

Registration Number

20182210170

Production Certificate

20162890

Non-invasive Vascular Screening Device

AVE-2000 Pro



Instruction for Use

- ◇ To ensure the correct use of the device, please read the manual carefully.
- ◇ Keep the manual near the device.
- ◇ To measure accuracy, please use the device in an appropriate way.
- ◇ The device can be used to measure AVI & API, CSBP & CAPP, Systolic & Diastolic blood pressure and the P.R. of adults.



Read before use

<Preface>

- Thank you for choosing the Non-invasive Vascular Screening Device **AVE-2000 Pro**.
- The value of blood pressure measured by the device is equivalent to that picked up by the auscultatory method, and the error rate conforms to the requirements specified in YY 0667-2008.
- The device has passed clinical verification according to the requirements in YY 0670-2008, and its safety and effectiveness has been proved to conform to the related regulations in YY 0670-2008. Please contact the company's customer service to acquire the performance verification method of this device.
- Applicable scope: it is applicable for measuring blood pressure, Arterial Velocity Pulse Index (AVI), Arterial Pressure Volume Index (API), Central Systolic Blood Pressure (CSBP, **estimated value**) and Central Aortic Pulse Pressure (CAPP, **estimated value**). The values are only for diagnostic reference.
- The device should be used under the direction of a physician.

<About this Manual>

- This manual will provide you with instructions on how to use Non-invasive Vascular Screening Device **AVE-2000 Pro**. Please read this manual carefully and keep it in a safe place for future reference.
- No part of this published manual may be reproduced, transmitted, transcribed, stored in a retrieval system or translated into any language or computer language, in any form, by any means, without the prior written permission of our company.
- Every effort has been made to ensure that the contents of this manual are accurate. If you have any questions, please contact the customer service. If you have any question, please contact our customer service.
- Throughout this manual, ※ indicates useful information, and images are for reference only.

<Terminology>

Blood Pressure

The blood pressure is the pressure of the flowing blood against the vascular wall, and it also serves as the force to propel the blood flowing in the vessels.

- **High Blood Pressure (SYS, Systolic Blood Pressure)**
Systolic blood pressure refers to the maximum blood pressure appearing in an artery during systole when the heart contracts to drive blood into the arterial system.
- **Low Blood Pressure (DIA, Diastolic Blood Pressure)**
Diastolic blood pressure is the minimum blood pressure appearing in an artery during diastole when blood pressure in the artery keeps decreasing after the closure of the aortic valve.

Pulse Rate

- **Pulse Rate**
The frequency of arterial pulse wave detected by the cuff, which is generally comparable to heart rate except under some special situations, such as in subjects with arrhythmia or severe occlusive disease in artery or cardiac valve.

AVI & API

AVI & API are the new vascular index jointly researched and developed by RIKEN, AIST, and Shisei Datum in Japan.

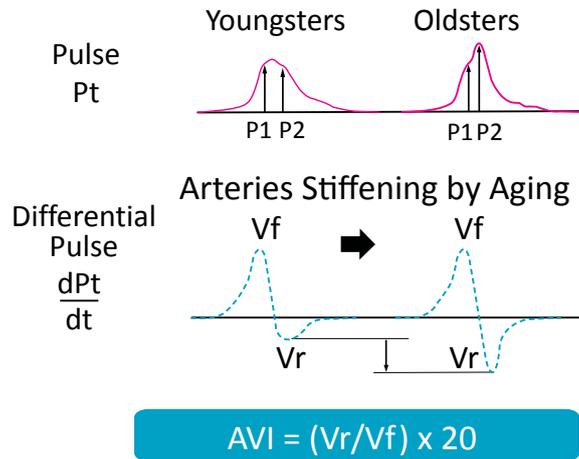
AVI & API are subject to the effect of age, gender, cholesterol level, blood pressure as the well as the history of diabetes, smoking and exercise, etc.

AVI may be reduced through regular exercise.

- **AVI (Arterial Velocity Pulse Index)**

AVI is a new vascular index that developed jointly by Shisei Datum in Japan and RIKEN. Himeno Ryutaro with his sub generation integration simulation team, and Gao muzhou with his dominant organ Scale study team, are the research and development teams of RIKEN. Gao muzhou is also a professor of Tokyo University.

Principle: AVI shows the characteristics of the pulse waveform when the cuff pressure is higher than maximum blood pressure, and meanwhile converts them into numerical values as the indices of the central arterial stiffness. The higher the value is, the higher risk of arterial stiffness it represents. The upper waveforms of below graph are those of cuff pressure pulse wave, and the lower ones are the differentiated waveforms (differentiated pulse wave). The shape of the cuff oscillation wave varies with the increase and early arrival of reflected pressure waves accompanying aging or arterial stiffening, presenting an enhanced pressure augmentation in late systole followed by a steeper pressure decrease. AVI is an index used to quantitatively assess such wave changes, which is calculated based on the ratio of the valley value (Vr) to the peak value (Vf) of the time-differentiated cuff wave ($AVI=(Vr/Vf)\times 20$).



- **API (Arterial Pressure Volume Index)**

API is a new vascular index that developed jointly by AIST and Shisei Datum in Japan.

Principle: The more elastic the arteries are, the more drastic the arterial volume changes when the cuff pressure decreases. The blood vessel stiffness is converted into numerical values using the gradient of the curve as an index. The higher the value is, the higher risk of upper-arm arterial stiffness it represents. The cuff pressure-artery volume curve is firstly measured by a cuff with a decreasing working pressure, then the curve is fitted with an arctan function ($A \cdot \arctan(B \cdot X + C) + D$). Finally, API is defined as the reciprocal of coefficient B ($API = 1/B$).

CSBP (Estimated Value) & CAPP (Estimated Value)

- **CSBP (Central Systolic Blood Pressure, estimated value)**

It is obtained by taking age, radial artery systolic pressure, pulse pressure, arterial velocity pulse index, arterial pressure volume index and other parameters as independent variables.

$$CSBP \text{ (Estimated Value)} = 0.0447 \cdot \text{age} + 0.8392 \cdot \text{PSBP} + 0.1793 \cdot \text{PDBP} + 0.2718 \cdot \text{AVI} + 0.2881 \cdot \text{API} + 2.3339$$

- **CAPP (Central Aortic Pulse Pressure, estimated value)**

It is obtained by taking age, radial artery systolic pressure, pulse pressure, arterial velocity pulse index, arterial pressure volume index and other parameters as independent variables.

$$CAPP \text{ (Estimated Value)} = 0.1613 \cdot \text{age} + 0.0923 \cdot \text{PSBP} + 0.8192 \cdot \text{PPP} + 0.2024 \cdot \text{AVI} + 0.2537 \cdot \text{API} - 13.1126$$

Safety Precautions

The symbols appearing in the manual are used to facilitate your correct and safe use of this device, and prevent the injury caused to you or others.

<Symbol Description>

 Warning	The sign shows that careless use may lead to injury or damage to the user.
 Caution	The sign shows that careless use may lead to inability for measuring or incorrect measurements.
	Insulation degree of equipment (Class II equipment).
	Electric shock protection degree of equipments (B type).
	Separated disposal symbol for waste electric and electronic equipments (Please follow local laws and regulations).
	Do not disassemble or modify the device by yourself.
	Caution! Refer to appendix documents.
	Pollution control sign of electronic information products This product can be used in an environmentally friendly manner for 10 or 5 years. It is recyclable and should not be discarded at will.
	Place up
	Pay attention to moisture-proof
	Fragile
	The maximum loading layer is 6 layers.

<Precautions>

Device Precautions

 Warning	This device is only applicable for adults, and do not use it on neonates, children or people who cannot express their feelings.
	The patients with severe blood circulation disorders and blood diseases should use it under the direction of physician.
	Pregnant patients or postoperative patients should use it under guidance of physician.
	Please follow the direction of physician. The result is not to be used for self-diagnosis or self-treatment. Users should seek advice of healthcare professional in case of any doubts about the measurement results.
	In the case of arrhythmia such as atrial extrasystole, ventricular extrasystole and atrial fibrillation, the measurement maybe inaccurate.
	Device cannot be used in environment that does not allow wireless communication.
	The patients with wound, inflammation, edema or hemorrhage tendency on the arms are not recommended to use the device.

