vive®
PRECISION

BLOOD PRESSURE MONITOR

User Manual

DMD1001

vivehealth.com

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PRODUCT DESCRIPTION

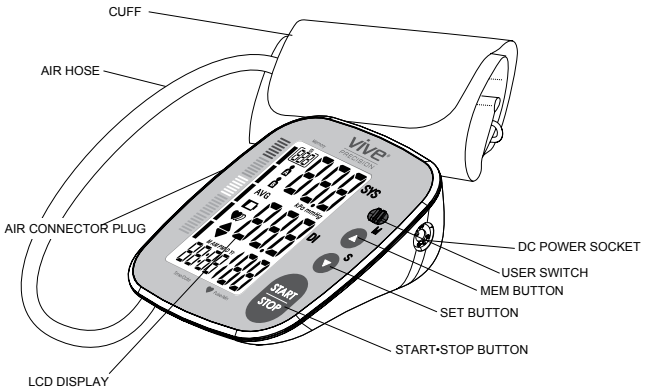
The Vive Precision blood pressure monitor is a portable device that allows you to accurately track blood pressure from the comfort of home. It is rigorously tested for accuracy and approved for use by the FDA, and has a built in alarm function to alert you of irregular heartbeats. Features a two-user functionality and a 250-combined measurement memory. Protected by a two-year warranty.

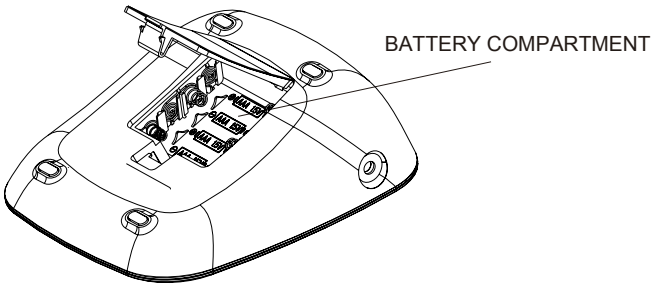
WHAT'S INCLUDED

- 1x Blood Pressure Monitor
- 1x Arm Cuff (Type BF applied part) 8 3/4"- 16 1/2"
- 4x AAA batteries
- Two-Year Warranty

PARTS LIST

1. Cuff
2. Air pipe
3. PCBA
4. Pump
5. Valve

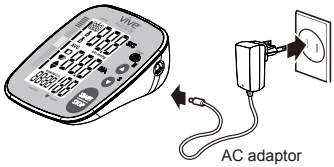




POWER SUPPLY

The Choice of Power Supply

1. Battery powered mode:
   6VDC 4×AAA batteries
2. AC adaptor powered mode:
   6V 1A
   (Please use the recommended AC adaptor model). (Not Included)



***Please unplug the adaptor when not in use.**

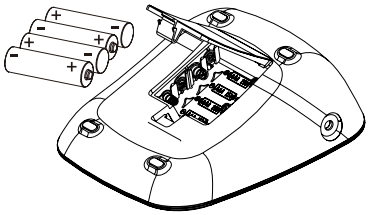
REPLACING BATTERIES

WARNING ⚠

In order to get the best effect and protect your monitor, please use the right battery and special power adapter which complies with U.S. safety standard.

Installing and Replacing the Batteries

- Open the battery cover.
- Install the batteries by matching the correct polarity, as shown.
- Replace the cover.



Replace the batteries when:

- The Lo+ shows
- The display dims
- The display does not light up

WARNING ⚠

- Remove batteries if the device is not likely to be used for some time.
- The old batteries are harmful to the environment, so please DO NOT dispose with other daily trash.
- Remove the old batteries from the device and follow your local recycling guidelines.
- Do not dispose of batteries in fire. Batteries may explode or leak.

