

TM-2440

Recorder for Ambulatory Blood
Pressure Monitor

INSTRUCTION MANUAL

Ambulatory Blood Pressure Monitor

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Compliance

Compliance with European Directive

The device conforms to Medical Devices Directive 93/42/EEC.

This is evidenced by the CE mark of conformity accompanied by the reference number of a designated authority.

The device conforms to RoHS Directive 2011/65/EU.

Compliance with the Australian EMD Framework




The device conforms to the following requirements:

EMD Emission standard for industrial, Scientific & Medical equipment AS/ NZS 2064:1997, EMD Generic Immunity standard AS/ NZS 4252.1:1994. The above is evidenced by the C-Tick label.




Warning Definitions

To prevent accidents due to inappropriate handling, this product and its manual contain the following warning signs and marks. The meaning of these warning signs and marks are as follows.

Warning Definitions

 Danger	An imminently hazardous situation that will result in death or serious injury, if not avoided.
 Warning	A potentially hazardous situation that could result in death or serious injury, if not avoided.
 Caution	A potentially hazardous situation that may result in minor or moderate injury, if not avoided. It may also be used to alert against unsafe practice.

Symbol Examples

	The symbol \triangle indicates "Caution". The nature of the caution required is described inside or near the symbol, using text or a picture. The example indicates caution against electrical shock.
	The symbol \circ indicates "Do not". The prohibited action is described inside or near the symbol, using text or a picture. The example indicates "Do not disassemble".
	The symbol \bullet indicates Mandatory action. The mandatory action is described inside or near the symbol, using text or a picture. The example indicates general mandatory action.

Other

Note	Provides information useful for the user to operate the device.
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Precautions for each operation are described in the pages of this manual. Read the instruction manual before using the device.

Precautions for Use

In order to use the TM-2440 (the recorder for ambulatory blood pressure monitor) safely and correctly, carefully read the following precautions before using the monitor. The following content summarizes general matters regarding the safety of patients and operators, in addition to safe handling of the monitor. Precautions for each operation are described in the pages of this manual. Read the instruction manual before using the device.

1. Precautions When Wearing and Storing the Recorder.

Danger



Keep the recorder away from areas where flammable anesthetics or flammable gases are present, high-pressure oxygen chambers, and oxygen tents. Using the recorder in these areas may cause an explosion.

Don't use the recorder combined with magnetic resonance imaging system (MRI).

Caution



To preserve capabilities of the device, consider the following environmental conditions when using and storing the recorder. Performance of the recorder may be affected by excessive temperature, humidity and altitude.

- Avoid locations where the recorder may be splashed by water.
- Avoid locations with high temperature, high humidity, direct sunlight, dust, salt and sulfur in the air.
- Avoid locations where the recorder may be tilted, vibrated, or impacted (including during transportation).
- Avoid locations where chemicals are stored or gas occurs.

Caution



- Operation conditions :
Temperature : +10 °C to +40 °C,
Humidity : 30 %RH to 85 %RH (no condensation).
- Transport and storage conditions :
Temperature : -20 °C to +60 °C,
Humidity : 10 %RH to 95 %RH (no condensation).

2. Precautions Before Using the Recorder.

Caution



- Confirm that the recorder operates safely and correctly.
- When the recorder is used in conjunction with other devices, it may cause an incorrect diagnosis or safety problems. Confirm that devices can be connected safely.
- Check for mutual interference with other medical devices. Confirm that the recorder can be used correctly.
- Use accessories, options and consumables specified by A&D.
- Carefully read the instruction manuals provided with optional items. Cautions and warnings are not described in this manual.
- For safe and correct use of the recorder, perform inspections before use.
- Leave the recorder in normal operation condition one hour or more before use and turn on it.



- Connect only **dedicated peripheral** to the USB connector. Do not connect other devices.
- Except for authorized cuff by A&D, do not connect to air socket.

Note

Preparation of the Recorder

- Delete last data stored in the recorder before it is used by the next patient.
- Replace batteries before the recorder is used by the next patient.

Device

- Use the recorder for diagnosis and countermeasures only.
- Confirm that the air hose and cuff are worn correctly. (Example : kink and tension of the air hose, position and direction of the cuff)

Instructions for Patient Wearing the Device


- Inform the patient how to suspend automatic blood pressure measurement to stop the recorder when alone if trouble occurs.
- Inform the patient to remove the recorder quickly when in pain or if any trouble occurs.
- Take care when using around babies and infants, as there is a danger of suffocation with air hose accidentally.

3. Precautions for Batteries Used for Blood Pressure Measurement.



Caution








- Install batteries in accordance with polarity signs "+" and "-" shown on the inside of the battery cover. (Caution for polarities)
- Replace consumed batteries to new ones at the same time.
- Remove batteries if the recorder is not to be used for a long period of time. The battery may leak and cause a malfunction.
- Use two alkaline batteries (size AA) or specified re-chargeable batteries (size AA, Ni-MH).
- Push and hold the "-" spring terminal with the battery. Slide and install the "+" terminal of the battery along the "+" terminal of the battery compartment. If the battery is installed from

	<p>the "+" terminal, the battery cover may be damaged.</p> <ul style="list-style-type: none"> □ Do not touch the battery and patient at the same time. It may cause an electric shock.
	<p>Do not mix an old battery with a new one. Does not use batteries of different type and maker. If these use, it may cause of leakage, heat and explosion. The malfunction of the recorder may occur.</p>

4. Precautions During Use.

 Danger	
	<p>Do not use the recorder while operating automobiles or other vehicles.</p> <p>Example : The recorder may inhibit motion of body or arms when operating vehicle. etc.</p>

 Warning	
	<p>This medical device can be only operated by doctor, authorized person by the law. Explain correct usage to the patient and ensure they can stop measurement when trouble occurs.</p>
	<p>Do not use a mobile phone near the recorder (less than 30 cm). It may cause a malfunction.</p>

 Caution	
	<ul style="list-style-type: none"> □ Stop the use of the recorder and suspend automatic blood pressure measurement if the patient feels pain in his arm or the measurement is incorrect. □ Do not use the recorder in a strong magnetic or electric field. □ Do not use the recorder on patient using a heart-lung machine.

Note

Instructions for Patient

If temperature is low, battery power becomes lower and measurement count is reduced.

5. Precautions After Using the Recorder.

Caution

Processing work of Measurement Data

- Be sure to process measurement data immediately using **dedicated peripheral**.

The Recorder

- After cleaning up accessories, arrange and store them.
- Clean up the recorder so as to be able to use next measurement.
- Suspend automatic blood pressure measurement. Otherwise, pressurization of the automatic measurement is started at next measurement start time and the cuff or other parts may be broken by the inflation.
- Remove batteries from the recorder if it is not used for a long period of time. Batteries may leak and break the recorder.
- Avoid using the recorder by a child oneself. Do not put the recorder in a place within reach of an infant. Doing so may cause accidents or damage.



Hold the connector housing when connecting and removing the cable. Do not pull the cable.

Note



Precautions After Using the Recorder (TM-2440)

Be sure to process measurement data immediately using **dedicated peripheral** after finishing measurement.

Backup Lithium Rechargeable Battery

The recorder is built with a backup lithium battery. This battery supplies power to the built-in clock when replacing AA batteries used for blood pressure measurement. The lithium battery is charged from AA batteries.

How to Extend the Life of the Backup Battery

- When first using after purchase or after storing for a month or more, replace batteries and charge the backup battery. It is enough if the backup battery is charged for 48 hours or more.
(The backup battery is always charged by AA batteries.)
- Replace with two new AA batteries when the battery indicator displays .
- When  is displayed at the battery indicator, the blood pressure measurement and data communication cannot be performed. Replace two new AA batteries.
- Remove batteries to prevent the recorder from liquid leakage of battery if the recorder is not used for a month or more.

6. The Countermeasures When the Device Has an Error

Warning



- Stop the operation and remove AA batteries. If battery terminals are shorted, battery may be hot.
- In a failure, the cuff may get hot during measurement, please handle it with care.

- Put the notice label of "**Malfunction**" "**Do not use**" on the recorder. Contact your dealer.
- Stop the recorder immediately when the measurement time is above 180 seconds and the air pressure becomes above 299 mmHg.

7. Precautions of Maintenance

Warning



- Confirm correct performance and safety of the recorder when it not used for a long period of time.
- To maintain correct measurement and safety, perform inspection and maintenance before use. The user (hospital, clinic, etc.) is responsible for management of the medical equipment. If inspection and maintenance are not performed correctly, an accident may occur.

Caution



- Use a dry lint free cloth for the care of the recorder.
Do not use volatile agents like a thinner, benzine.
Do not use wet cloth.



- Do not disassemble or modify the recorder (medical electronic device). It may cause damage.


8. Precautions and Countermeasures of Malfunction Due to Strong Electromagnetic Wave


Caution




- The recorder complies with EMD-standard IEC60601-1-2: 2014. However, to prevent electromagnetic interference with other devices, do not use mobile phones near the recorder.