⚠ Warning	Do not use it in case of receiving blood transfusion or intravenous drip.
	Do not use it when arteriovenous fistula is equipped for hemodialysis.
	Do not use it when there is possibility of thrombus formation due to blood flow obstruction or stagnation.
	Do not use it when there is possibility of peripheral circulation disorders due to blood flow obstruction or stagnation.
	Do not change the power supply or other parts by yourself. Maintenance should be done by local service representative authorized by the manufacturer. Otherwise, it may lead to inaccurate measurement.
	 Disassembly Prohibited Do not disassemble or modify the device.
	This device is a precision instrument, please take it gently in the handling and transportation process. Never crash or drop it.
	Do not leave liquids beside the device. Please wipe it off in time with soft cloth if there is spill of liquid on the device.
	Do not perform blood pressure measuring if there is arm-cuff break.
	Do not perform blood pressure measuring when the arm-cuff is placed upside down.
	Please use this device in the temperature range of 5°C to 40°C, with relative humidity not more than 80% but no direct sunlight.
	This device conforms to EMC specification. Do not place it in an environment with high-intensity magnetism, static electricity or electric wave (e.g., close to microwave oven).
	Please start the device after drying it if there is moisture condensation on the device.
	When moving the device from a low-temperature environment to a high-temperature environment, there may be water-drop condensation inside the device due to physical transformation, please start the device after it cooled down to room temperature.
	Do not use accessory parts or components other than what specified by the company.
	Do not connect any other removable porous sockets or extension cable to this system.
	Components not specified in the accessories supplied with this device should not be connected to it.
Please make the connection according to the instructions of each part in this manual. Do not mix the jacks together.	
⚠ Caution	Do not use the device on person with frequent occurrence of arrhythmia.
	Do not use the device on a moving transport vehicle (e.g., car or plane).
	Do not measure when your arm is not in the arm cylinder.
	Do not use cell phone beside the device in measuring process.
	Do not use the device in thundering weather.

- ※ If stored or used outside the range of temperature and humidity specified by the manufacturer, the system may not be able to achieve the claimed performance specifications.
- ※ There may be a risk when the airbag is over inflated.
- ※ Using other unauthorized attachments may cause safety hazards. Please follow the instructions in the manual for the connection of the external jacks. No random connection is allowed.

AC adapter Precautions

 Warning	Do not disassemble, repair or modify the AC adapter.
	Please connect the AC adapter to AC 100-240V power supply.
	Do not use damaged power cable or plug.
	Avoid any damaging, processing, heating, bending with force, pulling, twisting or pressing, etc. or lay heavy objects on the AC adapter and power cable.
	Please only use designated AC adapter for this device.
	When disconnecting the device from power supply, pull off the power plug with hand on it and do not pull the power cable.

Battery Precautions

 Warning	Please use batteries of designated type and specification. Do not mix new and old batteries or use different types of batteries. In battery replacement, please replace 4 batteries at the same time.
	Please dispose old batteries according to related regulations for environment protection of your residential area.
	In case battery liquid splashes into your eyes, please rinse your eyes with large amount of fresh water for at least 15 minutes and resort to medical assistance.
	Please check always the correct placement of batteries. Do not mix up batteries anode (+) and cathode (-).
	Please take out batteries in case device will not be in use for more than 3 months. Please replace with new batteries when the old ones expire.
	In case battery liquid sticks on your clothes or contacts your skin, please wipe it off with dry cloth, rinse the affected area with soap and rinse with large amount of fresh water.

Thermal Sensitive Printer Precautions

 Caution	Do not disassemble, repair or modify the printer or its accessories.
	Please use designated accessories and printing paper (Thermal sensitive paper of 384 spots with width of 58 mm, and effective printing width of 48 mm) for the printer.
	Please connect the mains charger to AC 100-240 V power supply.
	Avoid any damaging, processing, heating, bending with force, pulling, twisting or pressing, etc. or lay heavy objects on the RS232 connecting cable and power cable.
	Do not use damaged power cable or plug or RS232 connecting cable.
	When disconnecting the device from power supply, pull off the power plug with hand on it and do not pull the power cable.
	The note of measurements acquired from the printer can be kept for a month under normal conditions, but the storage time may be decreasing with change of storage conditions, such as intense lighting or high temperature.

Numerical keypad Precautions

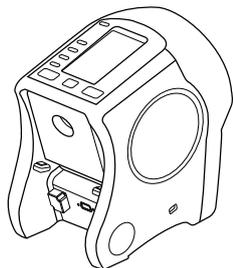
 Caution	Do not disassemble, repair or modify the keypad.
	Please only use designated numerical keypad for this device.
	Avoid any damaging, processing, heating, bending with force, pulling, twisting or pressing, etc. or lay heavy objects on the USB cable.

Preparation before Use

1 Packaging and Accessories

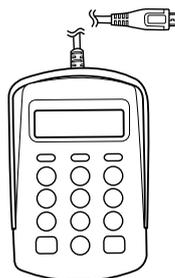
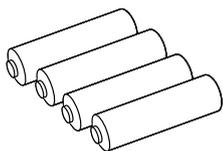
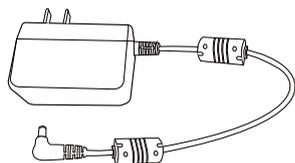
Open the box to check the product composition before use. If anything is missing or appears to be damaged, please contact your local supplier.

Main body



Non-invasive Vascular Screening Device **AVE-2000 Pro** (Non-detachable)

Accessories



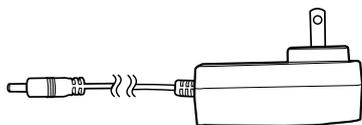
AC Adapter

AA Alkaline battery × 4

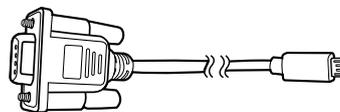
Numerical keypad

Thermal sensitive printer

- ※ Accessories can not be disassembled by yourself. After connecting main body and power supply, you can disconnect them and tidy them as an independent product.
- ※ The numerical keypad is an integrated design with a keypad and USB cable, 15 buttons and a LCD display screen.
- ※ The thermal sensitive printer in the accessories is the line thermal sensitive printer, it uses thermally sensitive paper with a width of 58 mm (Effective printing width of 48 mm), and there is a designated RS232 connecting cable and mains charger its box. Please refer to the instructions for its usage.



Dedicated power supply charger for thermal printer



Dedicated RS232 connection cable for thermal printer



Instruction for Use

Warranty card

3 Power Supply

The device supports two methods of power supply, alkaline batteries and connection to power supply with AC adapter.

3-1 Battery Insertion

1. **Locate the back of the device with battery cover in front of you** and take off the battery cover (Fig. ①, ②).
2. **Install** the batteries along the direction of anode (+) and cathode (-) marked in the battery chamber of the device.
3. Close battery cover (Fig. ③, ④).

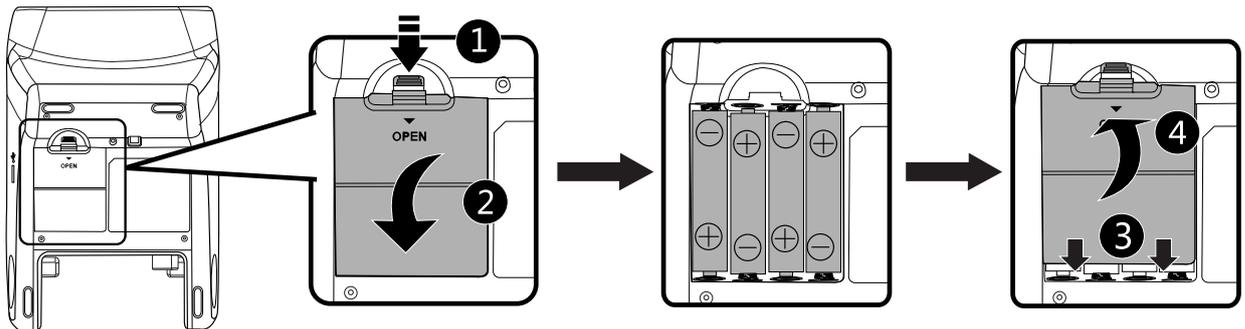


Fig. 3.1.1

- ※ **Even** when the AC adapter is used, it is recommended to also put in AA alkaline battery to avoid sudden power loss and affecting the measuring in the process.
- ※ Do not place the device in other directions (especially with display interface on the desk top) **while changing batteries**.
- ※ **The battery status is not shown on the display** when the power is sufficient (more than 30%).
 - ☐ represents the power of the batteries is **running out** (lower than 30%).
 - ☐ represents the power of the batteries has **run out**. Please replace the batteries.**The battery life depends on variety of factors. Please monitor the condition of the battery.**

3-2 Connection of AC Adapter

1. Fit the plug of AC adapter in the AC adapter port on the main body of the device (Fig. ①).
2. Fit the power plug of AC adapter in the socket of power supply (Fig. ②).

