ACCUNIQ

User Manual BP500

English. 06/2021. V3.02

selvas Healthcare

CE 0197

The device bears the CE label in accordance with the provisions of Medical Device Directive 93/42/EEC.

THE PERSONS RESPONSIBLE FOR PLACING DEVICES ON THE EC MARKET UNDER MDD 93/42/EEC

SELVAS Healthcare, Inc.
155, Sinseong-ro, Yuseong-gu, Daejeon, 34109 Republic of Korea
TEL: 82-42-879-3000, FAX: 82-42-864-4462

EC REP

Obelis s.a.
Bd. Général Wahis, 53, B-1030, Brussels, Belgium

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

CONTENTS

INTRODUCTION

We highly appreciate that you chose SELVAS Healthcare's product.

You are kindly requested to be familiar with these directions before using this product and always keep it together with the product. In case you are not sure about any directions or problems arising while using the product, please contact our service center.

We will provide you with detailed instructions.

INTENDED FOR PUBLIC USE

BP500 Automatic Blood Pressure Monitor is designed to measure systolic and diastolic blood pressure and pulse rate of Persons who are 18 years and older using the oscillometric method on a cuffed arm.

1) Target user: Persons who are 18 years and older

2) This medical device is not for home use

CONTRAINDICATIONS FOR USE

As with any non-invasive measurement device, there are clinical conditions which can influence the accuracy of the results. Also, the subject's position, physiological condition and other environmental factors can affect the measurement and/or calculation.

The BP500 Non-Invasive Blood Pressure Monitor should not be used with patients who have the following conditions:

1) PATIENTS with a known arrhythmia

2) PATIENTS with insufficient peripheral circulation, acute cases of low blood pressure or low temperature

3) PATIENTS experincing a seizure

4) Children younger than 18 years old

5) PATIENTS who should not have blood pressure measurements taken from their arms

6) PATIENTS with an artifical heart

7) PATIENTS whose artery cannot be found by palpation

WORD DEFINITIONS

To ensure safe operation and long term performance stability, it is essential that you fully understand the functions, operating and maintenance instructions by reading this manual before operating your unit.

Particular attention must be paid to all Notices, cautions and notes incorporated herein.

The following conventions are used throughout the manual to denote information of special emphasis.

Notice

Important information to indicate any possible hazard which can cause severe personal injury of death from substantial property damage when ignored.

Caution

Important information to indicate any possible hazard which will or can cause minor personal injury or property damage when ignored.

Note

Important information to notify to the user about installation, operation, or maintenance information which is important but not hazardous. Warnings against hazard are not to be included under the NOTE signal word.

CLASSIFICATION AND COMPLIANCE

1) This device is classified as;

- Class 1 type-BF against electric shock
- Ordinary equipment without protection against ingress of water
- Equipment not suitable for use in presence of a flammable anesthetic mixture by standard of EN 60601-1: 2006(Basic safety and essential performance of Medical Electrical Equipment)

2) This device is complied with Class A for Noise-Emission, Level B for Noise-immunity, by standard of IEC 60601-1-2:2007(Electromagnetic Compatibility Requirements).

3) This device is complies with the EN 1060-1: 1995+A2:2009 Non-invasive Sphygmomanometers general requirements as well as EN 1060-3: 1997+A2:2009 supplementary requirements for electro-mechanical blood pressure measuring systems.

SAFETY PRECAUTIONS

This device is designed and manufactured with consideration of safety of the operator and subject and also to the reliability of the unit.

The following precautions must be observed for additional safety;

1) The unit must be operated only by, or under supervision of a qualified person with SELVAS Healthcare or our distributors.

2) Medical Electrical Equipment.

- Do not touch or handle inner side of the system at any time.
- The INTERNAL ELECTRICAL POWER SOURCE is to be used if the integrity of the PROTECTIVE EARTH CONDUCTOR or the protective earthing system in the installation is in doubt.

3) Pressurization of the CUFF can temporarily cause loss of function of simultaneously used monitoring ME EQUIPMENT on the same limb;

4) Do not modify the unit. If any modification is needed, ask SELVAS Healthcare or its authorized dealer for service.

5) The unit has previously been adjusted in the factory for optimum performance.

- Do not attempt to adjust switches or any other things except those specified in this manual for operation.

6) Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

7) Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

8) If you have experienced any trouble with the unit, switch it off immediately, and contact SELVAS Healthcare or its authorized dealer for assistance.

9) If you plan to connect any device of other manufacturers electrically or mechanically to the unit, contact SELVAS Healthcare or its authorized dealer for instructions before doing so. When you connect computer or other system to the unit (RS-232C), the attached systems should be those certified by IEC 60950 or equivalent standards for data processing equipment. Configurations shall comply with the system standard IEC 60601-1:2005. Everybody who connects additional equipment to the signal input part or signal output part configures a medical system standard IEC 60601-1:2005. If in doubt, consult the A/S department of local distributor.

10) Avoid the following environments for storage;

- Where the ambient temperature falls -10°C or exceeds 60°C.
- Where the atmospheric pressure falls below 70kPa (700mbar) or exceeds 106kPa (1060mbar).
- Where the humidity is over 95% non-condensing.
- Where the unit is exposed to spray or splashing water.
- Where the unit is exposed to dust.
- Where the unit is exposed to water vapor.
- Where the unit is exposed to salty atmosphere.

- Where the unit is exposed to explosive gas.
- Where the unit is exposed to excessive shocks or vibrations.
- Where the angle of inclination of mounting surface exceeds 10 degrees.
- Where the unit is exposed to direct sunlight.

11) This equipment has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2:2007. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

12) Do not to touch signal input, signal output or other connectors, and the patient simultaneously.

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

14) No phthalates are used for this product and its container.

15) The cuff is not made with natural rubber latex

Caution

1. Measurements may be impaired if this device is used near televisions, microwave ovens, X-ray equipment or other devices with strong electrical fields. To prevent such interference, use the meter at a sufficient distance from such devices or turn them off.
2. Incorrect operation or failure of user to maintain the unit spares the manufacturer or his agent of the responsibility for system's non-compliance with specifications or responsibility for any damage or injury.

Caution

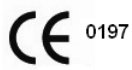
1. This manual is made for informational purpose and this manual and product are not meant to be a substitute for the advice provided by your own physician or other medical problem. You should not use the information contained in the product for diagnosis or treatment of health problem or prescription of medication by yourself.
2. If you have or suspect that you have a medical problem, consult with your physician promptly.
3. Defective unit or accessories must be packed in the replacement cartons to be shipped off from you to SELVAS Healthcare.
4. Shipping and insurance costs for return of defective unit must be prepaid by the users.

SAFETY SYMBOLS AND INFORMATION

The International Electro-technical Commission (IEC) has established a set of symbols for medical electrical equipment which classify a connection or Notice of any potential hazard.

The classifications and symbols are shown below. Save these instructions for your safety.

SYMBOL	INFORMATION
	Degree of protection against electric shock: TYPE BF
	Please observe operating instructions
	General warning sign
	General prohibition sign
	General mandatory action sign
	Caution
	Waste Electrical and Electronic Equipment (WEEE) The device could be sent back to the manufacturer for recycling or proper disposal after their useful lives. Alternatively the device shall be disposed in accordance with national laws after their useful lives.
	"OFF" (only for a part of equipment)

SYMBOL	INFORMATION
	"ON" (only for a part of equipment)
	This symbol is used inside system. Identifies the point where the safety ground of the system is fastened to the chassis.
	Do not open. This is for factory only.
	Alternating current
	Direct current
	Date of manufacture
	Manufacturer
	Non-ionizing radiation
	CE mark
	Serial No.
	Authorized representative in the European community.
	Keep dry
	This way up
	Fragile
	Use no hooks
	For indoor use only
	RoHS2
	Medical Device

Guidance for Electromagnetic compatibility (EMC)

Details about the electromagnetic compatibility (EMC) of the BP500 are given below. Before using the BP500, be sure to read and understand the following information.

