

注：此中虚线仅作工艺示意，无实际生产意义。

技术要求：

材质：80g双胶纸

尺寸：180x142.5mm

骑马订

第6页中标识“”图标中蓝色部分保持蓝色印刷：C90%，M60%，Y10%，K0

|    |    |       |    |   |                     |   |    |       |     |
|----|----|-------|----|---|---------------------|---|----|-------|-----|
|    |    |       |    |   | YE660F<br>英文说明书(CE) | YY-BPM0002C-01  |    |       |     |
|    |    |       |    |   |                     | 图样标记  | 数量 | 重量    | 比例  |
| 标记 | 处数 | 更改文件号 | 签字 | 日期  |                     | B   |    |       | 1:1 |
| 设计 |    |       | 视角 |  | 80g双胶纸              | 共 1 张   |    | 第 1 张 |     |
| 制图 |    |       | 工艺 |   |                     | <br><small>让科技律动生命</small><br>江苏鱼跃医疗设备股份有限公司 |    |       |     |
| 审核 |    |       | 版本 | A/0   |                     |   |    |       |     |
| 批准 |    |       | 日期 |   |                     |   |    |       |     |

# yuwell




## YE660F

### Electronic Blood Pressure Monitor

## User's Manual

Please read the user's manual closely before using!

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Date of issue: 2024.05

YY-BPM0002C-01(A/O) 

## Contents

### Before using

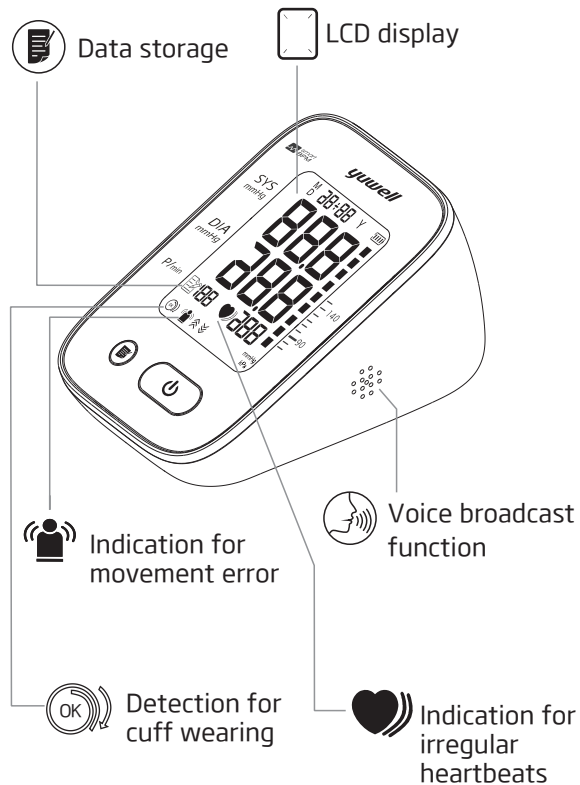
|                                    |    |
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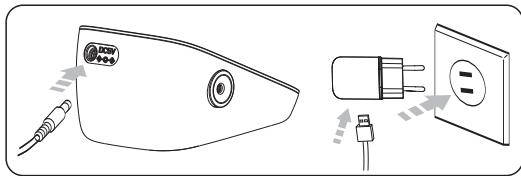


This device uses the oscillometric method of blood pressure measurement.

Please follow the steps as shown below.

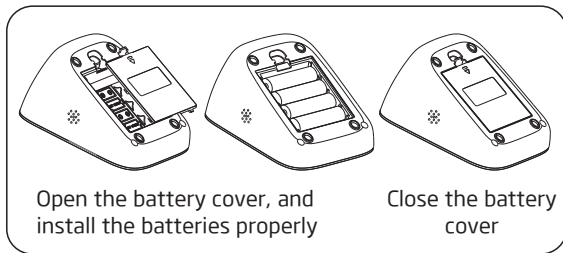
### Power-on

Connect the power source 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.