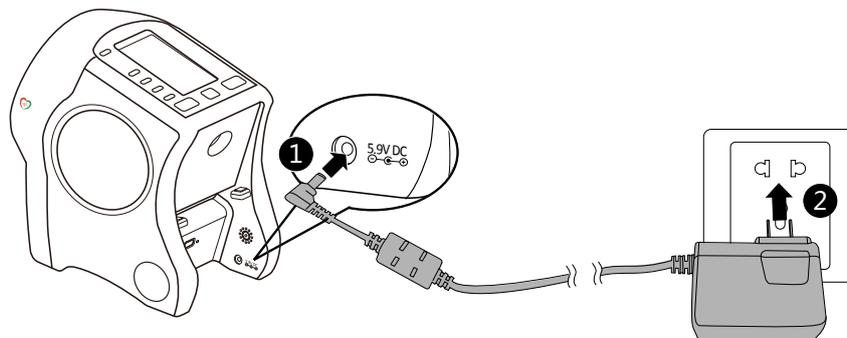


Fig. 3.2.1

- ※ **Only use the power supply delivered with the device. For replacement please contact your local service representative.**

Usage

<Pre-usage>

User preparation

No.	Content
1	The device is designed and validated for measurements on arm diameter of 19 to 32 cm. Arm diameter higher or lower than the range may lead to incorrect measurements.
2	Individuals should not eat, drink, smoke, exercise or take a bath/shower in 30 min before measuring.
3	Measurement should be done with emptied bladder.
4	Individuals should take off thick clothes, such as coat and sweater, etc. Thin clothes like shirts not disturbing the measurement. Expose the left upper arm for measurement. Do not compress the arm when rolling up the sleeve.
5	Individuals should rest statically for more than 10 min, and perform the measuring in a quiet and appropriate (Temperature 5 to 40°C, relative humidity not more than 80%) environment.
6	Please maintain both the body and mood in a peaceful state when performing the measuring.

Check List

Please check the following before performing the measuring.

	No.	Contents
Before turning on power supply	1	Ensure there is no damage or deformity, etc. on the device and its accessories.
	2	Ensure there is no moisture condensation on the device. If so, please dry it thoroughly first.
	3	Ensure the device is placed steadily with sufficient space around.
	4	Ensure there are no objects in the arm cylinder.
	5	Please connect the device to power supply as instructed in this manual, with the designated AC adapter or AA batteries.
	6	Ensure the device is correctly connected to the numerical keypad and printer.
After turning on power supply	1	Confirm there is no abnormal sound from the device.
	2	Ensure there is no smoke or unusual odor coming out from the device.
	3	Ensure there is no excessive heat in the device.
	4	Ensure the display of LCD screen on the device and numerical keypad is normal.
	5	Ensure the buttons on the device, numerical keypad and printer are normal.
	6	Ensure the emergency release button is in the pop-up status. For details see "handling of emergency situations in page 34.
	7	Ensure there is normal compression and air release in the cuff when pressing the  button.

1 How to Set Up Date and Time

At power-off state, press the (時間) button and (電源) button simultaneously to enter the date and time setup screen. While the indicator of the Year and Time is flashing, press the (▲) / (▼) buttons to adjust 「Year」 first, and then press the (設定/OK) button to save the setting.

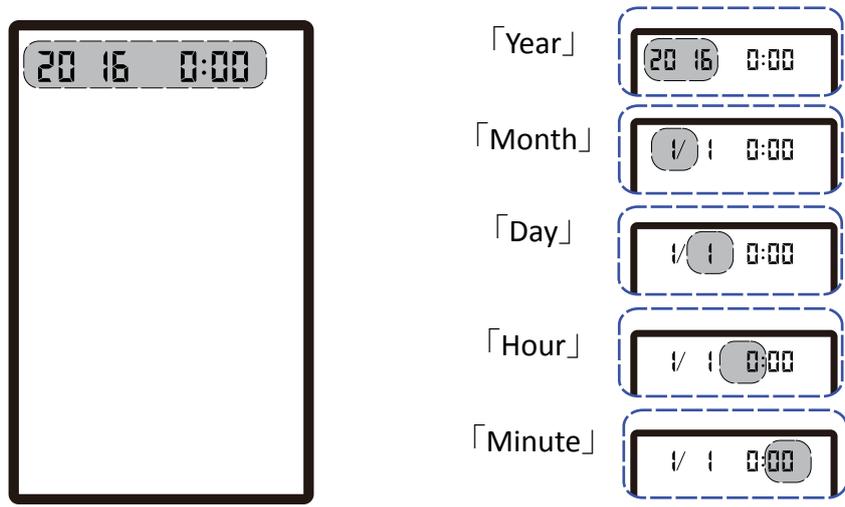


Fig. 1.1

Please sequentially set the 「Month」 / 「Date」 / 「Hour」 / 「Minute」 in the same way. After the settings are completed, return back to the age input screen (Standby screen).

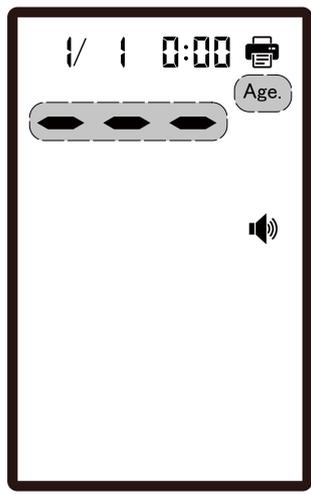


Fig. 1.2

- ※ Press the (電源) button of the device, its power indicator light will be on. The numerical keypad connected turns on automatically and lets out “beep” sound. Approximately 5 seconds later, the device lets out the prompt tone and enters the age input screen.
- ※ Please set up the date and time correctly before performing measuring. Incorrect date and time record may lead to deranged record of measurements and thus affect the correctness of the data of mean values of various items outputted from the device.

4 Measurement

1. Open the Elbow holder as shown below.

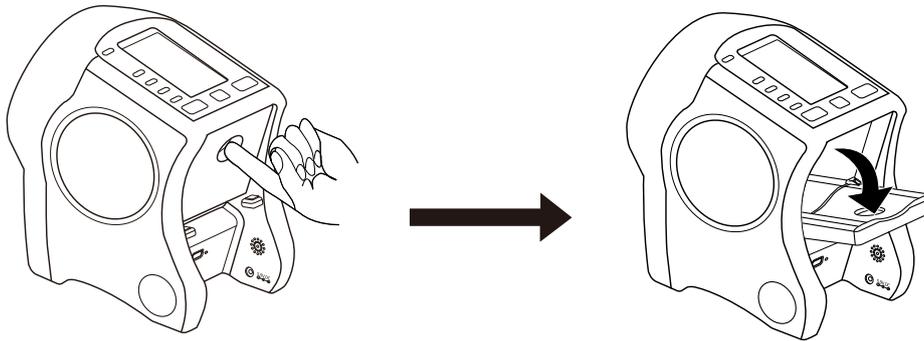


Fig. 4.1

2. Put the device on the center-left position near your body.

3. Relax, straighten your back, put your left hand through the arm cylinder, and place your elbow on the elbow holder with your palm facing up as shown below.