Guidance and manufacturer's declaration – electromagnetic emissions

The BP500 is intended for use in the electromagnetic environment specified below. The customer or the user of the BP500 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The BP500 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 B	The BP500 is suitable for use in all establishments, including domestic establishments 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	

Guidance and manufacturer's declaration – electromagnetic immunity

The BP500 is intended for use in the electromagnetic environment specified below. The customer or the user of the BP500 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	±6kV: Contact ±8kV: Air	±6kV: Contact ±8kV: Air	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 transition/burst IEC 61000-4-4	±2kV: Power supply lines ±1kV: Input/output lines	±2kV: Power supply lines ±1kV: Input/output lines	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Surge IEC 61000-4-5	±1 kV differential mode 2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage drops, dips, and fluctuations of input power supply line IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BP500 requires continued operation during power mains interruptions, it is recommended that the BP500 be powered from an uninterruptible power supply or a battery.
Magnetic field of commercial frequency (50/60Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note

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

Guidance and manufacturer's declaration – electromagnetic immunity 2

The BP500 is intended for use in the electromagnetic environment specified below. The customer or the user of the BP500 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
Conducted RF IEC 61000-4-6 Radiated RF	3 Vrms 150 kHz to 80 MHz 3 V/m	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the BP500, including cables, than the recommended separation

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
IEC 61000-4-3	80 MHz to 2,5 GHz		distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d =1.2$\sqrt{P}$ d =1.2$\sqrt{P}$ 80 MHz to 900 MHz d =2.3$\sqrt{P}$ 900 MHz to 2,5 GHz 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

Caution

1. At 80 MHz and 900 MHz, the higher frequency range applies.
2. 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 BP500 is used exceeds the applicable RF compliance level above, the BP500 should be observed to verify

normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BP500.

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

Recommended separation distances between portable and mobile RF communications equipment and the BP500

The BP500 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BP500 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BP500 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 900 MHz $d = 1.2\sqrt{P}$	900 MHz to 2,5 GHz $d = 1.2\sqrt{P}$
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.

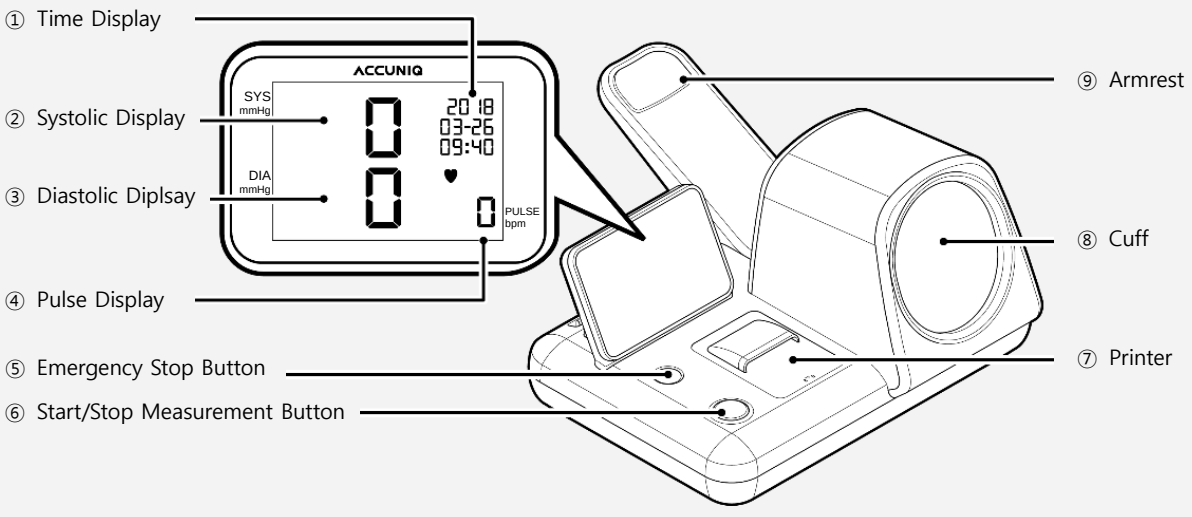
Caution

1. At 80 MHz and 900 MHz, the separation distance for the higher frequency range applies.
2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

FUNCTION

The front of the main unit

①	Time display	Displays the current date and time.
②	Systolic Pressure display	Displays measured systolic pressure.
③	Diastolic Pressure display	Displays measured diastolic pressure.
④	Pulse display	Displays the measured pulse.
⑤	Emergency stop button	If you press this button when you feel acute pain due to too high pressurization or the product runs abnormally, the cuff air will be expelled and the product will stop.
⑥	Start/Stop measurement button	If you press the button after you're ready for measurement, cuff pressurization will start automatically. If you press the button, measurement will stop and the cuff will return to its original state.
⑦	Printer	The printed paper is automatically ejected after measurement. You don't have to cut the paper when it comes out, an automatic cutter is installed inside the printer.
⑧	Cuff	Pressurize or expel air from the cuff during measurement.
⑨	Armrest	Fixes the position and posture of your arm when you put your arm inside the cuff.

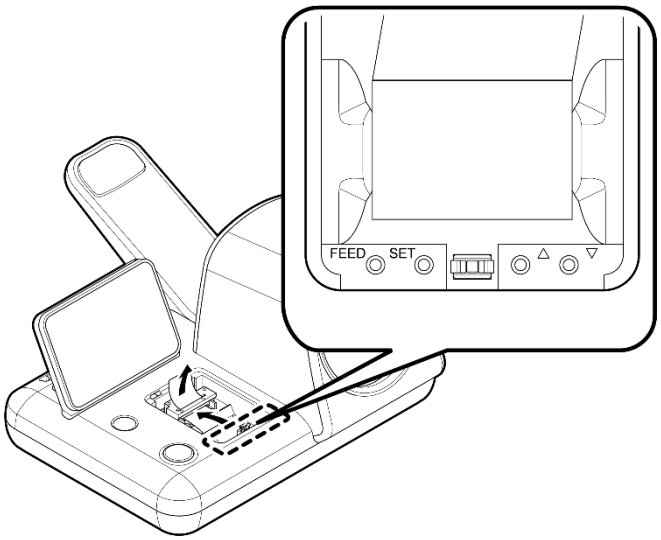


Printing Section

When you open the printer cover, you will see four buttons under the printer.

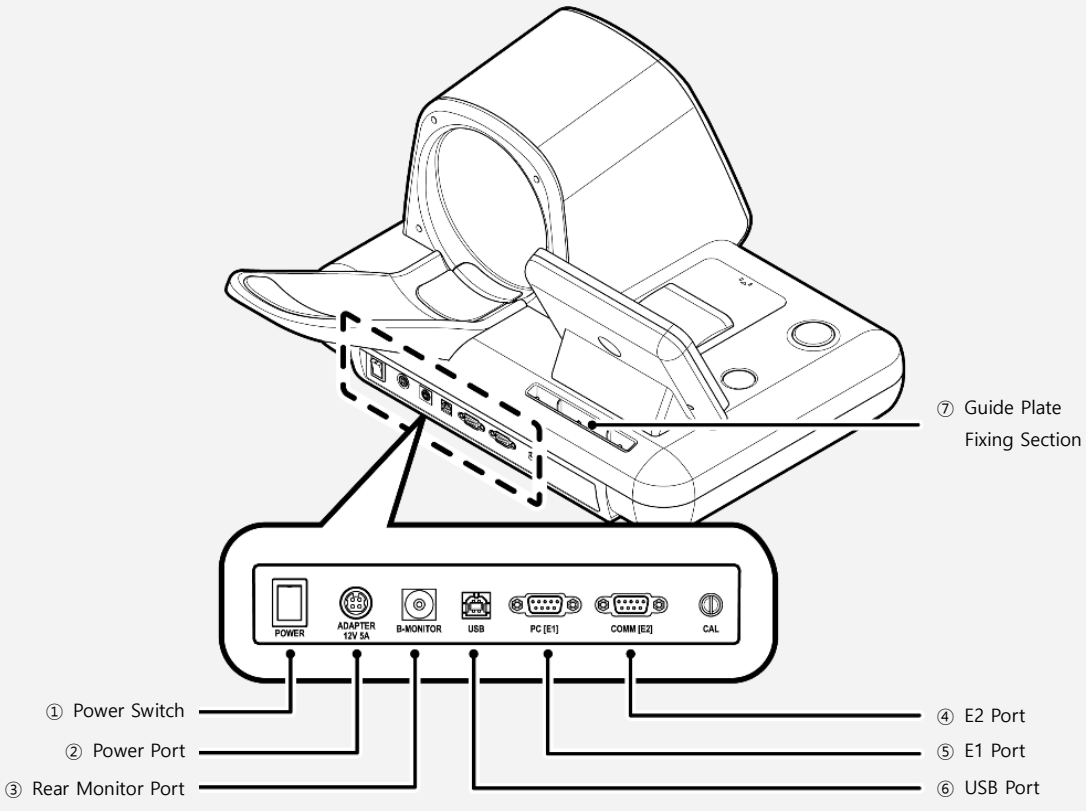
1) **[FEED]** button: If you press and hold the button, paper will be ejected and cut automatically.

