

Part no.	311-0099100-050
Product name	機器說明書/NO LOGO/英文/.標準品/
Spec	L297*W210mm/模造紙 80P/黑/共 36 頁/騎馬釘
Writer	Beryl
Color	■ K: 100

FORA

TD-3500A

**Automatic Blood Pressure Monitor
Operation Instruction**

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Dear 3500A Owner

Thank you for purchasing the **TD-3500A** Automatic Blood Pressure Monitor. This manual provides important information to help you to use this monitor correctly. Before using this product, please read the following contents thoroughly and carefully.

This **TD-3500A** Automatic Blood Pressure Monitor can reduce risks of operator errors and allow one hand operation through simple steps. If you have other questions regarding this product, please contact the place of purchase.

Intended Use

The **TD-3500A** Automatic Blood Pressure Monitor is a system designed to measure human systolic, diastolic blood pressure and heart rate in adult patient population. It is intended for use in clinical settings by clinicians or by one with a good understanding of the operation instruction, where the patient may be the operator. The device is not to be used for the diagnosis or screening of hypertension or for testing on newborns.

This **TD-3500A** Automatic Blood Pressure Monitor provides the speaking models and customized printed results for user's selection.

Test Principle

Blood pressure is measured non-invasively at the arm based on oscillometric method. This device is **NOT** able to take measurements in the presence of common arrhythmia, such as atrial or ventricular premature beats or atrial fibrillation. It may produce reading error.

Important Safety Precautions

READ BEFORE USE

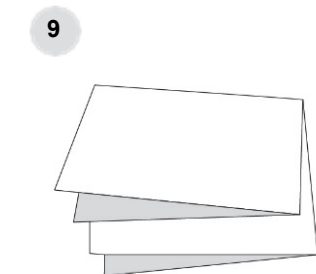
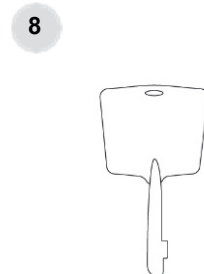
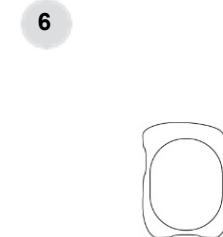
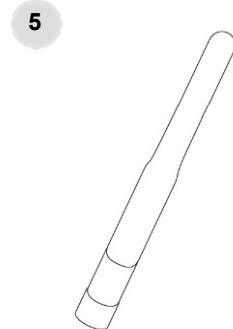
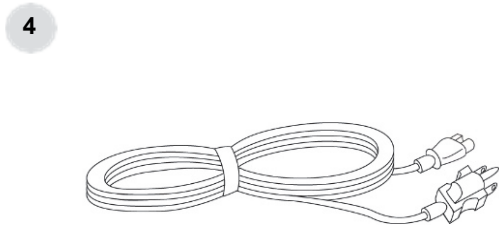
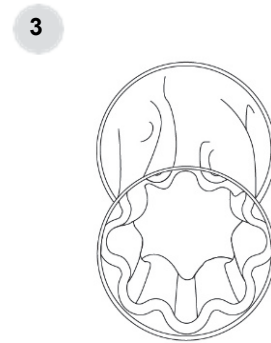
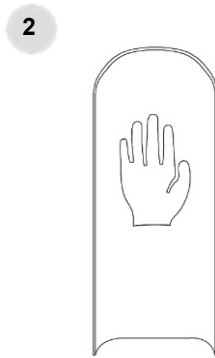
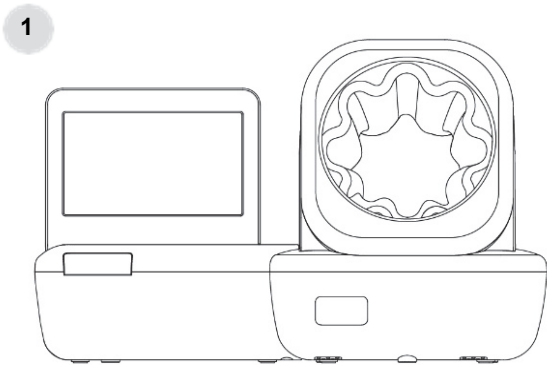
1. Use this device **ONLY** for the intended use described in this manual.
2. Do **NOT** use accessories which are not specified by the manufacturer. Other cables and accessories may negatively affect EMC performance.
3. Do **NOT** use the device if it is not working properly or damaged.
4. Do **NOT** use under any circumstances on newborns or infants.
5. This device does **NOT** serve as a cure for any symptoms or diseases. The data measured are for reference only. Always consult your doctor to have the results interpreted.
6. Do **NOT** try to maintain the device while it is in use.
7. Do **NOT** try to modify the device to prevent any dangers.
8. Do **NOT** place the device in liquid, nor put it where it could fall into liquid. If the device becomes wet, unplug the device before touching it.
9. Do **NOT** apply the cuff to areas other than the place directed.
10. Do **NOT** use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the accurate operation.
11. Do **NOT** connect the device with multiple socket-outlet or extension cord. Connecting multiple appliances on the same outlet may cause fire due to exceed rating.
12. Do **NOT** obstruct the mains power switch or position the equipment where the connection to the mains line can be accidentally disconnected.
13. Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging static discharges that may cause erroneous results.
14. For the reason of maintain basic safety and essential performance in regards to EMC, please always contact the manufacturer or the manufacturer's representative to report unexpected operation or event. Do **NOT** try to fix it by yourself.
15. Keep the equipment and its flexible cord away from hot surfaces.
16. Proper maintenance is essential to the longevity of your device. If you are concerned about your accuracy of measurement, please contact local customer service for help.
17. Used in close proximity or stacking to others, EMC must be tested and verified.
18. If abnormal behavior is observed due to EM disturbances, please relocate the device accordingly.
19. Medical electrical equipment needs special precautions regarding EMC and needs to be installed according to the EMC information provided.
20. That portable RF communications equipment can effect medical electrical equipment. We recommend a safety distance no closer than 22 cm (9 inches) to any part of an implantable medical device, including cables specified by the manufacturer.
21. This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

KEEP THESE INSTRUCTIONS IN A SAFE PLACE

Components of the Product

Component

1. Main unit
2. Armrest
3. Cuff cover (attach to the monitor)
4. Power cord
5. WiFi antenna
6. SD memory card (attach to the monitor)
7. Printer paper (one roll)
8. Printer key
9. Operation instruction



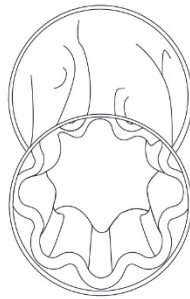
Options (sold separately)