Or install four AA batteries



Open the battery cover, and install the batteries properly

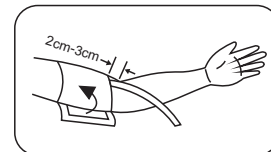
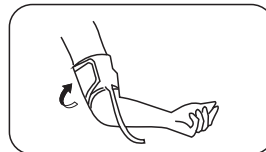
Close the battery cover

(Please turn to page 11 for details)

### Measurement

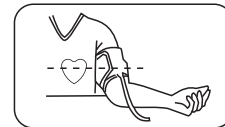
#### 1. Using method of cuff

Wearing the cuff and make the lower edge 2cm~3cm above the elbow, keep the air tube inside of the arm. (Please turn to page 14 for details.)




#### 2. Measuring posture


Sit straightly, keep the center of cuff and heart at the same level. (Please turn to page 15 for details.)



#### 3. Start measuring

Sit still for 5 minutes and then press the "  " button to measure. (Please turn to page 16 for details.)

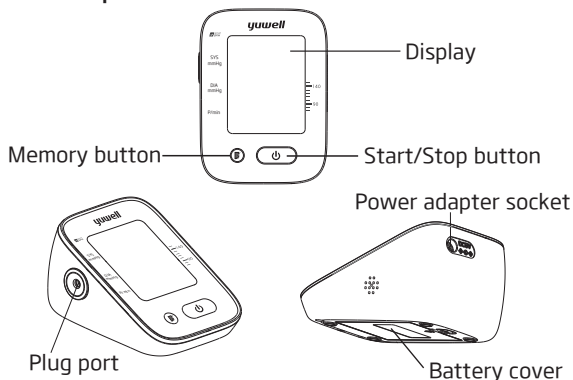
### Check the records

Press the "  " button to check the measuring records.

This monitor can display the average of three measurements and store 90 records. (Please turn to page 20 for details.)

## Product structure and parts

### 1. Main part



### 2. Cuff

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



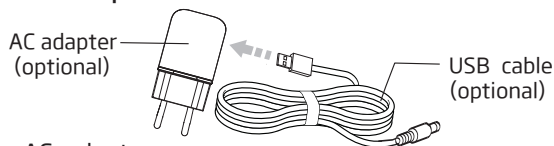
| Model                          | YE-61MC                | YE-61LC     | YE-62MC                | YE-62LC     | YE-63MC           | YE-63LC     |
|--------------------------------|------------------------|-------------|------------------------|-------------|-------------------|-------------|
| Characteristic                 | Without hard support   |             |                        |             | With hard support |             |
|                                | Fabric: 210T polyester |             | Fabric: 250D polyester |             |                   |             |
| The range of arm circumference | 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.

## Product structure and parts

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

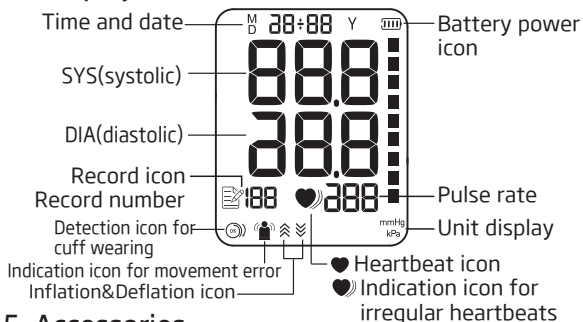
### 3. AC adapter and USB cable



AC adapter:

INPUT: 100-240V~ 50/60Hz 0.35A MAX  
 OUTPUT: 5V===1000mA  
 MFR: WEIHAI HITAI ELECTRONICS Co.,LTD.  
 EU Model: HT-C38B-0510EW  
 US Model: HT-C38B-0510WW  
 UK Model: HT-C38B-0510UW




















### 4. Display



### 5. Accessories

User's manual, Warranty card, 4 AA batteries, AC adapter(optional), USB cable(optional)