2) **[SET]** button, **[▲(UP)]** button, **[▼(DOWN)]** button: These buttons are used to change the product settings. Refer to "How to set basic functions" on page 23 or "How to set additional functions" on page 27" for the detailed operation method.



Rear of the main unit

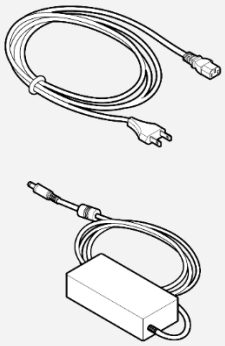
①	Power switch	Turns the power on/off.
②	Power port	Connect the adapter here.
③	Rear monitor port	Connect the dedicated cable for the rear monitor (optional) to the main unit here. If you input your ID, weight, and height when you use the rear monitor, you can check your systolic, diastolic, blood pressure measured value of the pulse, and body mass index (BMI).
④	Communication port No. 2 (E2)	Used to connect the main unit to a computer or other device using an RS-232C cable and transmits measurement data to the computer or other device. (Displayed as E2 on the settings screen.)
⑤	Communication port No. 1 (E1)	Used to connect the main unit to a computer or other device using an RS-2 32C cable and transmits measurement data to the computer or other device. (Displayed as E1 on the settings screen.)
⑥	USB port	Connect a USB cable here.
⑦	Guide plate fixing section	You can insert the product use guide plate here.



Accessories

User Manual

Power adapter and power cable



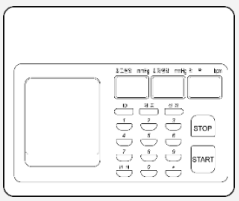
Measurement guide plate

Options

Dedicated cart and height adjustable chair

Thermal printer and thermal paper

Rear monitor

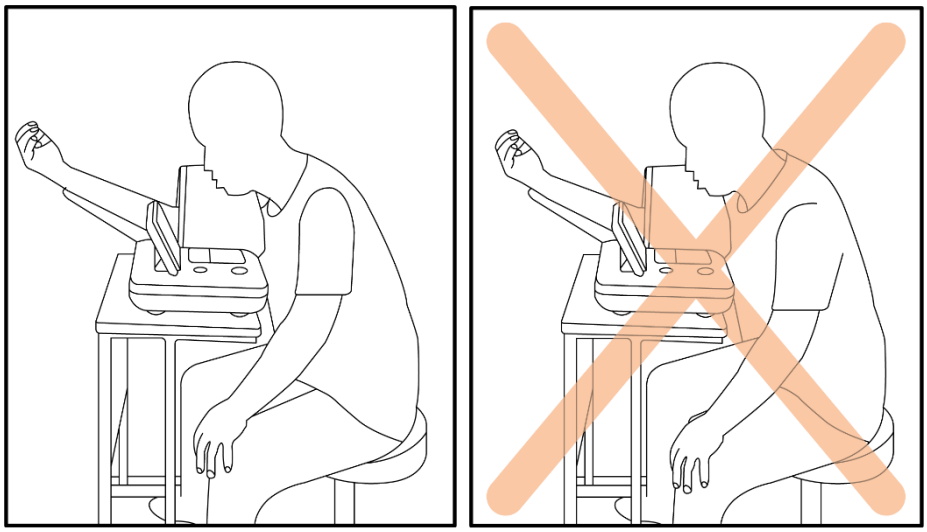


INSTALLATION

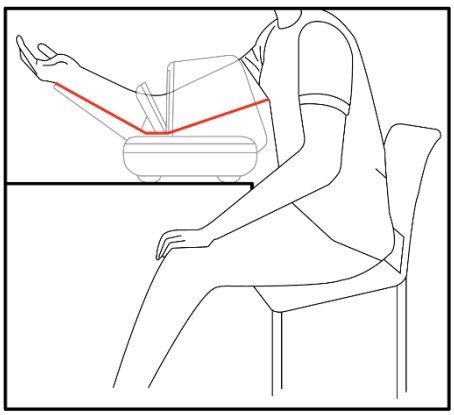
Installing on the Table

1) Install the device by pulling it to the end of the table so that user can measure blood pressure in the correct position.

2) Recommend that you use a chair or desk with adjustable height to allow measurements in the most comfortable postion.



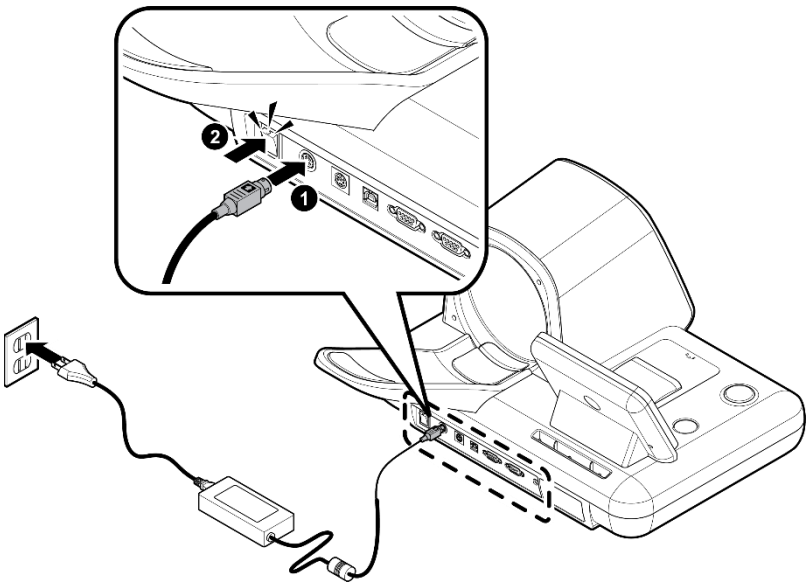
3) The device must be located so that the elbows an rest on the rubber botton of the armrest.



How to connect the power

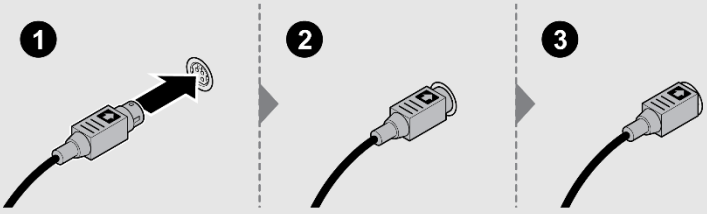
1) Connect the enclosed adapter to the power port installed on the rear side of the device.

2) Connect the power and turn on the Power switch on the left side of the input section.



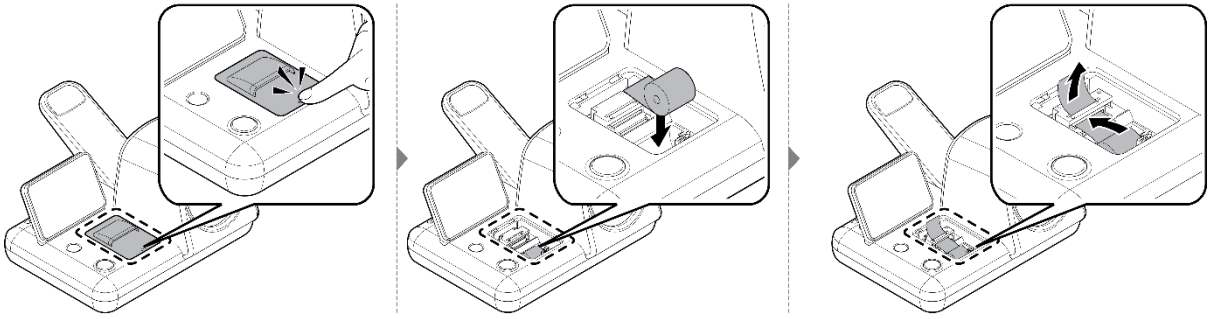
Caution

1. Make sure to use the enclosed adapter and cable to supply power to the device.
2. When connecting the adapter, connect it to the power input section on the back of the main unit accurately in such a way that the arrow on the adapter connection section faces upwards as shown in the figure below. If connected incorrectly, problems can arise in the product.



How to insert thermal paper

1) Check whether the device is turned on.
2) Press the bottom of the printer cover. The printer cover will move up. Open the cover at this time.
3) Place the printing paper in a proper position as shown in the figure.
4) If you insert the end of the paper deep under the black roll, it will automatically come out on the cutter.
5) Hold the paper with your hand and adjust it so that it is not slanting or shifting to one side.
6) Press the **[FEED]** button to cut the printer paper.
7) Close the printer cover.