1. Instruction panel
2. Cuff cover
3. Printer paper

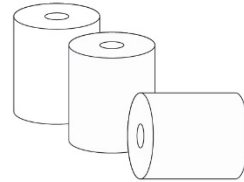
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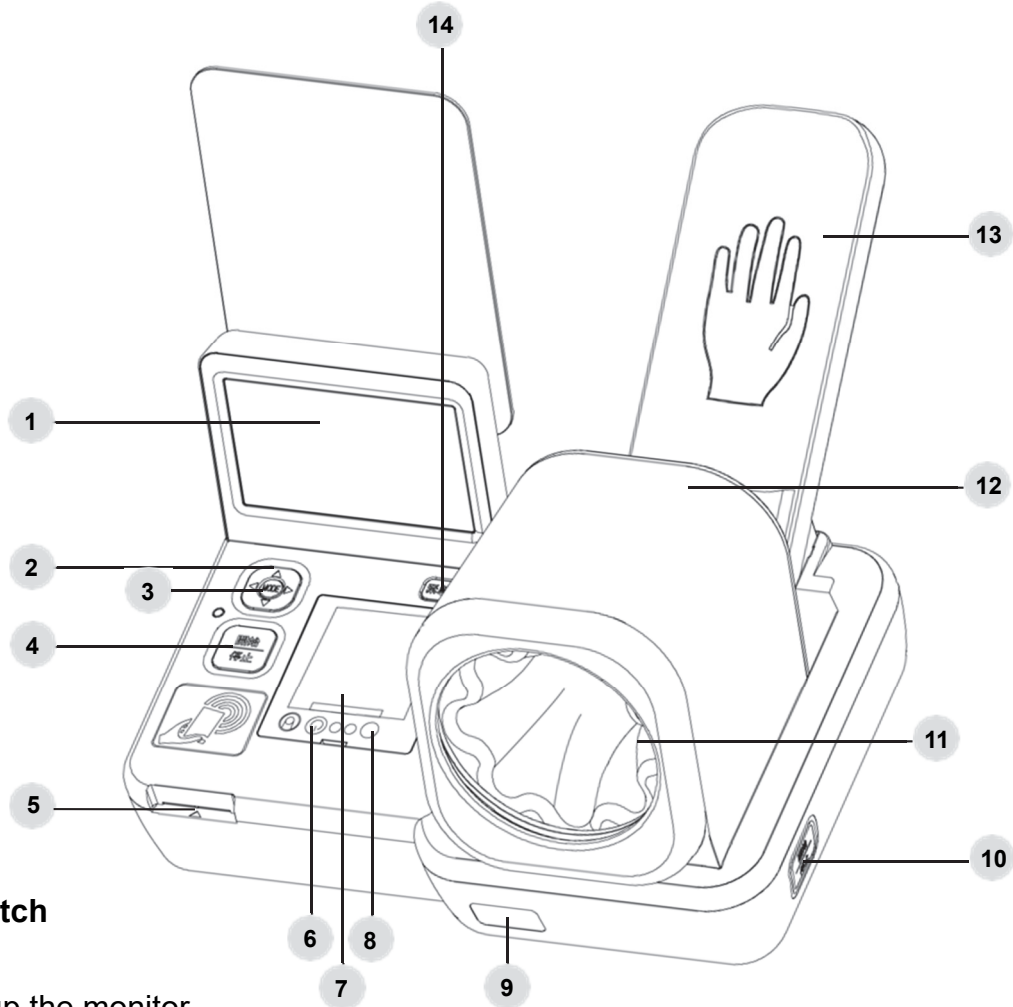
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3



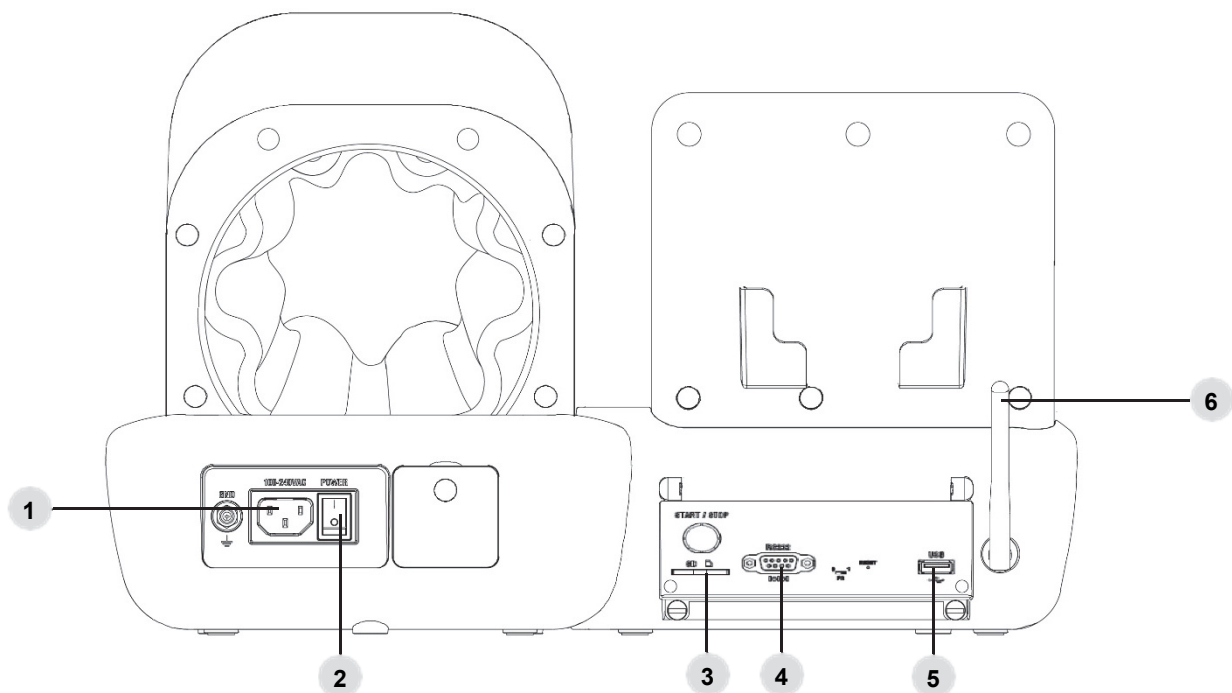
Meter Overview



Main unit

1. **Display**
2. **◀▶▼▲ Switch**
3. **Mode switch**
Press to set up the monitor
4. **Start/Stop button (L)**
Press to start or stop measurement
5. **Smart card reader**
Enables transmission of individual information from card to the monitor
6. **Printer power**
Turn on/off the printer
7. **Printer**
Prints measurement results.
8. **Paper eject button**
Press the button to eject paper.
9. **Sensor**
An on-screen instruction displays when user stay within sensing range
10. **Start/Stop button (R)**
Press to start or stop measurement
11. **Cuff cover**
12. **Cuff**
13. **Armrest**
Place the arm on it during measurement
14. **Emergency Stop**

REAR



1. AC port

2. Power switch

3. SD card slot

An SD memory card can be inserted in this slot

4. RS232 port*

Enables connection to a computer

5. USB port*

Enables connection to a computer

6. WiFi antenna

NOTE:

*The RS232 port and USB port are for the manufacturer for internal production use, without any function for the lay user.

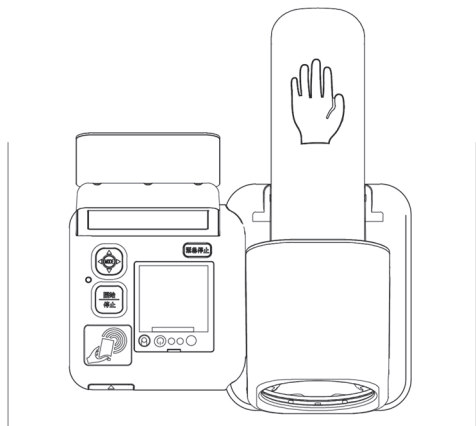
Before You Begin

Install the Monitor

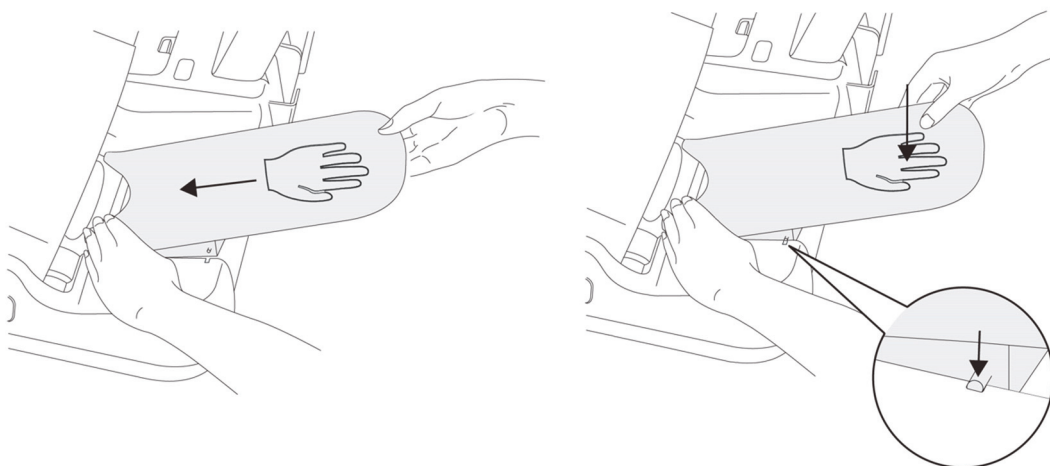
1. Place the monitor on the desk.