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

|  |  |   |  |
|--|--|---|--|
|  | Caution  |   |  |
|  | Type BF applied part   |   |  |
|  | Follow instructions for use  |   |  |
|  | Manufacturer   |   |  |
|  | Date of manufacture  |   |  |
|  | EC-Representative  |   |  |
|  | Recover waste electrical and electronic equipment  |   |  |
|  |   | Fragile   |  Keep Dry |
| <b>IP20</b>  | IP Classification  |   |  |
|  | CE marking and notify body number  |   |  |
|  | Class II Device  |   |  |
|  | Indicates a carrier that contains unique device identifier information   |   |  |
|  | DC   | Direct current  |  |
|  | Alternating current  |   |  |
|  | Serial Number  |  | Batch code   |
|  | Indicates the item is a medical device   |   |  |
|  | 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.

## Important notes

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- 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 reinstall the batteries and start again if cannot measure.
- For patient of arrhythmia, arterial sclerosis, poor perfusion, diabetes, pregnancy, 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.

## Important notes

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- 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 simultaneously 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.
- Please use the alkaline battery, do not use the rechargeable battery.
- 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.
- The different type battery might result in measurement error.
- 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.

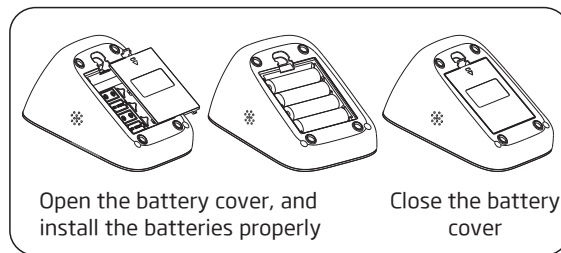
## Important notes



- 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 using soft dry cloth stained with 75% alcohol to clean the device in the case of many people use it, but do not let the alcohol flow into the monitor and arm cuff.
- 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.
- **Note:** Software version can be viewed in engineering mode by designated person. This mode is not accessible for regular users, and please contact 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.

## Battery installation

Open the battery cover and install four AA batteries properly. Then close the cover with a click sound.



1. The "  " icon means the battery is low.
2. The "  " icon means the battery is running out. Please replace all the batteries.
3. Please take out the batteries if the monitor will not be used for a long time (over three months).

⚠ Note: 5V/1000mA DC external power can be connected to the monitor. (Please use the power adapter supplied by us.)

⚠ Note: Please take out the batteries if use the DC external power for a long time.

### Tips!

Please use only the authorized Yuwell AC adapter (output DC 5V 1000mA). If you need to use a AC adapter, you can contact the local dealer for consultation about the relevant information.



## Time and date setting

### Time and date setting

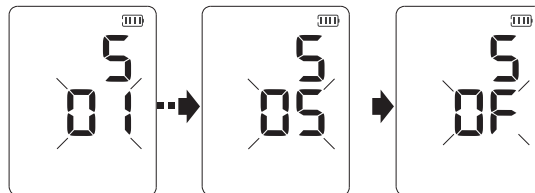
The monitor will store the measuring results automatically by the management system. It is necessary to reset time and date after installing new batteries or connecting to DC power. Please operate as following steps.

1. Year setting: Press the "🗓️" button and the "⏻" button for more than 3 seconds till the number starts flashing.
2. The year increase once press the "🗓️" button.
3. Press the "⏻" button to switch to the month setting.
4. Using the same way for other settings.

## Voice volume and unit setting

### Voice volume setting

After finishing the time and date setting, press the "⏻" button to enter the voice volume setting. The size of the sound ranges from 01 to 05 and OFF. Press the "🗓️" to choose sound which you need. Finish by pressing the "⏻" button.



Attention:  
In the condition of kPa unit, there is no voice prompt for measurement result.

### Unit setting

After finishing the voice volume setting, press the "⏻" button to enter the unit setting. Press the "🗓️" button to choose unit between mmHg and kPa. Press "⏻" button to finish setting.

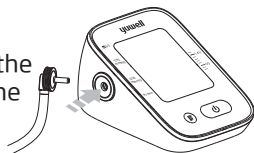
After finishing unit setting, press the "⏻" button to shut down.

