

UM-212BLE

Digital Blood Pressure Monitor

| | | |
|-------------------------|------------|----------|
| Instruction Manual | Original | English |
| Manuel d'instructions | Traduction | Français |
| Manual de instrucciones | Traducción | Español |
| Manuale di Istruzioni | Traduzione | Italiano |
| 使用手冊 | 翻譯 | 中文 |



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Dear Customers

Thank you for purchasing a state-of-the-art A&D blood pressure monitor. Designed for ease of use and accuracy, this device will facilitate your daily blood pressure regimen.

We recommend that you read through this manual carefully before using the device for the first time.

Preliminary Remarks

- ☐ This device conforms to the Medical Device Regulations (EU 2017/745) and UKCA Medical Device Regulations 2002 for Medical Products. This is made evident by the CE2797 and UKCA0086 mark of conformity. (2797 and 0086: The reference numbers to the involved notified body.)
- ☐ Hereby, A&D Company, Limited declares that the radio equipment type UM-212BLE is in compliance with Directive 2014/53/EU and Radio Equipment Regulations 2017. The full text of the EU and UKCA declarations are available at the following internet address:
https://www.aandd.jp/products/manual/manual_medical.html
- ☐ This device fulfils the following provisions.

 **Medical Device Regulation (EU 2017/745)**

 **UKCA Medical Devices Regulations 2002**

- ☐ This is a medical device.
- ☐ Intended user: The device is designed to be used by medical workers.
- ☐ The device is designed for use on adults and children of age 3 years and older.
- ☐ Environment for use: The device is designed to be used in medical facilities.
- ☐ This device is designed to measure blood pressure and pulse rate of people for diagnosis.
- ☐ Operating principle: This device is an oscillometric sphygmomanometer. When the cuff pressure is pressurized above systolic blood pressure and then is gradually depressurized, the device can detect the pulse synchronized to heart beat included in the cuff pressure. This pulsation starts small at the beginning, becomes large as the pressure decreases, eventually shows the maximum amplitude, then decreases again, and ultimately creates a mountain-shaped pattern. This oscillometric-type sphygmomanometer analyzes the signal information of this pulsation with

a microcomputer and determines systolic blood pressure and diastolic blood pressure values. Also this device is designed to monitor and display cuff pressure during cuff inflation and deflation while the user determines the patient's blood pressure level by listening to Korotkoff sounds with a stethoscope.

Intended Purpose

Digital Blood Pressure Monitor is intended to be used by healthcare professionals to measure systolic and diastolic blood pressure and pulse rate. It provides the user with an indication of an irregular heartbeat allowing further medical attention to be sort.

Clinical Benefit

Successful assessment of blood pressure reading in accordance with the device's intended purpose.

Contraindication

- ☐ Do not use the device where flammable gases such as anesthetic gases are present. Doing so may cause an explosion.
- ☐ Do not use the device in highly concentrated oxygen environments, such as a high-pressure oxygen chamber or an oxygen tent.
- ☐ Do not apply the cuff on an arm if another electrical medical device is already attached.
- ☐ Do not apply the cuff on an arm that is receiving an intravenous drip or blood transfusion. Doing so may cause injury or accidents.
- ☐ Do not use on patients with blood flow disorders.
- ☐ This device is not intended to diagnose heart arrhythmias. If the Irregular HeartBeat indicator illuminates frequently and is unrelated to patient movement during blood pressure measurement, further medical attention must be sort.
- ☐ Do not wrap the cuff on an arm with a wound. That may result in reopening the wound as well as cause an infection.
- ☐ Do not provide any servicing and perform maintenance while the medical device is in use.

Precautions

Installation or storage location for the device

- ☐ Extremes in room temperature, humidity, direct sunlight, shock or dust should be avoided.
- ☐ Use or keep the device in a stable location where there is no slope, no vibration and no mechanical shock.
- ☐ Use or keep the device in a location where the chemicals, medicines or gases are not present.
- ☐ The device and cuff are not water resistant.
- ☐ Measurement may be distorted if the device is used close to televisions, microwave ovens, cellular telephones, X-ray, electrocauterizers, defibrillators or other devices with strong electrical fields.
- ☐ A strong shock to the device may result in mechanical error or possible injury due to debris.
- ☐ Avoid tightly folding the cuff or storing the hose tightly twisted for long periods, as such treatment may shorten the life of the components.
- ☐ Keep distance of 30 cm or more away between the device and wireless communication devices (cell phones and smartphones). Failure to do so poses a risk of malfunction.

Confirmation before use

- ☐ Confirm that the device operates safely and correctly.
- ☐ Use the provided specified AC adapter for the device.
- ☐ Use only the specified options and consumables with this device.
- ☐ Clean the device properly before using it for next patient.
- ☐ This device is intended for use by doctors and clinical workers only in a medical environment. The monitor was not designed for the patient's own use so care must be taken to ensure accurate results and avoid possible accidents.
- ☐ Do not use the device in an ambulance or ambulance helicopter, doing so will prevent the device from providing accurate measurements.
- ☐ Do not use the device where plugging and unplugging of the AC adapter may be difficult.
- ☐ Clinical testing has not been conducted on newborn infants and pregnant women. Do not use on newborn infants or pregnant women. For the auscultation measurement, the device can be used for pregnant women.
- ☐ Confirm that there is no harm to the patient when the cuff is applied to the patient's arm and if the patient has had a mastectomy or lymph node clearance, then avoid the adjacent arm.
- ☐ Do not modify the device. Doing so may cause accidents or damage to the device.

- ❑ This is a medical device. Please consult your healthcare provider with any questions or concerns you may have regarding your condition.
- ❑ Confirm for proper operation before use, if the packaging is damaged, unintentionally opened and exposed to environmental conditions outside of those specified.

Cautions during use of the device

- ❑ Always check the condition of the device, its parts and the patient for safety.
- ❑ If a problem is found with the device, its parts or the patient, stop using the device, check the status of the patient and take appropriate actions.
- ❑ When an error display appears on the device or there are doubts regarding the measurement values, confirm the patient's vital signs by using the palpation or auscultation method. Check that the air hose has not been bent or blocked.
- ❑ Should an error appear on the device, or if the patient feels discomfort, stop the device and take the proper corrective action to regain a safe environment.
- ❑ Ensure that the position of the applied cuff is at the same level as the heart. (Otherwise, the blood pressure value results in an error.)
- ❑ Do not start to measure blood pressure without wrapping the cuff around the arm. That may result in the cuff bursting or other damage.
- ❑ Regularly confirm patient status when the measurement is performed frequently or for a long time. Otherwise, measurement may cause damage due to peripheral arterial disease.
- ❑ Use the device in a manner that the air hose is not bent or blocked. Using the cuff with the air hose kinked or bent may result in peripheral circulatory failure due to hemostasis in the arm (caused by air remaining in the cuff).
- ❑ Do not apply excessive force to the AC adapter cable, such as lifting the device or pulling the AC adapter out by holding the AC adapter cable.
- ❑ Do not pull out or connect the specified AC adapter with a wet hand. That may result in an electrical shock or burn.
- ❑ While measuring, do not connect or disconnect the AC adapter or battery or perform maintenance on the device or its accessories.
- ❑ Do not simultaneously touch the DC jack and the patient. That may result in electrical shock.
- ❑ To measure blood pressure, the arm must be squeezed by the cuff hard enough to cause some numbness and possibly a temporary red mark to the arm.
- ❑ Follow local instructions specified in the hospital when the cuff is used on several or infectious patients. Otherwise cross infection may result.

- ❑ If the patient has a very weak or irregular heartbeat, the device may have difficulty in determining the blood pressure.
- ❑ Do not short the battery, it may become hot and potentially cause burns.
- ❑ The patient should be relaxed and avoid moving or talking during the measurement. That may result in a measurement error.

Note

- ❑ To ensure accurate measuring, we recommend measuring the blood pressure after being in a relaxed state for at least five minutes.
- ❑ Blood pressure measurement may cause subcutaneous bleeding. This subcutaneous bleeding is transient and disappears over time.
- ❑ Do not use on patients that are using heart-lung support equipment.
- ❑ Blood pressure cannot be measured correctly on thick clothing.
- ❑ If the arm is compressed by tucked up clothing, it cannot be measured correctly.
- ❑ When any serious incident occurs in relation to this device, report to its manufacturer and the competent authority in your country.

Care for after use

- ❑ When the cuff is infected by blood or body fluid, it should be safely disposed of according to local instructions or protocol to avoid any potential spread of infectious disease.
- ❑ Clean the device and cuff with a dry, soft cloth or a cloth dampened with water and a neutral detergent. Never use benzine, thinner or other harsh chemical to clean the device. For full details please read section "**Cleaning**" or "**Maintenance**".
- ❑ When carrying out maintenance on the device, turn the power off and remove the power cable from the outlet to prevent a risk of electrical shock.
- ❑ Do not spray, do not pour or do not spill a liquid on the device, accessories, connectors, buttons or outlet ports.
- ❑ Do not perform autoclave or gas sterilization (EOG, formaldehyde gas or high concentration ozone etc.) on the device as this could result in degradation.
- ❑ The user authority (the hospital, clinic, etc.) is responsible for the safe use and maintenance of this electronic medical device. Care should be taken to follow the specified daily maintenance and inspection procedures for safe use.
- ❑ Store the cuff, air hose, and rubber bulb so that they are not bent or blocked. Doing so may cause an accident or damage to the device.
- ❑ When any serious incident occurs in relation to this device, report to its manufacturer and the competent authority in your country.

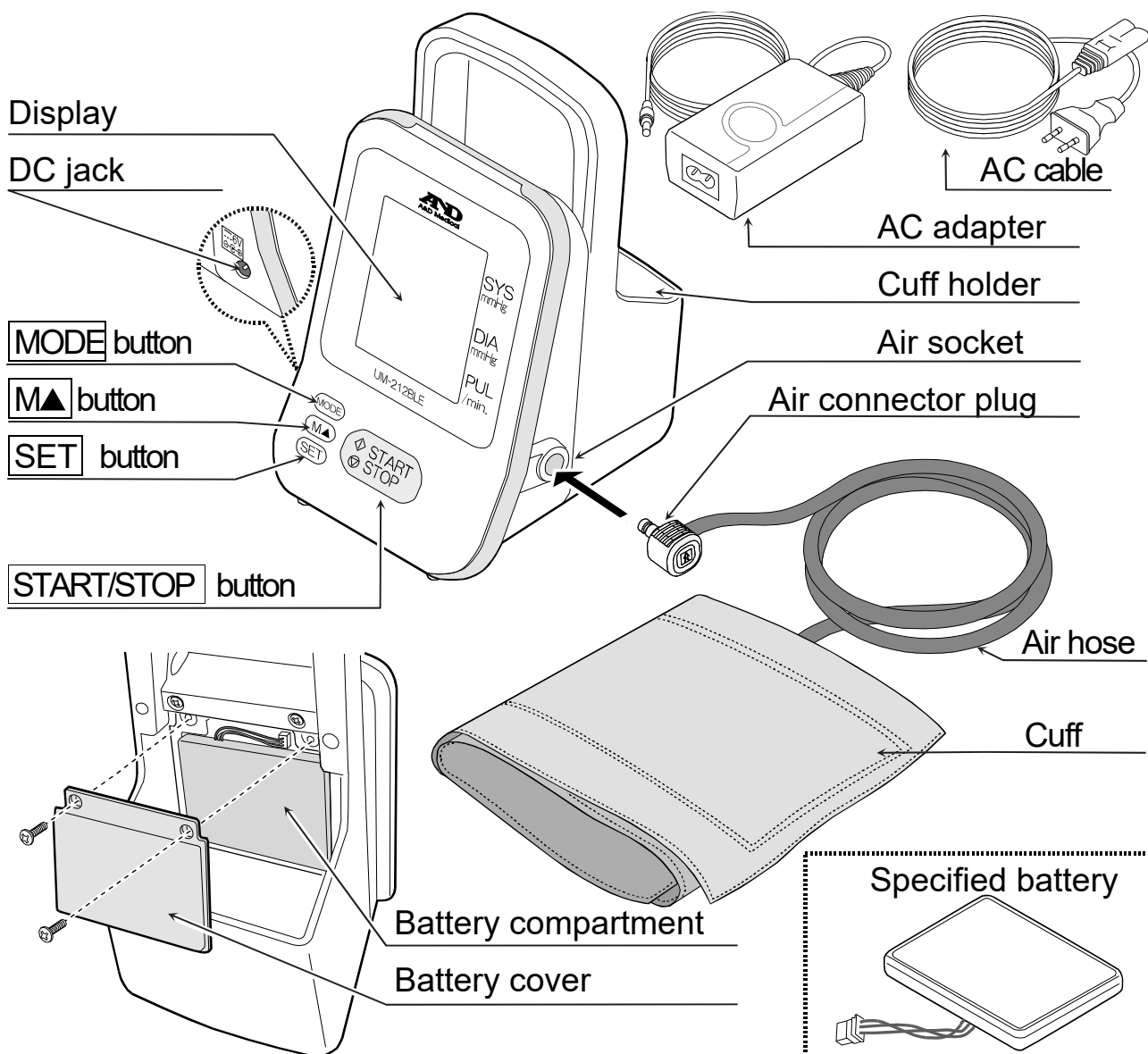
Specified battery pack

- ❑ Use only the specified battery pack authorized for this device.
- ❑ Used equipment, parts and battery are not treated as ordinary household waste, and must be disposed of according to the applicable local regulations.
- ❑ Be sure to remove the AC adapter from the device before the battery pack is re-installed in the device. Otherwise that may result in an electrical shock.
- ❑ If the device will not be used for a while, remove the battery pack before storing. Recharge the battery once every six months, otherwise the battery may degrade.
- ❑ Be sure to use the device after recharging the battery. Maintaining a charged battery allows for continual use.
- ❑ If liquid leaked from the specified batteries gets into the eyes, avoid rubbing the eye and fully rinse the liquid off using water, then immediately seek medical attention.
- ❑ The specified battery pack should be used with UM-211 or UM-212BLE.
- ❑ Do not heat the battery pack, or do not break it down. That may cause a heat generation, catching fire, short circuit or explosion.
- ❑ Do not apply a pressure or mechanical shock to the specified battery pack. That may result in an expansion or explosion.
- ❑ The specified battery pack is a consumable item. Replace the specified battery pack with a new one when the measurement time with this device is extremely short even after fully re-charging.
- ❑ If the specified battery pack is shorted during use, the temperature around the battery cover will become high and there is a risk of burns.