Place the front side of the monitor aligned with the desk edge.

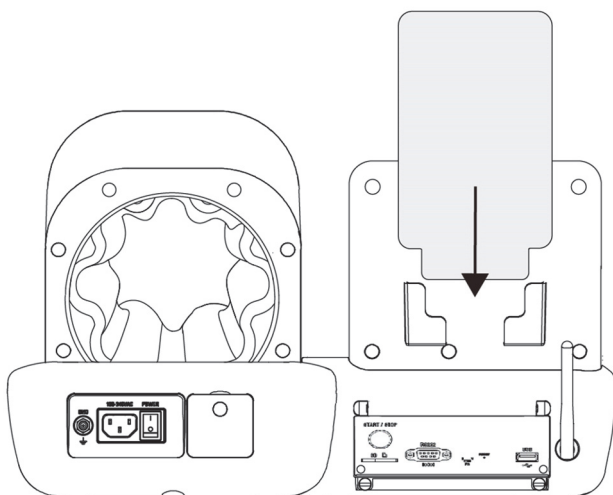
WARNING: Do **NOT** place the monitor on the ground.



2. Attach the armrest.



3. Attach the instruction panel (optional).



Connect to the power source

1. Connect the power cord to AC port of the monitor.
2. Plug the power cord into an electrical outlet.
3. Turn the power switch on. The power light will light up.
4. Wait for a while, the monitor will undergo several self-tests to verify its functionality and get ready for further operations.

WARNING:

- Do **NOT** use the power cord if it is damaged.
- Do **NOT** plug or unplug the power cord with wet hands.
- Unplug the power cord if the monitor will not be used for an extended period of time.
- The monitor must only be connected to a supply main with protective earth to avoid electric shock.

Check the monitor

Before switch on the power button

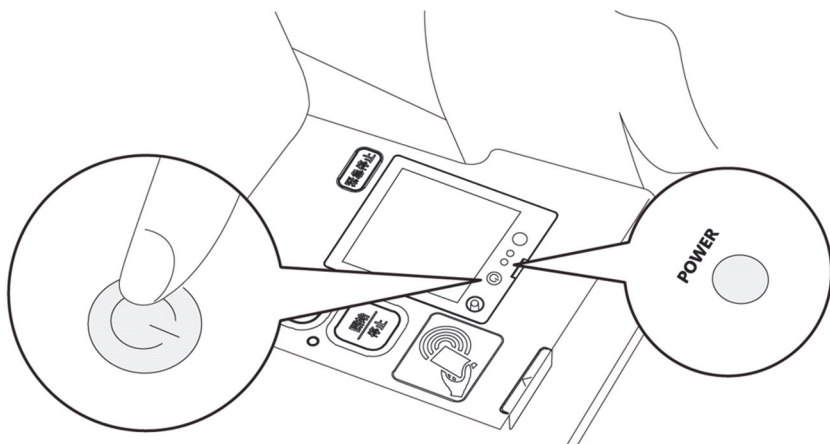
1. The power cord is firmly connected to the electrical outlet.
2. All accessories are installed properly.
3. The monitor and power cord are not wet and dirty.
4. The monitor and power cord are not damaged.

After switch on the power button

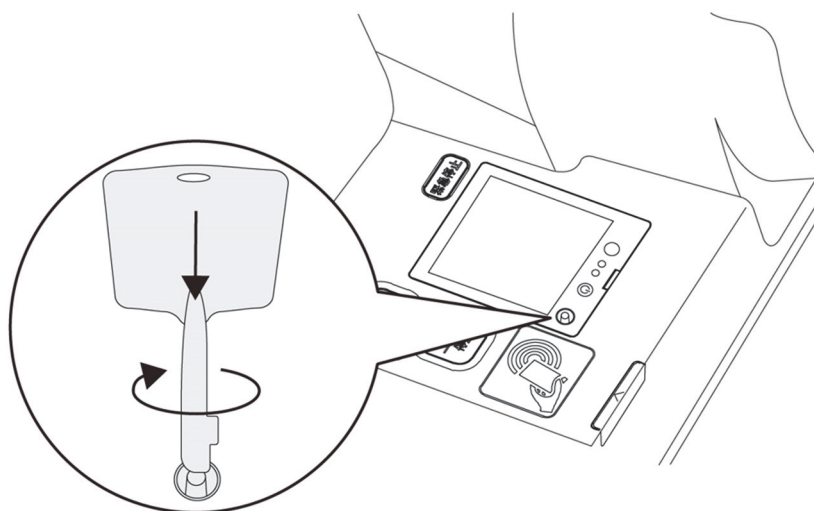
1. Wait for a while, the monitor will inflate and deflate automatically then perform several self-checks.
2. There is no smoke, bad smell or strong noises.
3. Press the buttons to make sure they are functional.
4. Date and Time settings are set correctly.

Load Printer Paper

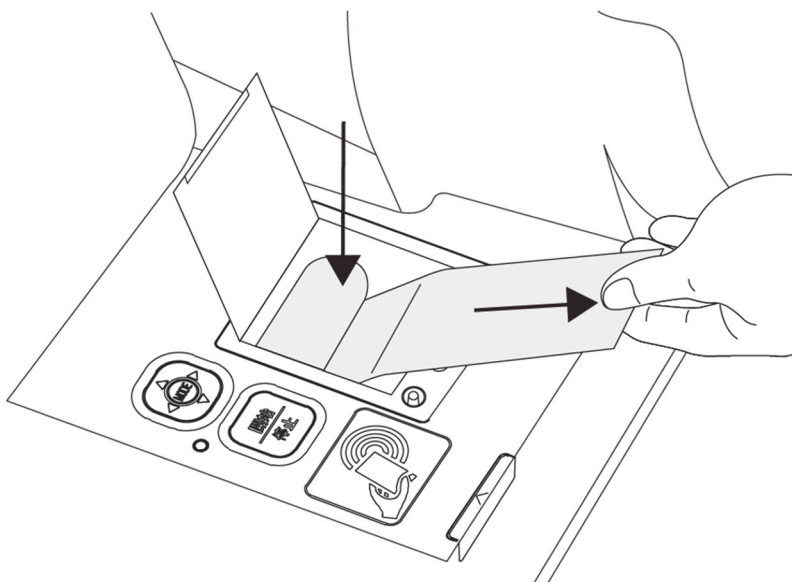
1. Press the power button of the printer. The printer power light will light up.