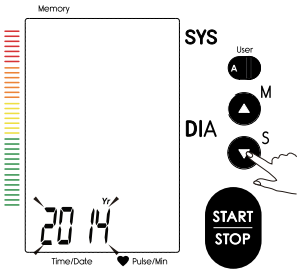
MEASUREMENT PRINCIPLE

This product uses the Oscillometric Measuring method to detect blood pressure. Before every measurement, the unit establishes a "zero pressure" equivalent to the air pressure. Then it starts inflating the arm cuff, meanwhile, the unit detects pressure oscillations generated by beat-to-beat pulsatile, which is used to determine the systolic and diastolic pressure, and also pulse rate. The device also compares the longest and the shortest time intervals of detected pulse waves to mean time interval then calculates standard deviation. The device will display a warning signal with the reading to indicate the detection of irregular heartbeat when the difference of the time intervals is over 25%.

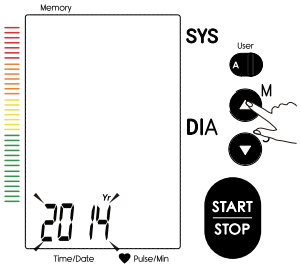
OPERATING INSTRUCTIONS - SETTING DATE, TIME, UNIT

It is important to set the clock before using your blood pressure monitor, so that a time stamp can be assigned to each record that is stored in the memory. (The setting range of the year: 2014—2054 time format: (12H/24H)

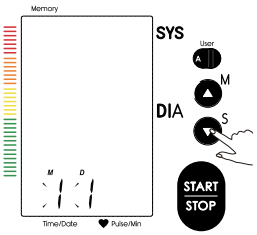
1. When the monitor is off, hold pressing "S" button for 3 seconds to enter the mode for year setting. Or when the monitor is off, press "S" button shortly, it will display the time. Then hold pressing "S" button to enter the mode for year setting.



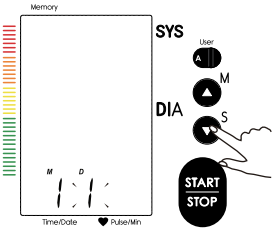
2. Press the "M" button to change the [YEAR]. Each press will increase the numeral by one in a cycling manner.



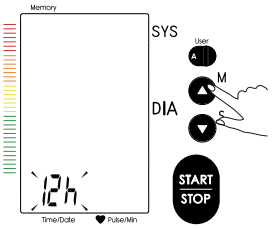
3. When you get the right year, press "S" button to set down and turn to next step.

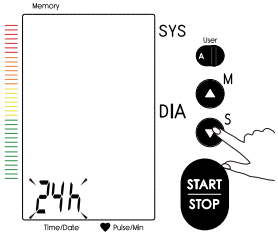


4. Repeat step 2 and 3 to set the [MONTH] and [DAY].

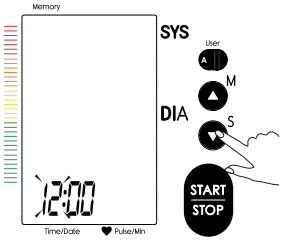


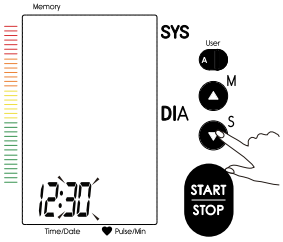
5. Repeat steps 2 and 3 to set the [TIME FORMAT between 12 hour time and 24 hour time.



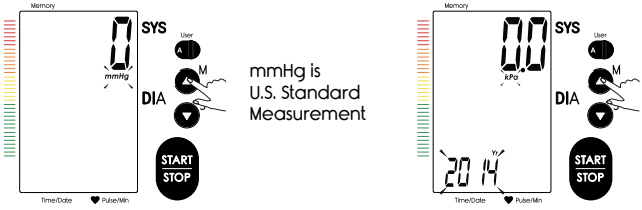


6. Repeat step 2 and 3 to set the [HOUR] and [MINUTE].



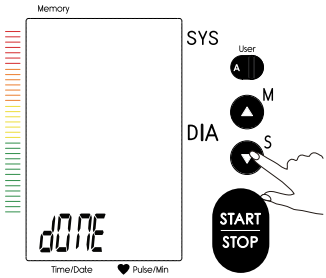


7. Repeat step 2 and 3 to set the [MEASUREMENT UNIT].



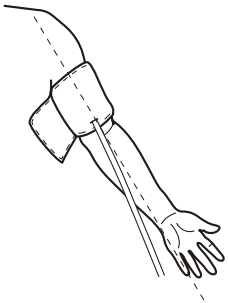
mmHg is U.S. Standard Measurement

8. After the unit is set, the LCD will display "done" first, then display all the settings you have done and then it will turn off.