- | | |
|--|--|
| | <ul style="list-style-type: none">□ If the recorder is located near strong electromagnetic waves, noise may invade in waveforms and malfunctions may occur. If unexpected malfunction occur during use, check the electromagnetic interference and take appropriate actions. |
|--|--|


 Caution	
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	The following examples are general causes of malfunction and countermeasures.
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- | | |
|---|---|
|  | <ul style="list-style-type: none">□ Use of mobile phones
Radio waves may cause unexpected malfunctions.<ul style="list-style-type: none">▪ Wireless communication devices, home networking devices such as walkie-talkies mobile phones, cordless phones and these types of communication devices can affect the recorder. Therefore, they are necessary to keep a minimum distance of 30 cm or more from the recorder.□ If there is static electricity in the usage environment (discharges from devices or the surrounding area)<ul style="list-style-type: none">▪ Before using the recorder, ensure that the operator and patient have discharged static electricity.▪ Humidify the room. |
|---|---|

9. Environmental Protection

 Caution	
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	Before disposing of the recorder, remove the lithium battery from the recorder.
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Precautions For Safe Measurement


The section describes precautions concerning the measurement and sensor. Always consult with a doctor for evaluation of the results and treatment. Self-diagnosis and self-treatment based on results can be dangerous.

Blood Pressure Measurement



Warning

	Ensure the tube is not bent excessively and that air flows properly. If a bent air hose is used, air pressure may remain the cuff, which may stop blood flow to the arm.
	<ul style="list-style-type: none">□ Do not measure the blood pressure on an arm if the patient has the following circumstances. This may cause an accident or aggravation of the injury.<ol style="list-style-type: none">1) An injury or disease exists on an arm.2) An arm receiving an intravenous drip or blood transfusion.3) Limb shunted for artificial dialysis.4) Bedridden situation for a long time (The situation that is possibility of thrombus).

Caution

	<ul style="list-style-type: none">□ Confirm the condition of the patient if there is measurement trouble. It guesses that the condition worsens over the limit of measurement or the bending air hose is stopped air flow.□ Measuring blood pressure too frequently may cause bodily harm due to blood flow interference. Confirm that the operation of the device does not result in prolonged impairment of blood circulation, when using the device repeatedly.□ Blood pressure measurement may not be accurate if the patient has continuous arrhythmia, or moves excessively.
---	--

Caution

	<ul style="list-style-type: none">□ Wear the cuff at the same level as heart. (If the level is different, it occurs an error of the measurement value.)□ The recorder corresponds to artifact and shock. If there are any doubts in the measurement value, measure blood pressure by auscultation or palpation.□ Measurement error may occur if the cuff is not of suitable arm circumference for the patient.
	<p>Do not inflate the cuff before it is wrapped around the arm of the patient. It may cause of damage and explosion of the cuff.</p>

Note

- Blood pressure measurement may cause subcutaneous bleeding. This subcutaneous bleeding is temporary and disappears with time.
- If the patient uses heart-lung machine, blood pressure cannot be measured due to absence of heartbeat.
- Blood pressure cannot be measured correctly if thick cloth is worn.
- Blood pressure cannot be measured correctly if the cloth is rolled up and arm is squeezed.
- Blood pressure cannot be measured correctly if peripheral circulation is insufficient, blood pressure is excessively low or if the patient has hypothermia (blood flow is insufficient).
- Blood pressure cannot be measured correctly if the patient has frequent arrhythmia.
- Blood pressure cannot be measured correctly with unsuitable cuff size.
- Blood pressure cannot be measured correctly if the cuff is not worn at the same level as heart.
- Blood pressure cannot be measured correctly if the patient is moving or talking during measurement.
- Clinical trials have not been conducted on newborn infants and pregnant women.
- Counsel a doctor before use if you have had a mastectomy.

Cuff

Warning



- Dispose of cuffs contaminated by blood to prevent infectious disease from spreading.
- Avoid manner storing the folded cuff or twisted air hose in a tightly for extended periods of time. Such treatment may shorten the life of the components.

Measurement of Pulse Rate

Warning



Do not use the displayed pulse rate for the diagnosis of the irregular heartbeat.

Note

The recorder measures the pulse rate when measuring the blood pressure.

Packing List

Caution



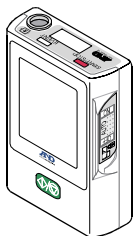
The recorder is a precision instrument so use with caution. Excessive shock may cause failure and malfunction.

Note

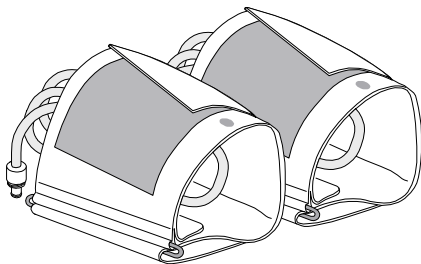
The recorder is shipped out using a special packing box designed to keep it from damage during transport. When you open this box, make sure you have everything on the packing list. If you have any questions, contact your local dealer or the nearest A&D dealer. We recommend keeping the special packing box.

Refer to "**10. Optional Items (requiring order)**" for options.

Blood pressure recorder	1	
Accessories		
Adult cuff 20 to 31 cm (7.8" to 12.2") for left arm		
TM-CF302A	2	
Adult cuff cover	2	
Carrying holder	AX-133025995	1
Belt	AX-00U44189	1
Clip	1	
Activity record sheet (10 sheets)	AX-PP181-S	1
USB cable	AX-KOUSB4C	1
ABPM Data Manager CD	1	
This instruction manual	1	

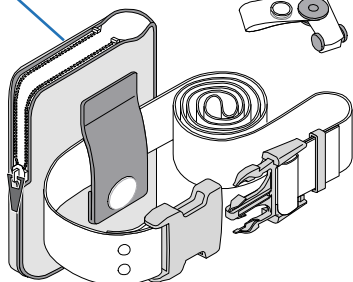


Blood pressure Recorder



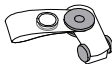
Adult cuff for left arm

Carrying holder

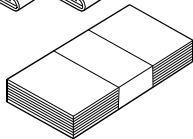
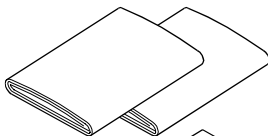


Belt

Clip

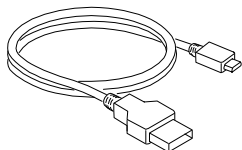


Adult cuff cover

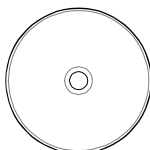


Activity record sheet (10 sheets)

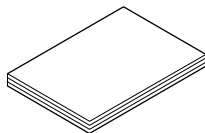
USB cable



ABPM Data Manager CD



This instruction manual



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1. Introduction

Thank you for your Purchase!

The TM-2440 ambulatory blood pressure recorder enables to accurate measurement of patient blood pressure automatically for preset times (e.g. 24-hours continuously). This manual explains the settings, operations, modes and programs of blood pressure measurement as well as communication to **dedicated peripheral**, maintenance, specifications and warning. Read this manual for proper use and keep it in an accessible place.

2. Features

Summary

The recorder is an ambulatory blood pressure monitor that can measure non-invasive blood pressure value and pulse rate of the patient under the guidance of a doctor. The purpose of use is to measure and store variation of the blood pressure in a day during their daily life. The recorder is designed so as to be equipped with portability, data management function and simple operation.

Blood pressure measurement target

This recorder is designed for adults (above 12 years old).

Purpose of use

The recorder enables automatic blood pressure measurement and manual blood pressure measurement. Blood pressure readings can be used for consulting with doctors and for self managing health.

Automatic blood pressure measurement (A-BPM)

A-BPM function can specify six pairs of arbitrary start times and intervals for every 24 hours and can automatically measure and record blood pressure.

Manual blood pressure measurement

Blood pressure can be measured manually at any time, including when the A-BPM function is activated.

Portability

The weight of the recorder is approximately 120 g (excluding batteries). It is palm size and equipped a micro-pump.
Two AA alkaline batteries can be used. (LR6 or AA size)
Two rechargeable batteries (AA size, Ni-MH battery) can be used.

Operability

The settings of the recorder and the program of blood pressure measurement program can be configured easily using ABPM Data Manager installed in the computer (**dedicated peripheral**).

Extensive analytical performance

Measurement interval time can be set for the automatic blood pressure measurement.

Blood pressure can be measured immediately using manual measurement anytime.

The analysis can be done effectively using ABPM Data Manager installed in the computer (**dedicated peripheral**).

Shorter measurement time










The deflation speed is controlled to minimize the measurement time.











The pressurization value is controlled to minimize the measurement time.

Simple convenience

Dedicated peripheral can receive data using USB cable. Received data can be analyzed and printed easily.

3. Abbreviations & Symbols

Symbols	Meaning
SYS	Systolic blood pressure
DIA	Diastolic blood pressure
PUL	Pulse rate
PP	Pulse pressure $PP = SYS - DIA$
kPa mmHg	Unit of blood pressure
/min	Unit of pulse rate /minute
	Displaying : A-BPM is performing.
	Memory full, Delete data to start the measurement.
	Battery indicator. When the level 1  is displayed, replace batteries to use the recorder.
	A-BPM sleep mark
	The mark is displayed during configuration.
Exx	Error codes. xx = 00 to 99
OLED	Organic light emitting diode
	Alert mark
	Degree of protection against electric shocks : Equipment type BF.
	Manufacturer of the CE Marking. Date of manufacture.