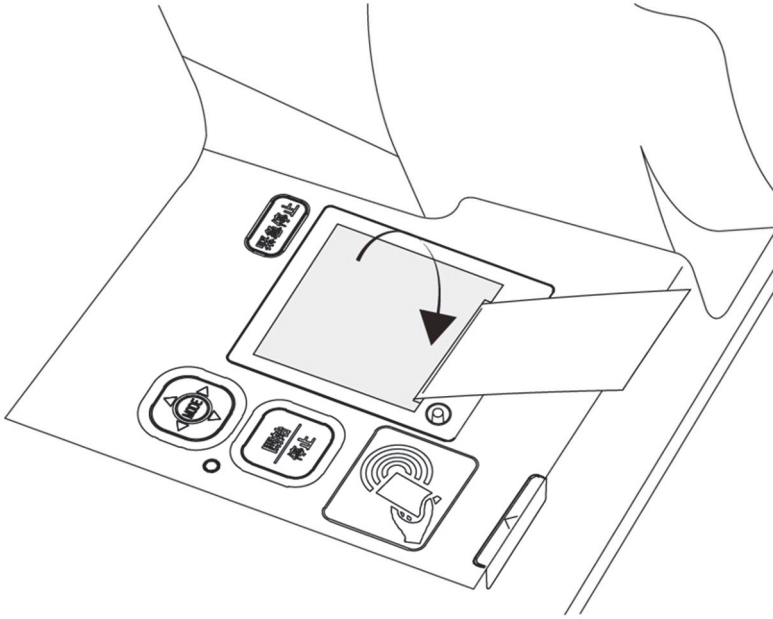
2. Insert the printer key into keyhole of the printer. Turn the key in clockwise direction to open the printer cover.



3. Insert the printer paper in orientation shown and pull out about 10 cm.



4. Firmly close the printer cover. The printer paper will be cut automatically.



NOTE:

- A red line will appear when the paper has 1 meter left. Load a new roll of printer paper.
- When printer error light lights up, turn the printer off and on to restart it.

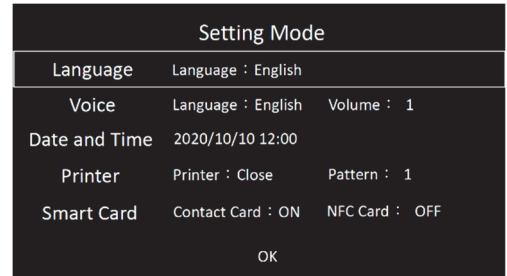
Set up the Monitor

Press **Mode** button for 3 seconds and release to get into setting mode. Press ▼ and ▲ to switch between different functions. Press **Mode** to get into each section. Select **OK** at the bottom to exit setting mode. This monitor provides following setting functions:

Language: Select the on-screen menu language.

Press **mode** to set up. Press ▲ and ▼ to switch between different language then press **mode** to confirm.

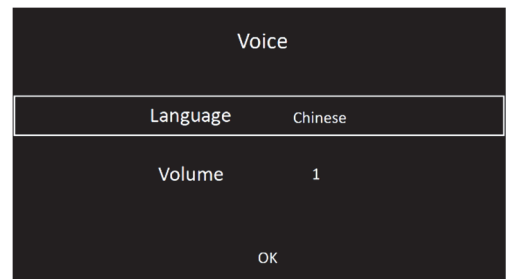
Select **OK** to save changes.



Voice: Choose desired speaking language and volume.

Language - Press **mode** to set up. Press ▲ and ▼ to switch between different languages then press **mode** to confirm.

Volume - Press **mode** to set up. Press ▲ and ▼ to switch between close and 0 to 7 then press **mode** to confirm. Select **OK** to save changes.

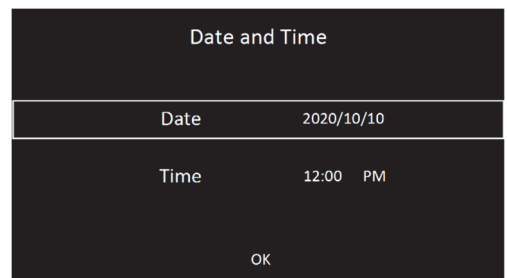


NOTE: Select “close” from **Volume** to deactivate beep sound and voice. Volume 0 indicates that the speaking function is turned off while beep sound still on. Volume 1 to 7 indicates speaking volume from low to high.

Date and time: Choose correct number of date and time.

Date - Press **mode** to set up. Press ▲▼◀▶ to switch between numbers then press **mode** to confirm.

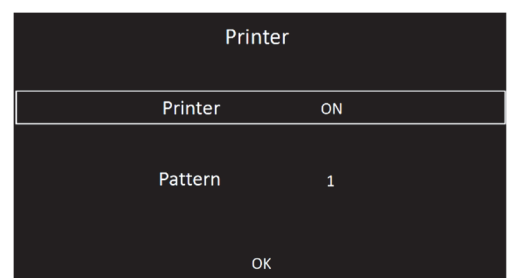
Time - Press **mode** to set up. Press ▲▼◀▶ to switch between numbers then press **mode** to confirm. Select **OK** to save changes.



Printer: Turn the printer on/off and select desired print pattern.

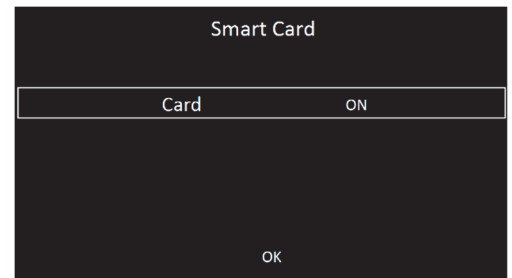
Printer - Press **mode** to set up. Press ▲ and ▼ to switch between ON and OFF then press **mode** to confirm.

Pattern - This monitor has three print patterns. Press **mode** to set up. Press ▲ and ▼ to switch between different print patterns then press **mode** to confirm. Select **OK** to save changes.



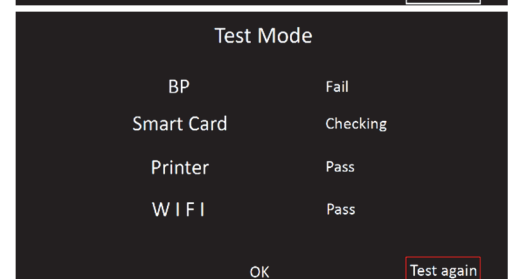
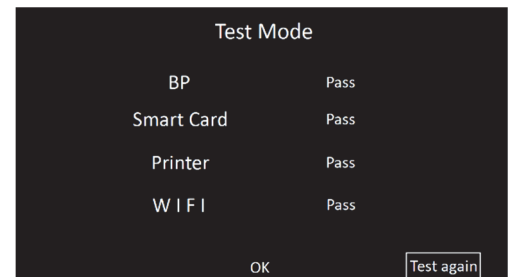
Smart Card Reader: Turn on/off the function of smart card reader.

Contact Card - Press **mode** to set up. Press ▲ and ▼ to switch between ON and OFF then press **mode** to confirm.



Test Mode: Check the function of this monitor.

In Test Mode, you can check the operating system of BP / Smart Card / Printer / WiFi. Select **Test again**, the monitor will in checking process. **Pass** means the function operates well while **Fail** indicates the system is not working properly. Select **OK** at the bottom to exit Test Mode.