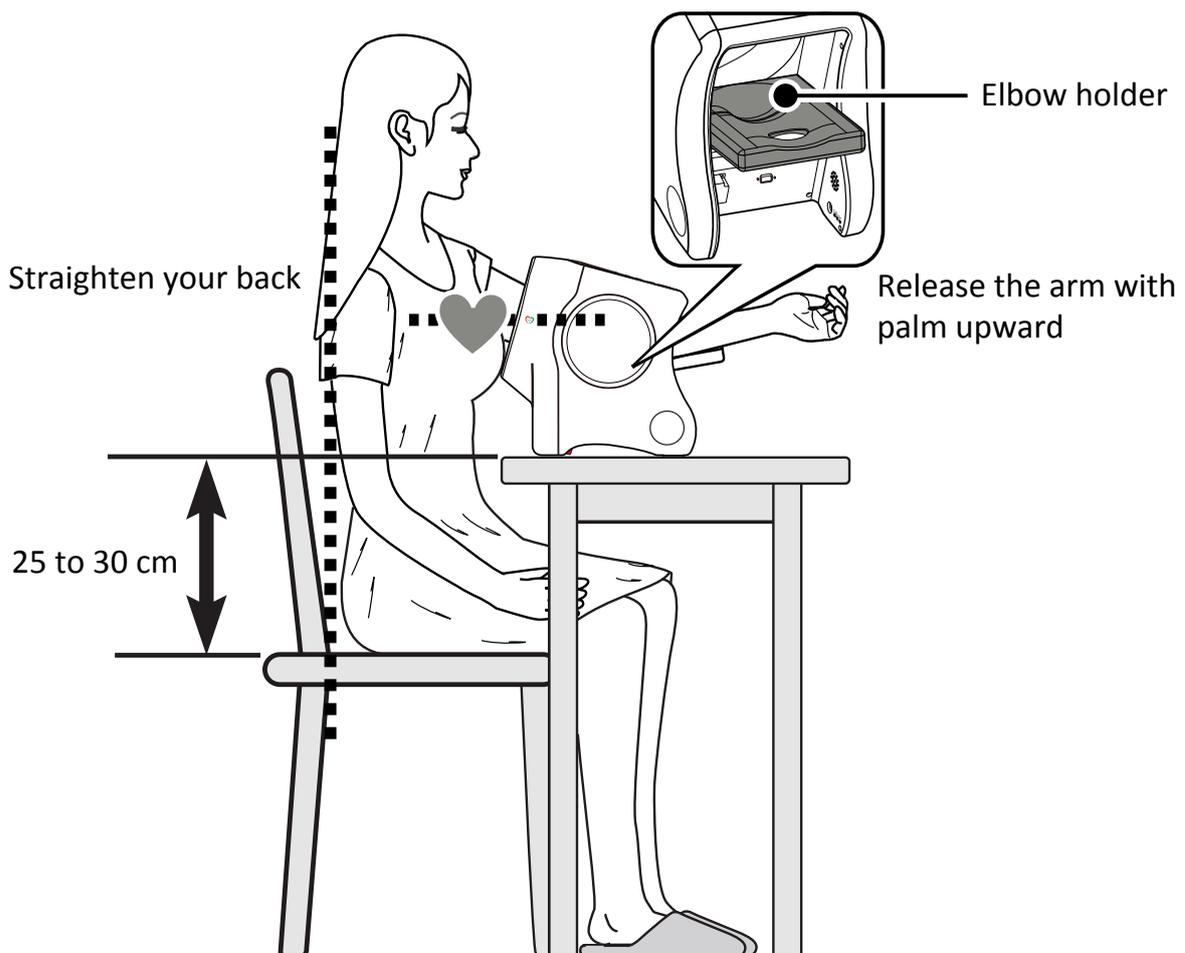


Fig. 4.2

※ The cuff cover, which installed on the arm cylinder of the main body if you have bought it, is designed for patients.

※ When measuring, please follow the instructions below:

- Relax your body and sit upright as much as possible. If you are nervous, take a deep breath.
- Keep your heart position in the same level as the heart symbol  on the arm cylinder.
Generally, the heart is in the thoracic cavity between the 2nd rib and the 5th rib of left chest bones from the body surface.
- The recommended height difference between the desk and chair is 25 to 30 cm. Please adjust the height of the desk or the chair to keep your heart position in the same level as the heart symbol  on the arm cylinder.

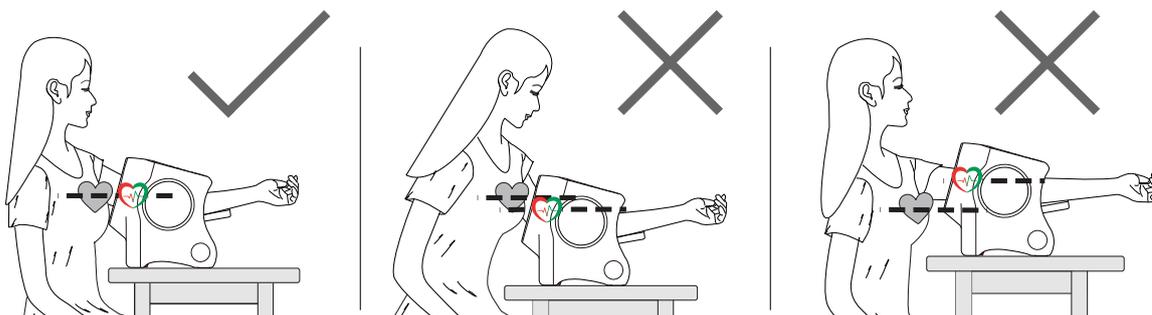


Fig. 4.3

- The distance between the device and the edge of the table, the body and the table edge is recommended to maintain about 2 cm each. The distance will be different as the height and weight of the user is different, anyway, please keep your back straight.

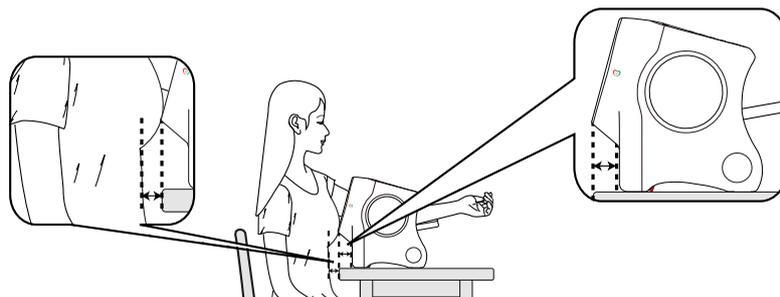


Fig. 4.4

- Do not speak, laugh, move or shake the body.

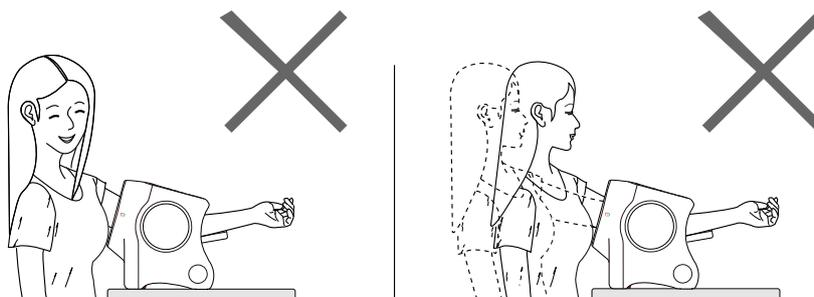


Fig. 4.5

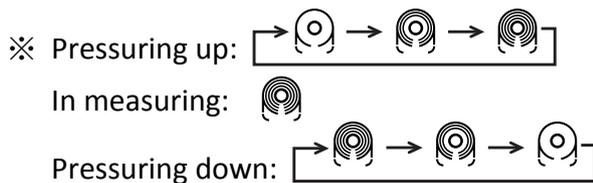
※ Incorrect posture when performing measuring (e.g., bowing, sitting on sofa or low desk with legs crossed, bending down, etc.) may lead to incorrect measurements.

4. Press the **開始/停止** button, and the cuff will pressure up automatically, and the icon of cuff pressure will **light up**. When the device picks up the pulse, the  icon will flicker.



Fig. 4.6

※ During the measurement, certain degree of numbness in the arm can normally occur. If you feel severe discomfort in your arm due to compression, please press the **緊急停止** button to stop the measuring. If there is poor blood circulation in finger tips due to arm compression, please raise your arm above your head, and then clench and unclench your palm repetitively for about 15 times to relieve the symptom.



※ In case you have an emergency, please press the **開始/停止** button or the **緊急停止** button to abort the measurement. After pressing the **緊急停止** button, and the power light will turn off sooner than the LCD screen does.

※ The measuring lasts for **nearly** 2 minutes. Please do not move your body or your arms during the process.

5. When the measuring comes to an end, the device will **release** a prompt tone. Pull your arm out from the arm cylinder after the pressure release from the cuff ends, and it is the end of this measuring.

6. Check the measurements: this measurements will be shown on the LCD screen.

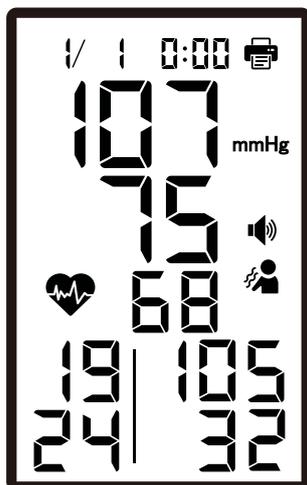


Fig. 4.7

※ If you have not input the age or the age is not in the valid range, the device is unable to provide CSBP or CAPP values. If the AVI or API picked up exceeded related range, the values will be not shown either.