## Using method of cuff

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

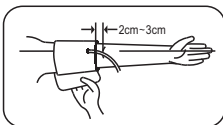
### Cuff connecting

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 2cm-3cm to the elbow joint and keep the air inlet which insert to the cuff at the inner side of arm.

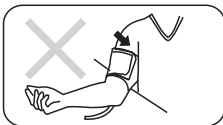


▶ Stick the cuff tightly.

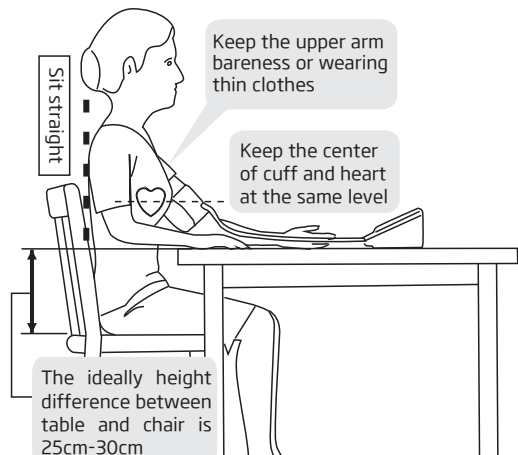
⚠ Note: The cuff should be wearing comfortably, avoiding too tight or loose.



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

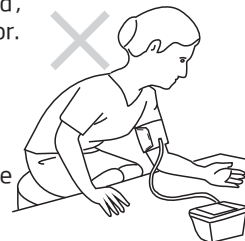


## Measuring posture



### 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.



## Start measuring

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

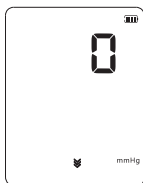
Sit still for 5 minutes before the measurement

### 1. Measurement

All icons on screen appear for 1 sec after pressing the "⏻" button, then disappear. After that the deflation icon "⏏" flickers 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 zeroing state

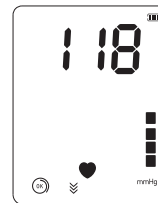


The inflation state

The monitor starts measuring automatically after inflation finished, and the measuring icon "♥" starts to flicker, pressure release value starts to decrease gradually.

## Start measuring

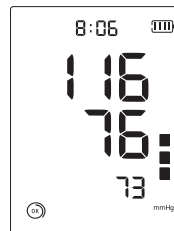
Please relax as much as possible and not talk or move during the measurement procedure.



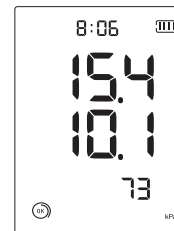
The measuring state

### 2. Measurement finished

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



mmHg display



kPa display

## Start measuring

3. Take off the cuff

4. Shut down

Press the "⏻" button to shut down. Also it will power off automatically in 3 minutes without any operation.

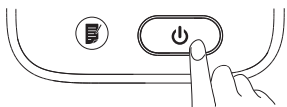
5. Power off

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

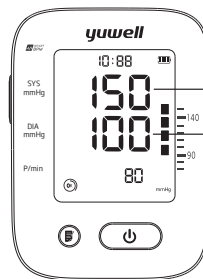
If the measurement need stopping for uncomfortableness or other reasons, please press the "⏻" button, the measurement will stop immediately and air releases fast. Take off the cuff manually if the "⏻" button is not working.



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

## Blood pressure range indicator

- ▶ 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.



Higher than 139mmHg

Higher than 89mmHg

### Tips!

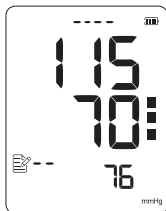
- ▶ The time interval between two measurements should be at least 2 minutes~3 minutes or longer.
- ▶ Estimate the blood pressure condition according to the BP classification table, and consult the doctor.

## Memory function

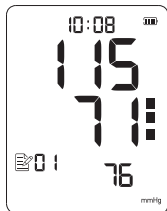
### Tips!

The monitor will store the measurement data automatically (including blood pressure and pulse), and the upper limit of records is 90. Press the " " button to check the records.

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 "1" to "90". "1" is the latest group and the "90" is the earliest one.