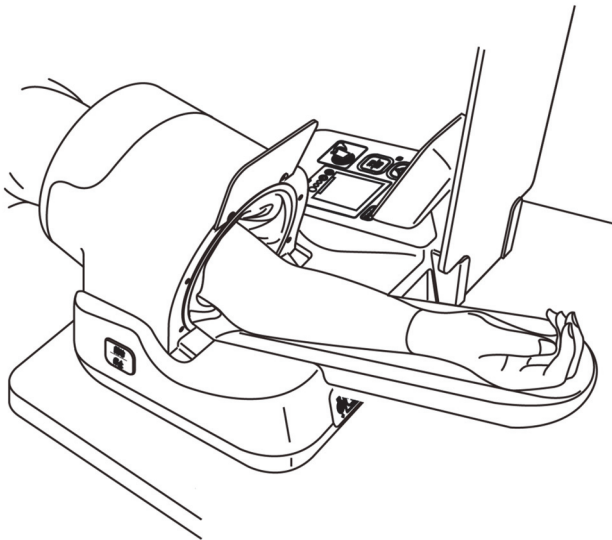
Start Measurement

Before measurement

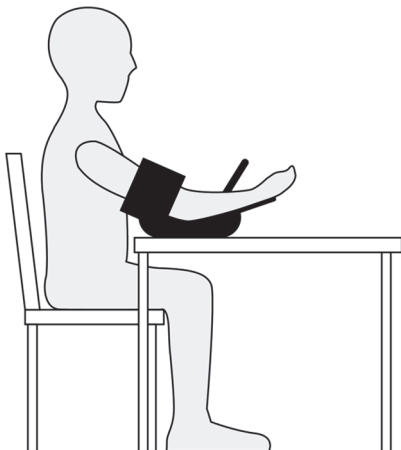
- Avoid caffeine, tea, alcohol and tobacco for at least 30 minutes before measurement.
- Wait 30 minutes after exercising or bathing before measurement.
- Sit or lie down for at least 10 minutes before measurement.
- Do **NOT** measure when feeling anxious or tense.
- Take a 5-10 minutes break between measurements. This break can be longer if necessary, depending on your physical condition.
- Keep the records for your doctor as reference.
- Blood pressure naturally varies between each arm. Always measure your blood pressure on the same arm.
- Remove thick garment from arm, measurement is possible on bare skin or over thin clothing.
- Do **NOT** measure if the arm has a wound.

Proper measurement position

1. Stretch left or right arm into the cuff, place elbow on the elbow rest. Relax the hand on the armrest with the palm facing up.



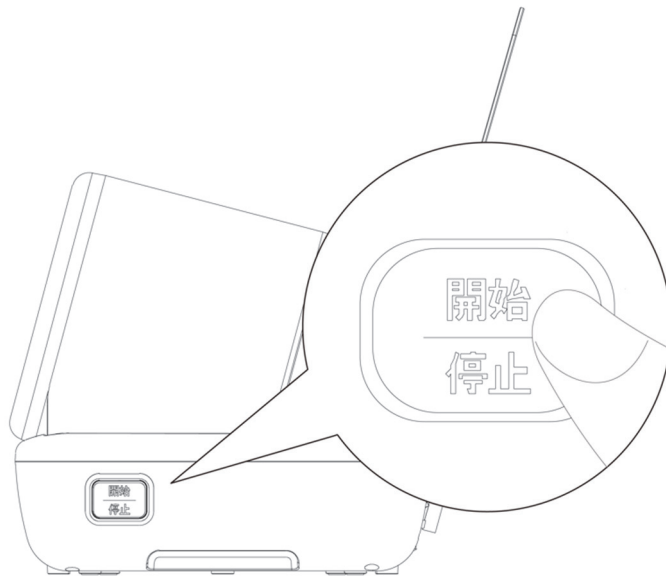
2. Remain still, do not talk or move during the measurement.



Take Blood Pressure

1. Press start/stop button to start measurement.

NOTE: The start/stop button on the right side of monitor is available for measurement with left arm.



2. The cuff start inflating. Relax and remain quiet.

3. Remove the arm when finish.

The cuff will automatically expand when the measurement is finished.

4. Read the measurement result.

The measurement result will display on the screen with systolic blood pressure, diastolic blood pressure and heart rate number. If voice function turned on, monitor will speak out the measurement result. The result displayed as a chart to show the level of blood pressure in 7 categories. Y-axis shows systolic blood pressure while x-axis shows diastolic blood pressure, it is clear to see the range of blood pressure.

WARNING:

- Cancelling measurement by pressing **start/stop** button if you feel hurt during measurement.
- If the cuff does not deflate after pressing **start/stop** button, press **EMERGENCY STOP** to switch the monitor off. Remove the arm from the cuff. After making sure conditions are safe, press **EMERGENCY STOP** again to reset the monitor.
- Always contact the manufacturer or the manufacturer's representative to report unexpected operation or event. Do **NOT** try to fix it by yourself.
- When a sudden reduction in the supply voltage (voltage dip) occur, the monitor will be powered off and automatically restart after the disturbance. The function needs to be restarted manually, and the function will be normal after restarting.

Printing the Measurement Data

If the printer switched on, the result of measurement will be printed. Take the paper after it cut by the printer automatically.

NOTE: Take the printed paper only after it cut by the printer. Do **NOT** pull it out during printing process. It may cause a paper jam.

Data Transmission

You can transmit your measuring results from the monitor to your devices (e.g. PC) via WiFi/Bluetooth. Follow the steps below to transmit data from your monitor.

Turn on the WiFi/Bluetooth of your device

Please make sure your device supports WiFi/Bluetooth functionality, the WiFi/Bluetooth setting on your device is turned on, and the meter is within the receiving range before transferring the data.

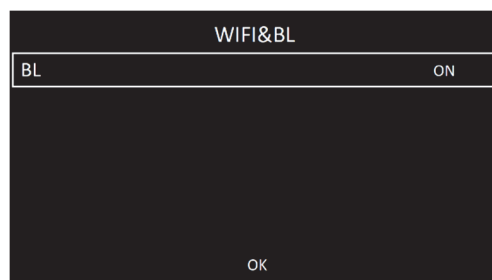
NOTE: Please read your device's user manual thoroughly before pairing.

Turn on the WiFi/Bluetooth of this monitor

Select **WiFi&BL** section in setting mode.

Pressing ▲ and ▼ to switch between WiFi and Bluetooth setting. Press **mode** to start the setup process.

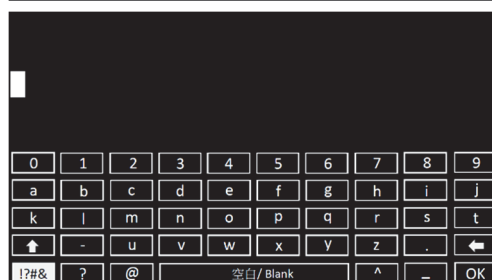
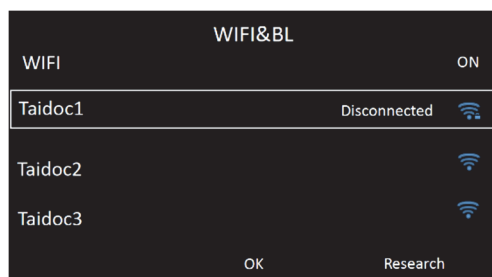
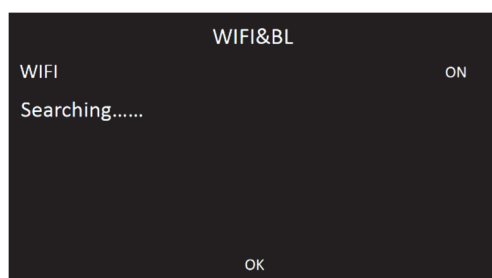
NOTE: You can only choose one method between WiFi and Bluetooth for data transmission. While WiFi turned on, Bluetooth will unable to setup.



WiFi Transmission - Pairing this monitor with management system via WiFi.