7. If there is no operation after the measurements have been shown for 30 seconds, the device will return to the age input screen.

※ Do not disconnect the power supply or press the (電源) button to force the device to terminate in the measuring or data saving process.

※ For better comparison of measurement results, make measurements at the same time each day. If multiple measurements are required, please keep the interval over 10 minutes.

5 Measurements Checking

1. Press the (時間) button and (設定/OK) button simultaneously longer than 3 seconds on standby screen to enter data check screen, and then press the (▲) / (▼) button to switch between measurements.

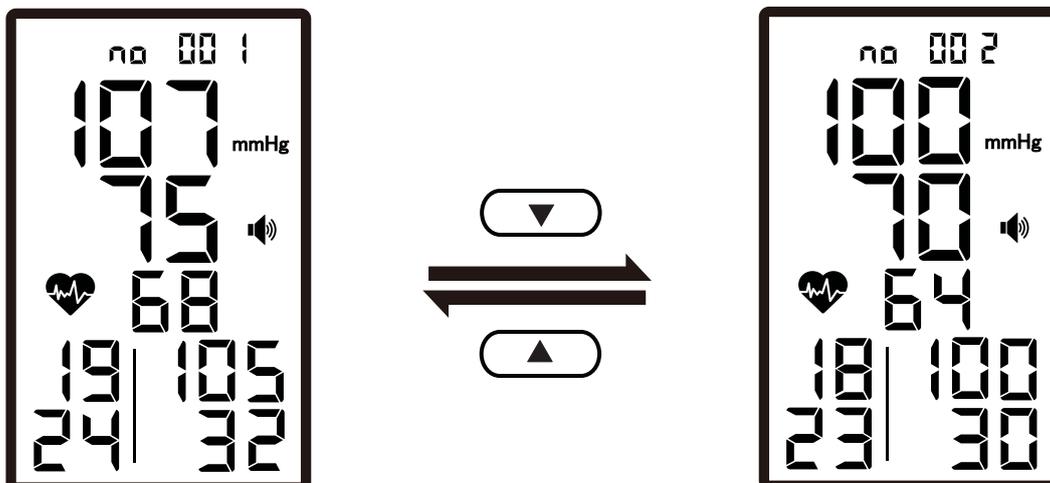


Fig. 5.1

2. After specific measurement number is selected, the measurement number, date and time, age will loop display.

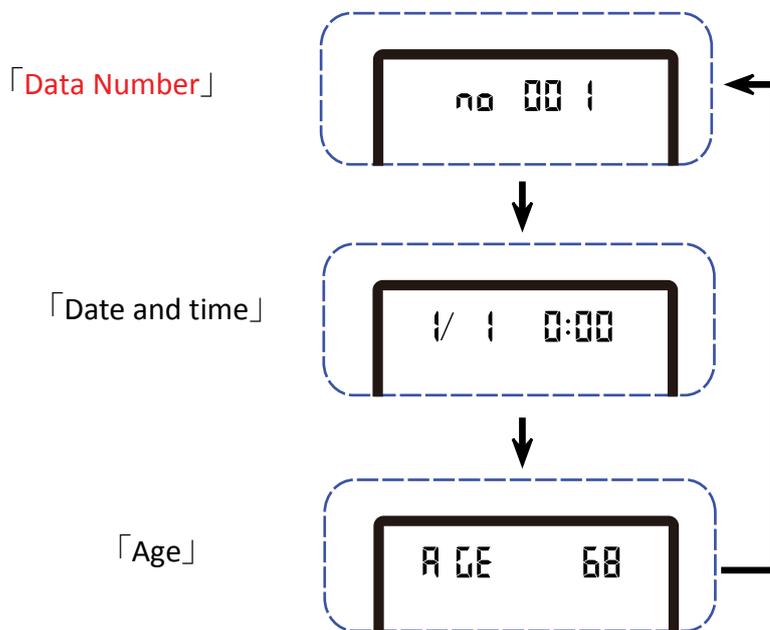


Fig. 5.2

3. The device will return to standby screen if there is no operation for 30 seconds.

6 Measurements Printing

1. Please first ensure proper thermal sensitive papers are put in the thermal sensitive printer, and the printer is correctly connected to the device and power supply.

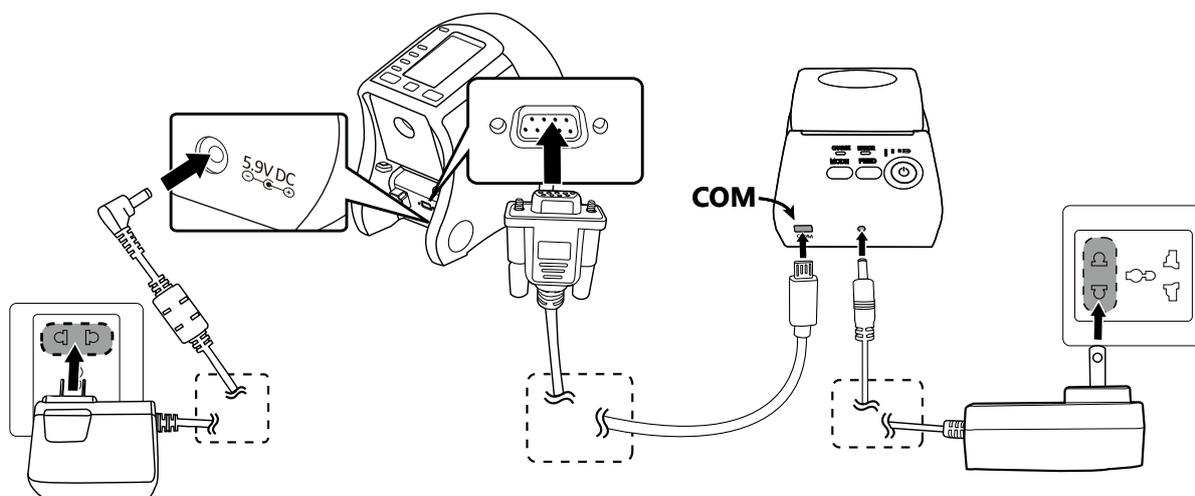


Fig. 6.1

※ Please refer to the instructions for use provided with the thermal sensitive printer for the methods of thermal sensitive printer installation and for operation by other people.

7 Measurements Analyzing

Systolic and Diastolic Blood Pressure

Blood pressure is subject to the influence of cardiac function, vascular tone, blood volume, nerves, body fluid, age, gender, season, climate and profession, etc.

Exercise, emotional stress and constipation may lead to an increase in blood pressure, whereas, longtime rest and deep sleep may lower blood pressure.

The increase of environment temperature, such as lukewarm bath, etc. may make diastolic pressure decrease, and the decrease of temperature, such as cold bath in winter, etc. may make systolic pressure increase.

The following tables are the reference value or range of blood pressure for adults:

Tab. 5.1 Definition and Classification of Blood Pressure Level for Adults

Type	SYS (mmHg)	DIA (mmHg)
Hypotension	≤100	≤60
Ideal blood pressure	<120	<80
Normal blood pressure	<130	<85
High-normal blood pressure	130 to 139	85 to 89
Borderline hypertension	140 to 149	90 to 94
Grade 1 hypertension (Mild)	140 to 159	90 to 99
Grade 2 hypertension (Moderate)	160 to 179	100 to 109
Grade 3 hypertension (Severe)	≥180	≥110
Isolated systolic hypertension	≥140	<90
Critical systolic hypertension	140 to 149	<90

Tab. 5.2 Reference of Mean Normal Blood Pressure of Chinese People

Age	Male		Female	
	SYS (mmHg)	DIA (mmHg)	SYS (mmHg)	DIA (mmHg)
16 to 20	115	73	110	70
21 to 25	115	73	110	71
26 to 30	115	75	112	73
31 to 35	117	76	114	74
36 to 40	120	80	116	77
41 to 45	124	81	122	78
46 to 50	128	82	128	79
51 to 55	134	84	134	80
56 to 60	137	84	139	82
61 to 65	148	86	145	83

Pulse Rate

Pulse rate is subject to the effect of many factors, such as age and gender.

Exercise and emotional stress can elevate pulse rate, while rest and sleep can drop the pulse rate down.