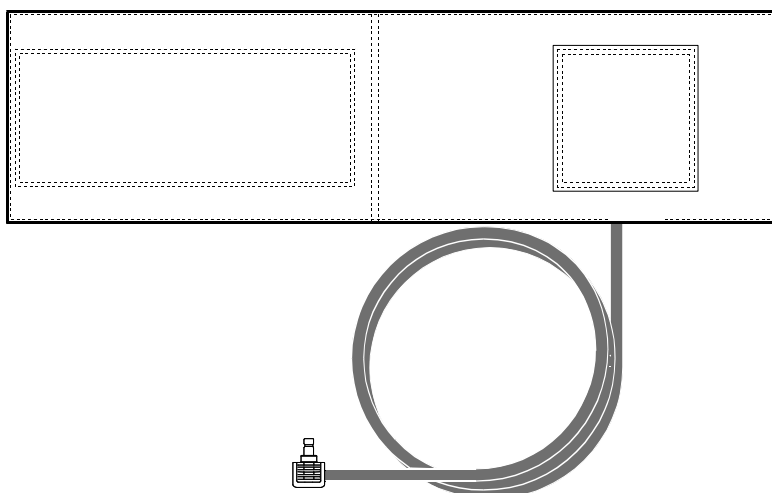
Wireless communication functions

- ❑ This device must be set to airplane mode when use of wireless communication is prohibited. The wireless communication functions cannot be used under such conditions.
- ❑ When using implantable heart pacemaker or implantable defibrillator, ask electronic medical manufacturers individually for negative effects about radio wave due to a use of this device.
- ❑ When using this device's Bluetooth communication close to another device that uses a radio wave of near 2.4 GHz, the processing speed of both devices may be decreased.
- ❑ Do not use this equipment at a location where a magnetic field, static electricity or wave interference around the microwave ovens appears. (Doing so may prevent the devices from communicating properly.)

Parts Identification

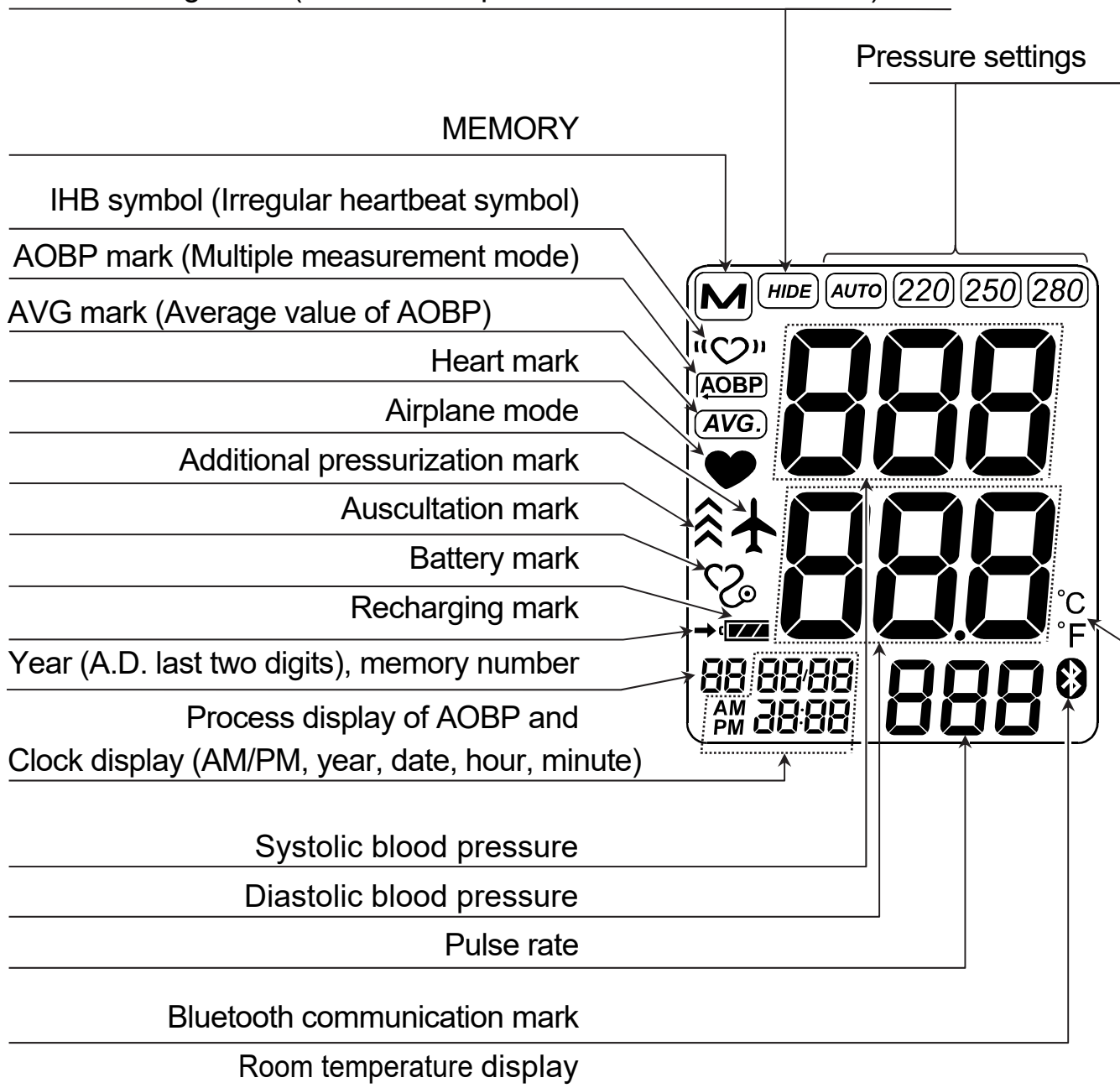


Cuff














Display








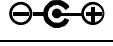











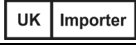
Mark of Hiding mode (to hide blood pressure measurement result)



Symbols














The symbols that are printed on the device and the packaging.

| Symbols | Function / Meaning | Recommended Action |
|---|--|--------------------|
|  START  STOP | <ul style="list-style-type: none"> <input type="checkbox"/> The blood pressure measurement is started when the START/STOP button is pressed when the device is in standby mode. <input type="checkbox"/> The blood pressure measurement stops and the device releases the air from the cuff when the START/STOP button is pressed while measuring the blood pressure. <input type="checkbox"/> The device proceeds to standby mode when the START/STOP button is pressed for at least three seconds. | _____ |
| MODE | Change the measurement mode. | _____ |
| M▲ | <ul style="list-style-type: none"> <input type="checkbox"/> During setting operation, items, setting contents, and setting values are changed. <input type="checkbox"/> Switches the display memory during memory display. <input type="checkbox"/> Press the M▲ button during the measurement in auscultation mode to apply additional pressure. | _____ |
| SET | Enables (confirms) the selected settings and advances to other setting modes. | _____ |
| SYS | Systolic blood pressure in mmHg | _____ |
| DIA | Diastolic blood pressure in mmHg | _____ |
| PUL | Pulse per minute | _____ |
|  | Direct current | _____ |
|  | Alternating current | _____ |
|  | Serial Number | _____ |
|  | Unique Device Identifier | _____ |
| 2023  | Date of manufacture | _____ |
|  | Type BF applied part | _____ |
|  | CE marking | _____ |
|  | European Authorized Representative | _____ |
|  | UK Conformity Assessed marking | _____ |

| Symbols | Function / Meaning | Recommended Action |
|---|--|--------------------|
|  | UK Responsible Person | _____ |
|  | International protection symbol | _____ |
|  | WEEE label | _____ |
|  | Manufacturer | _____ |
|  | Medical Device | _____ |
|  | Refer to instruction manual/booklet *1 | _____ |
|  | Class II device | _____ |
|  | Polarity of DC jack | _____ |
|  | UL Recognized Component Marks for Canada and the United States | _____ |
|  | Do Not Disassemble | _____ |
|  | crossed-out wheeled bin symbol | _____ |
|  | Indoor Dry Location Use Only | _____ |
|  | Consult the instruction manual | _____ |
|  | PSE Recognized Component | _____ |
|  | Warning-Hot surface | _____ |
|  | Temperature limit | _____ |
|  | Humidity limitation | _____ |
|  | Atmospheric pressure limitation | _____ |
|  | EU Importer | _____ |
|  | UK Importer | _____ |














*1 The symbol color: Blue




Symbols that are printed on the cuff

| Symbols | Descriptions |
|---|--|
|  | REF Code Used for ordering cuffs. |
|  | Index symbol Symbol for showing that the cuff is wrapped in a proper fit range if this symbol is within the RANGE line. |
|  | ARTERY symbol Place this symbol on the artery of the upper arm or thigh. |
|  | CE marking |
|  | Symbol for showing the manufacturing LOT number. The lot number is printed around this mark. |
|  | RANGE symbol The index symbol with the cuff should be in a range of this symbol. |
|  | Cuffs do not contain natural rubber latex |
|  | Refer to instruction manual/booklet *1 |
|  | Cuff Wrap position |
|  | Symbol for suggestions on operation. |
|  | Symbol for the patient side. |
|  | Symbol for the cuff size. |
|  | Medical Device |

*1 The symbol color: Blue

Symbols on the display

| Symbols | Function / Meaning | Recommended Action |
|---|---|---|
|  | This symbol is displayed while measurement is in progress. It blinks when the pulse is detected. | Measurement is in progress. Remain as still as possible. |
|  | Irregular Heartbeat symbol (IHB) This symbol appears when an irregular heartbeat is detected. It may light when a very slight vibration like shivering or shaking is detected. <ul style="list-style-type: none"> <input type="checkbox"/> When the pulse interval fluctuates more than a certain amount from the average value. <input type="checkbox"/> When you move your arm or sphygmomanometer. | Apply the cuff correctly, then take another measurement. If the «  » symbol continue to appear, we recommend you to consult with your physician. |
|  | Previous measurements stored in memory. | _____ |
|  | This symbol is displayed in order from bottom when the  button is pressed to add the pressurization during constant speed exhaust at the auscultation mode. | _____ |
|  | This symbol is displayed when the auscultation mode is ON. | _____ |
|  | This symbol is displayed when the AOBP (Automated Office Blood Pressure) mode is on. | _____ |
|  | This symbol is displayed while results (average value) at the AOBP mode is displayed. | _____ |
|  | This symbol is displayed at the Hiding mode (blood pressure result non-display mode). | _____ |
|  | This symbol is displayed during <i>Bluetooth®</i> communication. | _____ |
|  | This symbol is displayed while the blood pressure monitor is set to airplane mode. Bluetooth communication is prevented when the device is in airplane mode. | _____ |
|  | The battery power indicator during the measurement. | _____ |

| Symbols | Function / Meaning | Recommended Action |
|---|--|--|
|  | The battery power is low when it blinks. | Recharge the device using the AC adapter. |
|  | This symbol is displayed when the AC adapter is connected to the device and blinks while the battery is being recharged. | _____ |
| E_{rr} | Unstable blood pressure due to movement during the measurement. | Take measurement again. Remain still during the measurement. |
| | The systolic and diastolic values are within 10 mmHg from each other. | Apply the cuff correctly, and take measurement again. |
| | The pressure value did not increase during the pressurization. | |
| | The cuff is not applied correctly. | |
| E_{err} | PUL DISPLAY ERROR The pulse is not detected correctly. | |
| E_{rr} E E_{rr} F E_{rr} g | Blood pressure monitor internal error | Remove the batteries and press the START/STOP button, and then install the batteries again. If the error still appears, contact the dealer. |
| P_r E_{rr} | Means a pairing error. | Move the receiver as close as possible to the device and enable pairing again. |
| AM | Means morning when the clock function is set to 12H display. | _____ |
| PM | Means afternoon when the clock function is set to 12H display. | _____ |
|  220 250 280 | Pressure settings. Indicates the pressure value previously set by the user. | _____ |
| Room Temperature (°C, °F) | Means Celsius or Fahrenheit of room temperature. | _____ |

Mode List

Settings list of operation setting

| Settings | LCD display | Parameter |
|------------------------------|-------------|-----------------------------|
| Pressurization value setting | <i>F01</i> | AUTO / 220 / 250 / 280 mmHg |
| Auscultation exhaust speed | <i>F02</i> | Hi / Lo |
| Hiding mode | <i>F03</i> | oFF / on1 / on2 |

Some settings may be disabled depending on the selected measurement mode.