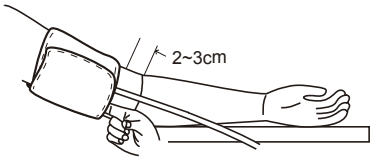


OPERATING INSTRUCTIONS - APPLYING THE CUFF

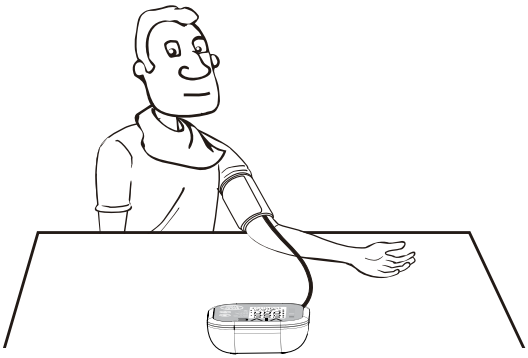
1. Attach the cuff tubing to the left side input for proper use.
2. Apply the cuff on your upper arm. Make sure the position of the tube is off-center; toward the inner side of arm in line with the little finger.



3. The cuff should be snug but not too tight. You should be able to insert one finger between the cuff and your arm.

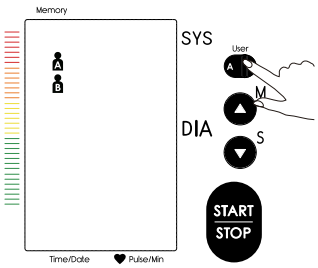


4. Sit comfortably with your test arm resting on a flat surface.
5. Patients with Hypertension: The middle of the cuff should be at the level of the right atrium of the heart; Before starting measurement, please sit comfortably with legs uncrossed, feet flat on the floor, back and arm supported. Follow these steps for accurate results:
    - Resting For 5 minutes before.
    - Wait at least 3 minutes between measurements. This allows your blood circulation to recover.
    - For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, position of upper arm, or as directed by a physician.

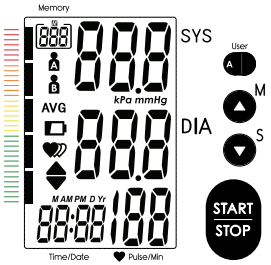


OPERATING INSTRUCTIONS - MEASURING

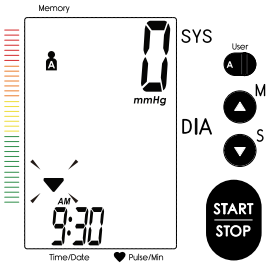
1. Before you start the measurement, switch the User button to select the user between User A and User B. Switch to right to select User A, switch to left to select User B. When the monitor is off,press the "START/STOP button to turn on the monitor, and it will finish the whole measurement. And save the measurement data for the desired user. (See image)



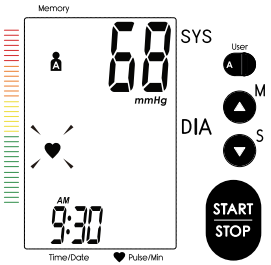
LCD Display



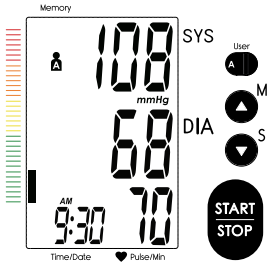
Adjust the zero.



Inflating and measuring.

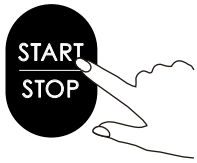


Display and save the results.