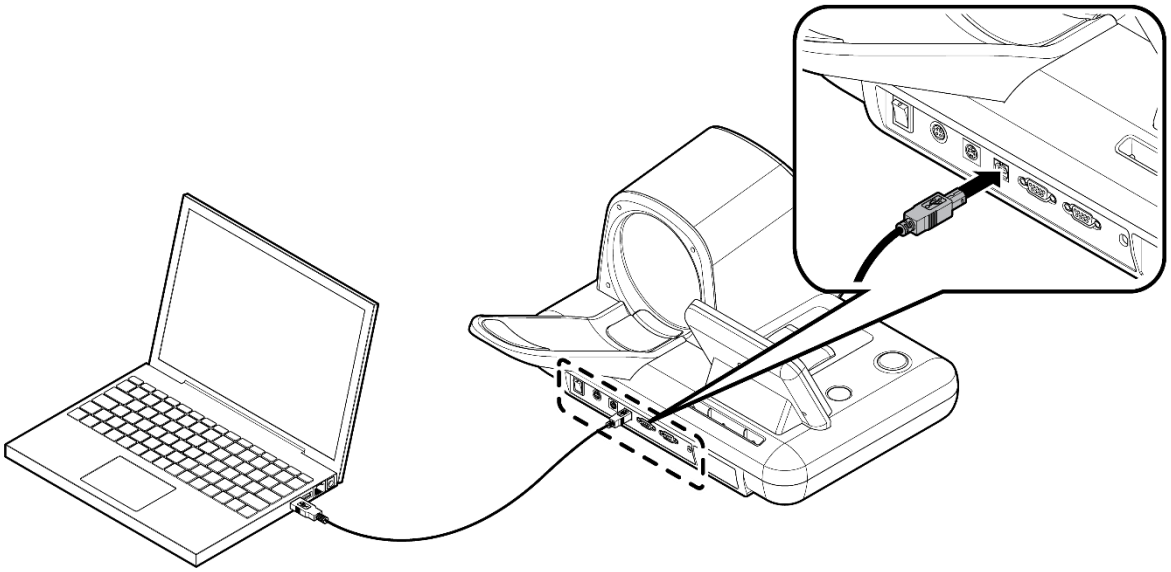


Note

1. As the printer paper is thermal paper, it prints on one side (smooth side) only and does not require ink.
2. Always check the residual quantity of printer paper and change it frequently.
3. If a red line appears on the right side of the printer paper, it must be replaced.
4. Exclusive printer paper sold by us should be used.
5. Printer paper should be kept in a well-ventilated, dark place.
6. Be careful not to get any foreign matter on the printer paper.
7. If you pull the paper during printing, the paper can become jammed.
8. If you don't insert the printer paper correctly, the paper may be pushed out or the printer may fail.
9. If you don't close the printer cover properly after replacing the paper, it may cause a paper jam during printing. Check the condition of the printer cover.

How to connect the communication port

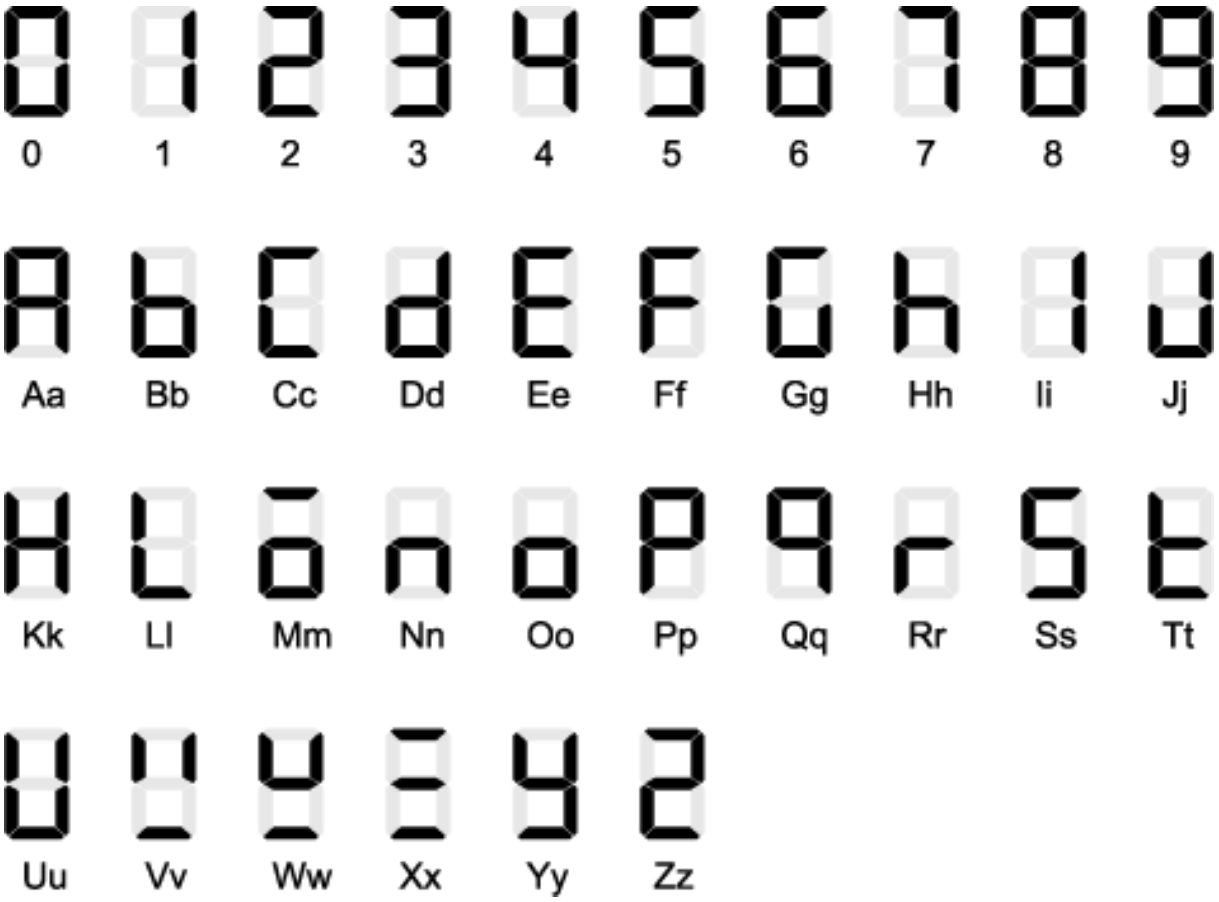
Connect the main unit and a computer or other device using a USB cable (optional) and transfer the measured data to the computer or other device. Connect a USB cable to the USB port at the rear side of the device and to the computer's communication port. (See the figure.)



How to set basic functions

There are two product setting methods — basic function setting mode and additional function setting mode. You can check the cumulative measurement count, set the date and time, set the thermal printer, and control the speaker volume in basic function setting mode.

- The following typography is used to display the function name and setting value during the function setting process.



How to enter basic function setting mode

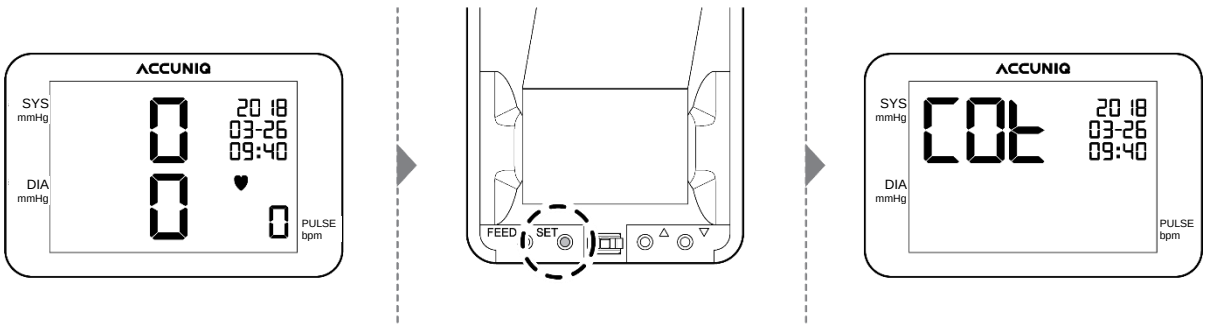
1) Press the printer cover to release the cover in measurement standby mode.

2) Press the **[SET]** button for 3 seconds to enter basic function setting mode.

3) When basic function setting mode is entered, the Cnt character is displayed and blinks in the Systolic Pressure display section.