Field of “-” in the table below shows settings disabled. Items corresponding to fields disabled are unavailable for selection.

| Settings | LCD display | Measurement mode | |
|------------------------------|-------------|-------------------------------|-------------------|
| | | Normal measurement, AOBP mode | Auscultation mode |
| Pressurization value setting | <i>F01</i> | Enabled | Enabled |
| Auscultation exhaust speed | <i>F02</i> | - | Enabled |
| Hiding mode | <i>F03</i> | Enabled | - |

Settings list of operation setting

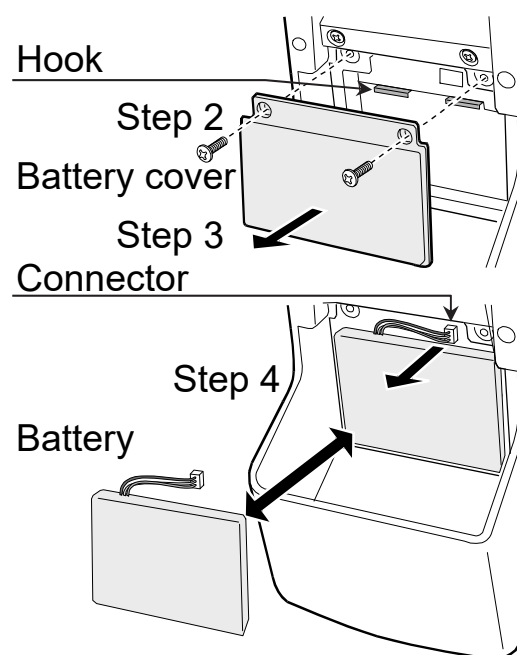
| Settings | LCD display | Parameter |
|---|--------------|--|
| Built-in clock adjusting | <i>F10</i> | Year (A.D. last 2 digits), month, date, hour, minute |
| Clock display setting | <i>F11</i> | 12 / <input type="text" value="24"/> hours |
| Automatic power-off timer | <i>F12</i> | <input type="text" value="5"/> / 10 minutes |
| Temperature unit | <i>F14</i> | A unit for displayed room temperature can be switched between <input type="text" value="°C"/> or °F. |
| Pairing type | <i>F15</i> | <input type="text" value="Single pairing"/> / multi pairing |
| Airplane mode | <i>F16</i> | ON / <input type="text" value="OFF"/> |
| AOBP mode Measurement count | <i>F17-1</i> | 2 / <input type="text" value="3"/> times |
| AOBP mode Waiting time | <i>F17-2</i> | <input type="text" value="0"/> / 3 / 5 / 10 minutes |
| AOBP mode setting Measurement interval | <i>F17-3</i> | 0.5 / <input type="text" value="1"/> / 2 minutes |

Factory setting




Using the Monitor

Inserting / changing the batteries

1. Confirm that the AC adapter is removed from outlet.
2. Remove the screws that secure the battery cover on the rear side of the main body.
3. Remove the battery cover.
4. Connect the battery's connector while pushing the hook at the left side to the connector in the battery compartment.
5. Close the battery cover.
6. Secure the battery cover by using the screws.

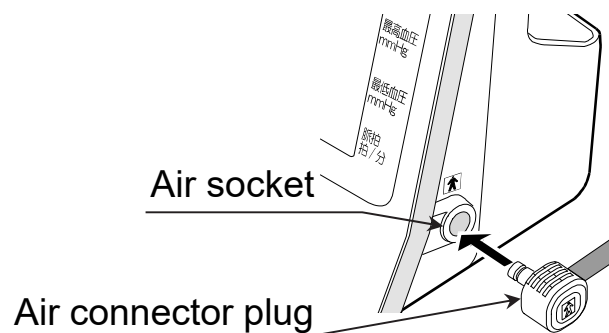


CAUTION

- ☐ When  (LOW BATTERY mark) blinks on the display, recharge the battery. If  appears even after the battery is replaced, take a blood pressure measurement. The device may then recognize the new battery.
- ☐ The battery life varies with the ambient room temperature and may become shorter at low room temperatures.
- ☐ Use the specified battery only.
- ☐ Remove the battery if the device is not to be used for a long time. The battery may cause leakage and operational issues.
- ☐ Exchange the battery with a new one when the operation time using the battery with this device is extremely short even after recharging.
- ☐ We recommend exchanging the battery once every two years.
- ☐ Be sure to reset the time after the battery is replaced.
- ☐  is not displayed when the battery is completely depleted or is not installed.
- ☐ The clock will be reset when the battery is completely depleted or specified battery pack is replaced.

Connecting the air hose

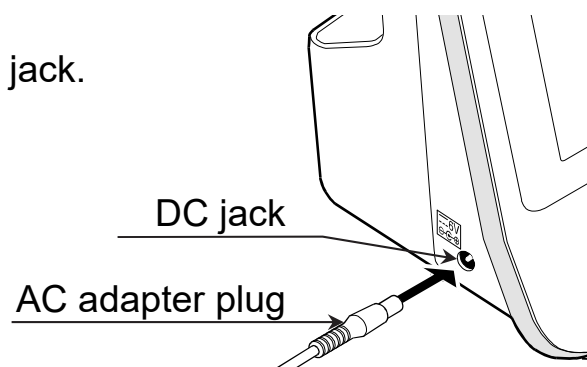
Insert the air connector plug into the air socket firmly.



Connecting the AC adapter

Insert the AC adapter plug into the DC jack.
Next, connect the AC adapter to an electrical outlet.

- ❑ Use the specified AC adapter.
(Refer to section "**Accessories Sold Separately**".)



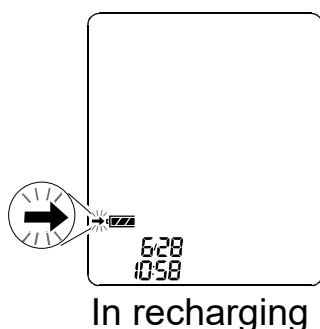
Note: The device is operated using the battery when the power is not supplied to the main body from the AC adapter.

Recharging the battery

- ❑ By connecting the AC adapter to the device, the recharging is started.
- ❑ The recharging completes about four hours after the AC adapter is connected to the device.
- ❑ During recharging, the recharging mark (➡) blinks and the temperature display disappears.
- ❑ The recharging mark continues to illuminate when completing recharging.

Note: A certain amount of time is required for the device temperature display to reach room temperature after recharging.

Recharging indicator



Operation

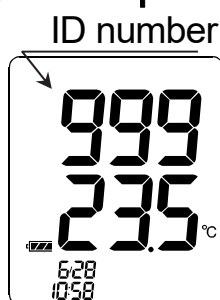
Standby mode

- The device will be in standby mode in the following cases.
 - The device goes into standby mode when the power is turned on (installing the batteries), and a current room temperature is displayed at the display for diastolic blood pressure.
 - The device proceeds to standby mode when the **START/STOP** button is pressed and held, or no operation is made for a regular time at all status other than blood pressure mode and auscultation mode.
- Press the **M▲** button to read out the memory.
- Press the **SET** button to proceed to the pressurization value setting mode.
- Press and hold the **SET** button to proceed to the clock setting mode.
- Press the **START/STOP** button to start the measurement.
- The measurement mode changes each time the **MODE** button is pressed.

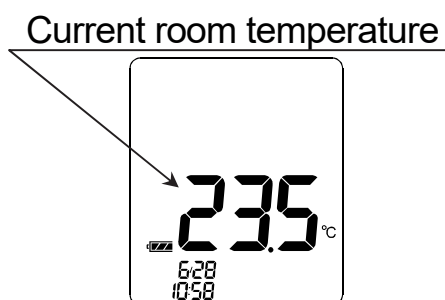


Note: The ID number can be displayed only when setting the ID number using an application software.

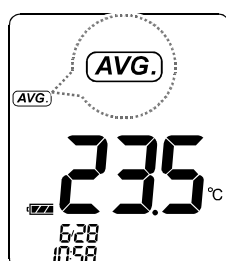
Display example



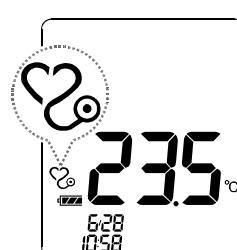
Normal measurement
ID number 999



Normal measurement
ID number non-setting



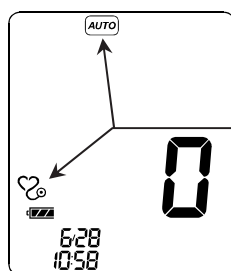
AOBP mode
ID number non-setting



Auscultation mode
ID number non-setting

Measurement standby mode

- It will be in measurement standby mode in the following cases.
 - When pressing the **SET** button to complete a cycle.
 - When pressing the **SET** button in auscultation exhaust speed changing mode.
 - When the measurement is interrupted.
 - When the measurement is completed. In this case, the device remains measurement results displayed.
- Press the **M▲** button to read out the memory.
- Press the **SET** button to proceed to the pressurization value setting mode.
- The device proceeds to the standby mode automatically after a regular time.
- Press the **START/STOP** button to start the measurement.
- The measurement mode changes each time the **MODE** button is pressed.



Display according to setting.

Measurement standby mode

When set to **AUTO**, Model UM-212BLE is designed to detect the pulse and to inflate the cuff to a systolic blood pressure level automatically.
 If re-inflation occurs repeatedly, use the following methods.

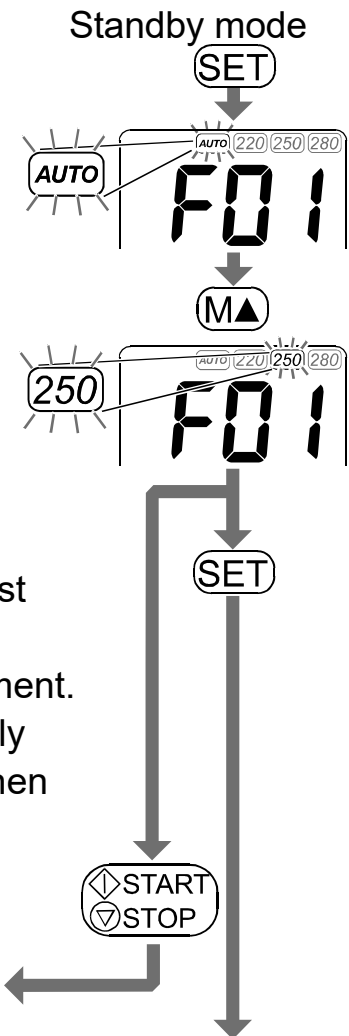
Pressurization value setting

During the blood pressure measurement, re-inflation may occur.
A fixed pressure value can be set to avoid re-inflation.

1. Press the **SET** button to go to the pressurization value setting mode (F01). The current setting blinks.
2. Press the **M▲** button to select a pressure value about 30 mmHg or more above your expected systolic blood pressure from the following.

AUTO : Automatic pressurization (default value)
220 : Pressure value of 220 mmHg (fixed)
250 : Pressure value of 250 mmHg (fixed)
280 : Pressure value of 280 mmHg (fixed)

3. Press the **SET** button to go to the auscultation exhaust speed changing mode or Hiding mode.
 Press the **START/STOP** button to start the measurement.
 The device will proceed to standby mode automatically when no operation is made for a regular time. And when entering standby mode, it becomes **AUTO**.



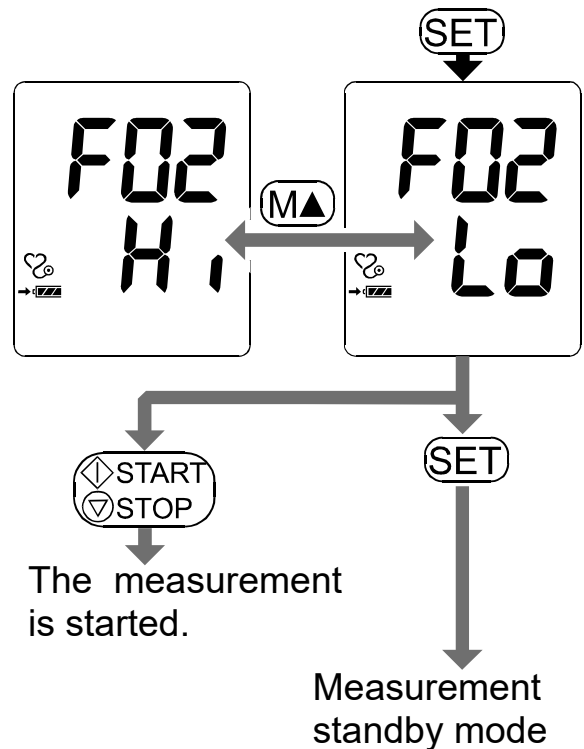
The measurement is started.

Auscultation exhaust speed changing mode or Hiding mode

Auscultation exhaust speed

Note: Select “Lo” when measuring normally. Should the patient’s pulse appear to be 100 or higher, measuring at the “Hi” is possible.

1. Press the **SET** button at the pressurization value setting mode (F01) when the auscultation setting is set to ON to go into auscultation exhaust speed changing mode. The “F02” is displayed at the display for systolic blood pressure, and the current status is displayed at the display for diastolic blood pressure.
2. Press to **M▲** button to switch between Hi or Lo.
3. Press the **SET** button to proceed to measurement standby mode. Press the **START/STOP** to start the measurement. Also, the device proceeds to standby mode automatically after a regular time. And when entering standby mode, it becomes “Lo”.