2. Press the "START/STOP" to power off, otherwise it will turn off within 1 minute.

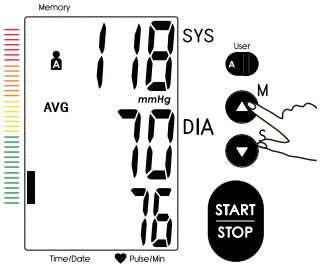
Tips: Combined maximum 250 records for User A and User B.



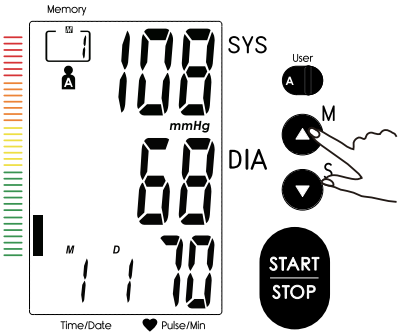
Recall the Records

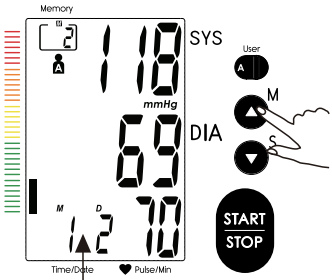
1. When the monitor is off, press the "M" button to show the average value of the latest three records for the selected user.
(Take User 1 for example. See right.)

Note: It will display the latest record first when the records are less than three groups.



2. Press "M" button or "S" button to get the record you want. Press and hold "M" button to look over ten groups of the historical records quickly.





The date and time of the record will be shown alternately.

3. If you want to look over another user's data, switch the User button to select the desired user. Then you can look over its historical records.

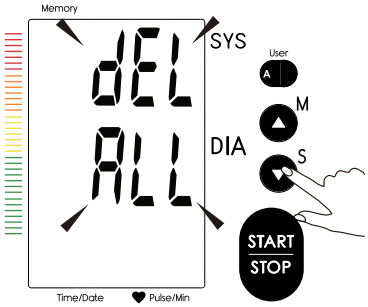
WARNING ⚠

The most recent record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (e.g., 2 becomes 3, and so on), and the last record (250) is dropped from the list.

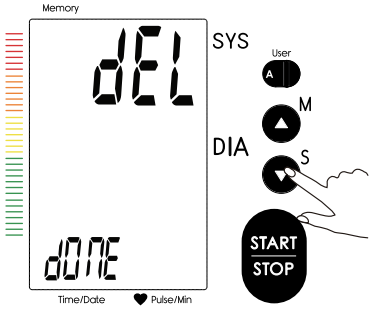
Delete the Records

If you did not get the correct measurement, you can delete each user A & B results by following the steps below.

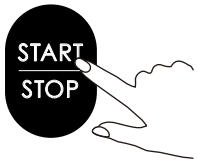
1. Hold pressing the "S" button for 3 seconds when the monitor is in the memory recall mode, the flash display "dEL ALL" will show.



2. Press the "S" button to confirm deleting and the LCD will display "dEL dOnE", and then turn off.



3. If you don't want to delete the records, press "START/STOP" button to escape.



INFORMATION FOR USER

Tips for Measurement

It can cause inaccuracy if the measurement is taken in the following circumstances.

1. Within 1 hour after eating or drinking.
2. Within 20 minutes after taking a shower/bath.
3. In a very cold environment

INFORMATION FOR USER

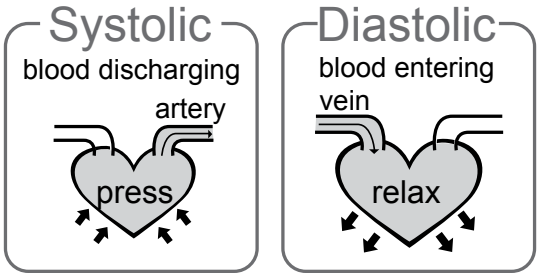
4. Immediate measurement after tea, coffee, or smoking.
5. When talking or moving your fingers.
6. When you need to urinate.