1. Press **mode** to set up. Press ▲ and ▼ to switch it ON then press **mode** to confirm.

2. After turning on the WiFi function, the monitor will start searching for nearby WiFi access point. Select desired WiFi access point then key in the password by pressing ▲ ▼ ◀ ▶ and **mode**. Press **OK** to confirm.



3. **Connected** indicates successful connection.

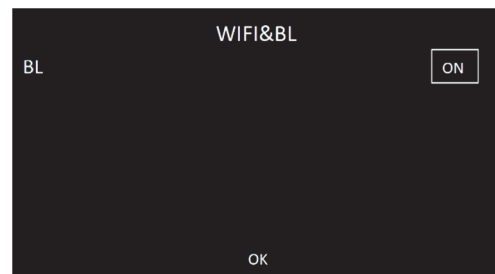
If you want to disable the connection with connected WiFi access point, select **Disconnect** at the bottom right corner. Select **OK** to exit WiFi & BL.



Bluetooth Transmission - Pairing this monitor with management system via Bluetooth.

Press **mode** to set up. Press ▲ and ▼ to switch it ON then press **mode** to confirm.

Select **OK** at the bottom to save changes.



NOTE:

- The meter will be unable to perform a test while it is in transfer mode.
- Do not switch off the monitor during data transmission. It may cause unsuccessful transmission or damage of the meter.
- If you have any problem in pairing, please contact your local customer service or place of purchase for assistance.
- The additional connection with other equipment to IT-network may cause previously unidentified risks to patients, operators or third parties. These risks should be identified, analyzed, evaluated and controlled.
- The changes of IT-network include configuration, connection of additional items, disconnection items, update and upgrade of the monitor could introduce risks and require additional analysis.

Maintenance

Monitor

To avoid the meter attracting dirt, dust or other contaminants, wash and dry the hands thoroughly before use.

Monitor storage

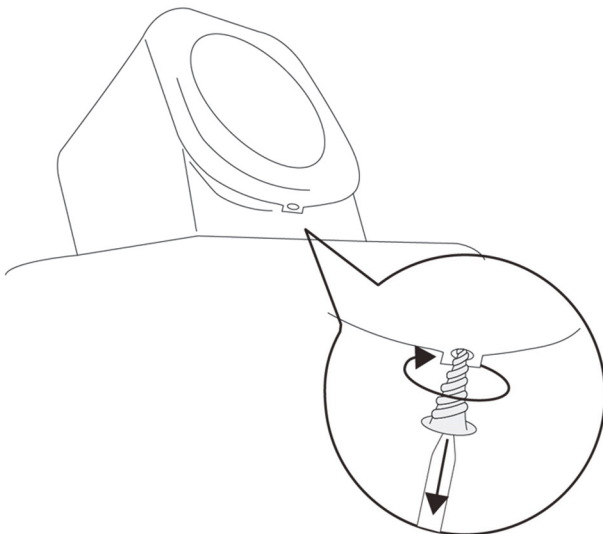
- Storage condition: -25°C to 70°C (-13°F to 158°F), 10% to 95% relative humidity.
- Avoid dropping or heavy impact.
- Avoid direct sunlight and high humidity.

Cuff Cover

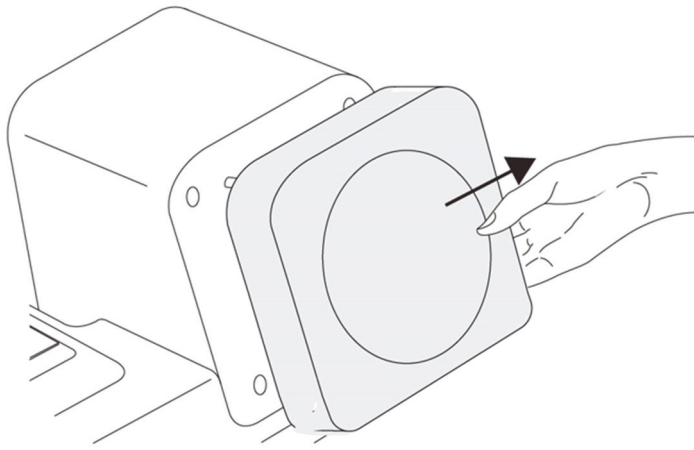
The cuff cover is replaceable. Replace the cuff cover when it is dirty or broken. A replacement cuff cover can be purchased separately. For details, please contact your local customer service or place of purchase for assistance.

Remove the cuff cover

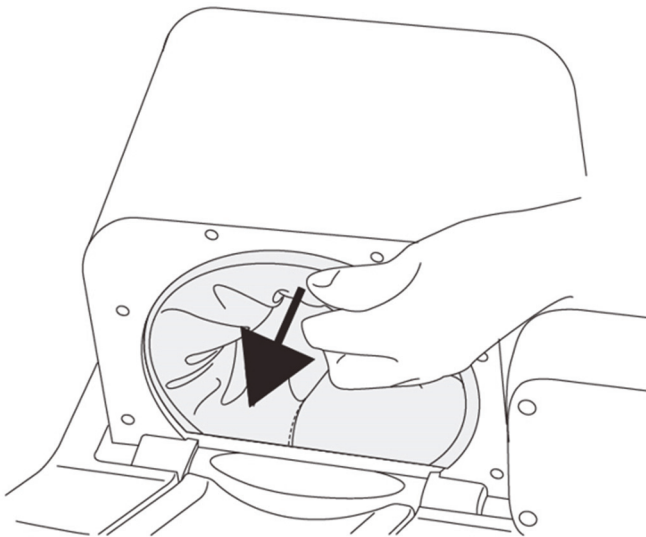
1. Lift the cuff up from front side to find the screw at the front bottom middle outside the cuff enclosure.



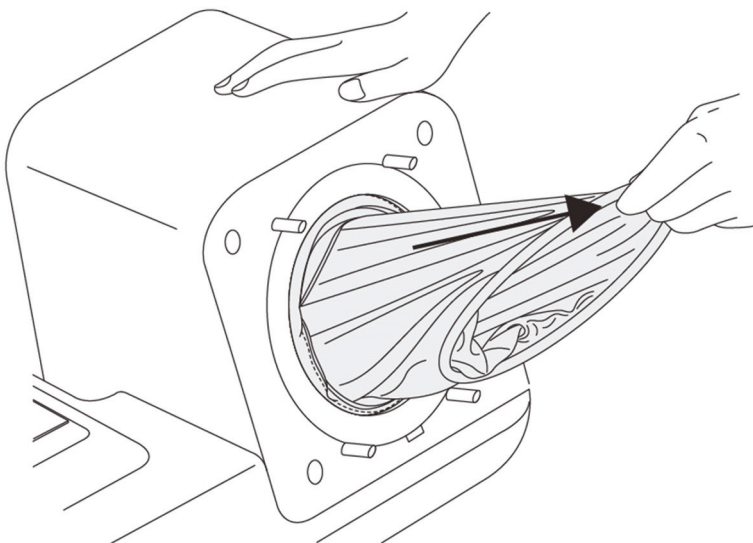
2. Remove the screw then take the front part of cuff enclosure off.