Hiding mode (to hide blood pressure measurement result)

Setting values of the Hiding mode (blood pressure result non-display mode) consist of three types of “oFF”, “on1” and “on2”.

oFF : Sets Hiding mode to OFF

on1 : Sets Hiding mode to ON

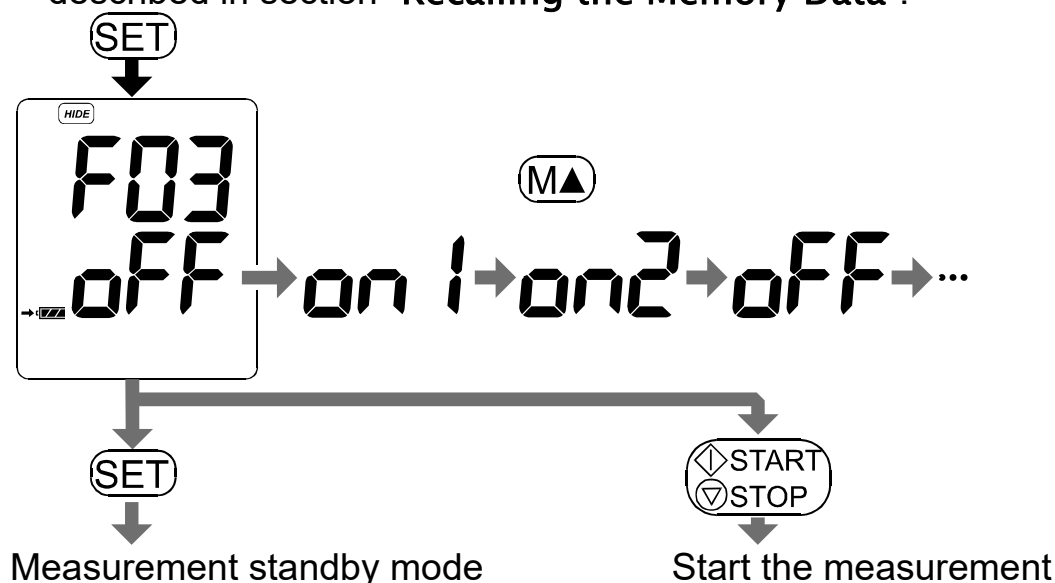
However, When this device returns to standby mode, Hiding mode is set to OFF.

on2 : Sets Hiding mode to ON

Even when this device returns to standby mode, Hiding mode keeps ON.

1. Press the **SET** button while the pressurization value setting at normal mode or AOBP mode is operated (F01) to display Hiding mode (F03). Display shows “F03” at systolic blood pressure display and shows current settings at diastolic blood pressure display.
2. Press the **M▲** button to toggle among “oFF”, “on1” or “on2”.
3. Select the following operations.
 - ☐ Press the **SET** button to proceed to measurement standby mode. After a regular time elapses, the device automatically proceeds to measurement standby mode.
 - ☐ Press the **START/STOP** button to start the measurement.

Note: When setting Hiding mode to ON, display shows all measurement results as blank. When confirming the measurement results, follow procedure described in section “Recalling the Memory Data”.

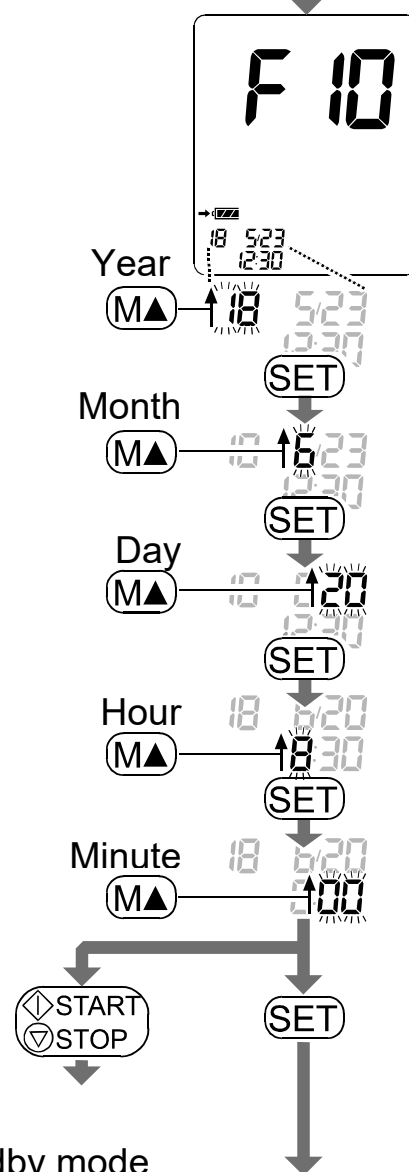


Adjusting the built-in clock

Adjust the clock prior to use.

Press and hold **SET**

1. Press and hold the **SET** button at the standby mode to go into clock setting mode. The “F10” is displayed at the display for systolic blood pressure, and the far right two digits of A.D. blink.
2. Select the year using the **M▲** button. Press the **SET** button to set the current year and move to month/day selection. Last 2 digits of a year between the years 2018 and 2059 can be set to the date.
3. Select the month using the **M▲** button. Press the **SET** button to set the current month and move to day selection.
4. Select the day using the **M▲** button. Press the **SET** button to set the current day and move to hour : minute selection.
5. Select the hour using the **M▲** button. Press the **SET** button to set the current hour and move to minute selection.
6. Select the minute using the **M▲** button. Press the **SET** button while the minute is being adjusted to proceed to clock display. Press the **START/STOP** button while the time is being set to proceed to standby mode.



Standby mode

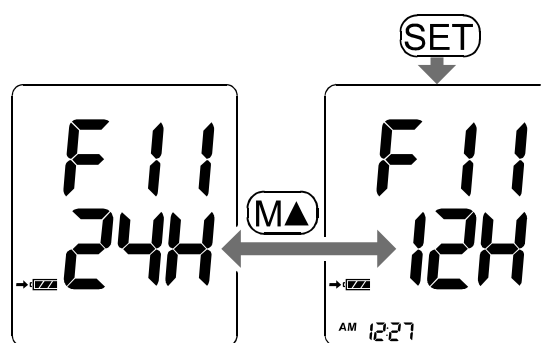
Clock display setting mode

Note:

- ❑ The device proceeds to standby mode when no operation is made for a regular time.
- ❑ Holding down the **M▲** button will change the value continuously.

Clock display

1. When “F11” is displayed in the systolic blood pressure display, either “12H” or “24H” will display in the diastolic blood pressure display.



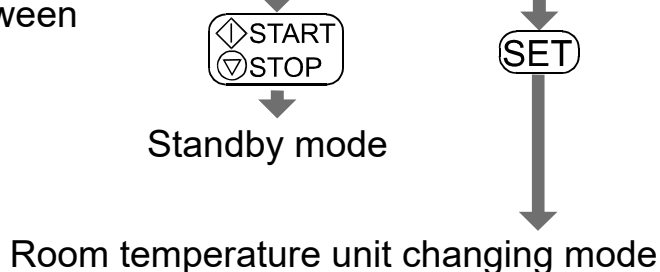
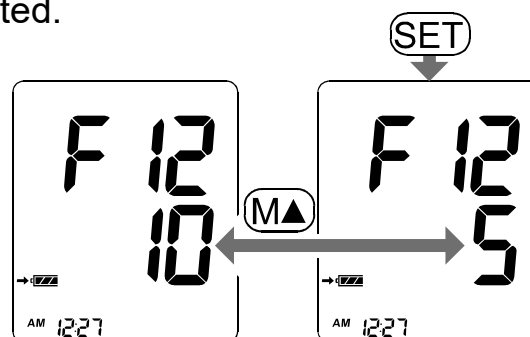
2. Press the **M** button to switch between 12H or 24H.
Press the **SET** button to proceed to automatic power-off timer mode.
Press the **START/STOP** button to proceed to standby mode.



Automatic power-off timer

Set a time for timeout for when no operation is made.
Either of five or ten minutes can be selected.

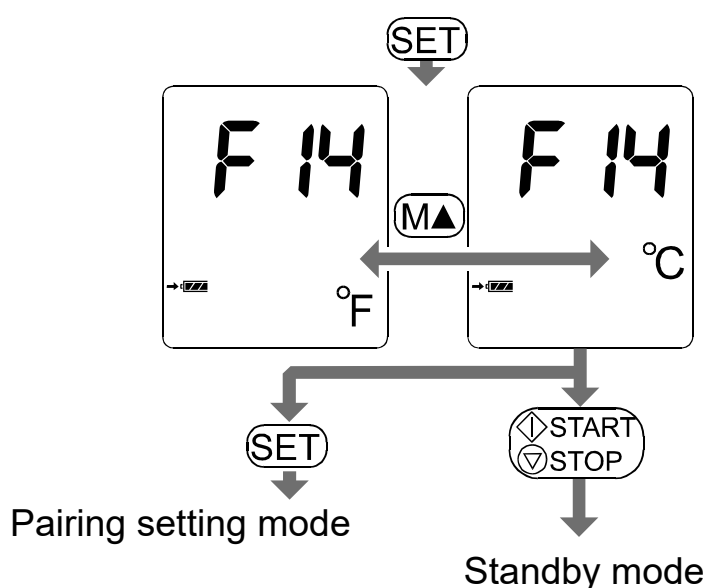
1. Press the **SET** button at the clock display setting mode to go into automatic power-off timer mode.
The “F12” is displayed at the display for systolic blood pressure, and the “5” or “10” is displayed at the display for diastolic blood pressure.
2. Press to **M** button to switch between five or ten minutes.
3. Press the **SET** button to proceed to temperature unit selection mode. Press the **START/STOP** button to proceed to standby mode.



Temperature unit

The unit for displayed room temperature can be switched between °C or °F.

1. Press the **SET** button at the automatic power-off timer mode to go into temperature unit selection mode.
“F14” is displayed at the display for systolic blood pressure.
2. Press to **M▲** button to switch between °C or °F at the right end on the display to switch the unit for room temperature.
3. Press the **SET** button to proceed to Pressure confirmation mode. Press the **START/STOP** button to complete the setting. The device proceeds to standby mode.

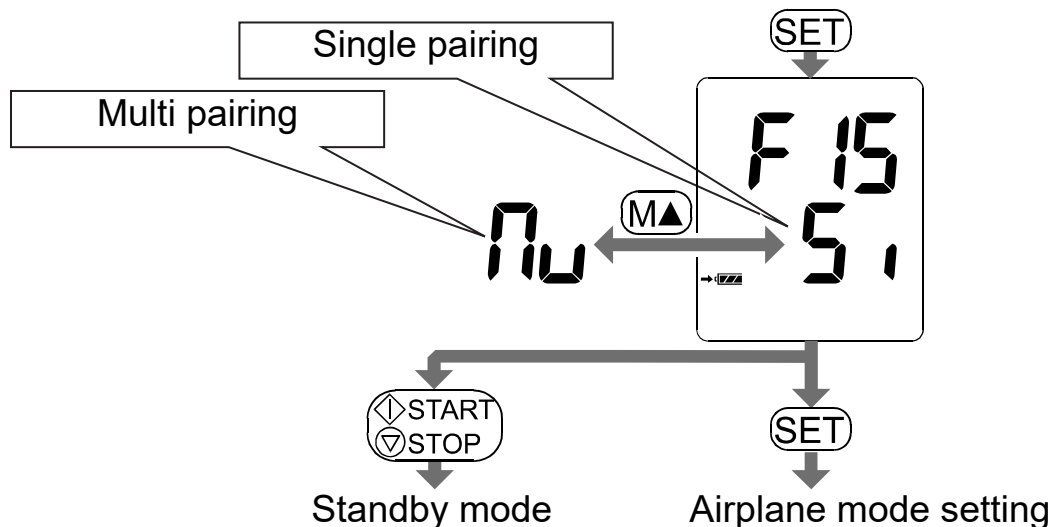


Pairing type

- Single pairing** Only one Bluetooth device (smart phone or tablet. etc) is available for pairing. When communicating to other Bluetooth devices, enable the pairing when needed individually.
- Multi pairing** This device allows Bluetooth devices to enable the pairing up to 15 units. When exceeding 15 units as pairing, this device rewrites newest pairing information on oldest one.

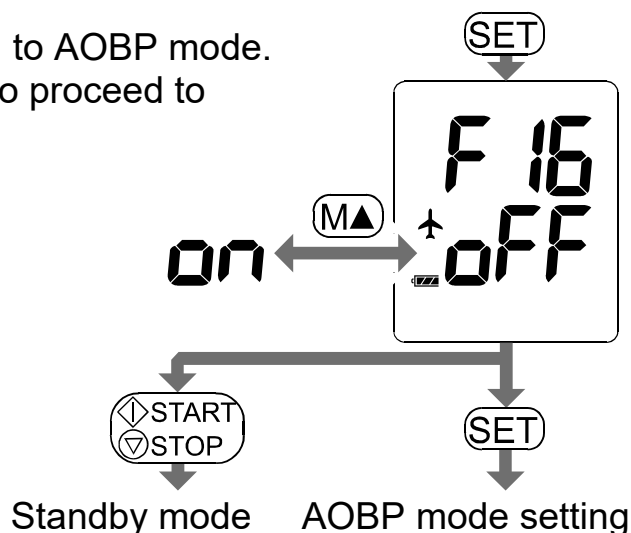
Note: When the pairing mode is switched, the pairing information maintained in the memory is cleared. Enable the pairing again after setting.

1. Press the **SET** button while the room temperature unit changing is operated (F14) to display pairing setting mode (F15). Display shows "F15" at systolic blood pressure display and shows current settings at diastolic blood pressure display.
2. Press the **M▲** button to switching the settings.
3. Select the following operations
 - ☐ Press the **SET** button to proceed to airplane mode.
 - ☐ Press the **START/STOP** button to proceed to standby mode.



Airplane mode

1. Press the **SET** button while the pairing setting is operated (F15) to display airplane mode (F16). Display shows “F16” at systolic blood pressure display and shows current settings at diastolic blood pressure display.
2. Press the **M▲** button to toggle between “on” and “off”.
3. Select the following operations
 - ☐ Press the **SET** button to proceed to AOBP mode.
 - ☐ Press the **START/STOP** button to proceed to standby mode.