Symbols	Meaning
	Symbol for small cuff Arm circumference 15 to 22 cm 5.9" to 8.7"
	Symbol for adult cuff Arm circumference 20 to 31 cm 7.8" to 12.2"
	Symbol for large cuff Arm circumference 28 to 38 cm 11.0" to 15.0"
	Symbol for extra large cuff Arm circumference 36 to 50 cm 14.2" to 19.7"
	Symbol printed on packing. Adult cuff is included in accessories.
	Refer to the instruction manual or booklet.
	Symbol for "Keep dry" and "Keep away from rain".
SN	Serial number
	Symbol printed in the battery compartment. Direction (polarity) to install battery.
	Symbol printed on packing. Batteries are excluded from accessories.
EMD	Electromagnetic disturbances
	Symbol for "Handle with care".
	The symbol of waste electrical and electronic equipment directive.

Symbols	Meaning
BPM	Blood pressure measurement
A-BPM	Automatic blood pressure measurement.
Sleep, Cycle, Hour, START, Operation	A-BPM symbols. #1
Not made with natural rubber latex.	Caution for patient. It is printed on the cuff.
<p>⚠ Caution</p> <ul style="list-style-type: none"> • Use alkaline batteries or specified rechargeable batteries and ensure correct polarity (+, -). • Do not mix new, used or different branded batteries. • Firmly secure cuff air hose to main body. 	<p>⚠ Cautions on battery cover.</p> <ul style="list-style-type: none"> □ Use alkaline batteries or specified rechargeable batteries and ensure correct polarity (+, -). □ Do not mix new, used or different branded batteries. □ Firmly secure cuff air hose to main body.

#1 : Refer to "6.1. Automatic Blood Pressure Measurement (A-BPM)" and "8.3. A-BPM Preset Programs" for 24-hours blood pressure recorder.

I.H.B.

The recorder detects an irregular heartbeat that differs $\pm 25\%$ from the average pulse rate as I.H.B. (Irregular Heartbeat).

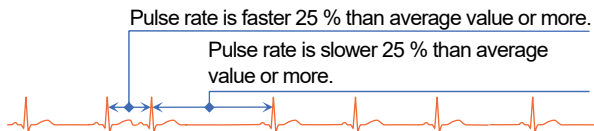
The principal factors of appearance for I.H.B. are physiological factors along with heart, disease and other factors.

Examples include body motion, an increase in body temperature, aging, physiological properties and emotional changes.

I.H.B. may be detected when a very slight vibration like trembling or shaking occurs.

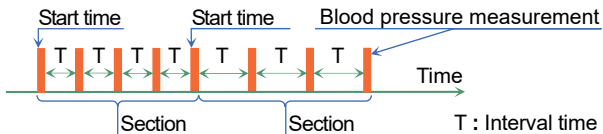
Carry out analysis using a **dedicated peripheral** to know whether I.H.B. has been detected or not.

Refer to the instruction manual of ABPM Data Manager for details.



Waiting mode

A-BPM **waiting mode** is a state that blood pressure is not being measured during the **interval time**.





Dedicated peripheral

Dedicated peripheral means the computer principally that ABPM Data Manager is installed. ABPM Data Manager is stored in accessory CD. Use peripheral device that is complied with the requirements for medical electrical equipment (IEC60601-1) when connecting the recorder to peripheral device. Do not connect the recorder to other device (Example: IEC60950) in the area using medical equipment. Use a USB cable shorter than 1.5 m (4.9 ft).

4. Specifications

4.1. Recorder

Items	Descriptions
Measurement method	Oscillometric measurement method
Pressure detection method	Semiconductor pressure sensor
Pressure display range	0 to 299 mmHg
Measurement accuracy	Pressure : ± 3 mmHg Pulse rate : ± 5 %
Minimum display division	Pressure : 1 mmHg Pulse rate : 1 beat/minute
Measurement range	Systolic pressure : 60 to 280 mmHg Diastolic pressure : 30 to 160 mmHg Pulse rate : 30 to 200 beat/minute
Depressurization	Constant exhaust with controlled leakage valve for safety mechanism
Exhaust	Electromagnetic valve
Pressurization method	Micro-pump
Automatic pressurization	85 to 299 mmHg
Interval time (of A-BPM)	Intervals at each section which divides 24 hours to six parts at the maximum. Interval : OFF, 5, 10, 15, 20, 30, 60, 120 minutes
Clock	24 hour clock
Display	OLED, 96 x 39 pixels, white characters
Measurement count	200 times or more. It varies due to measurement conditions.
Memory	Measurement data : 600 data max.

Items	Descriptions
Power supply	With the same type of batteries : <ul style="list-style-type: none"> □ 2 x 1.5V batteries (LR6 or AA size) □ Alkaline battery or Nickel-hydrogen battery (Ni-MH) 1900 mAh or more Backup battery for built-in clock : Lithium rechargeable coin cell battery ML2016H
Rated voltage	DC 2.4 V and DC 3.0 V
Interface	USB : USB1.1 compliant. Cable length : 1.5 m or shorter. Micro-USB B type terminal can connect to dedicated peripheral (using standard driver software).
Operating condition	Temperature : +10 to +40 °C Humidity : 30 to 85 %RH (no condensation)
Transport and storage conditions	Temperature : -20 to +60 °C Humidity : 10 to 95 %RH (no condensation)
Atmospheric pressure both for operation and storage condition	700 to 1060 hPa
Type of protection against electric shock	Internally powered ME equipment
Degree of protection against electric shock 	Type BF: The recorder, cuff and tubing are designed to provide special protection against electrical shocks.
CE Marking 	The EC directive label for medical device.
C-Tick Marking	The certification trademark registered to the ACA by the Trademark office.
Dimensions	Approx. 95 (L) × 66 (W) × 24.5 (H) mm
Mass	Approx. 120 g (excluding batteries)

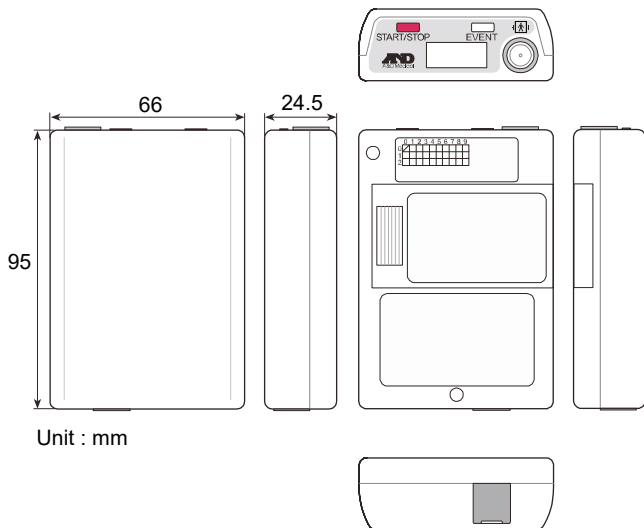
Items	Descriptions
Useful life	Recorder : 5 years. Self-authentication with internal data. Proper operation and maintenance in the best conditions. Durability varies with usage conditions.
Ingress protection	Device : IP22
Default mode	Continuous measurement
Restart time after defibrillation	Immediately
EMD	IEC 60601-1-2: 2014

Note:

- # Specifications are subject to change for improvement without prior notice.
- # Clinical trial for this device is performed in based on ISO 81060-2:2013.
- # The recorder is not medical device for monitoring patient. We don't recommend the way of use that has to monitor patient in real time at place like intensive care unit.

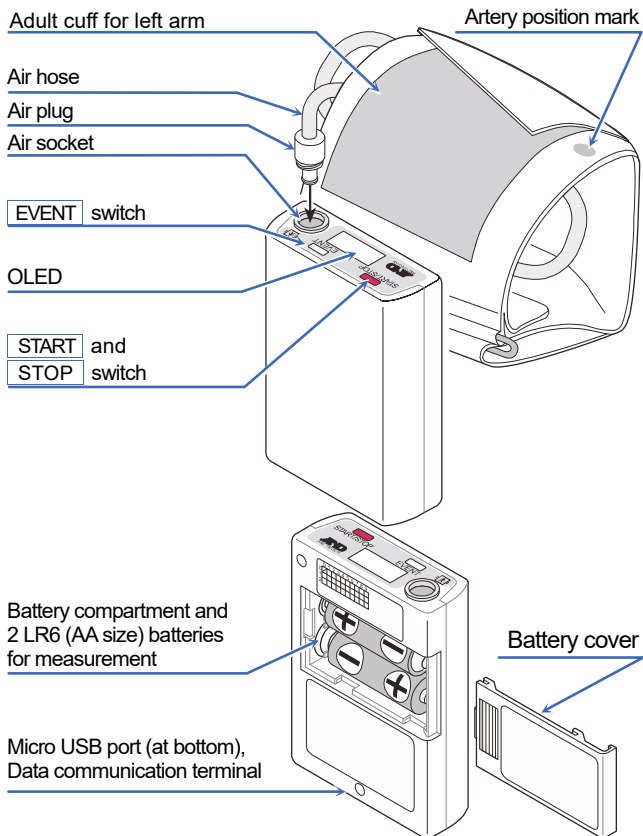
ACA: Australian Communications Authority

4.2. Dimensions



5. Component Names

5.1. Recorder



5.2. Display of OLED (Organic light emitting diode)

Note

To get accurate diagnosis, take care to accurately read the data displayed on the recorder and interpret it properly.