4) If the CnT character is displayed, you have entered basic function setting mode successfully.

5) Press and hold the **[SET]** button for 3 seconds to return to measurement standby mode.



How to check the cumulative count

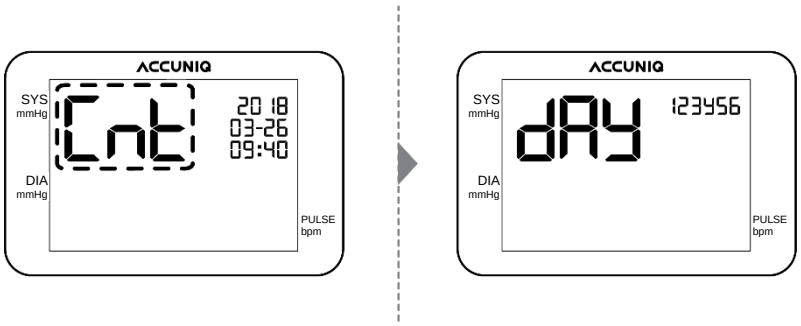
1) Enter basic function setting mode.

2) Press the **[SET]** button while CnT (cumulative count check mode) is blinking.

3) You can check dAy (daily cumulative measurement count), ALL (cumulative measurement count), and Prn (printer printing count) by pressing the **[▲(UP)]** or **[▼(DOWN)]** button after entering cumulative count check mode.

4) If a thermal printer is installed, you can print the measurement count and printing count by pressing the **[FEED]** button.

5) You can reset the daily cumulative data by pressing the **[▲(UP)]** + **[▼(DOWN)]** button at the same time for 3 seconds in dAy mode. ALL and Prn values cannot be initialized.



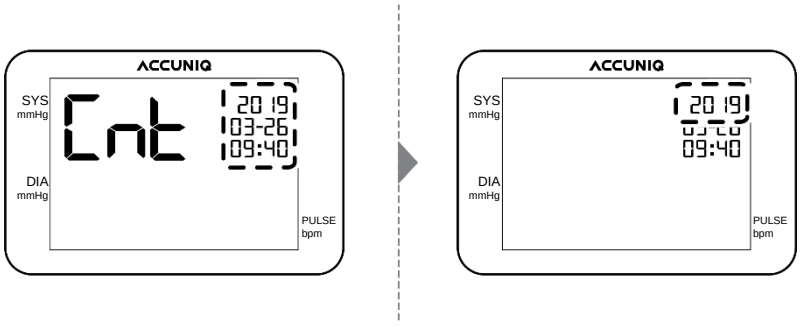
How to change the date and time

1) Enter basic function setting mode.

2) Press the **[▲(UP)]** button to enter date and time mode.

3) Press the **[SET]** button to enter date and time change mode.

4) Use the **[SET]** button to move in order of year → month → day → hour → minute and set the date and time with the **[▲(UP)]** or **[▼(DOWN)]** button.



How to set the voice guide volume

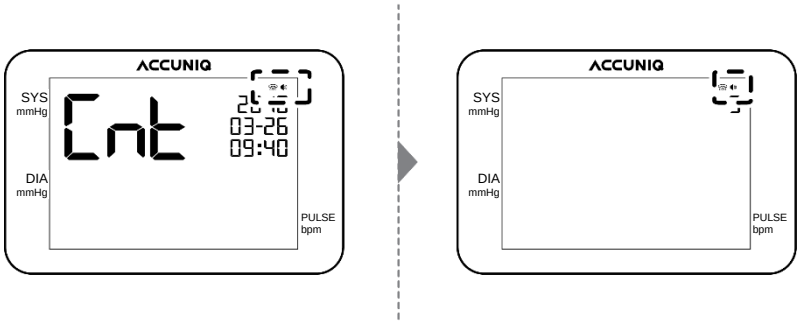
1) Enter basic function setting mode.

2) Press the **[▲(UP)]** button to move to printer and volume setting mode.

3) Press the **[SET]** button to enter printer and volume setting mode.

4) Select the volume icon using the **[SET]** button.

5) Select the volume using the **[▲(UP)]** or **[▼(DOWN)]** button.



How to set the thermal printer

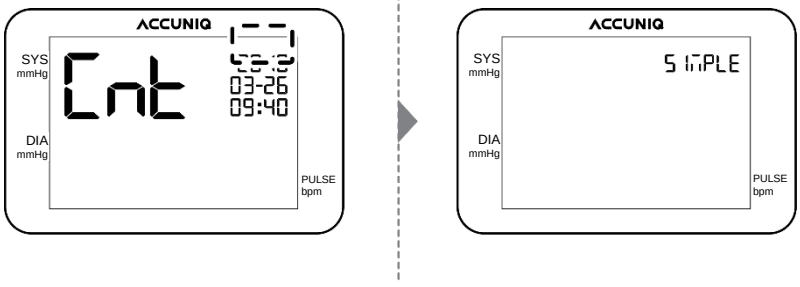
1) Enter basic function setting mode.

2) Press the **[▲(UP)]** button to move to printer and volume setting mode.

3) Press the **[SET]** button to enter printer and volume setting mode.

4) Select the thermal printer icon using the **[SET]** button.

5) Select thermal printer results paper using the **[▲(UP)]** or **[▼(DOWN)]** button. OFF (don't use the printer), SIMPLE (simple results paper), normaL (detailed results paper), nonPrP (simple results including a cardiac burden level)



How to set up additional functions

You can check the product version, set the USB and RS-232C communication port, and set whether the cuff sensor is enabled or not in additional function setting mode.

How to enter additional function setting mode

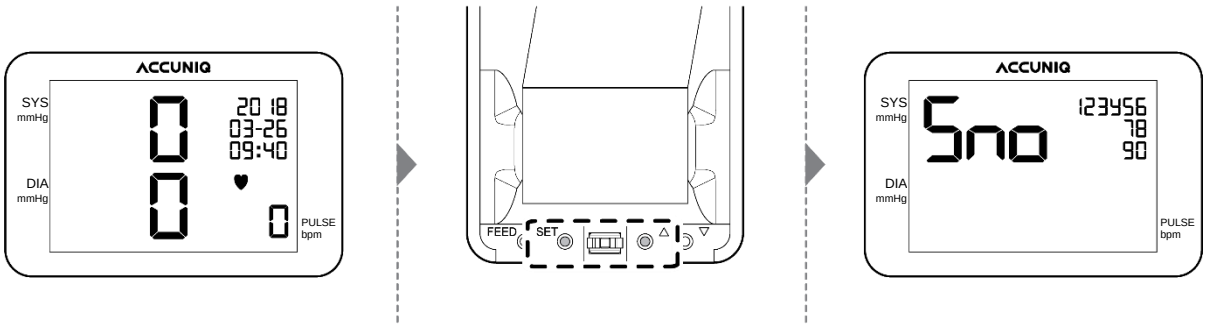
1) Press the printer cover to release the cover in measurement standby mode.

2) Press the **[SET]** + **[▲(UP)]** button for 3 seconds to enter basic function setting mode.

3) When additional function setting mode is entered, the Sno character is displayed in the Systolic Pressure display section.

4) If the Sno character is displayed, you have entered basic function setting mode successfully.

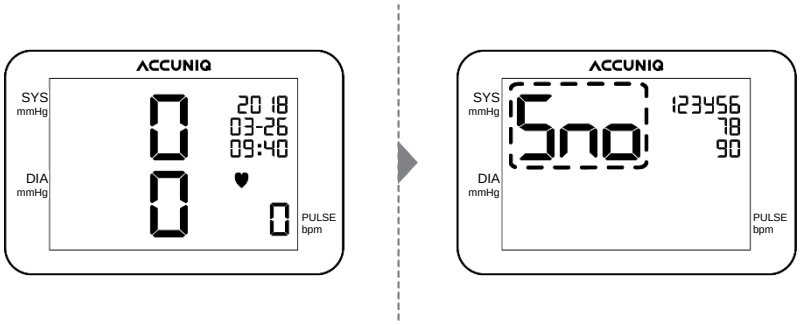
5) Press and hold the **[SET]** button for 3 seconds to return to measurement standby mode.



How to check the product software version

1) Enter additional function setting mode.

2) When the Sno character is displayed in the Systolic Pressure display section, you can check the software version in the date and time display section. The software version is information that is needed for product A/S and customer inquiries. The manufacturer may ask the customer for the software version for smooth follow-up maintenance.



How to set the communication port (RS-232C)

The communication port is used to connect a computer, Bluetooth, or body composition analyzer. The protocol may vary depending on the software version. Therefore, it is recommended to contact the vendor or manufacturer before setting the protocol.