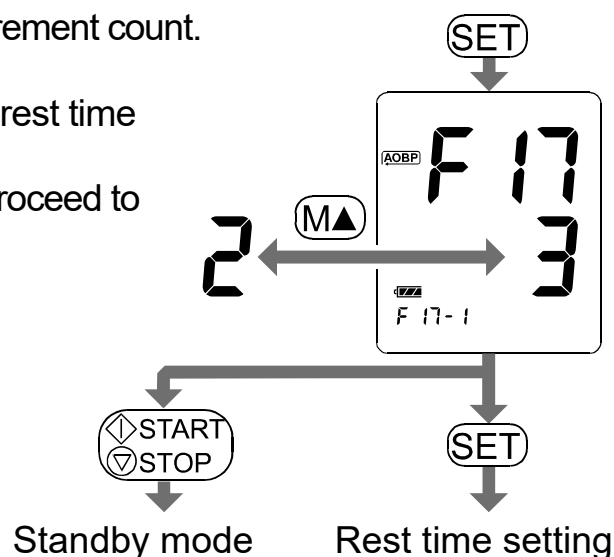


AOBP mode (multiple measurement mode)

Measurement count

1. Press the **SET** button while the airplane mode setting is operated (F16) to display measurement count setting of AOBP mode setting (F17-1). Display shows “F17” at systolic blood pressure display, shows “F17-1” at date display and shows “2” or “3” times as setting value at diastolic blood pressure display.
2. Press the **M▲** button to switch measurement count.
3. Select the following operations
 - ☐ Press the **SET** button to proceed to rest time setting mode.
 - ☐ Press the **START/STOP** button to proceed to standby mode.

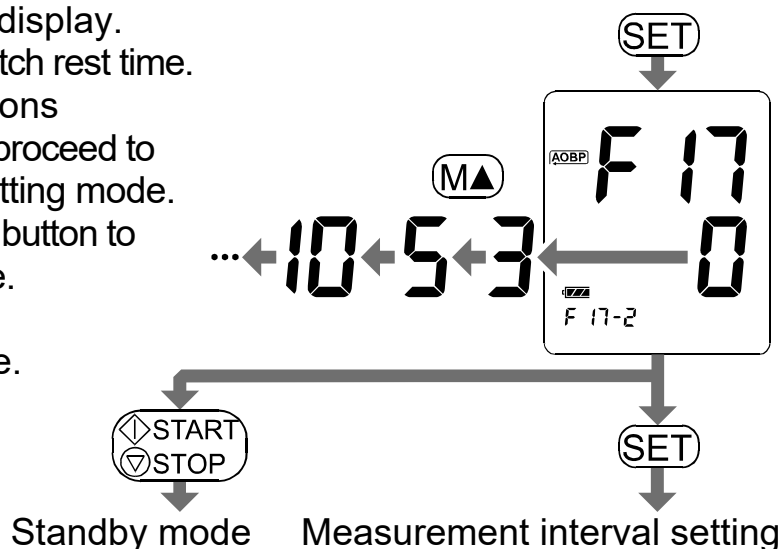
Note: Initial setting is 3 times.



Waiting time until next measurement of AOBP mode

1. Press the **SET** button while the measurement count setting is operated (F17-1) to display rest time setting of AOBP mode setting (F17-2). Display shows "F17" at systolic blood pressure display, shows "F17-2" at date display and shows any one of "0", "3", "5" or "10" minutes as setting value at diastolic blood pressure display.
2. Press the **M▲** button to switch rest time.
3. Select the following operations
 - ☐ Press the **SET** button to proceed to measurement interval setting mode.
 - ☐ Press the **START/STOP** button to proceed to standby mode.

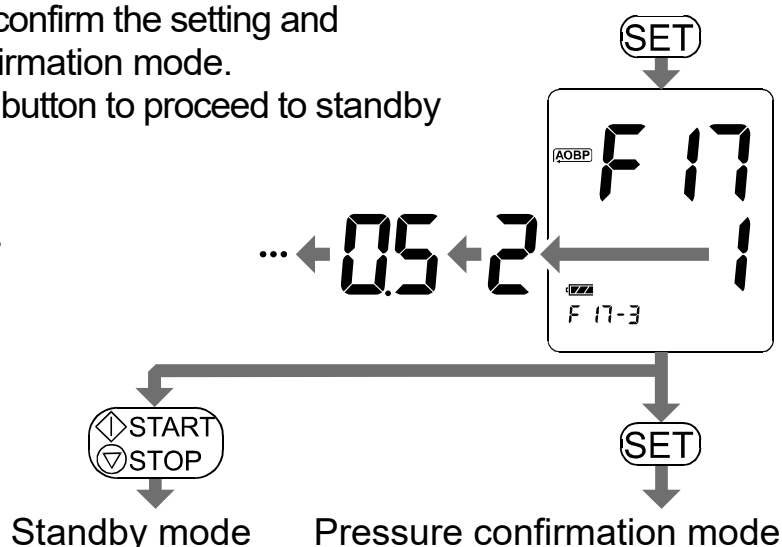
Note: Initial settings is 0 minute.



Measurement interval of AOBP mode

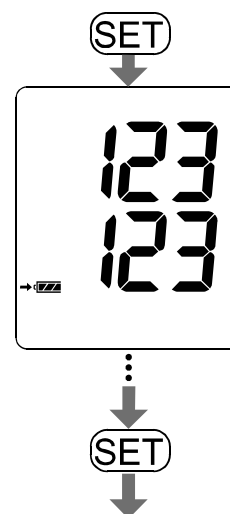
1. Press the **SET** button while the rest time setting is operated (F17-2) to display measurement interval setting of AOBP mode setting (F17-3). Display shows "F17" at systolic blood pressure display, shows "F17-3" at date display and shows any one of "0.5", "1" or "2" minutes as setting value at diastolic blood pressure display.
2. Press the **M▲** button to switch measurement interval.
3. Select the following operations
 - ☐ Press the **SET** button to confirm the setting and proceed to pressure confirmation mode.
 - ☐ Press the **START/STOP** button to proceed to standby mode.

Note: Initial setting is 1 minute.



Pressure confirmation mode

1. Press the **SET** button at the measurement interval setting mode (F17-3) to go into pressure confirmation mode.
The current pressure value is displayed at the display for systolic blood pressure and diastolic blood pressure.
2. When the pressure reaches 320 mmHg or higher, the value indicated on the display flashes 320 mmHg. After that, the display returns to previous one when the pressure display is less than 320 mmHg.
3. Press the **SET** button to proceed to maintenance mode. Press the **START/STOP** button to complete the confirmation. The device proceeds to standby mode.



Maintenance mode

Maintenance mode (F19)

Note: Do not use this mode.

Maintenance mode is only for use by certified maintenance facilities.

Data communication

Bluetooth®

- ❑ When this device causes a wave interference to other radio station, use it at another location or stop using it immediately.
- ❑ This device has wireless communication functions of Bluetooth Ver4.1 (Bluetooth low energy). The measurement data can only be communicated to Bluetooth devices corresponding to connection specifications conformed to Bluetooth 4.1(Bluetooth).

Bluetooth communication

Tips for Bluetooth communication

- ❑ Communicate at a location where nothing is blocking between this device and receiver. Communication distance becomes shorter depending on a structure of the building or obstructions. Particularly, when reinforced concrete etc. are blocking between them, there are cases when the communication cannot be performed.
- ❑ At Bluetooth connection, do not use this device and receiver around wireless LAN or other wireless communication devices, around a radio wave generating device such as microwave ovens, or at locations there are obstructions or there is a bad connection.
Otherwise, there are cases when the wireless communication frequently disconnects, the communication speed is very slow or the communication error occurs.
- ❑ When using this device and receiver close to a LAN device of IEEE802.11g/b/n, there are cases when the communication speed decreases or the wireless communication cannot be performed due to a wave interference between them. In such case, turn off the power of a device not being used or use it at another location.
- ❑ When this device and receiver cannot communicate properly around a radio station or broadcasting station, use them at another location.

Note

- ❑ We cannot guarantee for damages such as malfunctions or data loss due to a use of this device.
- ❑ This device cannot guarantee for connection operations on all devices corresponding to Bluetooth.


Bluetooth communication on this product

This product has Bluetooth wireless communication functions and can be connected to the following Bluetooth device.

Receiver device corresponding to Bluetooth low energy specifications.

Each device requires application software for receiving the data.

Refer to the instruction manual for application software of each device for details of connection method.

 **Bluetooth**[®] Bluetooth device has Bluetooth[®] logo mark printed on it.

Word mark and logo of Bluetooth is a registered trademark that belong to Bluetooth SIG, Inc.

A&D company, Ltd. is permitted using of those mark under the license.

Pairing

- ❑ Bluetooth device is necessary to enable the pairing on communication for a particular receiver. By enabling the pairing, the measurement data for this device can be communicated.
- ❑ Perform the following procedure to enable the pairing of this device and Bluetooth built-in receiver.

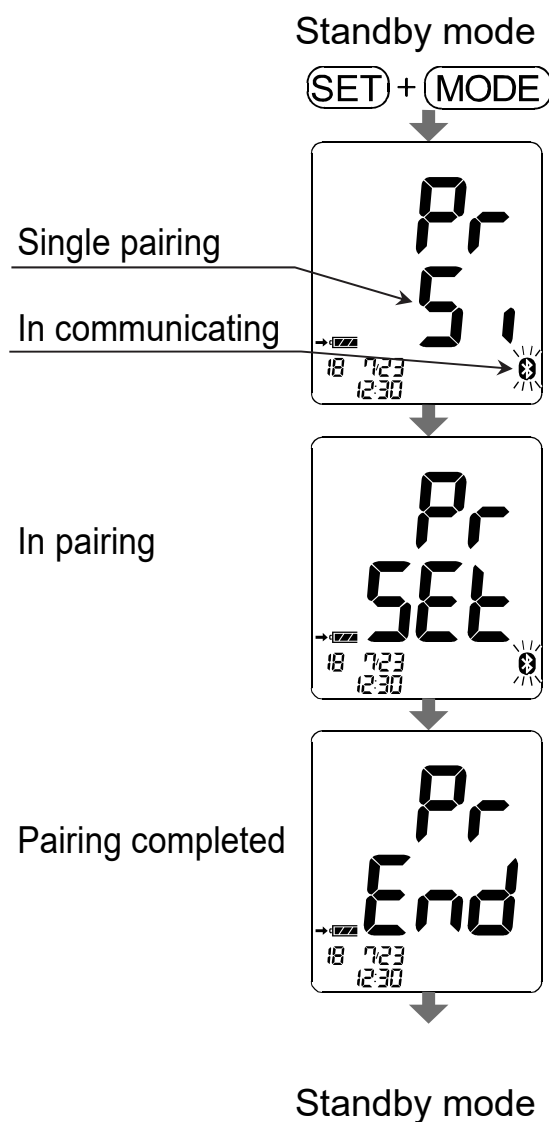
Also, refer to an instruction manual of pairing for the receiver.

If pairing wizard is provided, use it for pairing.

Single pairing

1. Select the “single pairing” while the pairing setting is operated (F15).
2. Press the **MODE** button while pressing the holding the **SET** button to start the pairing.
“Pr” is displayed at systolic blood pressure display and a current condition is displayed at diastolic blood pressure display.
3. Be sure that the receiver can make the pairing.
A pairing for this device must be made close to the receiver as possible as you can.

Note: When the pairing is not successfully made, this device displays “Pr Err” and returns to standby mode.



Multi pairing

1. Select the “Multi pairing” while the pairing setting is operated (F15).
2. The pairing can be made at the following mode after setting Standby mode, measurement standby mode, pressurization value setting (F01), auscultation exhaustion speed changing (F02), Hiding mode (F03), blood pressure measurement result non-display mode) and memory display
3. Be sure that the receiver can make the pairing.
Pairing for this device must be made as close to the receiver as possible.

Note: Confirm the success of the pairing by using the receiver.

Measurement and data communication

Note:

☐ **Measurement and data communication**

After pairing, the communication is automatically made by procedure below. Make sure the receiver is ready for communication.

1. Turn on the device power and take a measurement.
2. Transmit the measurement data after finishing the measurements.

☐ **Precautions on the measurements**

- The measurement data can be transmitted only while the measurement results are displayed.
Only prior measurement results can be transmitted as data.
- The communication distance between this device and the receiver vary depending on performances for a Bluetooth device to be communicated, battery remaining for each device and ambient environment.
For example, the communication distance becomes approx. 10 m under an environment where no obstruction is blocking.

☐ **Time**

This device a the built-in clock.

The measurement data includes the date and time measured.

Time can be adjusted using the application software for the receiver.

When removing the battery from this device, the time data is cleared.

Recalling the Memory Data

Note: This device stores the last 99 measurements in memory.

Recalling the memory data

1. Press the **M▲** button at standby mode or measurement standby mode to display a most recent memory data. Press the **START/STOP** button to start the measurement.