The average value



The 1st group of memory

### Tips!

The 90th data may be replaced by the 89th when the memory capacity is full.

## Memory function

- C. Read the recorded data by pressing the " " button as the sequence: "1", "2" ..... "90" (max). Then return to the 1st. Holding the " " button to search the data quickly.
- D. Press the " " button to shut off the monitor.

2. Delete the recorded data  
Press the both " " button and " " button until the display shown as the picture, which means the recorded data is cleared.  
Press the " " button to turn off the monitor after deleting.



⚠ Note: This operation will delete all of the recorded data.

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

Press the "⏻" button after battery installation, then the screen will show the "⚠" icon, which means the system is in zero testing. Several seconds later, the "⚠" icon disappears and the air pump starts inflating at the same time, which indicates the test ended. Then press the "⏻" 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

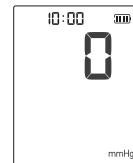
Press the "⏻" button and hold, meanwhile install the batteries. Hold on for about 3 seconds then release the "⏻" button. Then screen will show the pressure value "0". Now the system has restored and entered the static mode. Now can take the static test.

⚠ 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 "0", please operate again as the System restore. Please contact with the local distributor if it still does not work.



The static mode

▶ 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 "Y" 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.

## Common question of blood pressure measurement

### 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, 25~30 mmHg 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<br>kPa/mmHg | Diastolic pressure<br>kPa/mmHg | Counter<br>measures                                 |
|---------------------|-------------------------------|--------------------------------|---|
| Ortho-arteriotony   | 12.0~18.5kPa<br>90~139mmHg    | 8.0~11.9kPa<br>60~89mmHg       | Self check  |
| Mild hypertension   | 18.7~21.2kPa<br>140~159mmHg   | 12.0~13.2kPa<br>90~99mmHg      | Consult dr.   |
| Medium hypertension | 21.3~23.9kPa<br>160~179mmHg   | 13.3~14.5kPa<br>100~109mmHg    | Consult dr.   |
| Severe hypertension | ≥24.0kPa<br>≥180mmHg          | ≥14.7kPa<br>≥110mmHg           | Danger! Go<br>to hospital<br>as soon as<br>possible |

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

## Common fault and trouble shooting

| Common fault  | Solutions   |
|---|---|
| It doesn't work after pressing the "⏻" button with batteries installation     | Check the batteries are installed correctly<br>Replace new batteries  |
| Multiple occurrences of measuring failure, or measured value is low (or high) | Check the connection and winding of cuff<br>Check if the cuff wound too tight or too loose. Take off your clothes if rolled too tight<br>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   |

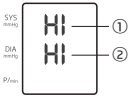
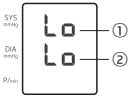
The table below shows the possible fault displaying icon, possible reason, and solutions.


| Wrong indication  | Fault cause                                     | Solution                                    |
|---|---|---|
| Err 4   | Unable to measure pressure                      | Fasten cuff correctly before measurement    |
| Err 5   | Pressurizing error                              | Check if there is air leakage from the cuff |
| Err 6   | Pressurizing error caused by arm or body motion | Keep arm and body still and measure again   |
| Err 7   | Cuff is too loose or fall off                   | Fasten cuff tightly                         |
| Err 8   | Pressure exceeds the maximum value (300mmHg)    | Measure again please                        |
|  | Battery is low                                  | Replace new batteries                       |
|  | Battery is running out                          | Replace new batteries                       |


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



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  |
|---|--|
|           | <p>① When SYS display area shows " HI ", it indicates the measurement result of systolic pressure exceeds 260mmHg.</p> <p>② When DIA display area shows " HI ", it indicates the measurement result of diastolic pressure exceeds 210mmHg.</p> |
|           | <p>① When SYS display area shows " Lo ", it indicates the measurement result of diastolic pressure is below 40mmHg.</p> <p>② When DIA display area show " Lo ", it indicates the measurement result of diastolic pressure is below 20mmHg.</p> |
| <p>When the above alarm indication shows, please measure again or consult the doctor.</p> |  |