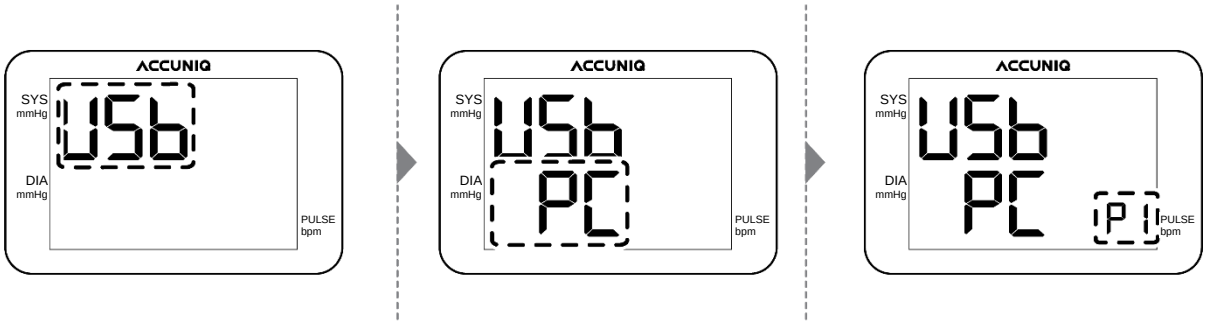
1) Enter additional function setting mode.

2) Press the **[▲(UP)]** or **[▼(DOWN)]** button to select a port to connect an external device among the USB, EP1, or EP2 communication ports.

3) Press the **[SET]** button to confirm the connected port.

4) Use the **[▲(UP)]** or **[▼(DOWN)]** button to select a device to connect to the confirmed port, and press the **[SET]** button to confirm.

5) Finally, select a protocol type to communicate with using the **[▲(UP)]** or **[▼(DOWN)]** button and press the **[SET]** button to confirm.

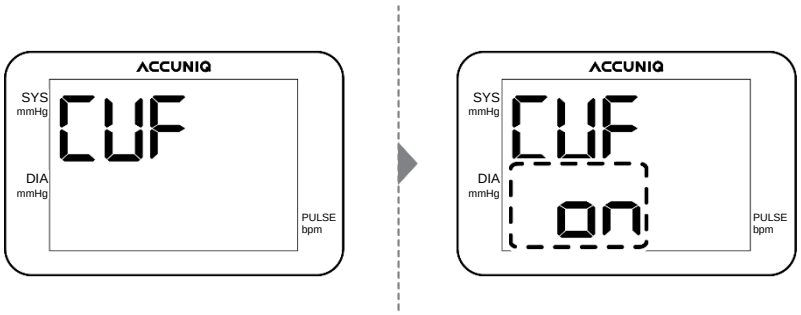


How to set the cuff sensor

1) Enter additional function setting mode.

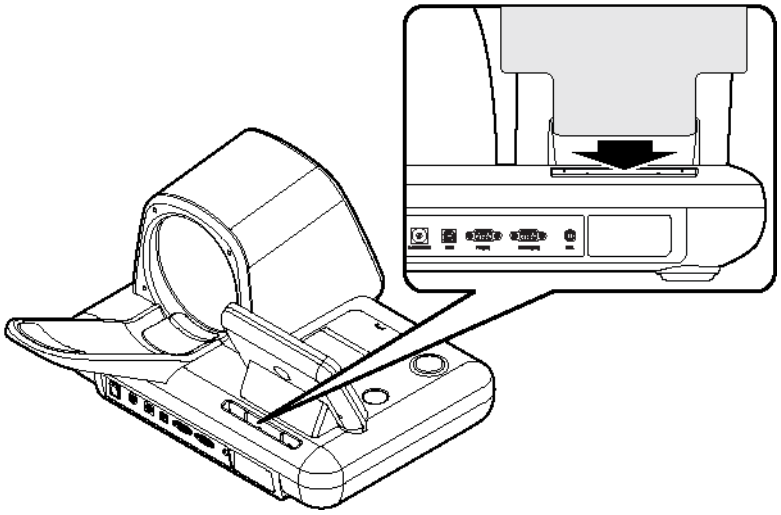
2) Press the **[▲(UP)]** or **[▼(DOWN)]** button to select CUF and press the **[SET]** button to enter cuff setting mode.

3) You can enable or disable the cuff sensor using the **[▲(UP)]** or **[▼(DOWN)]** button.



How to install the measurement guide plate

Insert the Measurement Guide Plate to the Guide Plate Fixing Section on back side of the display.

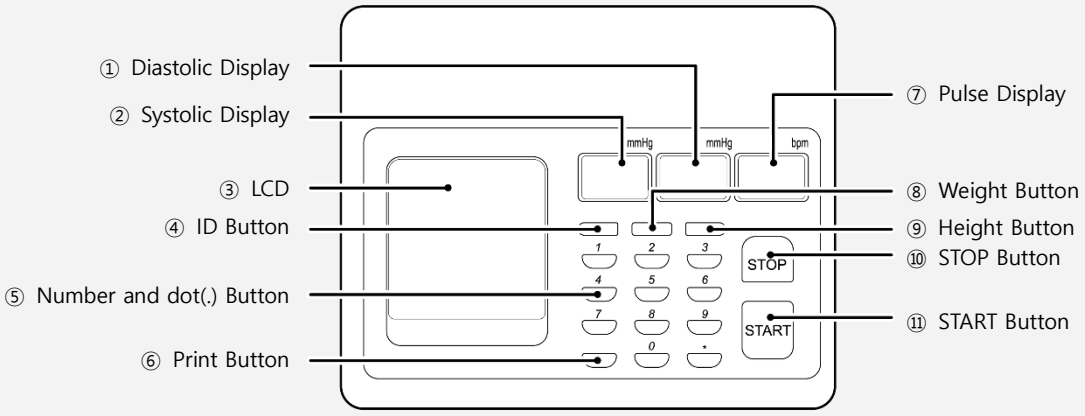


How to install the rear monitor

Composition and description

①	Diastolic Pressure display	Displays measured diastolic.
②	Systolic Pressure display	Displays measured systolic.
③	LCD	Displays the entered information and the progress.
④	ID button	Used to input the ID number of the user.
⑤	Number and dot (•) button	Used to input numbers such as the ID, weight, and height. Use the dot (•) button to input a decimal point for weight and height. e.g.,) If weight is 68.9 kg, input in the order of "Weight button → 6 → 8 → • → 9."
⑥	Print button	Press this button on the results screen to print the measurement results.
⑦	Pulse display	Displays the measured pulse.

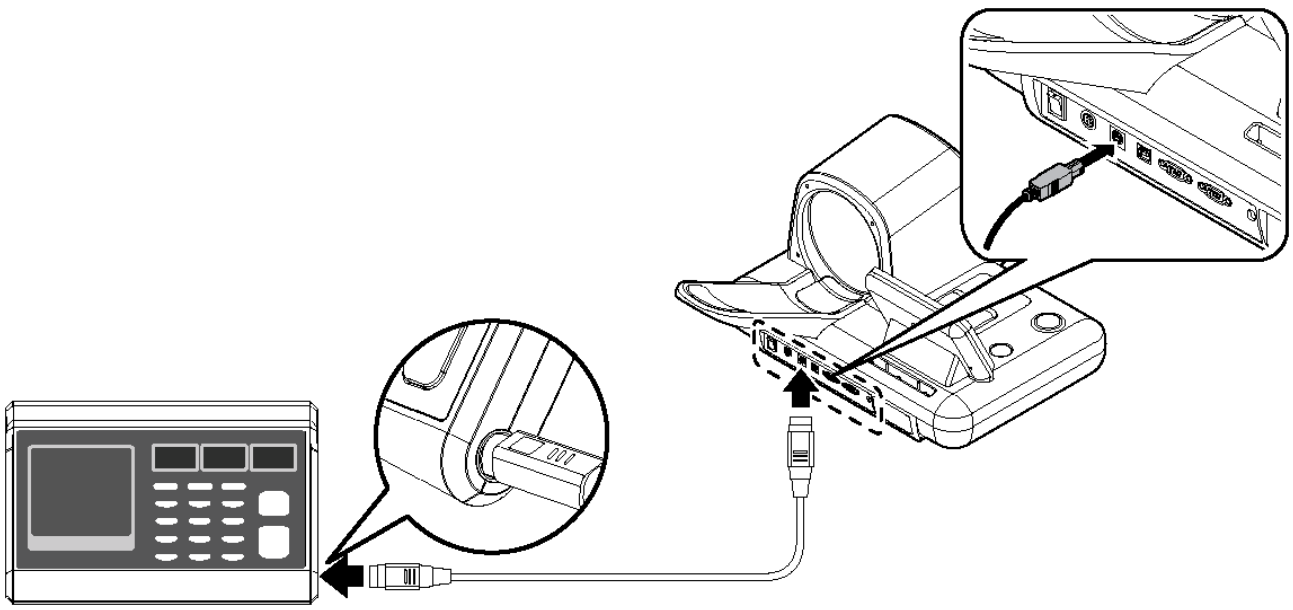
⑧	Weight button	Used to input the weight of the user.
⑨	Height button	Used to input the height of the user.
⑩	STOP button	If pressed while entering the information, the input information will be reset. If you press the button, measurement will stop and the cuff will return to its original state.
⑪	START button	Measurement will start if pressed after entering the ID, weight, and height.