2. Each time the **M▲** button is pressed, the memory data is displayed as follows.

Most recent data (Example: No.28)

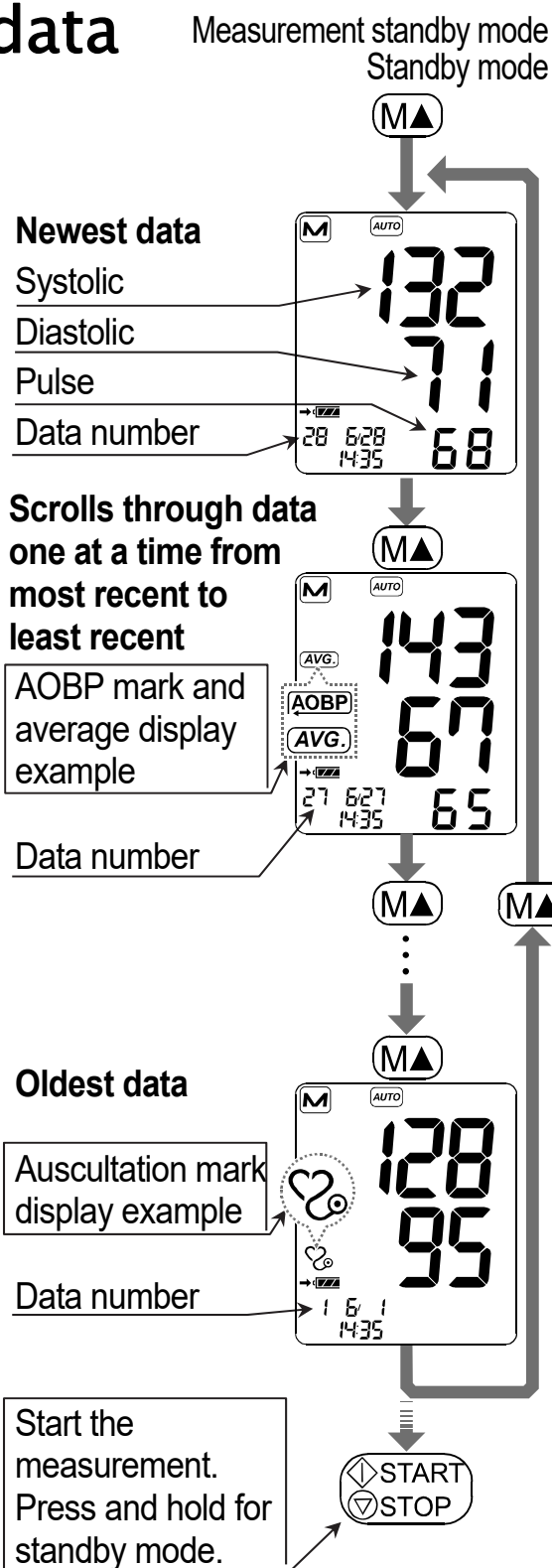


Previous data (No.1)

3. After the last data is displayed, press the **M▲** button to display the most recent data.

4. Select next operation.

- ☐ Press the **START/STOP** button to start the measurement.
- ☐ The device will proceed to standby mode automatically when no operation is made for a period of time.
- ☐ When the **START/STOP** button is pressed and held, the device will proceed to standby mode.
- ☐ When the auscultation measurement is completed, the device displays the auscultation mark and measurement results without displaying a pulse rate as shown in the figure at the right.
- ☐ If you use AOBP mode (a mode that measures multiple times), the **AOBP** mark is displayed.
- ☐ When the average value is displayed in AOBP mode, the **AVG.** mark is displayed.

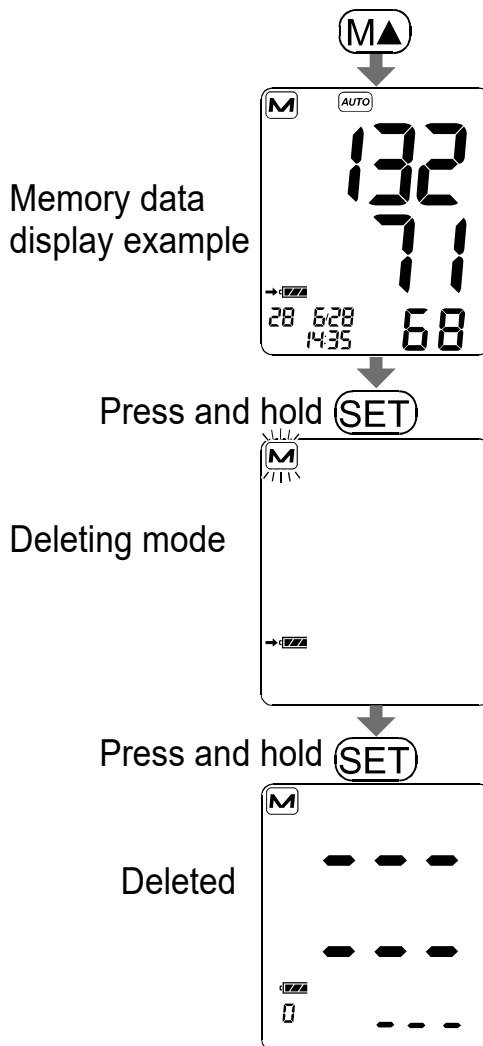


- If there is no data, the memory number, time, SYS, DIA and PUL is displayed in bar display.

Deleting all data stored in memory

1. If you press and hold the **SET** button for 3 seconds or more while displaying memory data, **M** will blink, the battery mark lights up.
2. If you press the **SET** button again for 3 seconds or longer, all the saved data will be deleted.
3. When erasing is complete, the memory number, time, SYS, DIA and PUL is displayed in bar display.

If you press the **M▲** button when there is no memory data, the display will be the same as when the deletion was completed.



Measurements

Selecting the correct cuff size

Using the correct cuff size is important for an accurate reading. If the cuff is not the proper size, an incorrect blood pressure value may be displayed.

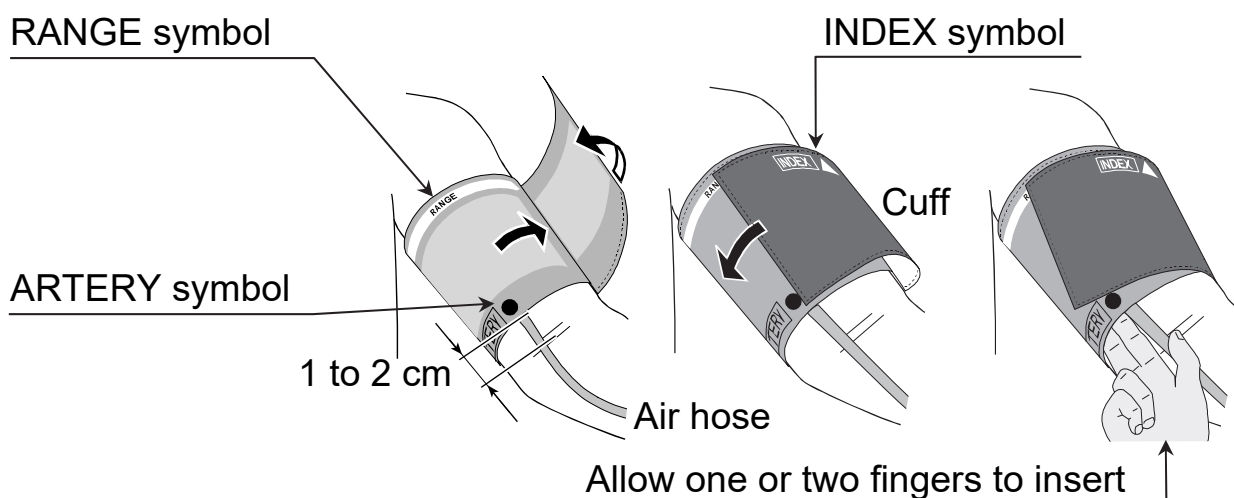
- ❑ The arm size is printed on each cuff.
- ❑ The arm cuff is a consumable. If it becomes worn, purchase a new one.

| Cuff Size | Arm Size | Symbols | Catalog Number |
|-----------|----------------|-------------|----------------|
| LL Cuff | 41 cm to 50 cm | LL | UM-LLRS4K1KEC |
| LA Cuff | 31 cm to 45 cm | LARGE ADULT | UM-LARS4K1KEC |
| A Cuff | 22 cm to 32 cm | ADULT | UM-AURS4K1KEC |
| SA Cuff | 16 cm to 24 cm | SMALL ADULT | UM-SARS4K1KEC |
| SS Cuff | 12 cm to 17 cm | SS | UM-SSRS4K1KEC |

Arm size: The circumference of an upper arm.

Applying the arm cuff

1. Face the palm of the left arm upward, and wrap the cuff around the upper arm, about 1 to 2 cm above the inside of the elbow.
A range where the INDEX mark can be overlapped on the RANGE mark shows a proper fit range for the cuff.
Note : Do not roll up shirtsleeve tightly.
2. Apply the cuff on the upper arm so that the ● mark overlaps the artery.
3. Wrap while keeping the looseness with the cuff around the upper arm so that it allows the one or two fingers to insert between the cuff and arm.



Normal measurement

1. Apply the cuff on the arm.
Sit quietly during the measurement.
2. When in standby mode or measurement standby mode, press the **START/STOP** button.
All of the display segments are displayed.
Zero (0) is displayed blinking briefly.
The display changes, as indicated in the figure on the right, as the measurement begins. The cuff starts to inflate. It is normal for the users to feel tight.

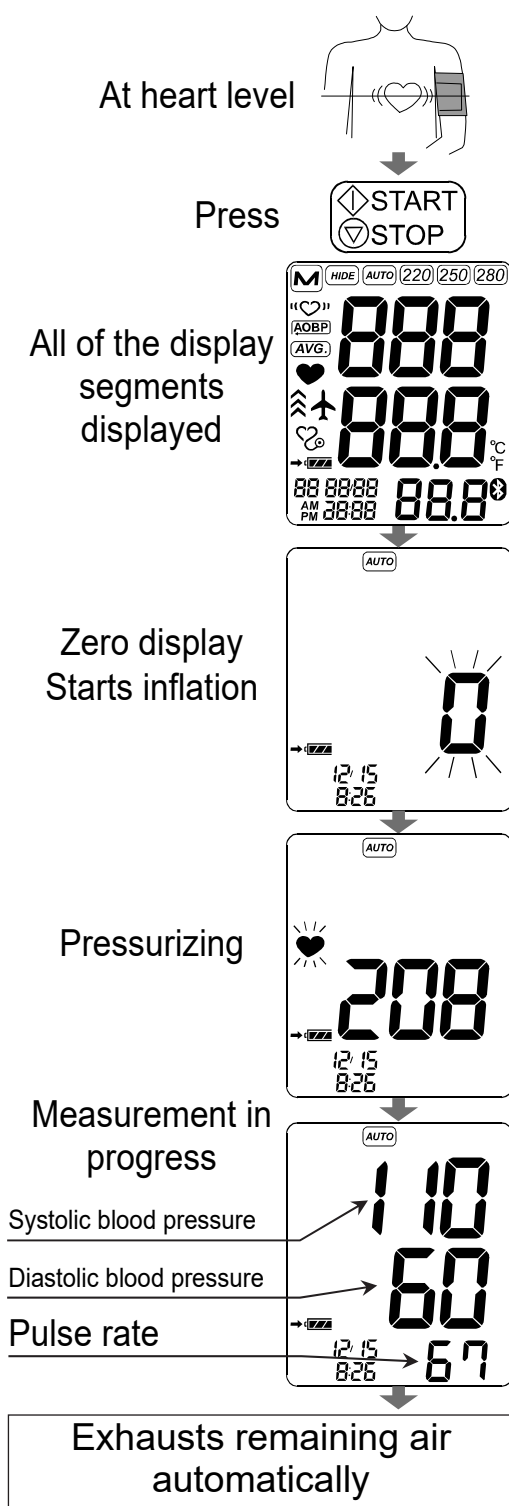
Note: If you want to stop inflation at any time, press the **START/STOP** button again.

3. When inflation is completed, deflation starts automatically and the ♥ (heart mark) blinks, indicating that the measurement is in progress. Once the pulse is detected, the mark blinks with each pulse beat.

Note: If an appropriate pressure is not obtained, the device starts to inflate again automatically.
To avoid re-inflation, see “Measurement with the SET Pressure” on the next page.

4. When the measurement is completed, the systolic and diastolic blood pressure readings and pulse rate are displayed. The cuff exhausts the remaining air and deflates completely.

5. Press the **START/STOP** button to carry out the measurement again.
The device will proceed to standby mode automatically when no operation is made for a regular time. And when the **START/STOP** button is pressed and held, device will proceed to standby mode.



Auscultation measurement

The auscultation measurement is performed when the auscultation setting mode is set to ON.

The auscultation measurement is returned to OFF automatically when the device goes into standby mode.

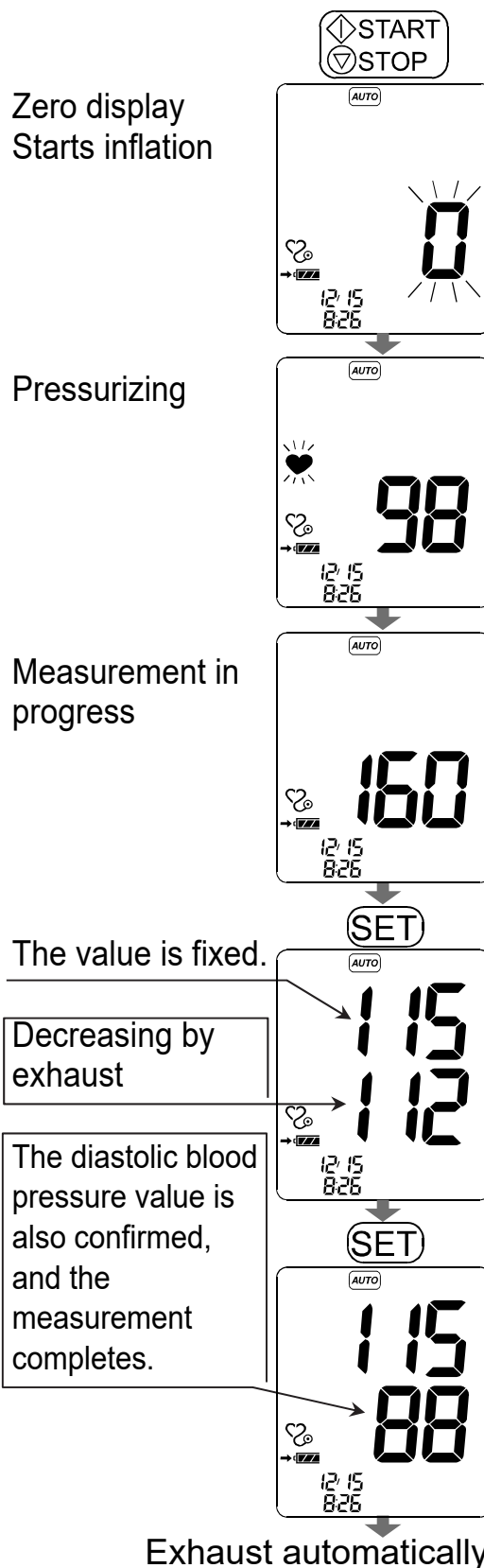
1. Press the **START/STOP** button to start pressurization. When the conditions for the end of pressurization are met, the device will automatically stop pressurizing. And it starts the constant speed exhaust.
2. The device exhausts at constant speed. Press the **SET** button to confirm the systolic blood pressure value. Press the **SET** button again to confirm the diastolic blood pressure value, and the device exhausts at quick speed.
3. Press the **M▲** button during exhausting at constant speed to perform the additional pressurization while the **M▲** button is being pressed. The additional pressurization mark illuminates in order from bottom during the additional pressurization. When additional pressurization is applied up to the systolic blood pressure value or more, the systolic blood pressure value is cleared.