Normal range of pulse rate for healthy adults under normal resting conditions: 60 to 100 beats/ minutes.

AVI & API

AVI & API are subject to the effect of age, gender, cholesterol level, blood pressure as the well as the history of diabetes, smoking and exercise, etc. AVI may be reduced through regular exercise.

The usefulness of AVI and API have been proved by a number of clinical studies:

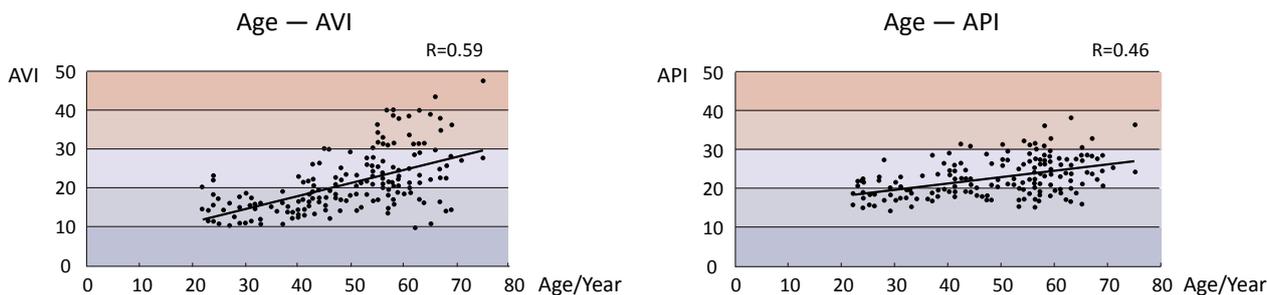


Fig. 7.1 Correlations between AVI, API and Age

AVI and API both increase with age. For a subject with a higher measurement of AVI or API, her/his risk of cardiovascular disease may be higher.

Vascular Indexes of AVI and API Values for Ordinary Healthy People of Different Age Stages

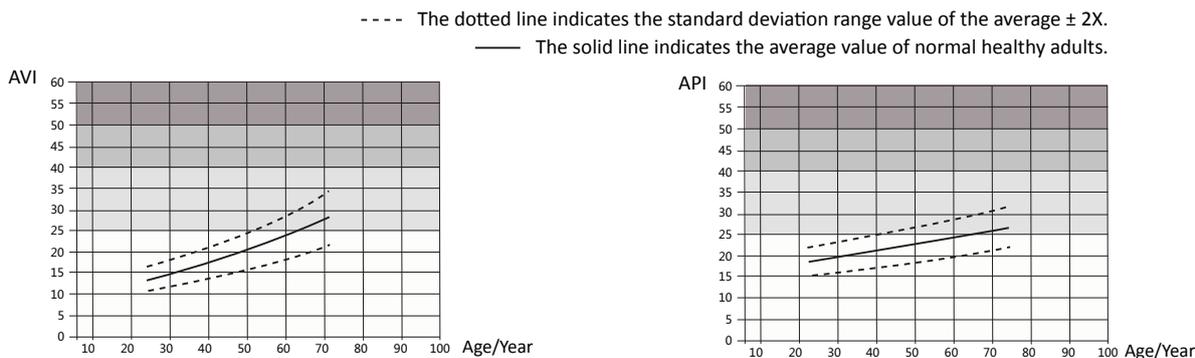


Fig. 7.2 Age-specific normal ranges of AVI and API

※ Whenever the result of AVI/API measurement exceeds the reference (normal) range, the screen display of AVI/API will flash.

References:

秋山義隆・久野裕輝・早川尚雅・重藤誠・榊澤政広・岡部正・松田昌文 (2010.7) 『2型糖尿病患者のオシロメトリック血圧測定による血管指標とFMD、IMTとの比較—オシロメトリック血圧測定血管指標の意義—』 [M]、Prog.Med.

CSBP (Estimated Value) & CAPP (Estimated Value)

CSBP (Estimated Value) rang is 19 to 300 mmHg (2.5 to 40 kPa), and its display resolution is 1mmHg (0.133kPa).

CAPP (Estimated Value) range is 1 to 180 mmHg (0.1 to 24 kPa), and its display resolution is 1mmHg (0.133kPa).

CSBP (estimated value) and CAPP (estimated value) are the items in the initial stage of clinical research. And these estimated values cannot be used as a basis for clinical diagnosis, they are just a reference for doctors.

8 Measuring Record Deleting

At power-off status, press the (設定/OK) button and (電源) button simultaneously to enter the setup screen, and then press the (時間) button and (設定/OK) button simultaneously **longer than 3 seconds** to delete all measurements.

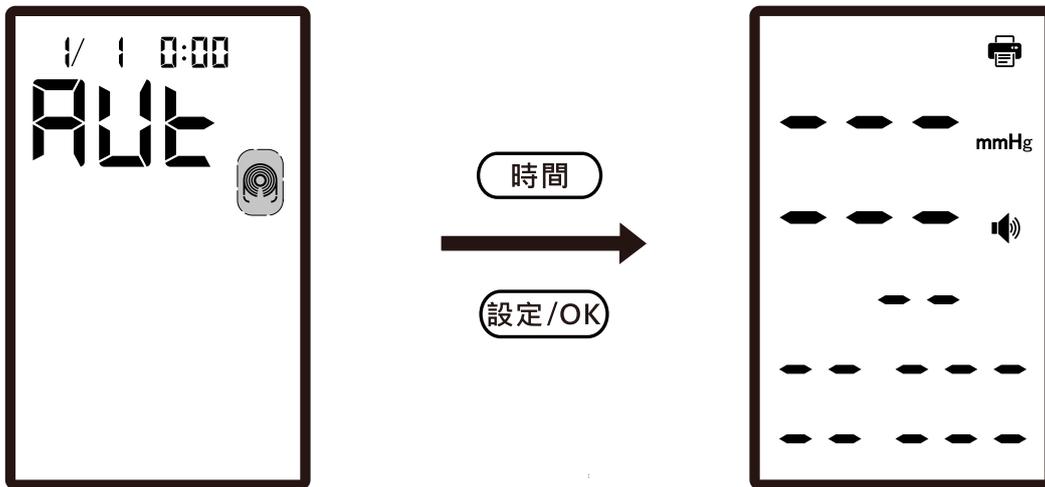


Fig. 8.1

9 Power Off

1. Press the (電源) button to turn off the device, the power light turns off, and then close the elbow holder. Press the (⏻) button on the thermal sensitive printer to turn off the printer.

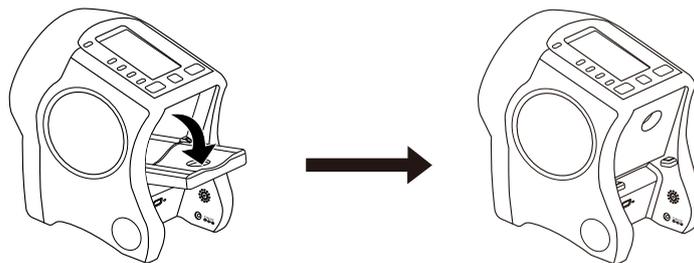


Fig. 9.1

2. Turn off the switch of the power supply socket, remove all accessories from the device and the power supply socket, such as the AC adapter, numerical keypad, thermal sensitive printer and mains charger, etc.