The state of A-BPM is indicated on the OLED.

Clock time.

The state of settings and operation.

The measurement value of A-BPM.



SYS Systolic blood pressure.
DIA Diastolic blood pressure.
PUL Pulse rate.

mmHg Unit for blood pressure value.
/min Unit for the pulse rate.

Refer to "3. Abbreviations & Symbols" for the meanings of symbols on the OLED.

Symbols	Meaning
	The mark is displayed during configuration.
	Displaying : A-BPM is performing.
	Memory full
	A-BPM sleep mark
	Battery indicator

5.3. Principal Switch Operations

5.3.1. A-BPM Operations

To start or suspend A-BPM.

Step 1. Store the preset program (of start times and intervals) for A-BPM.

Step 2. Press and hold the **EVENT** switch to switch between the following states.

"ON"..... A-BPM is started and the \ominus mark is shown.
Blood pressure measurements are performed in accordance with preset A-BPM program.

"OFF"..... A-BPM is suspended and the \ominus mark turns off.
Manual blood pressure measurement can be performed by pressing the **START** switch, though.

To expand A-BPM interval time.

Step 1. Set the sleep mode to "ON" before the measurement.

Step 2. Start A-BPM by pressing and holding the **EVENT** switch.
The \ominus mark is shown.

Step 3. When the **EVENT** switch is pressed during A-BPM, the interval time is doubled.

When the **EVENT** switch is pressed again, the interval time returns to basic value.

To Stop during A-BPM

When the **START/STOP** switch is pressed during the blood pressure measurement, the air is exhausted immediately and the current measurement is stopped. However, A-BPM is continued. The next blood pressure measurement is performed in accordance with A-BPM settings.

To set the program for A-BPM.

- Step 1. If the indication of the display is hidden, press the **START/STOP** or **EVENT** switch to return to the display of waiting mode.
- Step 2. If the \odot mark is shown, press and hold the **EVENT** switch to suspend A-BPM.
- Step 3. While pressing and holding the **START/STOP** switch, press and hold the **EVENT** switch until **Sleep** is displayed on the OLED.
- Step 4. Operation switches are as follows:
Refer to "8.3.1. A-BPM Items and Parameters"
EVENT switchChange the current parameter.
START/STOP switchDecision, next item, end of settings.

To measure blood pressure during A-BPM immediately. (Manual blood pressure measurement of A-BPM)

- Step 1. If the indication of the OLED is hidden, press the **START/STOP** or **EVENT** switch to return to the display of A-BPM waiting mode. A-BPM **waiting mode** is a state that blood pressure is not measured during the **interval time**.
- Step 2. Press the **START/STOP** switch during A-BPM waiting mode.

To adjust the clock.

To set the monitor function of A-BPM.

- Step 1. If the indication of the display is hidden, press the **START/STOP** or **EVENT** switch to return to the display of waiting mode.
- Step 2. If the ⌚ mark is shown, press and hold the **EVENT** switch to suspend A-BPM.
- Step 3. While pressing and holding the **START/STOP** switch, press and hold the **EVENT** switch until **Display** (after **Sleep**) is displayed on the OLED.
- Step 4. Operation switches are as follows:
Refer to "8.2.2. The Clock and the Monitor Function of Measurement"
EVENT switchChange the current parameter.
START/STOP switchDecision, next item, end of settings.

5.3.2. Other Operations

To return from waiting mode and show the monitor.

If the indication of the OLED is hidden, press the

START/STOP or **EVENT** switch to return to the display of waiting mode.

Deleting measurement data

Step 1. If the indication of the display is hidden, press the

START/STOP or **EVENT** switch to return to the display of waiting mode.

Step 2. If the ⌚ mark is shown, press and hold the **EVENT** switch to suspend A-BPM.

Step 3. While pressing and holding the **START/STOP** switch, press and hold the **EVENT** switch until **DataClear** (after **Sleep** and **Display**) is displayed on the OLED.

Step 4. Select an operation.

- If you delete data, press and hold the **START/STOP** switch. **Erasing** blinks under **DataClear** on the OLED and deletion of data is started.

Proceed to step 5 after deletion.

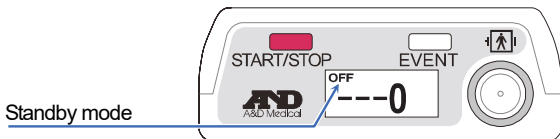
Step 4. Deleting
OLED **DataClear**
Erasing

- If you keep (don't delete) data, press the **EVENT** switch and proceed to step 5.

Step 5. The recorder returns to waiting mode.

To start data communication with dedicated peripheral using the USB cable.

- Step 1. Connect the micro USB cable between the recorder and **dedicated peripheral**.
- Step 2. The buzzer will sound and the following symbol appears on the OLED. The state of data communication enters standby mode.



- Step 3. Carry out analysis using the **dedicated peripheral**. The state of data communication only enters active online mode during USB communication.


6. Blood pressure measurement Functions

The recorder is equipped with automatic blood pressure measurement (A-BPM) and can store measurement states and measurement results.

6.1. Automatic Blood Pressure Measurement (A-BPM)


Caution



When the A-BPM function is not used, suspend the function by pressing and holding the **EVENT** switch so that the  mark turns off. Otherwise, the measurement will start at the next start time and the cuff may burst.

The A-BPM function measures the blood pressure at preset intervals using the built-in clock and stores the measurement result in the memory.

A-BPM can be started and suspended by pressing and holding the **EVENT** switch.

The  mark is displayed on the OLED while A-BPM is used. Blood pressure is measured automatically at the A-BPM start time.

The initial pressurization value is set to 180 mmHg at the factory. If the first pressurization is not enough, re-pressurizations are performed automatically up to two times.

When you delete data in the memory or suspend A-BPM, the pressurization value is reset to the initial pressurization value.

When a measurement error occurs and the waiting time until the next start time is longer than 8 minutes, blood pressure is

measured once after 120 seconds. The measurement result is stored in the memory.

If you want to suspend A-BPM, press and hold the **EVENT** switch.

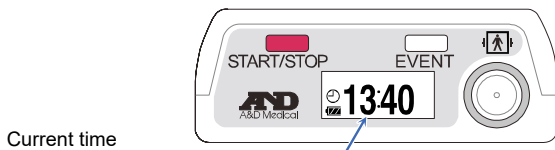
6.1.1. A-BPM Waiting Mode

In the A-BPM waiting mode, the OLED shows the current time together with the ⌚ mark as follows.

In waiting mode, the indicators are automatically hidden.

Press any switch to show items.

A-BPM **waiting mode** is a state that blood pressure is not measured during the interval time.



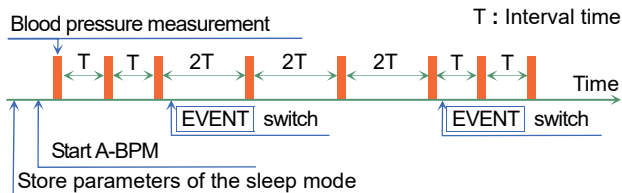
6.1.2. Sleep Function and Interval time

Set the sleep mode to "ON" in the preset program.

When the EVENT switch is pressed during A-BPM, the interval time doubles.

When the EVENT switch is pressed again in A-BPM, the interval time returns to original length.

Refer to "8.3. A-BPM Preset Programs" for information on how to set the sleep mode.



6.1.3. Stopping Measurement

When the **START/STOP** switch is pressed during the blood pressure measurement, the air is exhausted immediately and the current measurement is stopped. However, A-BPM is continued. The next blood pressure measurement is performed in accordance with A-BPM settings.

Note

When measurement is stopped, the stop code **E07** is displayed on the OLED and is stored in the memory.

6.2. Measurement Result

6.2.1. Displaying Measurement Results

The monitor function can select "**Display ON**" or "**Display OFF**" command of the measurement result of A-BPM.

The content of "**Display ON**" command includes "Pressure value during the measurement", "measurement result" and "Error code for the measurement result".

When "**Display OFF**" command is selected, the clock is displayed.

The factory settings is set to "**Display ON**".

Refer to "**8.2.2 The Clock and the Monitor Function of Measurement**".

6.2.2. Storing Measurement Results


Caution



Data processing of the measurement result

Do not use in a strong electromagnetic field.

The memory capacity for the measurement result is 600 data set.

When the memory is filled, the  mark is displayed and the recorder cannot perform measurement until data is deleted from the memory.

Note


Delete data in the memory before giving the recorder to a new patient. We recommend to use the memory data of the recorder for each person separately. If the recorder memorizes data of multiple people, data may be difficult to process correctly.