Note: When the device is pressured at 300 mmHg or more, the device performs forced exhaust automatically.

A mark for the additional pressurization



4. Press the **START/STOP** button after measuring to carry out the auscultation measurement again.



Measuring using the AOBP mode

Select AOBP mode by setting measurement conditions of “AOBP mode setting (Multiple measurement)” to enable AOBP mode measurement.

If this device enters standby mode, it automatically returns to normal measurement mode from AOBP mode.

Setting example

Measurement count “F17-1” : 3 times
 Rest time “F17-2” : 3 minutes
 Measurement interval “F17-3” : 1 minute

1. Wrap the cuff on the arm.
 In measurement, sit in rest.
2. Select AOBP mode by using the **MODE** button to display **AOBP** mark.
3. Press the **START/STOP** button to start countdown for the rest time.
4. After the rest time elapses, the device will start to inflate until it reaches the proper pressurization. Deflation will then begin. The heart mark ♥ will blink when the device is detecting a pulse.

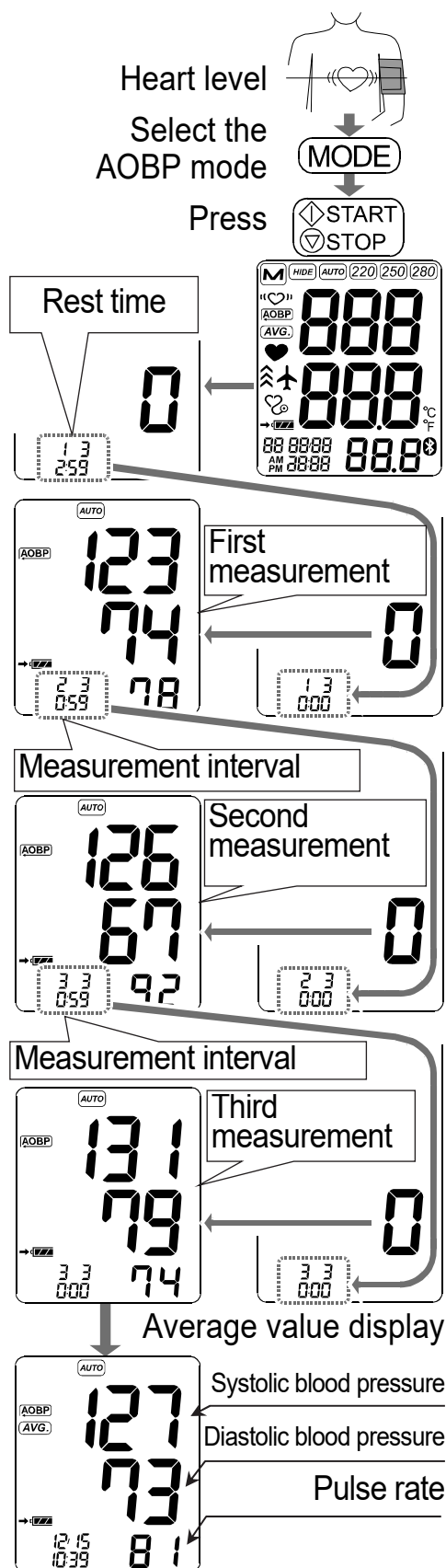
Note: When the blood pressure value cannot be obtained properly, this device automatically performs re-inflation.

When you wish to avoid re-inflation, perform the measurement after setting the re-inflation value properly.

Refer to “Measurement with the SET Pressure” for details.

To stop pressuring, press the **START/STOP** button again.

5. After ending the measurement, the air remaining in the cuff is automatically exhausted. The Display shows each measurement result of the systolic blood pressure value, diastolic blood pressure value and pulse rate. Countdown for the measurement interval starts.
6. If the device is set up for multiple measurements, the next measurement will start.
7. When all measurements are completed, the display will show results for the average value **AVG.**



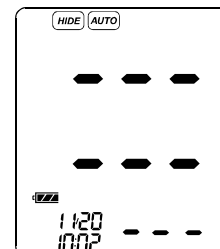
Note: When displaying average values of the measurement data, this device transmits “average values in addition to measurement data each”

When the measurement error occurs during the measurement at AOBP mode, this device automatically stops measuring.

Hiding mode

When enabling Hiding mode, this device does not display measurement results as shown in the figure at the right.

When confirming the measurement results, follow the procedure described in “Recalling the Memory Data”.



After measurement

- ❑ Press the **START/STOP** button if you want to start a new measurement.
- ❑ After measurement, the device proceeds to the standby mode when the **START/STOP** button is pressed and held (Three seconds). The device will proceed to standby mode automatically when no operation is made for a period of time. Remove the cuff and record the data.

Notes for accurate measurement

- ❑ Have the patient sit in a comfortable position. Ensure the patient's legs aren't crossed, that their feet touch the floor (if possible), their back is supported, and the arm being used for the measurement is supported. Have the patient place their arm on a table with the palm facing upward and ensure the cuff is at the patient's heart level.
- ❑ Have the patient relax for about five to ten minutes before taking the measurement. If the patient is excited or depressed by emotional stress, the blood pressure reading may be higher (or lower) than a normal blood pressure reading and the pulse reading will usually be faster than normal.
- ❑ An individual's blood pressure varies constantly, depending on what a patient is doing and what a patient has eaten. What a patient drinks may have a strong and rapid effect on patient's blood pressure.
- ❑ This device bases its measurements on the heartbeat. If a patient has a weak or irregular heartbeat, the device may have difficulties determining the patient's blood pressure.
- ❑ If the device detects an error, it will stop the measurement and the error symbol will be displayed. Refer to section "**Symbols on the display**".
- ❑ The blood pressure measurement may be affected by cuff position, patient's posture (standing, sitting or supine), exercise or physiological conditions.

- ❑ The automatic blood pressure monitor's performance may be affected by extreme temperature, humidity, impact, or altitude.

For the auscultation measurement

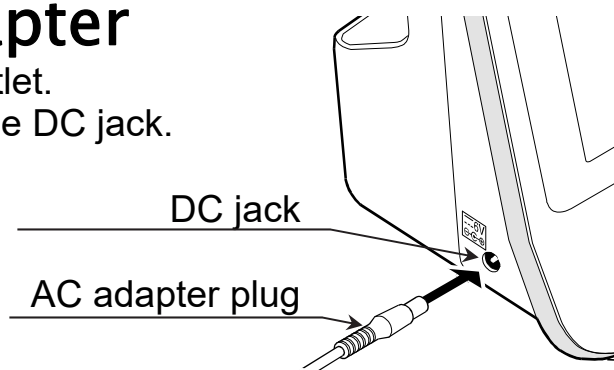
- ❑ K5 is recommended for the auscultation measurement in adults.
- ❑ K4 is recommended for the auscultation measurement in children aged 3 to 12 years.
- ❑ K5 is recommended for the auscultation measurement in pregnant women, however, K4 should be used if the sounds can be heard even with the cuff deflated.
- ❑ During the auscultation measurement, the operator should be in a position where the pressure value is clearly visible.

Note: K5 is the point at which the Korotkoff sounds can no longer be heard. K4 is the point at which the Korotkoff sounds changed in the tones heard through a stethoscope from a clear tapping sound to a muffled sound.

Removing the AC adapter

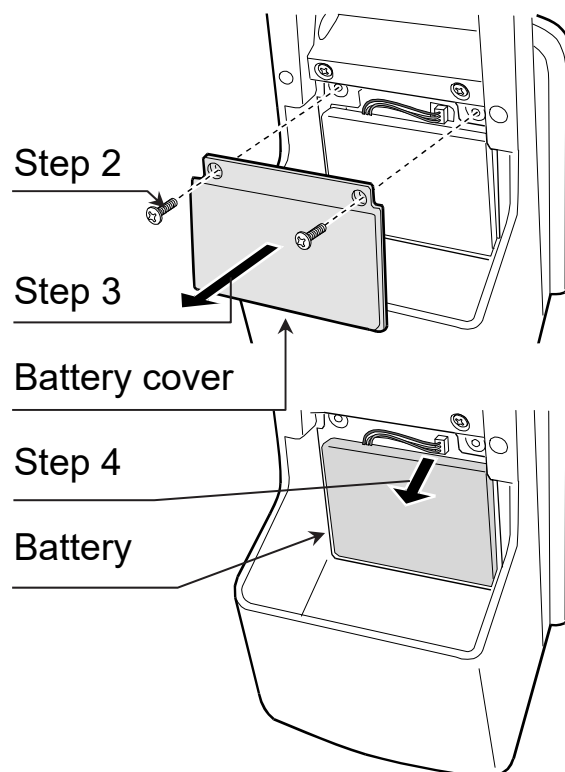
Remove the AC adapter from the outlet.

Remove the AC adapter plug from the DC jack.



Removing the battery

1. Confirm that the AC adapter is removed from outlet.
2. Remove the screws that secure the battery cover on the rear side of the main body.
3. Remove the battery cover.
4. Unplug the battery connector by depressing the hook on the left side.
6. Close the battery cover.
Secure the battery cover by using the screws.



Note: Should both the AC adapter and battery be disconnected from the device, the clock is initialized.

What is an Irregular Heartbeat?

The UM-212BLE blood pressure monitor provides a blood pressure and pulse rate measurement even when an irregular heartbeat occurs.

Irregular heartbeat (IHB)

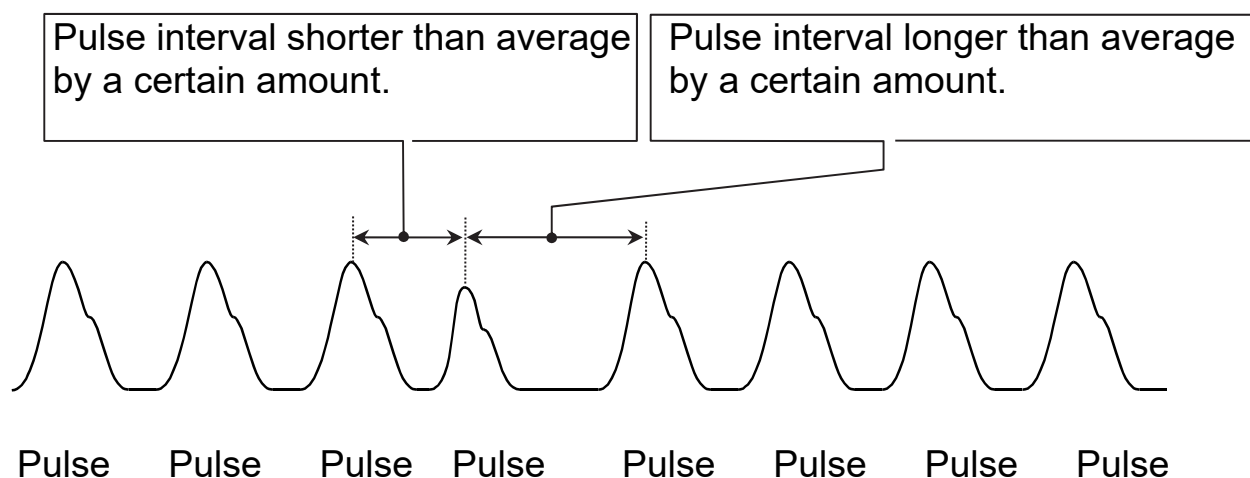
IHB (Irregular HeartBeat) means a fluctuation of the pulse interval. Among pulse intervals during the measurement, a pulse more than certain regular amount compared to an average of the pulse interval is called IHB.

When this device detects IHB, it indicates IHB mark «♡». Illuminating the IHB mark «♡» does not mean a detection for symptoms such as irregular pulse.


This device can measure blood pressure and pulse rate even when the IHB mark appears.

A fluctuation of the pulse interval appears due to various factors such as heart or other diseases in addition to physiological factor.

For example: exercise, body temperature rising, aging, constitution, mood changes.



Troubleshooting

| Problem | Possible Cause | Suggestion |
|---|---|---|
| Nothing appears on the display, even when the power is turned on. | Battery is drained. | Recharge the battery. |
| | Useful life for the battery was over. | Replace the old battery with new one. |
| The cuff does not inflate. | Battery power is too low.  (LOW BATTERY mark) blinks. If the battery is drained completely, the mark does not appear. | Recharge the battery. |
| The device does not measure. Readings are too high or too low. | The cuff is not applied properly. | Apply the cuff correctly. |
| | Patient moved patient's arm or body during the measurement. | Make sure patient remain still and quiet during the measurement. |
| | Movement is detected | Sit comfortably and still. Place patient's arm on a table with patient's palm facing upward and the cuff at the same level as patient's heart. |
| | _____ | If patient have a very weak or irregular heartbeat, the device may have difficulties in determining patient's blood pressure. |
| The battery runs out soon even after recharging the battery. | The battery has exhausted. | Replace the old battery with new one. |
| Other | _____ | Remove the batteries. Put them back properly and take measurement again. |

Note: If the suggestions described above do not solve the problem, contact the authorized dealer. Do not attempt to open or repair this product, otherwise your warranty may be invalid.

