbeats Indication for Movement Error 60 groups of memory

Average value display of three times measurement

2. Technical parameters

Displaying: LCD digital display

Operating principle: oscillation mensuration

Measuring range:

Diastolic: 20-210mmHg Cuff pressure: 0~300mmHg Systolic: 40-260mmHq Pulse rate: 40~200 beats/min

Precision:

Pressure: within ± 3 mmHq (± 0.4 kPa) Pulse rate: within 5% of reading value Working system: continuous operation

IP Classification: IP20

- against ingress of solid foreign objects: ≥12.5mm diamater

Flectric classification:

Class II, type BF applied part (cuff is applied part)

Service life:

5 years (6 times for each day) for the monitor

5000 times for cuff

Power supply battery: DC 3.7V

AC adapter: input 100-240V~ 50/60Hz 0.35A MAX

output 5V === 1000mA

Maximum battery life: the battery can be used about

250 times on a full charge

Suitable upper-arm circumference: 22-32cm or

22-45cm (optional)

Dimension: Approx.127x92x68 (mm)

Weight: about 306g

3. Operation and storage conditions Operation conditions:

a temperature range of $+5^{\circ}$ C to $+40^{\circ}$ C; a relative humidity range of 15% to 90%, non-condensing; and an atmospheric pressure range of 70kPa to 106kPa.

Transportation and storage conditions:

 -25° C to $+5^{\circ}$ C, and

 $+5\%^{\circ}$ C to $+35^{\circ}$ C at a relative humidity up to 90%, non-condensina:

> 35°C to 70°C at a water vapour pressure up to 5kPa.

Operation environment:

Avoid electromagnetic interference, violent shock and noise environment.

Recovery time:

1. When the ambient temperature is 20°C, the time required for the device to warm from the minimum storage temperature (-20°C) until the device is ready for use is 2 hours.

2.When the ambient temperature is 20°C, the time required for the device to cool from the maximum storage temperature (55°C) until the device is ready for use is 2 hours.

Features and technical Parameters

The contact materials detail of product

Part	Rear Cover	Top Cover	Cuff	Air tube	Air plug connect
Material	ABS	PC	Nylon polyester PVC	PVC	ABS

The SPHYGMOMANOMETER was clinically investigated according to the requirement of ISO 81060-2.

The SPHYGMOMANOMETER complies with IEC 80601-2-30.

Electromagnetic compatibility information

Essential performance:

1. Limits of the error of the manometer:

Over the temperature range of 5° C to 40° C and the relative humidity range of 15° % to 90° % (noncondensing), the maximum error for the measurement of the CUFF pressure at any point of the NOMINAL measurement range shall be less than or equal to ± 3 mmHg (± 0.4 kPa) of the reading.

2. Reproducibility of the BLOOD PRESSURE DETERMINATION:

The laboratory reproducibility of the BLOOD PRESSURE DETERMINATION of the AUTOMATED SPHYGMOMANOMETER shall be less than or equal to 3.0mmHg (0.4 kPa).

A Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the SPHYGMOMANOMETER, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ This equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

⚠ When the instrument is in use, never put it near other instruments or stack it on other instrument. if you have to put it near other instruments or instruments, please inspect and verify if the instrument could run normally.

Electromagnetic compatibility information

⚠ WARNING: The Operator should not use the system and should inform the customer service, if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES.

⚠ WARNING: Use of accessories 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.

List of cables and accessories is as follows:

Cable Name	Cable Length	Cable Shielded	Comments
DC power supply cord	≤1.2m	Unshielded	None

There is the potentia risk of radio frequency interference between the device and other devices. If there is, please find out the problems and take the following measures:

- (1) Turn off the device, and turn on again.
- (2) Change the direction of the device.
- (3) Keep the product away from the interferential devices.

Table 1 For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture's declaration-electromagnetic emission		
The YE650ARS Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of YE650ARS Electronic Blood Pressure Monitor should assure that it is used in such an environment.		
Emission test Compliance		
RF emissions CISPR 11	Group1	
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IFC 61000-3-3	Complies	

Electromagnetic compatibility information

Table 2 For all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacture's declaration-electromagnetic emission

The YE650ARS Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the YE650ARS Electronic Blood Pressure Monitor should assure that it is used in such an environment.

Immunity test IEC 60601 test level		Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air
Electrical fasttransient /burst IEC 61000-4-4	± 2 kV 100kHz repetition frequency	± 2 kV 100kHz repetition frequency
Surge IEC 61000-4-5	± 1 kV line(s)to line(s) ± 2 kV line(s)to earth	± 1 kV line(s)to line(s)
Voltage dips	0% U ₁ ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0% U _T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225° 270° and 315°
IEC 61000-4-11	0% U _T ; 1 cycle and 70% U _T ; 25/30 cycles Single phase: at 0°	0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0°
Voltage interruptions IEC 61000-4-11	0% Uτ; 250/300 cycles	0% Uτ; 250/300 cycles
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m 50Hz or 60Hz	30A/m 50Hz or 60Hz
Proximity magnetic fields IEC 61000-4-39	8A/m, CW for 30kHz 65A/m, 2,1kHz Pulse modulation for 134,2kHz 7,5A/m, 50kHz Pulse modulation for 13,56MHz	8A/m, CW for 30kHz. 65A/m, 2,1kHz Pulse modulation for 134,2kHz. 7,5A/m, 50kHz Pulse modulation for 13,56MHz

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

Table 3 For ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration-electromagnetic immunity

The YE650ARS Electronic Blood Pressure Monitor is intended for use in the electromagnetic environments pecified below. The customer or the user of the YE650ARS Electronic Blood Pressure Monitor should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 Vrms 0,15 MHz-80 MHZ 6 V rms in ISM and amateur radio bands between 0,15 MHz and 80 MHZ 80 % Am at 1 kHz	3 Vrms 0,15 MHz-80 MHZ 6 V rms in ISM and amateur radio bands between 0,15 MHz and 80 MHZ 80 % Am at 1 kHz
Radiated RF IEC 61000-4-3	10 V/m 80 MHZ to 2.7 GHz	10 V/m 80 MHZ to 2.7 GHz

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE2 These quidelines may not apply in all situations.

Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 4 Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation	IMMUNITY TEST LEVEL (V/m)
385	380 to 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM ±5 kHz deviation 1 kHz sine	28
710			Pulse	
745	704 to 787	LTE Band 13, 17	modulation ^{b)}	9
780			217 Hz	
810		GSM 800/900. TETRA 800.	Pulse	
870	800 to 960	iDEN 820, CDMA 850,	modulation ^{b)}	28
930		LTE Band 5	18 Hz	
1720			Pulse	
1845	1700 to 1990	GSM 1800; TETRA 1900; GSM 1900; DECT; LTE Band	modulation ^{b)}	28
1970		1, 3, 4, 25; UMTS	217 Hz	
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^ы 217 Hz	28
5240			Pulse	
5500	5100 to 5800	WLAN 802.11 a/n	modulation ^{b)} 217 Hz	9
5785			21,112	

If necesary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1m test distance is permitted by IEC61000-4-3.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the YE650ARS is used exceeds the applicable RF compliance level above, the YE650ARS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the YE650ARS.

 $^{^{\}rm b}$ Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50% duty cycle square wave signal.

c) As an alternative to FM modulation, the carrier may be pulse modulated using a 50 % duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.

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.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment .This equipment should be installed and operated with minimum distance 20cm between the radiator& your body.