6.2.3. Outputting Measurement Results

The measurement data stored in the memory can be output to the peripheral using USB data transfer.

Refer to "**8.7 Connecting the Recorder to Dedicated Peripheral**".

Note

When the battery indicator displays , data transfer cannot be used. Replace batteries to use data transfer.

6.2.4. ID numbers

The factory default ID number is "0".

Configure ID numbers using **dedicated peripheral**.



Note

ID numbers cannot be configured with the recorder and require use of **dedicated peripheral**.




7. Preparing the Recorder

7.1. Installing Batteries (Replacing Batteries)


Caution

- | | |
|---|---|
|  | <ul style="list-style-type: none">□ Install two new batteries in accordance with the correct "+" and "-" direction inside the battery compartment before attaching the recorder.□ Replace both batteries at the same time.□ Remove batteries from the recorder if it is not used for a long period of time. Batteries may leak and cause a malfunction.□ Use two alkaline batteries : type LR6 or designated rechargeable AA Ni-MH batteries.□ When installing the battery in the battery compartment, first, push the spring terminal using the "-" terminal of the battery. Next, insert the "+" terminal.
If the battery is installed from the "+" terminal, the coating of the battery may be damaged by the spring terminal. |
|  | <p>Do not mix and use different kinds of batteries or used batteries and new batteries. It may cause a leak, heating or damage.</p> |

Note

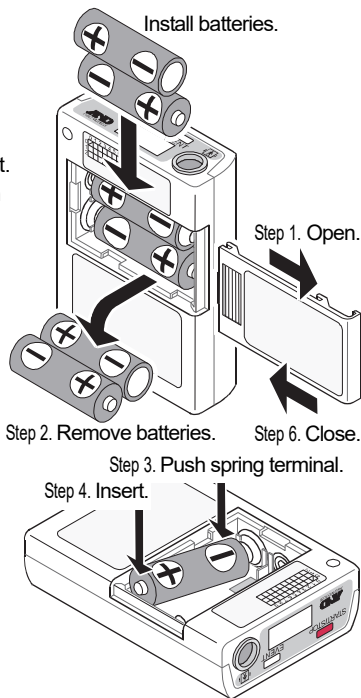
- | |
|---|
| <ul style="list-style-type: none">□ When the level 1  of the battery level is displayed, replace with two new batteries before attaching the recorder.□ The recorder cannot perform blood pressure measurement or data transfer while the level 1  is displayed.□ When the battery and built-in battery are dead, nothing is displayed.□ Install batteries in accordance with the direction symbol (). |
|---|

Procedure

- Step 1. Open the battery cover.
- Step 2. Remove used batteries.
- Step 3. Refer to the direction symbol () inside of the battery compartment. Insert two new batteries in the proper "+" and "-" direction.

Push the spring terminal using the "-" terminal of the battery.

- Step 4. Insert the battery by pushing the "+" terminal.
- Step 5. Insert the second battery using the same method.
- Step 6. Close the battery cover.



Caution



- Keep batteries and the battery cover away from infants and children with reach, to prevent accidental swallowing or other accidents.
- Use standard AA batteries. Do not use an inflated battery rechargeable battery, or one that wrapped in tape. It may become difficult to open the cover.

7.1.1. How to Replace Batteries

Measurement results and setting parameters are saved when batteries are removed. When the built-in battery runs out charge, the date is reset to 01/01/2017 00:00.

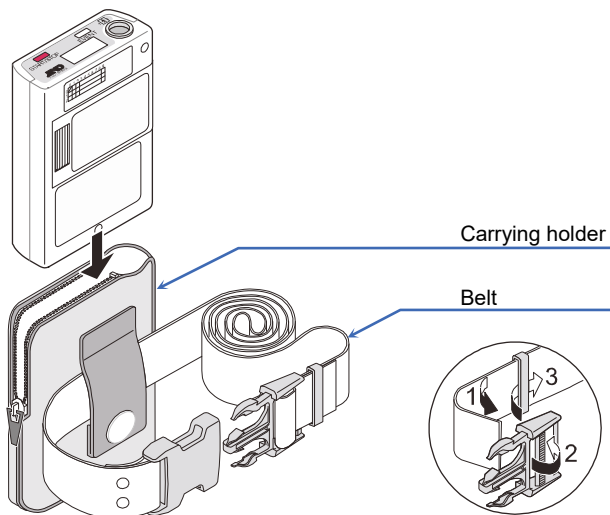
Check and adjust the current time when batteries are replaced. Refer to "**8.2.2. The Clock and the Monitor Function of Measurement**" to adjust the clock.

7.2. Preparing the Carrying Holder

Note

When the carrying holder is attached, use the accessory belt.
We recommend to use a belt to fit the recorder to the patient.

Use accessory carrying holder when the recorder is used.
To attach the carrying holder, put the carrying holder through
accessory belt or the belt of the clothes wearing.



7.3. Inspection for Use

Caution



Inspect the recorder to maintain the performance, safety, effectively before use.

Confirm the following checklist before / after installing batteries. If a problem is found, stop to use the recorder and put the message of "**Malfunction**" or "**Not use**". Contact your local dealer to repair it.

7.3.1. Battery Pre-installation Checklists

No.	Item	Description
1	Exterior	No damage and deformation due to drop.
		No damage and shaky fixation to switches and etc.
2	Battery	Check batteries not to be consumed. Replace with two new batteries before the patient is used.
3	Cuff	Check that the cuff has not frayed. If the cuff is frayed, it may cause burst due to internal pressure.
4	Cuff connection	Check that there are no kinks and folding of the air hose.
		Check that the air socket and connector is connected firmly.
5	Attachments	Check that there is no damage to accessories. (Carrying holder, belt, etc.)

7.3.2. Battery Post-installation Checklists

No.	Portion	Description
1	Battery	Check that there is no fire, smoke and offensive smells.
		Check that there is no strange sound.
2	Display	Check that there is no strange display.
3	Operation	Check that the recorder operates correctly.
4	Measurement	Check that the measurement operation can be performed correctly. Attachment cuff, measurement, display and result are correct.

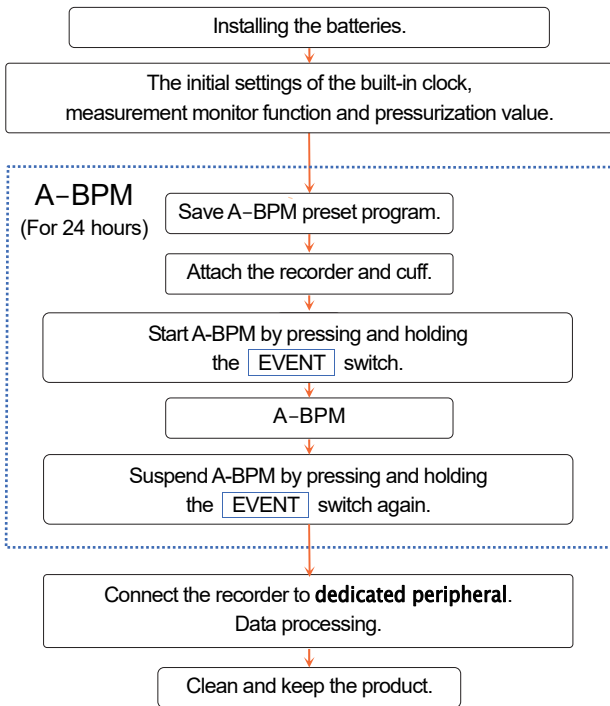
8. Operations

8.1. Operation Flowchart

Note

The initial settings (of the built-in clock, monitor function and initial pressurization value) and preset program for A-BPM do not need to be performed every time. Perform the settings when the recorder is used for the first time, when the settings have been lost, or when the settings should be changed.

These settings can be performed using a **dedicated peripheral**, too. Refer to the instruction manual of ABPM Data Manager for details.



The whole procedure of use

8.2. Initial Settings

8.2.1. Factory Settings

The factory settings (initial settings) are described below :

Common items of the settings

Item	Factory setting
Monitor function	ON (is indicates them)
Year, Month, Day, Hour, Minute	Date of shipment

Items of A-BPM

Item	Factory setting
Sleep mode	OFF
Interval time when the sleep mode is ON	30 minutes
Start time of the section 1	0 hour
Interval time of the section 1	30 minutes
Start time of the section 2	0 hour #1
Start time of the automated measurement	OFF
Operation time of the automated measurement	OFF

The content of the factory settings

When the EVENT switch is pressed and held, A-BPM is started. Blood pressure is measured every 30 minutes until A-BPM is suspended by pressing and holding the EVENT switch again.

#1 : The settings between the interval time of the section 2 and the interval time of the section 6 are omitted because the start time of the section 1 and 2 is the same value.

8.2.2. The Clock and the Monitor Function of Measurement

The initial settings can be configured using the following methods.

- The method to use switches on the recorder.
- The method to use **dedicated peripheral** that is connected to the recorder using the USB cable.