Maintenance

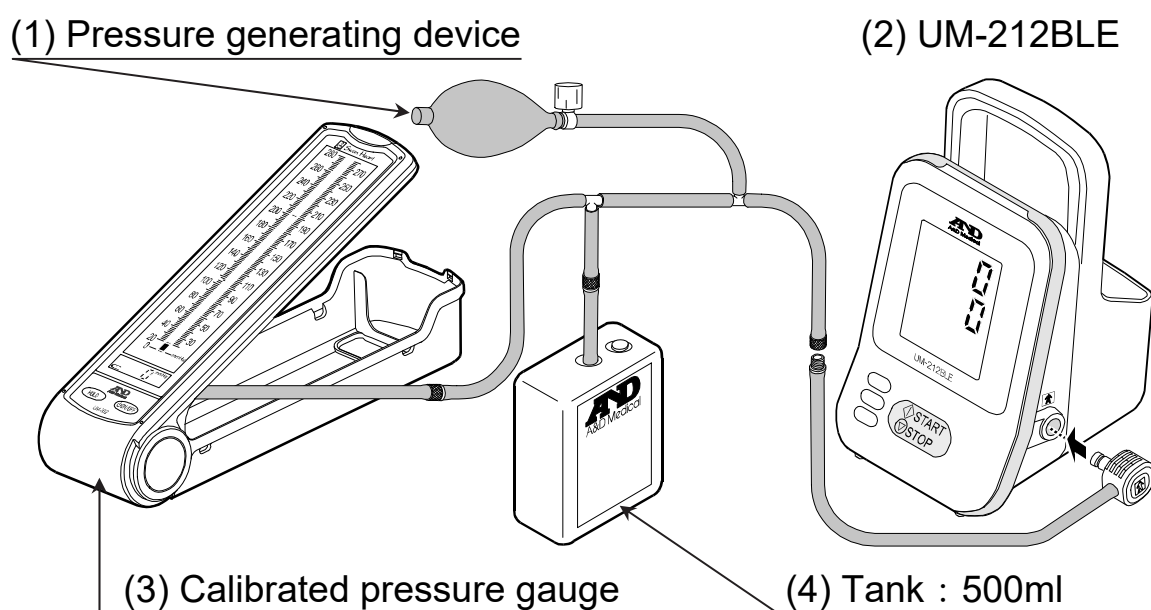
Maintenance

Do not attempt to open the device as the delicate electrical components and intricate air unit inside could be damaged. If you cannot solve the problem using our troubleshooting guide, request assistance from your authorized dealer or from any A&D service group.

The device is designed and manufactured for a long service life. However, it is generally recommended to have the device inspected every 2 years, to ensure proper functioning and accuracy. Please contact either your authorized dealer or A&D service group for maintenance.

Pressure confirmation

Example of connection



1. Press and hold the **SET** button at standby mode. The device goes into the built-in clock adjusting mode, and F10 is displayed at the display.
2. Press the **SET** button several times to proceed to pressure confirmation mode.

* Refer to the page 30 in this manual for its setting.

Zero display

3. Add the pressure using the pressure generating device once the display at the UM-212BLE becomes zero display, and confirm the pressure at the pressure gauge and UM-212BLE.

| |
|---|
| 0 |
| 0 |

Cleaning

- ☐ Remove the AC adapter from the device when cleaning the device.
- ☐ When the main body or cuff is dirty, wipe them fully by using a gauze or cloth dampened with warm water and a neutral detergent avoiding excess water.
- ☐ Do not use the dampened cloth etc. to wipe the DC jack and air socket. The DC jack and air socket must remain dry.
- ☐ To prevent a risk due to infection, disinfect the main body and cuff regularly. When disinfecting them, wipe them gently by using the gauze or dampened cloth with local antiseptic solution then wipe the moisture off the surface by using a dry soft cloth.
- ☐ Use the following disinfectants to clean the main body and cuff.

| |
|---|
| Ethanol (76.9% - 81.4%) |
| Isopropanol (70%) |
| Chlorhexidine Gluconate Solution (0.5%) |
| Benzalkonium Chloride Solution (0.1%) |

- ☐ Clean the device about once every month, based on your facility policy.

CAUTION

- ☐ The blood pressure monitor is not a waterproof device. Do not splash water on it and avoid exposure to moisture.
- ☐ Do not use an organic solvent such as thinner or benzine.
- ☐ The blood pressure monitor cannot be sterilized by autoclave, EOG or formaline gas etc.
- ☐ Do not rub the cuff with a brush or other abrasive cleaning material.
- ☐ Do not use maintenance mode(F19).

Regular inspection

- ☐ The blood pressure monitor is a precision device. Therefore, inspect it regularly. Request an inspection from the dealer where you have purchased the device when the device is in need of an inspection.
- ☐ The cuff is a consumable. Regularly exchange the cuff with new one.

Disposal

This equipment and battery are not treated as ordinary household waste and must be disposed of according to the applicable local regulations.

| Item | Parts | Material |
|---------------------------|----------------|-------------------------------|
| Package | Box | Cardboard |
| | Cushion | Cardboard |
| | Bag | PE |
| Main unit and accessories | Enclosure | ABS, SR |
| | Internal parts | General electronic components |
| Battery pack | Outer case | ABS |
| | Cell battery | Nickel-hydrogen battery |
| | Internal parts | General electronic components |

Accessories Sold Separately

Cuff

| Cuff Size | Arm Size | Catalog Number |
|-----------|----------------|----------------|
| LL Cuff | 41 cm to 50 cm | UM-LLRS4K1KEC |
| LA Cuff | 31 cm to 45 cm | UM-LARS4K1KEC |
| A Cuff | 22 cm to 32 cm | UM-AURS4K1KEC |
| SA Cuff | 16 cm to 24 cm | UM-SARS4K1KEC |
| SS Cuff | 12 cm to 17 cm | UM-SSRS4K1KEC |

Arm size: The circumference of an upper arm.

Rechargeable battery






| Catalog Number |
|----------------|
| UM-211-30 |

Mobile Stand

| Catalog Number |
|----------------|
| UM-ST002 |

Specifications

| | |
|--------------------------------|--|
| Type | UM-212BLE |
| Measurement method | Oscillometric measurement |
| Measurement range | Pressure: 0 - 299 mmHg Systolic blood pressure: 60 - 279 mmHg Diastolic blood pressure: 40 - 200 mmHg Pulse: 40 - 200 beats / minute |
| Measurement accuracy | Pressure: ± 3 mmHg Pulse: $\pm 5\%$ |
| Temperature unit | $^{\circ}\text{C}$ or $^{\circ}\text{F}$ |
| Temperature accuracy | ± 2.5 $^{\circ}\text{C}$ ($+5$ $^{\circ}\text{C}$ to $+40$ $^{\circ}\text{C}$) ± 4.5 $^{\circ}\text{F}$ ($+41$ $^{\circ}\text{F}$ to $+104$ $^{\circ}\text{F}$) |
| Power supply | Built-in 3.6 V battery (UM-211-30) or AC adapter (TB-268) |
| Number of measurements | Approx. 300 measurements, when built-in battery is used, with pressure value of 180 mmHg at room temperature of 23 $^{\circ}\text{C}$ (73.4 $^{\circ}\text{F}$) |
| Classification | Internally powered ME equipment (Supplied by batteries) / Class II (Supplied by adapter) Continuous operation mode |
| Clinical test | According to ISO81060-2 2013 In the clinical validation study, K5 was used on 85 subjects for determination of diastolic blood pressure. |
| EMD | IEC 60601-1-2: 2014+A1: 2020 |
| Memory | Last 99 measurements |
| Operating condition | $+5^{\circ}\text{C}$ to $+40^{\circ}\text{C}$ ($+41^{\circ}\text{F}$ to $+104^{\circ}\text{F}$) 10 %RH to 85 %RH (Not condensed), 800 hPa to 1060 hPa |
| Transport / Storage conditions | -20°C to $+60^{\circ}\text{C}$ (-4°F to $+140^{\circ}\text{F}$) 10 %RH to 95 %RH (Not condensed), 700 hPa to 1060 hPa |
| Dimensions | Approximately 120 [W] x 200 [H] x 140 [D] mm 4.7 [W] x 7.9 [H] x 5.5 [D] inch |
| Weight | Approximately 550 g (19.4 oz, 1.2 lb), excluding the battery |

| | |
|-------------------------------------|--|
| Instruction manual | |
| Ingress protection | Device: IP21 |
| Applied part | Cuff Type BF  |
| Useful life | Device: 5 years (when used six times a day) Cuff: 1 year (or used 30000times) AC adapter: 5 years(when used six times a day) |
| Contents *2 | 1 Blood Pressure Monitor, 1 Instruction Manual 1 Cuff, 1 Battery, 1 AC adapter, 1 AC cable |
| Rechargeable Battery (UM-211-30) | Nickel-Metal Hydride Battery 3.6 V Typ. 2000 mAh, Min.1750 mAh |
| AC adapter (TB-268) | The AC adapter is required to be inspected or replaced periodically. Input: 100-240 V, 50-60 Hz, 0.3A Output: 6 V  2000 mA,    |
| Communication | Bluetooth Ver.4.1 Low Energy technology BLP |
| Communication specification | Frequency band used: 2402-2480 MHz Modulation method: GFSK Effective radiation power: 2.1 dBm |

*2: Confirm that all of the parts are included to ensure that the medical device is ready to perform safely and as intended.

Note: Specifications are subject to change without prior notice.

IP classification is the degrees of protection provided by enclosures in accordance with IEC 60529. This monitor is protected against solid foreign objects of 12 mm diameter and greater such as a finger. This monitor is protected against vertically falling drop of water.

Technical Data

EMD Technical Data Battery-operated or AC Adapter-operated Blood Pressure Monitor.

This product complies with the EMD (electromagnetic interference) standard IEC60601-1-2: 2014+A1: 2020 for the safe use of medical electrical equipment. Below is a technical description of EMD.

Medical Electrical Equipment needs special precautions regarding EMD and needs to be installed and put into service according to the EMD information provided in the following. Portable and mobile RF communication equipment (e.g. cell phones) can affect Medical Electrical Equipment. The use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the unit. Medical electrical equipment must be installed and provided according to the EMD information provided below.

Table 1 EMISSION Limits–

| Phenomenon | Compliance |
|--|------------------|
| Conducted and radiated RF EMISSION CISPR 11 | Group 1, Class B |
| Harmonic distortion IEC 61000-3-2 | Class A |
| Voltage fluctuations and flicker IEC 61000-3-3 | Compliance |

Table 2 IMMUNITY TEST LEVELS:Enclosure Port–

| Phenomenon | IMMUNITY TEST LEVELS |
|---|--|
| Electrostatic discharge IEC 61000-4-2 | ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air |
| Radiated RF EM fields IEC 61000-4-3 | 10 V/m, 80 MHz - 2.7 GHz 80 % AM at 1 kHz |
| Proximity fields from RF wireless communications equipment IEC 61000-4-3 | See table 4 |
| Rated power frequency magnetic fields IEC 61000-4-8 | 30 A/m 50 Hz or 60 Hz |
| Proximity magnetic fields IEC 61000-4-39 | See table 5 |

Table 3 IMMUNITY TEST LEVELS:Input a.c. power Port–

| Phenomenon | IMMUNITY TEST LEVELS |
|--|---|
| Electrical fast transients / bursts IEC 61000-4-4 | ±2 kV 100 kHz repetition frequency |
| Surges Line-to-line IEC 61000-4-5 | ±0.5 kV, ±1 kV |
| Conducted disturbances induced by RF fields IEC 61000-4-6 | 3 V 0.15 MHz - 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz |

| | |
|--|--|
| Voltage dips IEC 61000-4-11 | 0 % U_T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° |
| | 0 % U_T ; 1 cycle And 70 % U_T ; 25/30 cycle Single phase: at 0° |
| Voltage interruption IEC 61000-4-11 | 0% U_T ; 250/300 cycle |
| NOTE U_T is the AC mains voltage prior to application of the test level. | |

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

| Test frequency (MHz) | Band (MHz) | Service | Modulation | Maximum power (W) | Distance (m) | IMMUNITY TEST LEVEL (V/m) |
|----------------------|-------------|--|--------------------------------------|-------------------|--------------|---------------------------|
| 385 | 380 - 390 | TETRA 400 | Pulse modulation 18 Hz | 1.8 | 0.3 | 27 |
| 450 | 430 - 470 | GMRS 460 FRS 460 | FM ±5 kHz deviation 1 kHz sine | 2 | 0.3 | 28 |
| 710 745 780 | 704 - 787 | LTE Band 13,17 | Pulse modulation 217 Hz | 0.2 | 0.3 | 9 |
| 810 870 930 | 800 - 960 | GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5 | Pulse modulation 18 Hz | 2 | 0.3 | 28 |
| 1720 1845 1970 | 1700 - 1990 | GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1,3,4,25 UMTS | Pulse modulation 217 Hz | 2 | 0.3 | 28 |
| 2450 | 2400 - 2570 | Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7 | Pulse modulation 217 Hz | 2 | 0.3 | 28 |
| 5240 5500 5785 | 5100 - 5800 | WLAN 802.11 a/n | Pulse modulation 217 Hz | 0.2 | 0.3 | 9 |

Table 5 — Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields —

| Test frequency | Modulation | IMMUNITY TEST LEVEL (A/m) |
|----------------|-----------------------------|------------------------------|
| 30 kHz | CW | 8 |
| 134.2 kHz | Pulse modulation 2.1 kHz | 65 |
| 13.56 MHz | Pulse modulation 50 kHz | 7.5 |

MEMO

[illegible]

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