3. Pull the cuff cover at upper back and remove it from the groove of the cuff.

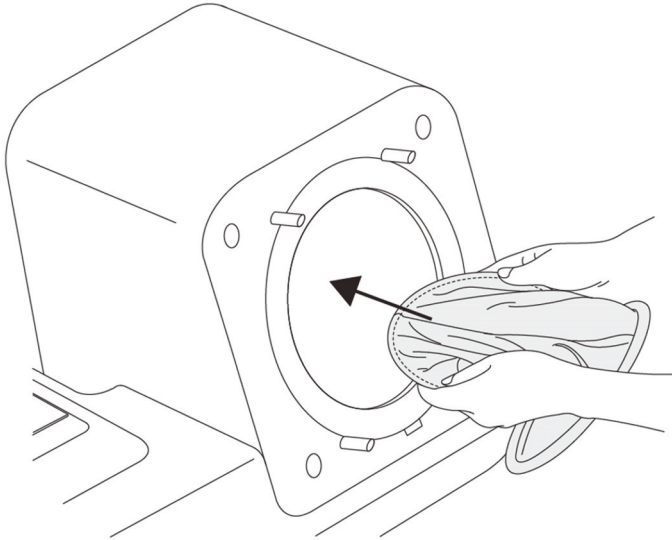


4. Pull out the cuff cover from the cuff.

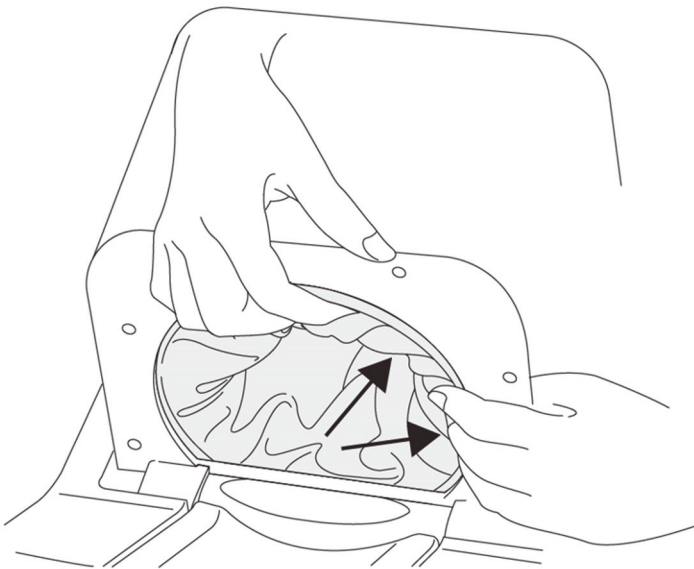


Attach the cuff cover

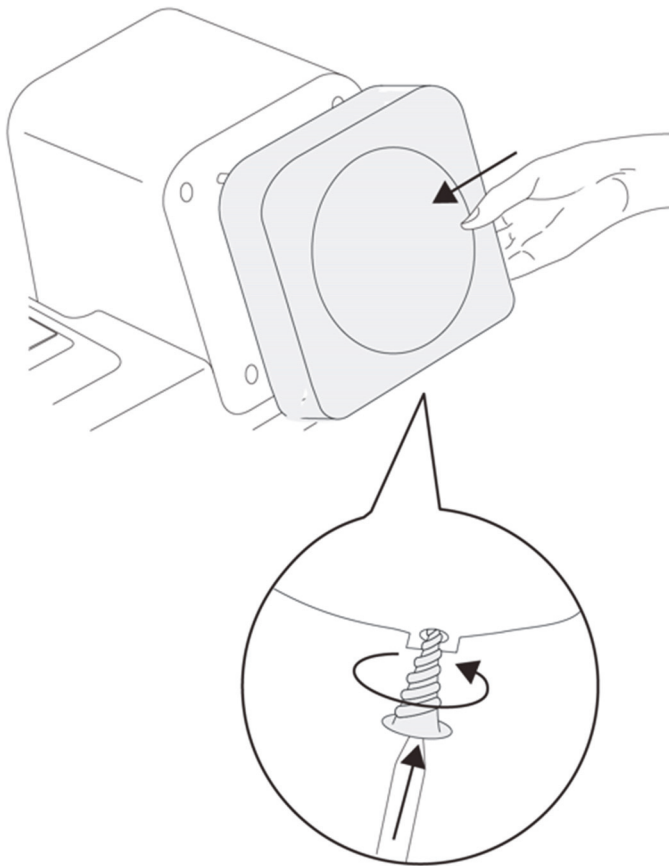
1. Insert the cuff cover to the cuff from the front, and pull the cover ring to the back.



2. Gently insert the back of cover ring into the groove.



3. Attach the front part of cuff enclosure back on the cuff and tighten the screw.



4. Make sure the cover rings are completely inserted and the seam of cuff cover is at the bottom.

NOTE:

- Do **NOT** pull out the inner cuff cover which is fixed in the cuff.
- Make sure the power button is switched off when replacing the cuff cover.

Cleaning and Disinfecting

We recommend that you clean the monitor once a day to maintain accurate results. Please unplug the power cord from the electronic outlet before cleaning and disinfecting the monitor.

- Use a soft dry cloth or a cloth moistened with 70% isopropyl or ethyl alcohol to clean the body of the monitor. Wipe the monitor dry with a clean cloth.
- Please make sure the cloth is moistened but not saturated to avoid moisture entering the openings of the monitor (e.g. ports, power switch, printer, smart card reader)
- Do **NOT** use abrasive cleaners to clean the monitor.
- Do **NOT** place the monitor under a running tap or immerse in water or any liquids.
- Make sure the cuff is clean and dry prior to use. The improper cleaning process may affect the accuracy.

Disposal

The used meter should be treated as contaminated to the environment. Please make sure the meter is disposed in accordance with local regulations.

Detailed Information

Reference Value

Human blood pressure naturally increases after reaching middle age. This symptom is a result of continuous ageing of the blood vessels. Further causes include diabetes, lack of exercise and cholesterol (LDL) adhering to the blood vessels. Rising blood pressure accelerates hardening of the arteries, and the body becomes more susceptible to apoplexy and coronary infarction.

Definitions and Classification of blood pressure levels according to 2018 ESC/ESH Guidelines for the management of arterial hypertension:

Category	Systolic (mmHg)		Diastolic (mmHg)
Optimal	< 120	and	< 80
Normal	120–129	and/or	80–84
High normal	130–139	and/or	85–89
Grade1 hypertension	140–159	and/or	90–99
Grade2 hypertension	160–179	and/or	100–109
Grade3 hypertension	≥ 180	and/or	≥ 110
Isolated systolic hypertension	≥ 140	and	< 90

Isolated systolic hypertension should be graded (1, 2, 3) according to systolic blood pressure values in the ranges indicated, provided that diastolic values are <90mmHg.

Source: The European Society of Hypertension and European Society of Cardiology Task Force Members.

2018 ESC/ESH Guidelines for the management of arterial hypertension. Journal of Hypertension: October 2018 - Volume 36 - Issue 10 - p 1953–2041.

Calibration

- The meter is initially calibrated at the time of manufacture. If the meter is used according to the instructions in this manual, periodic readjustment is not required. However, we recommend checking calibration every 6 months or at least once a year to ensure the level of accuracy. When the clinical accuracy of the device is in question, you can check calibration by contacting local customer service for assistance.
- Users should always comply with legal requirements for the control of the measurement, functionality, and accuracy of the device required by the relevant laws and regulations where the device is used.

System Troubleshooting

If you follow the recommended action but the problem persists, or error messages other than the ones below appear, please call your local customer service. Do **NOT** attempt to repair by yourself and never try to disassemble the meter under any circumstances.

Error Message

MESSAGE	CAUSE	WHAT TO DO
Error 01	Inflation or pressure error.	Please contact local customer service for help.
Error 02	Blood pressure measurement error.	Relax and repeat the measurement. If error still remains, contact local customer service for help.
Error 04	Cuff deflates too slow.	Please contact local customer service for help.
Error 05	Cuff deflates too fast.	
Error 06	Problems with the meter.	Review the instructions and repeat the test. If error still remains, contact local customer service for help.
Error 09		
Error 59	User stop BP measurement.	Relax and repeat the measurement after the measuring instruction show on the screen.
BPM Error	Bluetooth transmission errors.	Please contact local customer service for help.
Voice Error	Communicate to voice chip error.	Please contact local customer service for help.
Card RD Error	Card reader errors.	Please contact local customer service for help.
WiFi Error	WiFi error.	Please contact local customer service for help.
Printer Error	Printer function error	Please make sure the printer paper is loaded correctly. If error still remains, contact local customer service for help.