How to connect the port

1) Connect the cable to the port on right side of the rear monitor.

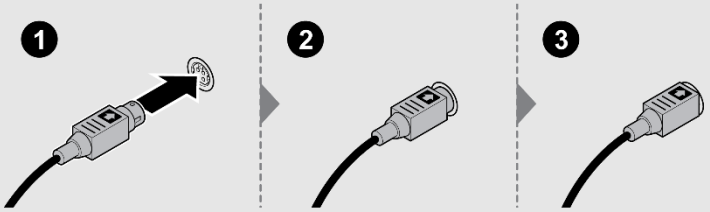
2) Connect the rear monitor to the rear monitor port on the rear side of the main unit.



Caution

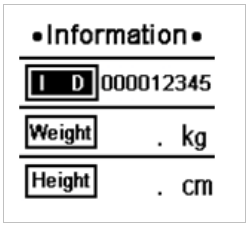
10. Make sure to use the enclosed cable to to the device.

11. When connecting the rear monitor and the main unit, connect it to the rear monitor port on the back of the main unit accurately in such a way that the arrow on the cable section faces upwards as shown in the figure below. If connected incorrectly, problems can arise in the product.



Measurement method

Data input



Press the “ID” button on the initial screen and input the ID using the number buttons (0 – 9).

- The ID range that can be entered is 000000000 to 999999999.

Press the “Weight” button after entering the ID and input weight using the number buttons (0 – 9) and the dot (•) button.

- The weight range that can be entered is 10.0 – 248.0kg.

Press the “Height” button after entering the weight and input height using the number buttons (0 – 9) and the dot (•) button.

- The height range that can be entered is 80.0 – 238.0 cm.

Measurement

When all necessary information is entered, press the “START” button to start measurement.

- When measurement is in progress, an animation is displayed indicating that measurement is in progress.

Note

If you input data on the rear monitor, you should press the "START" button on the rear monitor screen to print or display height, weight, and BMI on the rear monitor screen.

Input the weight and height correctly because the data is reflected in the BMI.

Result

When measurement is complete, the BMI based on the entered weight and height is displayed on the LCD.

Body Mass Index (BMI): A health index expressed in weight and height (m^2). The value resulting from dividing height by weight (kg/m2).

Section	thin	normal	overweight	obese
	<18.5kg/m^2	18.5~<23.0kg/m^2	23.0~<25.0kg/m^2	25.0kg/m^2 and over

MEASUREMENT

Operations

Operation principles

The cuff pressure is raised to approximately 40 mmHg higher than the PATIENT's systolic pressure and then gradually depressurized. The oscillations of pressure in a cuff are recorded during gradual deflation. By analyzing the recorded data, the systolic is estimated at the oscillations begin, and the diastolic is estimated at oscillations disappear.

Operation warnings

1) Frequent measurements can cause injury to the PATIENT due to blood flow interference.
2) The application of the CUFF over a wound, as this can cause further injury.
3) The application of the CUFF and its pressurization on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present because of temporary interference to blood flow and could result in injury to the PATIENT.
4) If due to a recent surgery under the care of a physician and it may cause further injury of the region.
5) Pressurization of the CUFF can temporarily cause loss of function of simultaneously used monitoring ME EQUIPMENT on the same limb
6) The need to check (for example, by observation of the limb concerned) that operation does not result in prolonged impairment of the circulation of the blood of the PATIENT.

Operating conditions

Blood pressure monitor must be used in the correct environment. PATIENT position in normal use, including:

1) comfortably seated
2) legs uncrossed
3) feet flat on the floor
4) back and arm supported
5) middle of the CUFF at the level of the right atrium of the heart

Please rest 5 minutes shoud elapse before the first measurement.

Do not measure while holding a drink that can be spilled such as water or coffee.

Spilled water may flow into the product and cause problems.

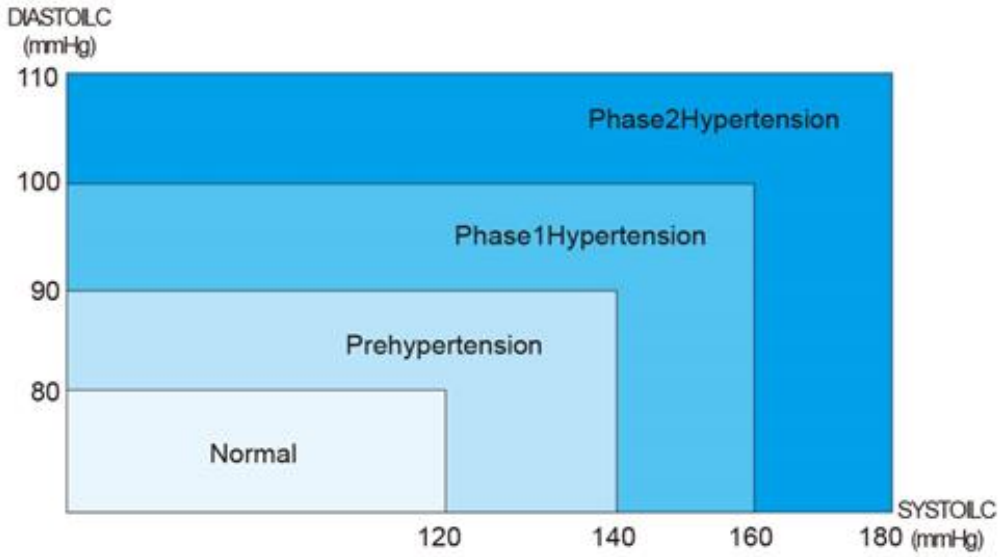
			
Please remove thick coats or sweaters before taking a measurement	Take a rest before taking a measurements and measure in a stable state.	Do not move or speak during measurement.	Do not take a measurement if you're standing, sitting down incompletely, or sitting with your legs crossed.
			
Do not take a measurement if you're sweating heavily.	If you've rolled up your sleeve, your sleeve should not put pressure on the brachial section.	Measurement can fail if it is difficult to hear artery sounds using a stethoscope.	If you flex your arm, the measured value may not be correct. Therefore, relax your arm and straighten your back to take a measurement in a correct posture.

Operating steps

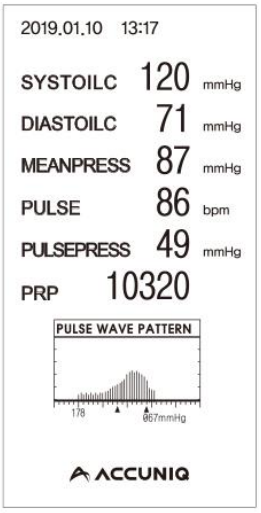
1) Check the voltage, connect the power plug, and turn on the power.
2) When the power is turned on, the LCD screen is ready for measurement.
3) Put your right arm in the cuff.
4) When placing your arm, make the palm of your hand face upward and put your arm deep inside the elbow support. Then, adjust the height of your chair so that the height of your arms is equal to that of your heart. If your arm is lower than your heart, the blood pressure goes up. On the contrary, if your arm is higher than your heart, the blood pressure goes down.
5) Press the Start button. The cuff is automatically pressurized and measurement begins.
6) When measurement begins, you can hear a voice message saying "Starting measurement. Do not move or speak." If you feel pain due to too high pressure during measurement or if you want to stop measurement, press the Emergency stop switch.
7) When measurement is finished, the measurement result is displayed on the LED. At the same time, you can hear a voice message saying "Measurement completed." Then, the cuff is automatically returned to its original state.
8) The device announces the results of blood pressure measurement by voice.
9) If PRINT is set to "Off" in the device settings, the results will not be printed after measurement.
10) When use is complete, turn off the power switch first then unplug the unit.