Maintenance
In order to get the best performance, please follow the instructions below.

WARNING ⚠
If you have any problems with this device, such as setting up, maintaining or using, please contact service@vivehealth.com. Don't open or repair the device by yourself. Please report to vivehealth.com if any unexpected operations or events occur. Please use a soft cloth to clean the whole unit. Don't use any abrasive or volatile cleaners.

ABOUT BLOOD PRESSURE

What is systolic pressure and diastolic pressure?
When ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cycle, which is called systolic pressure. When the ventricles relax, the blood pressure reaches its minimum value in the cycle, which is called diastolic pressure.



What is the standard blood pressure classification?
The chart below is the standard blood pressure classification published by American Heart Association (AHA).

AHA Home Guideline for Upper Limit of Normal BP

SYS	135mm Hg
DIA	85mm Hg

This chart reflects blood pressure categories defined by American Heart Association.			
Blood Pressure Category	Systolic mmHg (upper#)		Diastolic mmHg (lower#)
Normal	less than 120	and	less than 80
Prehypertension	120-139	or	80-89
High Blood Pressure (Hypertension) Stage 1	140-159	or	90-99
High Blood Pressure (Hypertension) Stage 2	160 or higher	or	100 or higher
Hypertensive Crisis (Emergency care needed)	Higher than 180	or	Higher than 110

WARNING ⚠

Only a physician can tell your normal BP range. Please contact a physician if your measuring result falls out of the range. Kindly note that only a physician could tell whether your blood pressure value has reached a dangerous point.

Irregular Heartbeat Detector

This Blood Pressure Monitor is equipped with an intelligent function of Irregular Heartbeat (IHB) Detector. During each measurement, this equipment records the heartbeat intervals and works out the standard deviation. If the calculated value is larger than or equal to 15, this equipment will light up the IHB symbol on the screen when displaying the measuring result.

WARNING ⚠

The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heart-beat was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often,

we recommend you seek medical advice. Please note that the device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

Why does my blood pressure fluctuate throughout the day?
1. Individual blood pressure can change on a daily basis. It is also affected by the way you apply the cuff and the measurement position. Please take measu-rements using the same method to ensure accuracy.
2. The variations in the pressure can be greater or smaller, depending on the actual medicine taken.
3. Waiting at least 3 minutes for another measurement.

Why do I have different readings when I take my blood pressure at the doctor's office and my home?
Blood pressure can fluctuate over a period of 24 hours based on: weather, emotions, exercise, stress, etc.

When you take your blood pressure at home, make sure to pay close attention to the following:
- If the cuff is secured properly.
- If the cuff is too tight or too loose.
- If the cuff is secured on the upper arm.
- If you feel anxious.

You had better take 2-3 deep breaths. Advice: Wait at least 4-5 minutes until you calm down.

Can you take measurement from both arms?
You may choose to measure both arms and then average the two readings to get your blood pressure result. The norm is to measure the left arm closest to your heart. For accuracy use the same method each time.

TROUBLESHOOTING

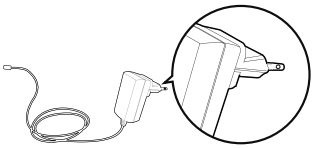
This section includes a list of error messages and frequently asked questions for problems you may encounter with your blood pressure monitor. If the products not operating as you think it should, check here before arranging for servicing.

PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display will not light up.	Batteries are exhausted.	Replace with new batteries
		Batteries are inserted incorrectly.	Insert the batteries correctly
		AC adaptor is inserted incorrectly.	Insert the AC adaptor tightly
Low batteries	Display is dim or show 	Batteries are low.	Replace with new batteries
Error message	E 1 shows	The cuff is not secure.	Refasten the cuff and then measure again.
	E 2 shows	The cuff is very tight.	Readjust the cuff ,not too loose or too tight and then measure again.
	E 3 shows	The pressure of the cuff is excess.	Relax for a moment and then measure again.
	E1O or E11 shows	The monitor detected motion,talking or the pluse is too poor while measuring.	Relax for a moment and then measure again.
	E2O shows	The measurement process does not detect the pulse signal.	Loosen the clothing on the arm and then measure again
	E21 shows	The treatment of the measurement failed.	Relax for a moment and then measure again.
	EExx,shows on the display.	A calibration error occurred (XX can be some numeric characters,such as O1, O2 and so on .	Retake the measurement. If the problem persists, contact the retailer or our customer service department for further assistance.Refer to the warranty for contact information and return instructions.