Trouble Shooting

1. If nothing appears after switching on power button.

POSSIBLE CAUSE	WHAT TO DO
The power cord is not connect properly.	Insert the power cord into electrical outlet correctly.

2. If the monitor does not inflate after pressing start/stop button.

POSSIBLE CAUSE	WHAT TO DO
The monitor is in setting mode.	Select OK from setting mode to finish setting. The screen will show the stand by display.

3. If the result is higher/lower than user's average measurement:

POSSIBLE CAUSE	WHAT TO DO
May not be in correct position while measuring.	Adjust to the correct position to measure.
Movement during measurement.	Do not move the arm or body during measurement and repeat the measurement.

4. If the printer is not working.

POSSIBLE CAUSE	WHAT TO DO
The printer is turned off.	Turn on the printer by pressing the power button of printer or turn on the printer function from setting mode.
Printer paper is not loaded correctly.	Load the paper in correct orientation.
The printer is out of paper.	Load a new roll of printer paper.

Specification

System performance

Model No.: TD-3500A

Power Supplier: AC 100~240V, 47/63Hz, 0.7-1.3A

Power Consumption: 64W

Size of Meter w/o Cuff: 295 (L) x 440 (W) x 282 (H)mm, 5.5 kg

Cuff Size: 17~42 cm

Display: 7 inch TFT panel

Firmware version: TD3500A-2022041200

Card Reader(Optional):

External Powered 5V±5% ,500mA

Standby Mode: 0.12 Watt

Active/Read Card Mode: ISO/IEC7816 => Varied by Different Card Type.

External Output:

Bluetooth (Frequency: 2.4GHz, Programmable GFSK modulation mode)

WiFi (802.11a/b/g/n: 2.4 GHz, Channels 1 (2142 MHz) through 13 (2472MHz))

Rear I/O: USB 2.0 (Type A), COM Port (RS-232)

Memory card slot: SD Card

Printer(Optional):

Print method: Thermal-line dot method

Effective printing width:48mm

Print speed: Max:90mm/s

Paper type: Thermal paper roll

Paper width: 58mm

Interface: Serial (RS232 / TTL) + USB + Cash Drawer

Power: DC 24V, Rated current 2A

Peak current 4A

Talking function: Mandarin / Taiwanese / English

Operating Conditions: 5°C to 40°C (41°F to 104°F), 15% to 93% relative humidity

Storage / Transportation Conditions: -25°C to 70°C (-13°F to 158°F), 10% to 95% relative humidity

Atmospheric Pressure Range: 700 hPa to 1060 hPa

Type of protection against electric shock: Class2 / Type B

Expected Service Life: 2 years

Blood pressure measurement performance

Systolic Measurement Range: 60 mmHg – 255 mmHg

Diastolic Measurement Range: 30 mmHg – 195 mmHg

Pulse Rate Measurement Range: 40 – 199 beats / minute

Maximum Inflation Pressure: 300 mmHg

Accuracy of Pressure: ± 3 mmHg or $\pm 2\%$ of reading

Accuracy of Pulse rate: $\pm 4\%$ of reading

NIBP Measuring method: Oscillometrics during deflation

Inflation method: Auto inflation by pump















Measurement Unit: Fixed mmHg

This device has been tested to meet the electrical and safety requirements of:
IEC/EN 60601-1, IEC/EN 60601-1-2, EN 301 489-17, EN 301 489-1, EN 300 328.

Reference to Standards:

- IEC60601-1 General requirement for safety
- IEC60601-1-2 Requirements for EMC

Symbol Information

SYMBOL	REFERENT	SYMBOL	REFERENT
	Manufacturer		RoHS compliance
	Consult instructions for use		Caution
	Temperature limit		Humidity limitation
	Use-by date		CE mark
	Serial number		Type B applied part
	Manufacture date		Medical Device
	Authorized representative in the European Community		
	This device does not belong to household waste and must be returned to a collection point for recycling electric and electronic devices according to local laws. If it contains batteries, the batteries should be removed and disposed in accordance with local regulations for separate collection of spent batteries.		

Electromagnetic Compatibility (EMC) Information

Manufacturer's declaration-electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Compliance	

Manufacturer's declaration-electromagnetic immunity

The device is intended for use in the electromagnetic environment (for professional healthcare) specified below.

The customer or the user of the device should assure that it is used in such an environment.


Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ± 8 kV Air ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	Contact: ± 8 kV Air ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines Not applicable	Mains power quality should be that of a typical professional healthcare environment.
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV line(s) to line(s) ± 0.5 kV, ± 1 kV, ± 2 kV line(s) to earth	± 0.5 kV, ± 1 kV line(s) to line(s) $+0.5$ kV, $+1$ kV, $+2$ kV line(s) to earth	Mains power quality should be that of a typical professional healthcare environment.
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage dips: 0% UT; 0,5 cycle 0% UT; 1 cycle 70% UT; 25/30 cycles Voltage interruptions: 0% UT; 250/300 cycle	Voltage dips: 0% UT; 0,5 cycle 0% UT; 1 cycle 70% UT; 25, 30 cycles Voltage interruptions: 0% UT; 250, 300 cycle	Mains power quality should be that of a typical professional healthcare environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50, 60 Hz) magnetic field IEC 61000-4-8	30 A/m 50, 60 Hz	30 A/m 50, 60 Hz	The device power frequency magnetic fields should be at levels characteristic of a typical location in a typical professional healthcare environment.

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

Manufacturer's declaration-electromagnetic immunity

The device is intended for use in the electromagnetic environment (for professional healthcare) specified below.

The customer or the user of the device should assure that it is used in such and environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6	3 Vrms: 0,15 MHz – 80 MHz 6 Vrms: 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 Vrms: in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	<p>Portable and mobile RF communications equipment should be used no closer to any part of the device including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance: $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 80MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800MHz to 2,7 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
Radiated RF IEC 61000-4-3	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	

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distance between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	80 MHz to 800 MHz $d = 1,2\sqrt{P}$	800 MHz to 2,7 GHz $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Manufacturer's declaration-electromagnetic immunity

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The device is intended for use in the electromagnetic environment (for professional healthcare) specified below.

The customer or the user of the device should assure that it is used in such an environment.

Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance LEVEL (V/m)
385	380 – 390	TETRA 400	Pulse modulation ^{b)} 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM ^{c)} ±5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 – 787	LTE Band 13,17	Pulse modulation ^{b)} 217 Hz	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{b)} 18 Hz	2	0,3	28	28
870							
930							
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ^{b)} 217 Hz	2	0,3	28	28
1845							
1970							
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{b)} 217 Hz	2	0,3	28	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation ^{b)} 217 Hz	0,2	0,3	9	9
5500							
5785							

NOTE 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 IEC 61000-4-3.

^{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, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

FEDERAL COMMUNICATIONS COMMISSION STATEMENT

15.21

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

15.105(a)

Federal Communications Commission (FCC) Statement

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

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 of the device.

FCC RF Radiation Exposure Statement:

1. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. For body worn operation, this device has been tested and meets FCC RF exposure guidelines. When used with an accessory that contains metal may not ensure compliance with FCC RF exposure guidelines.



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