Procedure of operation using switches

- Step 1. If the indication of the display is hidden, press the **START/STOP** or **EVENT** switch to return to the display of waiting mode.
- Step 2. If the ⌚ mark is shown, press and hold the **EVENT** switch to suspend A-BPM.
The ⌚ mark turns off.
- Step 3. While pressing and holding the **START/STOP** switch, press and hold the **EVENT** switch until **Display** (after **Sleep**) is displayed on the OLED.
- Step 4. Operation switches are as follows:
EVENT switchChange of the current parameter.
START/STOP switchDecision, next item, end of settings.
Thereafter, use these switches in another items.
- Step 5. After configuring settings, press the **START/STOP** switch to return to waiting mode.

Item	OLED	Range
Monitor function	Display xx	xx = OFF, ON
Year	Clock Year xx	xx = 17 to 99. Last two digits of year.
Month	Clock Mon. xx	xx = 1 to 12 month
Day	Clock Day xx	xx = 1 to 31 day
Hour	Clock Hour xx	xx = 0 to 23 hour
Minute	Clock Min. xx	xx = 0 to 59 minutes

Enclosed characters : Factory settings and initial settings when batteries are consumed completely.

8.2.3. Initial Pressurization Value

The initial pressurization value is set to 180 mmHg at the factory.



8.3. A-BPM Preset Programs

The initial settings can be configured using the following methods.

- The method to use switches on the recorder.
- The method to use **dedicated peripheral** that is connected to the recorder using the USB cable.

A-BPM can use only while the automated measurement can be performed.

Procedure of operation using switches

- Step 1. If the indication of the display is hidden, press the **START/STOP** or **EVENT** switch to return to the display of waiting mode.
- Step 2. If the  mark is shown, press and hold the **EVENT** switch to suspend A-BPM. The  mark turns off.
- Step 3. While pressing and holding **START/STOP** switch, press and hold the **EVENT** switch until **Sleep** is displayed on the OLED.
- Step 4. Specify the sleep mode using the following switches.
If sleep mode is "ON", proceed to step 5.
EVENT switchChange of the current parameter.
START/STOP switchDecision, next item.
- Step 5. Specify the **start time** and **interval** up to six sections using the following switches.
EVENT switchChange of the current parameter.
START/STOP switchDecision, next item.
- Step 6. Specify the **start time** and **operation time** of the automated measurement using the following switches.
EVENT switchChange of the current parameter.
START/STOP switchDecision, next item, end of the settings.
- Step 7. After completing settings, the recorder returns to waiting mode.


Caution



Do not remove batteries while charging the settings.
If batteries are removed, input settings again.

8.3.1.A-BPM Items and Parameters

The preset program for A-BPM is as follows :

Item		OLED	Parameter	
Sleep mode		Sleep xx	xx = ON, OFF	#1, #2
	Interval time	Cycle xx	xx = OFF, 5, 10, 15, 20, 30 , 60, 120 minutes	
Section 1	Start time	Hour 1 xx	xx = 0 to 23 hour	
	Interval time	Cycle 1 xx	xx = OFF, 5, 10, 15, 20, 30 , 60, 120 minutes	
Section 2	Start time	Hour 2 xx	xx = 0 to 23 hour	
	Interval time	Cycle 2 xx	xx = OFF , 5, 10, 15, 20, 30, 60, 120 minutes	
Section 3	Start time	Hour 3 xx	xx = 0 to 23 hour	
	Interval time	Cycle 3 xx	xx = OFF , 5, 10, 15, 20, 30, 60, 120 minutes	
Section 4	Start time	Hour 4 xx	xx = 0 to 23 hour	
	Interval time	Cycle 4 xx	xx = OFF , 5, 10, 15, 20, 30, 60, 120 minutes	
Section 5	Start time	Hour 5 xx	xx = 0 to 23 hour	
	Interval time	Cycle 5 xx	xx = OFF , 5, 10, 15, 20, 30, 60, 120 minutes	
Section 6	Start time	Hour 6 xx	xx = 0 to 23 hour	
	Interval time	Cycle 6 xx	xx = OFF , 5, 10, 15, 20, 30, 60, 120 minutes	
	Start time	START xx	xx = OFF , 0 to 23 hour	#3, #4
	Operation time	Operation xx	xx = OFF , 1 to 27 hour	#3, #4

Automated measurement

Enclosed characters : Factory settings.

#1 : When the sleep mode is set to "ON", the **start time** and **operation time** of the automated measurement and **interval time** of the sleep mode can be used. The **interval time** of these sections (1 to 6) cannot use.


#2 : When sleep mode is set to "OFF", the **interval time** of the sleep mode is not displayed.

#3 : Example for automated measurement.

Start time : Stores a time. (0 to 23 hour)

Operation time : Set to "OFF"

Response : A-BPM starts the blood pressure measurement at the preset **Start time** and continues until A-BPM is suspended.


If the EVENT switch is pressing and holding until the  mark is shown, A-BPM starts at the preset **Start time**.

#4 : Example for automated measurement.


Start time : Set to "OFF"

Operation time : Stores time to be continued. (1 to 27 hours)

Response : A-BPM starts blood pressure measurement and stops after the **Operation time**.

If the  mark is hidden by pressing and holding the EVENT switch during the

Operation time, A-BPM stops.

If the  mark is shown by pressing and holding the EVENT switch again, A-BPM is performed for the **Operation time**.

The content of the item

Sleep mode :

The **Interval time** for the automated measurement can be specified.

The **Interval time** of section 1 to 6 cannot use. Refer to "6.1.2

Sleep Function and Interval time".

Section :

24 hours can be separated to six sections in maximum. Each section can specify the **Start time** and **Interval**. A-BPM can use only while the automated measurement can be performed.

Automated measurement :

The whole of A-BPM can be controlled. Specify the **Start time** and **Operation time**. Refer to "8.3.2. A-BPM Program Examples".

8.3.2. A-BPM Program Examples

Example Start times and intervals. Simplified input.

Double sections

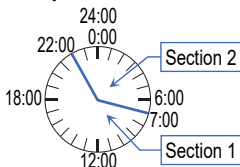
The **start time** of section 1 = 7:00

The **interval time** of section 1 = 15

The **start time** of section 2 = 22:00

The **interval time** of section 2 = 60

The **start time** of section 3 = 7:00 The same as section 1



Section 3 and the following items are not displayed because the start time of section 3 is the same as section 1.

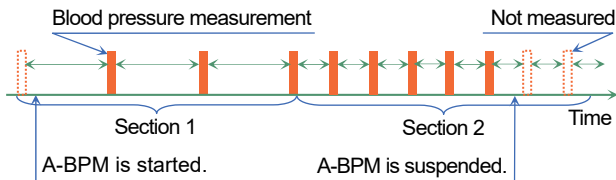
When the **start time** of section 2, 3, 4, 5 or 6 is the same as section 1, these **start times** and **intervals** are not displayed.

Example 1 Automatic measurement

The **start time** of the automated measurement = OFF,

The **operation time** of the automated measurement = OFF.

After A-BPM is started, blood pressure measurement is performed according to the **start time** and **interval** of each section until A-BPM is suspended.

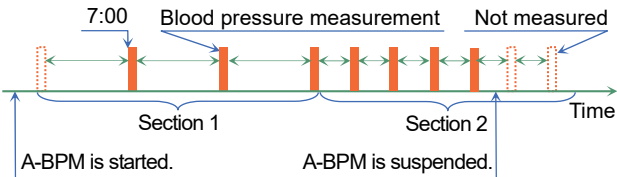


Example 2 Automatic measurement

The **start time** of the automated measurement = 7:00,

The **operation time** of the automated measurement = OFF.

After A-BPM is started, blood pressure measurement is started at 7:00. A-BPM is continued according to the **start time** and **interval** of each section until it is suspended.

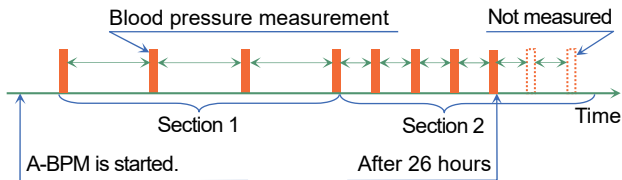


Example 3 Automatic measurement

The **start time** of the automated measurement = OFF,

The **operation time** of the automated measurement = 26 hours.

After A-BPM is started, blood pressure measurement is performed according to the **start time** and **interval** of each section for 26 hours.



8.4. Deleting Measurement Data

Purpose of operation and explanation of function

Measurement data is deleted but settings are not deleted.

The initial settings can be configured using the following methods.

- The method to use switches on the recorder.
- The method to use **dedicated peripheral** that is connected to the recorder using the USB cable.

Caution



- If measurement data is deleted, it cannot be used again. Backup data before deletion.
- Delete measurement data of last patient before next patient uses the recorder.
- Several minutes may be needed to delete data. Keep no-operation to delete data correctly.

Procedure of operation using switches

- Step 1. If the indication of the display is hidden, press the **START/STOP** or **EVENT** switch to return to the display of waiting mode.
- Step 2. If the ⌚ mark is shown, press and hold the **EVENT** to suspend A-BPM. The ⌚ mark turns off.
- Step 3. While pressing and holding the **START/STOP** switch, press and hold the **EVENT** switch until **DataClear** (after **Sleep** and **Display**) is displayed on the OLED.
- Step 4. Select an operation.
- If you delete data, press and hold the **START/STOP** switch. **Erasing** blinks under **DataClear** on the OLED and deletion of data is started. Proceed to step 5 after deletion.
 - If you keep (don't delete) data, press the **EVENT** switch and proceed to step 5.
- Step 5. The recorder returns to waiting mode.