 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 clean 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 arameters

### 1. Features

Voice function

90 groups of memory

### 2. Technical parameters

Displaying: LCD digital display

Operating principle: Oscillometric method

#### Measuring range

Diastolic: 20mmHg-210mmHg

Systolic: 40mmHg-260mmHg

Cuff pressure: 0mmHg~300mmHg

Pulse rate: 40beats/min~200beats/min

#### Precision:

Pressure: within  $\pm 3\text{mmHg} (\pm 0.4\text{kPa})$

Pulse rate: within 5% of reading value

Working system: continuous operation

IP Classification: IP20

└ Non-protected  
└ against ingress of solid foreign objects:  
   $\geq 12.5\text{mm}$  diamater

Electric classification: Class II and internally powered, type BF applied parts (cuff is applied part)

#### Service life:

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

5000 times for cuff

#### Power supply

battery: 4 AA batteries

AC adapter: input 100-240V~ 50/60Hz 0.35A MAX  
output 5V---1000mA

Battery life: the battery can be used about 300 times

Suitable upper-arm circumference: 22cm-45cm

Dimension: Approx.125x98x72 (mm)

Weight: 300g (Without batteries)

## Features and technical arameters

### 3. Operation and storage conditions:

#### Operation conditions:

a temperature range of  $+5^{\circ}\text{C}$  to  $+40^{\circ}\text{C}$  ;

a relative humidity range of 15% to 90%, non-condensing;  
and an atmospheric pressure range of 70kPa to 106kPa.

#### Transportation and storage conditions:

$-25^{\circ}\text{C}$  to  $+5^{\circ}\text{C}$ , and

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

$> 35^{\circ}\text{C}$  to  $70^{\circ}\text{C}$  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  $20^{\circ}\text{C}$ , the time required for the device to warm from the minimum storage temperature ( $-20^{\circ}\text{C}$ ) until the device is ready for use is 2 hours.2.When the ambient temperature is  $20^{\circ}\text{C}$ , the time required for the device to cool from the maximum storage temperature ( $55^{\circ}\text{C}$ ) until the device is ready for use is 2 hours.

### The contact materials detail of product

| Part     | Rear Cover | Top Cover | Cuff                      | Air tube | Air plug connect |
|----------|------------|-----------|---------------------------|----------|------------------|
| Material | ABS        | PC        | Nylon<br>polyester<br>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% (non-condensing), 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  $\pm 3\text{mmHg}$  ( $\pm 0.4\text{kPa}$ ) 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).

⚠ 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 | $\leq 1.2\text{m}$ | Unshielded     | None     |

There is the potential 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 YE660F Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of YE660F Electronic Blood Pressure Monitor should assure that it is used in such an environment. |            |
| Emission 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  | Complies   |

## Electromagnetic compatibility information

Table 2 For all ME EQUIPMENT and ME SYSTEMS

| Guidance and manufacture' s declaration-electromagnetic emission  |  |  |
|---|--|--|
| The YE660F Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the YE660F 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)<br>IEC 61000-4-2  | ± 8 kV contact<br>± 15 kV air  | ± 8 kV contact<br>± 15 kV air  |
| Electrical fasttransient /burst IEC 61000-4-4   | ± 2 kV<br>100kHz repetition frequency  | ± 2 kV<br>100kHz repetition frequency  |
| Surge IEC 61000-4-5   | ± 1 kV line(s)to line(s)<br>± 2 kV line(s)to earth   | ± 1 kV line(s)to line(s)   |
| Voltage dips<br>IEC 61000-4-11  | 0% U <sub>i</sub> ; 0.5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° <sup>a</sup>                   | 0% U <sub>i</sub> ; 0.5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° <sup>a</sup>                     |
|   | 0% U <sub>i</sub> ; 1 cycle and 70% U <sub>i</sub> ; 25/30 cycles<br>Single phase; at 0°                         | 0% U <sub>i</sub> ; 1 cycle and 70% U <sub>i</sub> ; 25/30 cycles<br>Single phase; at 0°                           |
| Voltage interruptions<br>IEC 61000-4-11   | 0% U <sub>i</sub> ; 250/300 cycles   | 0% U <sub>i</sub> ; 250/300 cycles   |
| Power frequency (50/60 Hz) magnetic field<br>IEC 61000-4-8  | 30A/m<br>50Hz or 60Hz  | 30A/m<br>50Hz or 60Hz  |
| Proximity magnetic fields<br>IEC 61000-4-39   | 8A/m, CW for 30kHz<br>65A/m, 2.1kHz Pulse modulation for 134,2kHz<br>7,5A/m, 50kHz Pulse modulation for 13,56MHz | 8A/m, CW for 30kHz.<br>65A/m, 2.1kHz Pulse modulation for 134,2kHz.<br>7,5A/m, 50kHz Pulse modulation for 13,56MHz |
| NOTE: U <sub>i</sub> is the a.c. mains voltage prior to application of the test level.  |  |  |