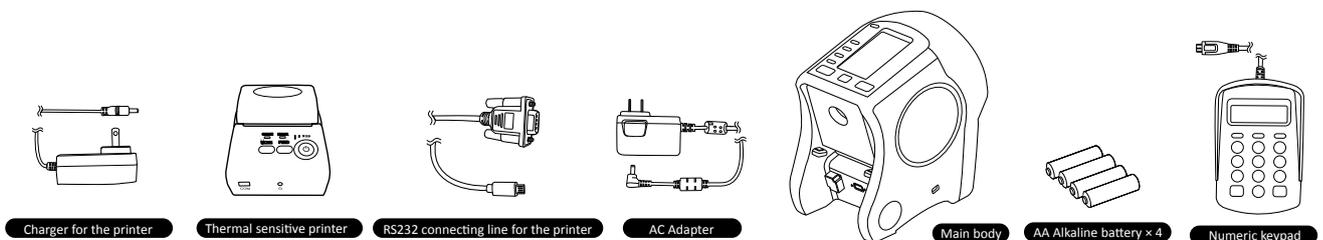


Fig. 9.2

Appendix

1 Specifications

Tab. 1.1 Specifications 1

Product Model	AVE-2000 Pro
Product Name	Non-invasive Vascular Screening Device
Application Scope	It is applicable for measuring blood pressure, Arterial Velocity Pulse Index (AVI), Arterial Pressure Volume Index (API), Central Systolic Blood Pressure (CSBP, estimated value) and Central Aortic Pulse Pressure (CAPP, estimated value). The values are only for diagnostic reference.
Medical Instrument Registration No.	Guangdong mechanical note 20182210170
Production Certificate	Medical Device Manufacturing Permit from Guangdong Food and Drug Administration No. 20162890
Product Technical Requirement No.	Guangdong mechanical note 20182210170
Category of Electric Shock Protection	II
Grade of Electric Shock Protection	B
Measuring Method	Oscillographic determination method
Pressuring Up	Intelligent automatic pressuring method of force pump
Pressure Releasing	Electromagnetic valve controller automatic pressure releasing method
Air Releasing	Electromagnetic valve controller quick air-releasing method
Pressure Detection	Diffuse-type semiconductor pressure sensor
Detecting Position	Upper arm
Perimeter of Arm Measured	Approx. 19 cm to 32 cm
LCD Display Screen	55 × 90 mm TN Type
Age Input Range	0 to 200
Measuring Range	Pressure range: 0 to 280 mmHg (0 to 37.3 kPa) Pulse rate range: 30 to 199 bpm AVI / API ranges: 5 to 60 CSBP (Estimated Value) range: 19 to 300 mmHg (2.5 to 40 kPa) CAPP (Estimated Value) range: 1 to 180 mmHg (0.1 to 24 kPa)
Measuring Accuracy	Pressure: ±3 mmHg (0.4 kPa) Pulse rate: ±1 bpm AVI / API: ±3 CSBP (Estimated Value) : ±5 mmHg (0.67 kPa) CAPP (Estimated Value) : ±5 mmHg (0.67 kPa)

Tab. 1.2 Specification Sheet 2

Tone Reminding	Yes	
Retention Time of the Set Clock	40 days	
Memory Function	400 cycle	
Printing Function	Yes	
Languages Support	Simplified Chinese, Traditional Chinese	
Port	DCIN Jack, Micro USB, RS232	
Communication Function	USB Communication	Yes (Numerical keypad)
	RS232 Communication	Yes (Thermal sensitive printer)
Power Supply	AC Adapter	Input: AC100-240 V 50-60 HZ Output: DC5.9 V/1.5 A
	Batteries	AA Alkaline battery × 4
Operating Environment	+5 °C to +40 °C, 15% RH to 80% RH, 80 kPa to 105 kPa	
Environmental Conditions of Transport and Storage	-20 °C to +55 °C, 40% RH to 93% RH, 80 kPa to 105 kPa	
Out Dimension	Approx. 180 x 266 x 260 mm	
Weigh of Main Body	Approx. 2.6 kg (W/O batteries)	
Composition	Main body / AC Adapter / Thermal sensitive printer / Numerical keypad	
Accessories	AC Adapter / AA Alkaline battery × 4 / Thermal sensitive printer / Numerical keypad / User manual / Warranty card	
Fuse Type	F0603CP2500V032T (2.5A)	
Standard of Performance Requirements	YY 0670-2008	
Safety Standard	GB 9706.1-2007	
EMC Standard	YY 0505-2012	
Biological Assessment of Medical Device	GB/T 16886.1, 5, 10-2011	
Symbols, Marks and Information Icons for Medical Device	YY 0466.1-2009	
Environmental Requirements and Test Methods for Medical Electrical Equipment	GB/T 14710-2009	
<i>Provisions on the Management of Instructions and Labels of Medical Devices</i>		
State Food and Drug Administration Decree Provision No.6		
Product Life	3 years	
Manufacturing Date	See product label for details	
Date of publish	2017.02.27	

2 Error Codes

When there is error in the device, the LCD screen will display a corresponding error code. In case of continuous occurrence of the same undesirable phenomenon, please restart the device for another confirmation.

Tab. 2.1 Error Code 1

Error Code	Cause	Solution
Err 1	Increase of pressure exceeds 285 mmHg due to motion of arms or body, etc. in the measuring process.	<p>Turn off the power supply and restart it, Err will be lifted.</p> <p>Further, check your instruction for use to ensure your re measurement with correct operation and posture.</p> <p>After starting the measurement, do not move the arm to be measured and keep quiet.</p> <p>If Err appears again, please contact your local service representative.</p>
Err 2	Measurement can not be completed even if it exceeds 3 minutes from the start of the measurement.	
Err 4		
Err 5	Pressure is unstable at the beginning of the measurement.	
Err 6	Pressure rise is not completed.	
Err 7	Cuff pressure suddenly dropped during pressurization.	
Err 8	Cuff pressure suddenly increased during pressurization.	
Err 10	The cuff pressure can not be reduced during the measurement.	
Err 11	Cuff pressure suddenly decreased during decompression.	
Err 12	Arm or body motion, etc. in the measuring process.	
Err 13	The phenomenon of stopping pressure occurs 3 times in a row.	
Err 14	The pressure drop sharply after completion of pressurization.	
---	Failure of calculation of the measurements.	

Tab. 2.2 Error Code 2

Error Code	Cause	Solution
E 101	It is displayed when there is an abnormality in the measurement relation at the device startup.	Press the  button to restart the device.
E 102		
E 103	It is displayed when there is a function error.	
E 104		
E 105		
E 106		
E 107		
E 108	It is displayed when there is an abnormality in printer USB cable.	
E 111	It is displayed when there is an abnormality in printer.	
E 112	It is displayed when winding operation is abnormal.	
E 113		
E 114		
E 115	It is displayed when there is a function error.	
E 116	It is displayed when there is an abnormality in emergency exhaust function after measurement is completed.	Press the emergency release button to reduce the pressure (See “Handling of Emergency Situations” in page 34 in the user manual for details).
E 118	It is displayed when there is an abnormality in the USB cable (keypad) power supply.	Press the  button to restart the device.
E 119	It is displayed when there is an abnormality in the printer communication.	Press the  button to restart the device.

3 Troubleshooting

Tab. 3.1 Troubleshooting

Abnormalities	Cause	Solution
Sudden power lost in pressuring-up process	Battery exhausted due to no usage.	Replace with new batteries (See “Battery Insertion” in page 12 of the user manual for details).
	Poor contact between the AC adapter, device and power supply.	Re-connect to the power supply (See “Connection of AC Adapter” in page 12 of the user manual for details).
	Press the  button by mistake.	Press the  button to restart the device.
No display on the LCD screen of the device after pressing the  button.	No batteries in the device.	Insert batteries (See “Battery Insertion” in page 12 of the user manual for details).
	Poor contact between the AC adapter, device and power supply.	Re-connect to the power supply (See “Connection of AC Adapter” in page 12 of the user manual for details).
	Battery exhausted.	Replace with new batteries (See “Battery Insertion” in page 12 of the user manual for details).
	Reverse anode and cathode of batteries.	Re-insert the batteries correctly (See “Battery Insertion” in page 12 of the user manual for details).
The measured values are abnormally low or high.	Incorrect use of the arm cylinder.	Use the arm cylinder correctly.
	Talking or arm motion in the measuring.	Perform the measuring under static state.
	Talking or arm motion in the measuring.	Take another measuring after taking off the clothes that compressed the arm (See “Measurement” in page 19 of the user manual for details).
	Cuff damage of the arm cylinder.	Terminate the measuring and contact the customer service.
Non-pressurized	Air leakage from the arm cylinder.	Contact your local supplier .
The date/time is flickering after setting the clock, and turning on the power.	The time retention period is overdue.	Re-set the date and time (See “How to Set Up Date and Time” in page 15 of the user manual for details).
	The internal lithium battery exhausted.	Change a new lithium battery from a point of sale or a maintenance point designated by the company and replace the old one.
Other faults		Press the  button to re-operate the device. Restart the device after battery replacement. Please contact your local supplier if the fault cannot be resolved after taking above measures.

4 Solutions for Emergencies

In case the arm is locked in the device because of sudden power loss, please press the red emergency release button at the bottom of the device.