Measurement result

The Korean government revised the clinical practice guidelines by accepting the blood pressure classification of the Joint National Committee (JNC) in the U.S. (JNC7, 2003) as described below.



The measurement results are printed on three results sheets, and the type of result paper can be changed in the settings.



Note

If it is not the results you expect, Please rest 1 minute then mesurment again. If the measured results do not differ then please consult with your doctor.

Blood pressure monitor must be used in the correct environment. See the Operation Conditions.

STORAGE & MAINTENANCE

1) Pay attention to the allowable value of the electric current.
2) Avoid direct sunlight, humidity, dust, thick oil, salty air or extreme changes in temperature.
3) **Do not install or store the device in a place where chemicals or gas are stored.**
4) **Do not use the device in unstable environments with a high amount of vibrations or heavy impacts.**
5) Connect the ground located on the backside of this device to the terminal plate to prevent any electric shock from power surges or other electrical current changes.
6) **Do not place heavy objects on or drop anything on to the device, and avoid strong impacts.**
7) **Do not disassemble or modify the device.**
8) If the unit has not been used for an extended period, confirm with an expert that all functions and physical mechanisms are in good condition before use.
9) **Do not introduce any liquid on to the device or insert any foreign substances.**
10) If foreign substances are introduced, or if the device is exposed to harmful environments, the unit must be examined by a qualified technician before use.
11) Use only the power cable, adapter, and fuses provided by SELVAS Healthcare.
12) Please confirm the covering of the cable, the state of the adapter connection, and other safety checks as below:
    - RS-232C cable
    - USB port
    - Adapter
13) When disconnecting the power cable, turn off the power switch first then unplug the unit.
14) Store the unit in an environment with an ambient Temperature -10 ~ 60 °C, Humidity lower than 95 % (non condensing)
15) The operating environment should have an ambient Temperature 10 ~ 40 °C, Humidity 15 ~ 85 % (non condensing)
16) **Do not store or use this device in environments under 70 kPa (700 mbar) or over 106 kPa (1060 mbar) of atmospheric pressure.**
17) **We recommend the device be tested for accuracy every 2 years. Please contact the manufacturer or authorized dealer.**
18) Cleaning & Disinfection
    - Please turn off the power switch first then Cleaning & Disinfection the unit.

- Cleaning: When cleaning, use a soft cloth but do not use volatile solvent like benzene and alcohol or a wet cloth. Wipe out minute dust once per 2 ~ 3 days with a dry cloth.
- Disinfection: Spray alcoholic water of glutaraldehyde disinfect solution. Then, wipe the enclosure with a soft lint.

19) Please refer to and abide by the "SAFETY PRECAUTIONS."

Caution

Users must be sure to use sterile safety equipment such as gloves when in contact with or cleaning electrodes.

SELVAS Healthcare is not responsible for safety accidents caused by users' carelessness.

ERROR & REPAIR

Error code	Cause	Repair
M01	• A small number of pulse waves were acquired	• Take off your coat and take a measurement after resting enough • Please check the measurement posture • If the same error is repeated, please contact the manufacturer or authorized dealer
M02	• Too many pulse waves acquired.	• Please measure after taking sufficient rest • If the pressure does not decrease during measurement or if the same error is repeated, please contact the manufacturer or authorized dealer
M09	• Pulse pressure is abnormally low	• Take off your coat and take a measurement after resting enough • Please check the measurement posture • If the same error is repeated, please contact the manufacturer or authorized dealer
M15	• Blood pressure measurement was not completed to reach minimum pressure.	• Take off your coat and take a measurement after resting enough • Please check the measurement posture • If the same error is repeated, please contact the manufacturer or authorized dealer
M16	• Measurement timeout exceeded	• Please measure after taking sufficient rest • If the pressure does not decrease during measurement or if the same error is repeated, please contact the manufacturer or authorized dealer
M18	• Attempted to measure more than 3 times, but failed to measure blood pressure	• Take off your coat and take a measurement after resting enough. • Please check the measurement posture.

		• If the same error is repeated, please contact the manufacturer or authorized dealer
D01	• Inner cuff pressure does not rise	• Please contact the manufacturer or authorized dealer
D06	• It has generated more than 300mmHg and the pressure.	• It is installed where vibration occurs during measurement. Change the installation location and try again. • If the same error is repeated, please contact the manufacturer or authorized dealer
D12	• There is a problem with the internal memory.	• Please contact the manufacturer or authorized dealer
D23	• Blood pressure measurement is not possible because the pressure is not stable.	• Change the installation location and try again. • If the same error is repeated, please contact the manufacturer or authorized dealer
D24	• Inner cuff pressure does not rise	• Please contact the manufacturer or authorized dealer

AFTER SERVICE

Applying for A/S

If there is any problem with the unit, please follow the steps below;

1) Contact SELVAS Healthcare's Overseas Service Department immediately.

After gathering the model name, Serial Number, date of purchase and description of the problem, contact SELVAS Healthcare with information shown below.

2) Try to solve the problem over the phone with the personnel of local service department.

3) If the problem cannot be solved over the phone, return the unit directly to service department.

4) SELVAS Healthcare or local distributor will make available on-request circuit diagrams, component part list, descriptions, calibration or other information which will assist your appropriately qualified technical personnel to repair those parts of the unit which are designated by SELVAS Healthcare as repairable.

How to contact SELVAS Healthcare

Write us at:

SELVAS Healthcare, Inc.

155, sinseong-ro, Yuseong-gu, Daejeon, 34109 Republic of Korea

TEL: +82 42 879 3000

FAX: +82 42 864 4462

(You can also contact the following representative or your local distributor)

PACKING AND TRANSPORT

SELVAS Healthcare packages this device using the most suitable methods to protect it from impact or damage during shipping and transport. This device can be damaged during delivery if it is packed in methods that deviate from those SELVAS Healthcare uses. Please handle this device carefully to avoid unnecessary impact during packing and delivery.

If this device needs to be transported, repack it carefully and transport it as follows.

1) Turn off the power.

2) Turn off the power of the peripheral devices and disconnect all cables.

3) Disassemble the device in reverse order of assembly.

4) Pack the device using the original packing materials.

5) Transport it carefully.

SPECIFICATION

This medical device complies with IEC 80601-2-30:2017

DIVISION	SPECIFICATION
Model	BP500
Measuring method	Oscillometric
Display mode	Mono LCD (130 X 90mm)
Result Contents	Systolic/Diastolic/Mean blood pressure, Pulse pressure, Pulse, Blood pressure assessment, Pulse wave pattern Rear Monitor(Optional): Systolic and diastolic pressures, pulse, ID Number and B.M.I.
Upper Arm Circumference	20 to 40 cm
Measurement Range	Systolic Pressure: 60 to 280 mmHg Diastolic Pressure: 30 to 200 mmHg Pulse rate: 30 to 240 beat/minute
Accuracy	Pressure ±2mmHg, Pulse ±1.5%
Resolution	1mmHg
Pressurizing method	DC Motor
Printer	Thermal printer (Option)
Power supply	Input-AC 100~240V, 50/60Hz Output-DC 12V, 5A ADAPTER
Power consumption	60VA
Ambience for operation	Temperature 10~40℃, Humidity 15~85% (non-condesing)
Ambience for storage	Temperature -10~60℃, Humidity Less than 95%
Atmospheric pressure	70kPa (700mbar) to 106kPa (1060mbar).
Data transmission	RS-232C, USB
Dimension (W x D x H)	450 × 502.4 × 278.7 mm
Weight	Approx. 4.8kg

WARRANTY

Item	Automatic Blood Pressure Monitor	Warranty period
Model	BP500	1 year (main unit only)
Serial NO.		
Date of purchase	Month Day Year	
Dealer	Name Tel.	
	Address:	
Customer	Name Tel.	
	Address:	

Date	Defection	Confirmation

Note

1. When you receive this warranty, make sure that the name of the dealer and the month, day and year of purchase are all completed.
2. This warranty will not be reissued, please keep it in a safe place.

SELVAS Healthcare, Inc.

HEADQUARTERS 155, Sinseong-ro, Yuseong-gu, Daejeon, 34109 Republic of Korea **Tel** 82 42 879 3000 **Fax** 82 42 864 4462

If the problems continue, call the service center. When you ask for service, the manufacturer's label, serial number, date of original purchase and explanation of malfunction will be required.

Service center Tel +82 42 879 3000

* For purpose of improvement, specifications and design are subject to change without notice.