## Electromagnetic compatibility information

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

| Guidance and manufacture' s declaration-electromagnetic immunity   |   |   |
|--|---|---|
| The YE660F Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the YE660F Electronic Blood Pressure Monitor should assure that it is used in such an environment.  |   |   |
| Immunity test  | IEC 60601 test level  | Compliance level  |
| Conducted RF<br>IEC 61000-4-6  | 3 Vrms<br>0,15 MHz-80 MHz<br>6 V rms in ISM and amateur radio bands between 0,15 MHz and 80 MHz<br>80 % Am at 1 kHz | 3 Vrms<br>0,15 MHz-80 MHz<br>6 V rms in ISM and amateur radio bands between 0,15 MHz and 80 MHz<br>80 % Am at 1 kHz |
| Radiated RF<br>IEC 61000-4-3   | 10 V/m<br>80 MHz to 2.7 GHz   | 10 V/m<br>80 MHz to 2.7 GHz   |
| NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.<br>NOTE2 These guidelines may not apply in all situations.<br>Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.   |   |   |
| <sup>a</sup> 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 YE660F is used exceeds the applicable RF compliance level above, the YE660F should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the YE660F. |   |   |
| <sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.  |   |   |

# Electromagnetic compatibility information

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

| Test frequency (MHz)  | Band <sup>a)</sup> (MHz) | Service <sup>a)</sup>  | Modulation                               | IMMUNITY TEST LEVEL (V/m) |
|---|--------------------------|--|--|---------------------------|
| 385   | 380 to 390               | TETRA 400  | Pulse modulation <sup>b)</sup><br>18 Hz  | 27                        |
| 450   | 430 to 470               | GMRS 460, FRS 460  | FM<br>±5 kHz deviation<br>1 kHz sine     | 28                        |
| 710   | 704 to 787               | LTE Band 13, 17  | Pulse modulation <sup>b)</sup><br>217 Hz | 9                         |
| 745   |                          |  |  |                           |
| 780   |                          |  |  |                           |
| 810   | 800 to 960               | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5           | Pulse modulation <sup>b)</sup><br>18 Hz  | 28                        |
| 870   |                          |  |  |                           |
| 930   |                          |  |  |                           |
| 1720  | 1700 to 1990             | GSM 1800; TETRA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS | Pulse modulation <sup>b)</sup><br>217 Hz | 28                        |
| 1845  |                          |  |  |                           |
| 1970  |                          |  |  |                           |
| 2450  | 2400 to 2570             | Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7             | Pulse modulation <sup>b)</sup><br>217 Hz | 28                        |
| 5240  | 5100 to 5800             | WLAN 802.11 a/n  | Pulse modulation <sup>b)</sup><br>217 Hz | 9                         |
| 5500  |                          |  |  |                           |
| 5785  |                          |  |  |                           |
| If necessary 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 1 m test distance is permitted by IEC61000-4-3.   |                          |  |  |                           |
| <p>a) For some services, only the uplink frequencies are included.<br/> b) The carrier shall be modulated using a 50% duty cycle square wave signal.<br/> 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.</p> |                          |  |  |                           |