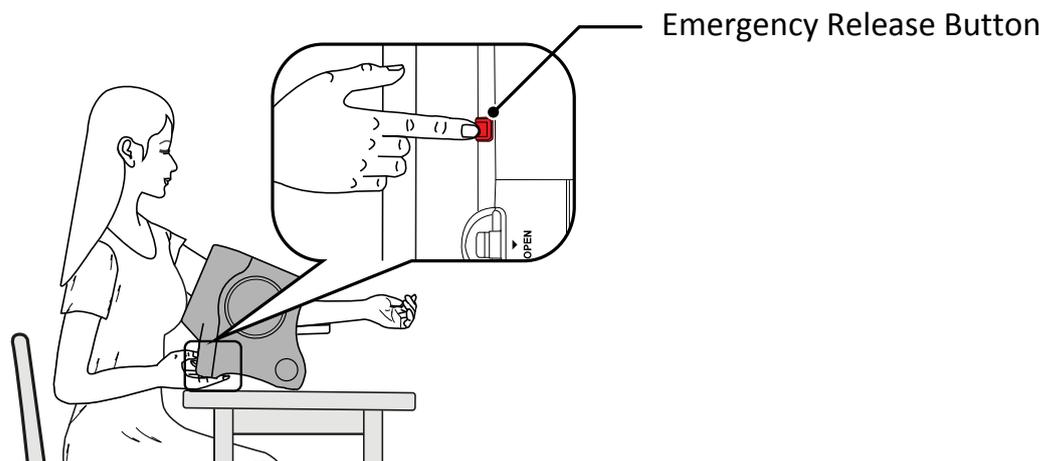


Fig. 4.1

※ Do not press this button without emergencies.

After taking out your arm, press the  button to restart the device, and the internal components will reset, and the emergency release button will spring up to return to the reset state.

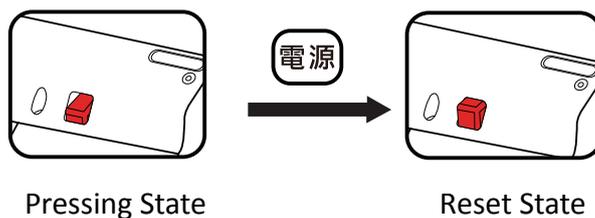


Fig. 4.2

※ If the emergency release button is unable to return to reset state after pressing the  button, please contact **your local supplier**.

5 Safety Management

Cleaning, Maintenance and Safekeeping

In order to ensure the safety and effectiveness of the device conform to the requirements, the device and related accessories must be **cleaned, maintained and properly kept**.

Suggestions on maintenance:

Regularly clean the device and related accessories. Generally once **a month**, and the frequency is subject to adjustment according to the actual smudge status of the device. **It is recommended that you clean it before each use.**

Notes on cleaning:

- Turn off the power, and remove the AC adapter and other accessories from the socket of power supply.
 - Do not spray water to the device or its accessories and do not let them soak in water.
 - Do not spill any disinfectant, like hypochlorous acid, peracetic acid, etc., or use an autoclave or gas, such as EOG, high-concentration ozone, formaldehyde gas, on the device, which may damage the device.
 - Clean the smudges with a dry and soft cloth which on the shell of the device or its accessories, like AC adapter, numeric keypad, thermal printer, etc. Do not use corrosive, ethanol or organic solvent containing cleanser to clean them.
 - Dilute a neutral cleanser with water, and clean the smudges on the LCD screen with a soft cloth containing small amount of the cleanser solution.
 - Clean the smudges on the cuff with a soft cloth with ethanol for disinfection (Concentration of 75%) (Dip the cloth in the ethanol first and then take it out and squeeze the remaining ethanol out).
- ※ If the cuff is accidentally contaminated with blood, please contact our customer service to replace the new cuff to minimize the possibility of risking of infectious diseases.

Suggestions on safekeeping:

After use, please turn off the power. In case of long-term, more than 3 month no use, remove the accessories such as AC adapter, numerical keypad and thermal sensitive printer form the device first, and remove them form the socket of power supply, and put them in the packing box.

Keep them in a dry, appropriate (Temperature: - 20 -+55 °C, relative humidity: 40 - 93%) and clean environment, not in the following places:

- Easy to splash
- High temperature, humidity, direct sunlight, dust and salt
- Tilts, easy to produce vibrations and strikes
- Chemicals stored or corrosive gases released

Regular Examination

In case of reuse of the device after long-term storage, ensure the device is in normal and safe working conditions before reuse. Please regularly check the following items to ensure safe and correct use of the device.

Tab. 5.1 Regular Check Items

	Items	Content
Before turning on the power	Appearance	No smudge, rust, deformity, damage, looseness, distortion and dampness.
	Buttons	No damage or looseness. Emergency release button is in the pop-up reset state. You can press this button to release your arm in case your arm is locked in the device because of sudden power loss.
	LCD Screen	No smudges or damage of the LCD external cover.
	Connection of power supply	No damage of the AC adapter and power cable. No heavy object hanging from the AC power cable. The AC adapter plug is correctly fit in the device. The AC adapter plug is correctly fit in the socket.
	Numerical keypad	No deformity, damage or looseness.
	Thermal sensitive printer	No deformity, damage or looseness. No deformity or damage in the supporting mains charger or RS232 connecting cable.
	Cuff	There is no smudging, deformity, damage, looseness or distortion.
After turning on the power	Appearance	No smoke or abnormal odor. No abnormal sound or heat.
	Buttons	Button pressing is normal.
	LCD Screen	Display of measuring screen is normal.
	Measuring	All connectors are correctly connected.
	Pressure	Cuff pressuring-up and air release are normal.
	Date/Time	Setup of date and time are normal.

Calibration

Do not attempt to calibrate the device by yourself.

Calibration should be performed only by authorized service only. If you need this service, please contact your local supplier.

※ If the device is used for 300,000 times, the LCD screen will flicker automatically (About 5 seconds). Please contact **your local supplier** to return the device to the factory for **recalibration**.

Repair

Do not test or repair the device by yourself. Repair should be done only by customer service personnel authorized by the manufacturer.

Disposal

Please dispose of and recover the device under the direction of the local environmental protection authority based on environmental protection principles.

※ After the use period of the product of 3 years expires, it should be returned to the factory for performance testing, and it can be used further if all indexes are to the standard; the company will not assume responsibilities for further use without performance testing.

Scope of Warranty

The warranty is only applicable for the customers and users in Mainland China (including Hong Kong and Macao).

1. In case of the occurrence of a fault during normal usage as per the user manual, the 2-year warranty since the purchasing date can be obtained, and the warranty card and purchase invoice are needed to enjoy complete warranty right.
2. The product has three guarantees (repair, replacement or compensating of faulty products), but only limited to products purchased in Mainland China (including Hong Kong and Macao).
3. In warranty period, maintenance cost will be collected for following repairs:
 - 3.1 Damage caused by operation and maintenance not in accordance with the requirements in the user manual.
 - 3.2 Damage caused by falling, water penetration or improper storage after purchase.
 - 3.3 Person damage caused by battery leakage, body bending, display screen breakage or keypad deformity.
 - 3.4 Failure or damage caused by repairs or modifications in the maintenance station that not designated by our company.
 - 3.5 Regular examination, maintenance or regular part/component replacement (Cuff or extended air soft tube, etc.) caused by regular torn.
 - 3.6 The date of purchase, commodity type or manufacturing code on the warranty card is altered, torn up or unrecognizable.
 - 3.7 Damage caused by majeure of natural disaster.
 - 3.8 Damage caused by external factors such as abnormal voltage, etc.
4. No compensation will be made for the release, deletion or alteration of audio/video data caused by device fault or in maintenance or battery replacement.
5. The accessories, software or consumables (Power supply adapter and cables, etc.) provided with the product are not in the scope of warranty.
6. Please properly keep the warranty card, and it is not reissued if it is missing.

Product Consultation and Customer Service Contact Window

Registrant/manufacturer: SHENZHEN SINTAI OPTICAL CO., LTD.

Registrant/address of manufacturer: 1st, 2st, 3st Bldg, Qiwei Ind Sec, Lisonglang Village, Gongming Town, Bao'an District, Shenzhen, Guangdong, China

Free Service Phone: (852) 3575 9513; **E-MAIL:** info@winhorizon.com.hk

Production Certificate: 20162890

Dealer: WINHORIZON LTD.

Unit 1202, 12/F, No.29 Austin Road, Tsimshatsui, Kowloon, Hong Kong

Service Time: Monday to Friday (except legal holidays)
09:00 a.m. to 12:00 p.m.; 1:00 p.m. to 6:00 p.m.

Website: www.winhorizon.com.hk
www.pasesa.com.hk