8.5. Attaching the Product to the Patient

8.5.1. Information for Patients

Explain the following to the patient so that they can use the recorder safely.


Precautions during the blood pressure measurement

- Relax the arm and stay quiet when inflation begins.
- Keep the same position throughout the measurement.
- Avoid vibration and noise during the measurement.
- Blood pressure is measured for approximately 1 minute after pressurization. Be quiet until measurement finishes. The measurement process between inflating the cuff to releasing the air requires up to 170 seconds.
- The recorder may re-inflate to measure the blood pressure again after the end of pressurization. This may be caused by body motion, etc.
- The recorder may start the blood pressure measurement after approximately 120 seconds when measurement data is invalid and next measurement is after 8 minutes. This may be caused by body motion, etc.
- The recorder may obstruct vehicle and machine operation. Avoid vehicle and machine operation while wearing the recorder.

How to stop or suspend the measurement



Press the **START/STOP** switch to stop blood pressure measurement. An error code is stored in the memory. Blood pressure is measured again after 120 seconds.


Concerning of A-BPM, only the current blood pressure measurement is stopped, and measurement will be performed at the next **start time**.

To suspend A-BPM, press and hold the **EVENT** switch so that the  mark turns off.

Remove the cuff if the current blood pressure measurement cannot be stopped using the **START/STOP** switch.

Caution

-  □ Press the **START/STOP** switch to stop blood pressure measurement. An error code is stored in the memory. During A-BPM, only the current blood pressure measurement is stopped, and measurement will be performed at the next **start time**.
- When a pain of the arm or unexpected condition occur, stop the measurement, remove the cuff and consult the doctor. Suspend A-BPM by pressing and holding the **EVENT** switch so that the  mark turns off.

Press and hold the **EVENT** switch again to resume A-BPM automated measurement. The  mark is shown on the OLED. Recording of data is carried out continuously except during the suspended period.

How to use manual measurement during A-BPM

The procedure for a temporary measurement that is not included in preset program.


- Step 1. If the indication of the OLED is hidden, press the **START/STOP** or **EVENT** switch to return to the display of A-BPM waiting mode.
- Step 2. Press the **START/STOP** switch to immediately measure the blood pressure during A-BPM.
- Step 3. Measurement results are stored in the memory.

When the **START/STOP** switch is pressed during measurement, the measurement is suspended.

Precautions when wearing the recorder

- The recorder is precision instrument. Do not drop or shock the recorder.
- The recorder and cuff are not waterproof (water resistant). Prevent the product from contacting rain, sweat and water.
- Do not put anything on the product.
- When the cuff is moved by excessive motion and exercise, attach the cuff again.
- Arrange the air hose so that kinks do not form and so that it does not wrap around the neck at bedtime.

Replacing Batteries

When the  mark is displayed, the recorder can not measure blood pressure or communicate with **dedicated peripheral**. Replace with two new batteries immediately.

8.5.2. Cuff Cover

Note

Keep the cuff and cuff cover clean.

- Change the cuff cover for each person.
- Use the cuff cover appropriate optional cuffs.

8.5.3. Attaching the Cuff, Carrying holder and Recorder

Caution

- ❑ Do not attach the cuff if the patient has dermatitis, external wounds, etc.
- ❑ Remove the cuff and stop use if dermatitis or other symptom appear to the patient.
- ❑ Prevent air hose from coiling around neck and body.
- ❑ Take care when using around infants, as there is a danger of suffocation.
- ❑ Insert the connector of the air hose firmly until the end of rotation. If the connection is improper, it may cause air leakage and measurement error.

Note

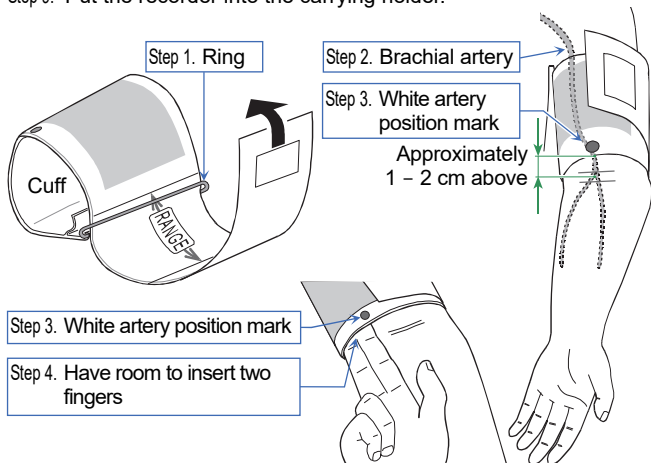
- ❑ Attach the cuff at the right position and wrap around the arm to measure the blood pressure correctly.
- ❑ Prevent the cuff and air hose from vibrating during measurement. The recorder measures delicate change of the air pressure inside the cuff.
- ❑ The accessory cuff is an adult cuff for the left arm. If cuff size does not fit, purchase optional cuff.

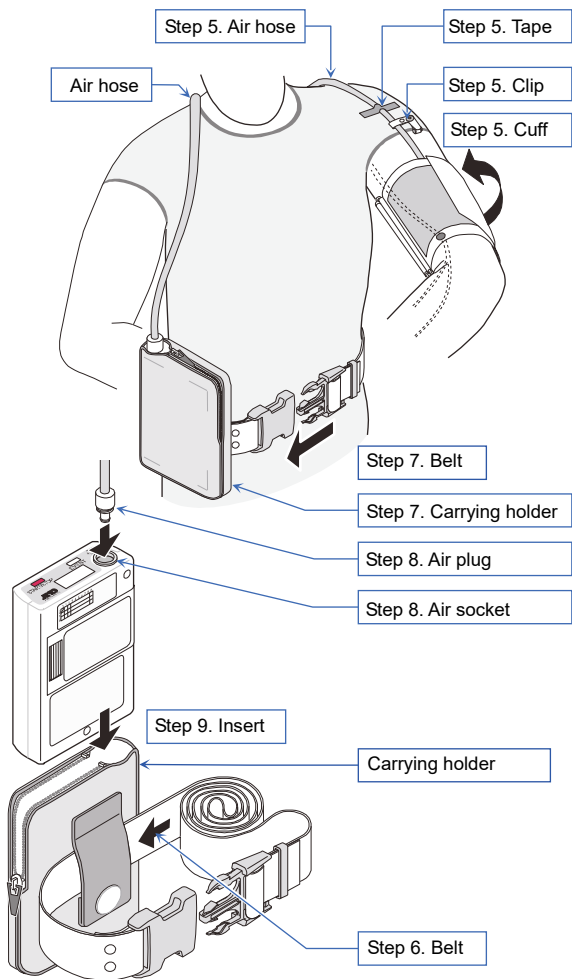
	Arm circumference	
Small cuff	15 to 22 cm	5.9" to 8.7"
Adult cuff	20 to 31 cm	7.8" to 12.2"
Large cuff	28 to 38 cm	11.0" to 15.0"
Extra large cuff	36 to 50 cm	14.2" to 19.7"

- ❑ Keep the cuff clean.
- ❑ We recommend the patient use the carrying holder and belt.
- ❑ The cuff is not made with natural rubber latex.

How to put on the cuff, recorder and holder

- Step 1. Pass the end of the cuff through the ring and make the shape of bracelet.
- Step 2. Find the brachial artery of left arm using palpation.
- Step 3. Attach the cuff directly against the skin so that the white mark is directly over the brachial artery and the lower edge of the cuff is put on approximately 1 – 2 cm above the inside of the elbow.
- Step 4. Wrap the cuff so that the ring is within the range, it is flat and does not slip down, but has room to insert two fingers.
- Step 5. Fix the air hose using adhesive tape so as to pass over the shoulder.
- Step 6. Pass the belt through the carrying holder.
- Step 7. Adjust the belt so that the carrying holder is on left side.
- Step 8. Connect the air plug to the air socket on the recorder.
- Step 9. Put the recorder into the carrying holder.






8.6. Blood Pressure Measurement Operations

8.6.1. A-BPM Operations


When A-BPM is started, blood pressure is measured in accordance with the preset parameters.

Note

- Set the built-in clock and initial pressurization value before measurement because A-BPM uses them. Refer to "8.2.2. The Clock and the Monitor Function of Measurement" and "8.3. A-BPM Preset Programs".
- When the recorder is removed, suspend A-BPM by pressing and holding the **EVENT** switch.
If the recorder is removed during A-BPM, the inflation of the cuff is started next **start time**, the cuff may break.
To resume A-BPM, press and hold the **EVENT** switch again.
- The  mark is displayed while A-BPM is activated.
- Manual blood pressure measurement can be performed during A-BPM waiting mode.
- The measurement result of the manual blood pressure measurement can be stored in the memory.
- When A-BPM is stopped, the error code **E07** is displayed on the OLED and stored in the memory.