AUTHORIZED COMPONENT

Use the Vive® authorized adaptor. (Not Included)

Adaptor
Type: UE08WCP-060100SPA
Input: 100~240V, 50~60Hz,400mA
Output: 6V 1A
(Conforms to UL certificate)



COMPILED STANDARDS LIST

Risk management	ISO/EN 14971:2012 Medical devices — Application of risk management to medical devices
Labeling	ISO/EN 15223-1:2012 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
User manual	EN 1041: 2008 Medical equipment manufacturers to provide information
General Requirements for Safety	IEC 60601-1: 2005+A1; 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
Electromagnetic compatibility	IEC/EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard:Electromagnetic compatibility - Requirements and tests
Performance requirements and Clinical Investigation	IEC 80601-2-30:2009 Medical electrical equipment- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers ANSI/AAMI SP10:2002/A2: 2008 Manual, electronic, or automated sphygmomanometers
Software life-cycle processes	IEC/EN 62304:2006+AC: 2008 Medical device software - Software life cycle processes

FCC STATEMENT

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.

SPECIFICATIONS

- **Power Supply:** Battery Powered Mode: 6V DC 4 x AAA Batteries
  AC Adaptor Powered Mode: 6V ⎓ 1A (Please only use recommended AC adaptor - not included.)
- **Display Mode:** Digital LCD V.A. 60mm x 92mm
- **Measurement Mode:** Oscillographic testing mode
- **Measurement Range:** Rated cuff pressure: 0 kPa - 40 kPa (0mmHg~300mmHg)
  Measurement Pressure: 5.3kPa - 30.7kPa (40mmHg-230mmHg)
  Pulse Value: (40-199) beat/minute
- **Accuracy:** Pressure: 5kPa - 40kPa within ± 0.4kPa (3mmHg)
  Pulse Value: ± 5%
- **Normal Working Condition:** Temperature: 5°C-40°C Relative Humidity: ≤ 85%
  RH Atmospheric Pressure: 86kPa - 106kPa
- **Storage & Transportation Condition:** Temperature: -20°C - 60°C
  Relative Humidity: 10% RH - 93% RH
  Atmospheric Pressure: 50kPa - 106 kPa
- **Measurement Perimeter of the Upper Arm:** About 22cm~42cm
- **Weight:** Approx: 366g (Excluding the dry cells)
- **Exterior Dimensions:** Approx: 140mm x 130mm x 49.7mm
- **Mode of Operation:** Continuous Operation
- **Degree of Protection:** Type BF applied part
- **Protection against ingress of water:** IP21
- **Software Version:** V.01

⚠ **WARNING:** No modification of this equipment is allowed.

SAFETY INFORMATION

The signs to the right might be in the user manual, labeling or other component. They are the requirement of standard and using.

SAFETY INFORMATION

	Symbol for "THE OPERATION GUIDE MUST BE READ"
	Symbol for "MANUFACTURER"
SN	Symbol for "SERIAL NUMBER"
	Symbol for "DIRECT CURRENT"
	Symbol for "MANUFACTURE DATE"
	Symbol for "TYPE BF APPLIED PARTS"
	Symbol for "ENVIRONMENT PROTECTION-Waste electrical products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice" Symbol for "CAUTION" These notes must be observed to prevent any damage to the device.

WARNING ⚠

- This device is intended for adult use only.
- This device is intended for non-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the arm or for functions other than obtaining a blood pressure measurement.
- Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure. Do not begin or end medical treatment. Consult your physician for treatment or advice.
- If you are taking medication, consult your physician to determine the most appropriate time to measure your blood pressure. Never change a prescribed medication without consulting your physician.
- If the cuff pressure exceeds 40kPa (300 mmHg), the unit will automatically deflate. Should the cuff not deflate when pressure exceeds 40 kPa (300 mmHg), detach the cuff from the arm and press the START/STOP button to stop inflation.
- To avoid measurement errors, carefully read this manual before using the product.

WARNING ⚠

- The equipment is not AP/APG equipment and not suitable for use in the presence of a flammable anesthetic mixture
- with air of with oxygen or nitrous oxide.
- The operator shall not touch output of batteries and the patient simultaneously.
- To avoid measurement errors, please avoid the condition of strong electromagnetic field radiated interference signal or electrical fast transient/burst signal when using the AC adaptor.
- The user must check that the equipment functions safely and see that it is in proper working condition before being used.
- Please use ACCESSORIES and detachable parts specified/ authorized by MANUFACTURE. Otherwise, it may cause damage to the unit or danger to the user/ patients.
- Manufacturer will make available on request circuit diagrams, component parts list, etc.
- This unit is not suitable for continuous monitoring during medical emergencies or operations. Otherwise, the patient's arm and fingers will become anesthetic, swollen and even purple due to a lack of blood.
- Please use the device under the environment which was provided in the user manual. Otherwise, the performance
- and lifetime of the device will be impacted and reduced.
- During using, the patient will contact with the cuff. The materials of the cuff have been tested and found to comply
- with requirements of ISO 10993-5:2009 and ISO 10993-10:2010. It will not cause any potential allergic reaction or contact injury.
- The device doesn't need to be calibrated in two years of reliable service.
- Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines.
- When the device was used to measure patients who have common arrhythmias such as atrial or ventricular premature beats or arterial fibrillation, the best result may occur deviation. Please consult your physician about the result.
- The device is contraindicated for any female subject who may be suspected of, or is pregnant. Besides provided inaccurate readings, the effects of this device on the fetus are unknown.
- When using this device, please pay attention to the following situation which may interrupt blood flow and influence blood circulation of the patient, thus cause harmful injury to the patient: Too frequent and consecutive multiple measurements; The application of the cuff and its pressurization on any arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present; Inflating the cuff on the arm on the side of a mastectomy.

WARNING ⚠

- Do not apply the cuff over a wound, otherwise it can cause further injury.
- Do not inflate the cuff on the same limb which other monitoring ME EQUIPMENT is applied around simultaneously, because this could cause temporary loss of function of those simultaneously-used monitoring ME EQUIPMENT. Using it in case to result in prolonged impairment of the circulation of the blood of the PATIENT.
- Don't kink the connection tube, otherwise, the cuff pressure may continuously increase which can prevent blood flow and result in harmful injury to the PATIENT.
- The device has been evaluated clinically used manual cuff/stethoscope auscultations the reference. Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method, within the limits prescribed by the "American National Standard, Manual, electronic or automated sphygmomanometers".
- The patient is an intended operator. The patient can measure under normal circumstances and maintain the device and its accessories according to the user manual.
- The blood pressure monitor, and the cuff are suitable for use within the patient environment. If you are allergic to dacron or plastic, please don't use this device.
- Please keep the unit out of reach of infants, children or pets, since inhalation or swallowing of small parts is dangerous or even fatal.
- If Luer lock connectors are used in the construction of tubing, there is a possibility that they might be inadvertently connected to intravascular fluid systems, allowing air to be pumped into a blood vessel.
- The device is not suitable for public use.
- The device is not intended for PATIENT transport outside a healthcare facility.
- This device cannot be used with HF surgical equipment at the same time.
- Be careful to strangulation due to cables and hoses, particularly due to excessive length.

EMC GUIDANCE

1. MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS

2. Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d=3, 3m away from the equipment.

(Note: As indicated in Table 6 of IEC 60601-1-2:2007 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields d=3, 3m at an IMMUNITY LEVEL of 3V/m)

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