To start A-BPM

Step 1. Press and hold the **EVENT** switch.

Step 2. The  mark is shown on the OLED. A-BPM is started.

To suspend A-BPM

Step 1. Press and hold the **EVENT** switch.

Step 2. The  mark is hidden. A-BPM is suspended.

To Stop during A-BPM

When the **START/STOP** switch is pressed during the blood pressure measurement, the air is exhausted immediately and the current measurement is stopped. However, A-BPM is continued. The next blood pressure measurement is performed in accordance with A-BPM settings.

To measure blood pressure during A-BPM immediately (Manual blood pressure measurement of A-BPM)

Step 1. If the indication of the OLED is hidden, press the

START/STOP or **EVENT** switch to return to the display of A-BPM waiting mode. A-BPM **waiting mode** is a state that blood pressure is not measured during the **interval time**.

Step 2. Press the **START/STOP** switch during A-BPM waiting mode.

To expand the interval time, or bring back it

When sleep mode is "ON" and the **EVENT** switch is pressed during A-BPM waiting mode, the interval time is doubled.

8.6.2. Manual Measurement

Use the manual blood pressure measurement for a tentative test measurement and immediate blood pressure measurement.

Note

- Manual blood pressure measurement can start immediately in a waiting mode.
- The measurement result is stored in the memory.

To measure blood pressure during A-BPM immediately. (Manual blood pressure measurement of A-BPM)

Step 1. If the indication of the OLED is hidden, press the

START/STOP or **EVENT** switch to return to the display of A-BPM waiting mode. A-BPM **waiting mode** is a state that blood pressure is not measured during the **interval time**.

Step 2. Press the **START/STOP** switch during A-BPM waiting mode.

8.6.3. Stopping and Suspending Measurements

The A-BPM function can be suspended when necessary. And ongoing A-BPM or manual blood pressure measurement can be stopped immediately.

Note

When blood pressure measurement is stopped, the stop code **E07** is displayed on the OLED and is stored in the memory.

To suspend A-BPM

Step 1. Press and hold the **EVENT** switch.

Step 2. The  mark is hidden. A-BPM is suspended.

To stop ongoing blood pressure measurement

When the **START/STOP** switch is pressed during blood pressure measurement, the air is exhausted immediately and the current measurement is stopped.

However, during A-BPM, this function is not suspended. The next blood pressure measurement is performed in accordance with the A-BPM settings.

8.7. Connecting the Recorder to Dedicated Peripheral

8.7.1. Connecting with USB cable

Refer to the instruction manual of ABPM Data Manager concerning of the communication settings.

Caution

Connection of the cable

- Connect an authorized USB cable to the micro USB terminal.
- Insert the cable in the correct direction. Improper connection may cause failure and malfunction. Confirm that the terminal cable is properly connected.
- ! □ Blood pressure cannot be measured during USB communication.
- Do not attach to the patient when the recorder is connected to the cable. Cable may become wrapped around the body or neck.

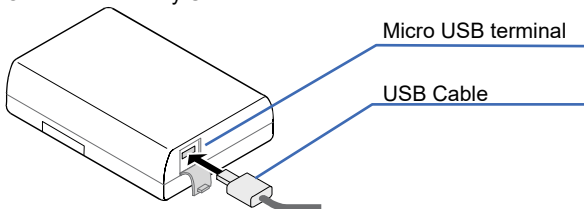
Preparation of dedicated peripheral

- Remove the recorder and cuff from the patient before connecting the recorder (TM-2440) to **dedicated peripheral**.

To connect the recorder to dedicated peripheral using the USB cable

Step 1. Open the micro USB terminal on the recorder.

Connect accessory USB cable.

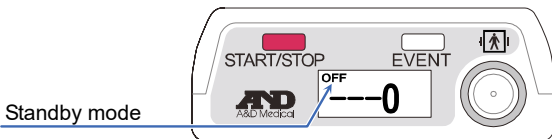


To start data communication with dedicated peripheral

Step 1. Connect the micro USB cable between the recorder and **dedicated peripheral**.

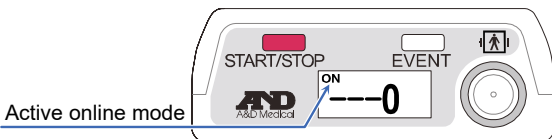
Step 2. The buzzer will sound and the following symbol appears on the OLED.

The state of data communication enters standby mode.



Step 3. Carry out analysis using the **dedicated peripheral**.

The state of data communication only enters active online mode during USB communication.



To stop data communication with dedicated peripheral

Step 1. Remove the cable in the standby mode.

9. Maintenance

9.1. Product Storage, Inspection and Safety Management

Medical instruments such as this recorder must be managed so that they function properly when necessary and to reliably maintain the safety of the patient and operator. As basic rule, it is necessary that the patient inspects this instrument with daily checks such as the "Inspection before use".

Daily management such as the inspection before use is necessary to maintain the performance, safety and effectiveness of the recorder.

We recommend to a periodic inspection the recorder every year.

Note
Medical institution must perform the maintenance management to ensure the safe use of the medical instrument.

9.2. Cleaning the Product

Caution

- Clean the recorder before use and after use.
Clean the recorder before attaching to next patient.
- Do not spray water and sink into water for cleaning the recorder. It may cause of malfunction.
- Clean the recorder after wiping water and antiseptic solution so as not to invade inside the recorder.
- Disinfect the recorder periodically so as to keep infection prevention. Do not use sterilizer to the recorder.
- ! □ Do not use organic solvent (Example: thinner), povidone-iodine solution to clean the recorder. It may cause of discoloration, damage and malfunction.
- Do not use hair dryer etc. to dry the recorder. It may cause malfunction and damage.

Check after Cleaning

Confirm that the cuff bladder is correctly inserted inside the cuff cloth. If it is not correctly inserted, the cuff bladder inflates outside during inflation, it may cause damage or explosion.

Cleaning the recorder

Wipe the dirt and dust on the exterior case of the recorder using gauze that is moistened with water or warm water and is squeezed well. When blood or medicines, etc. is adhered on the case, in first, clean using gauze that is moistened with antiseptic solution and is squeezed well, next, wipe wet case using gauze that is moistened with water or warm water and is squeezed well. We recommend useable chemicals (Ingredient name) of antiseptic solution on the table (**Example of useable antiseptic solution (Ingredient name)**).

Cleaning the cuff

When you clean and disinfect cuff cover and cuff cloth, remove the cuff bladder inside the cuff cloth. Clean the dirt and dust using gauze that is moistened with water or warm water and is squeezed well. Refer antiseptic solutions of the table (**Example of useable antiseptic solution (Ingredient name)**) when disinfecting them.

Example of useable antiseptic solution (Ingredient name)

Component Name	Product Name
Benzalkonium chloride	Benzalkonium chloride 10% solution
Isopropanol	70% in 1-propanol
Ethanol	Ethanol for disinfection 76.9 to 81.4 vol%

Read prescription described on product and use it.

Note

Cuff and air hose are consumables.
If measurement error occurs frequently or blood pressure cannot measure, it is necessary to replace to new ones.
Refer to "**10. Optional Items (requiring order)**" of this manual.

9.3. Periodic Inspection

Perform the daily periodic inspection to use recorder correctly.

The inspection is described below :

9.3.1. Battery Pre-installation Inspection

Items	Description
Exterior	No damage or deformation from drops.
	No dirt, rust and scratches on any part.
	No cracking or rattling of the panel.
Operation	No damage for rattling of switches and buttons.
Display	No dirt or scratches on the display panel.
Measurement Cuff	Replace the cuff when a problem is found. The cuff is disposable. <ul style="list-style-type: none">□ If there is a crack or adhesive matter in the connection between the cuff and cuff bladder.□ If the air hose loses its flexibility and becomes hard.□ When the surface of the air hose becomes glossy or feels oily.□ When the air bladder has cracks. We recommend to replace cuffs every three years, regardless of frequency of use.
	The air hose is not to be folded. If air remains in the cuff, it may cause peripheral dysfunction due to stopping the blood flow of the arm.
	The cuff bladder is correctly inserted inside the cuff cloth.
	No fraying of the cuff. The cuff doesn't ravel.
Wearing tools	No damage in the carrying holder, belt and cuff.
Connection	The air plug is connected to the air socket correctly.

9.3.2. Battery Post-installation Inspection

Item	Description
Exterior	No fire, smoke or offensive smells.
	No strange sounds.
Operation	No trouble with functioning of switches and buttons.
Measurement Cuff	Measurement values are closely in usual value.
	No strange sounds or actions during measurement.
Inspection of blood pressure value	If blood pressure values are incorrect, contact your local dealer.

9.4. Disposal

Concerning the disposal and recycle of the product, for environment protection, follow the laws of the local government.

Disposal of the cuff

The cuff worn on the patient is medical waste.

Dispose of it properly as medical waste.

Disposal of the rechargeable built-in battery

Caution



The recorder equipped backup battery inside. When dispose the recorder, dispose of the battery properly in accordance with the local regulations concerning environmental protection.

Others

Name	Part	Material
Package	Case	Cardboard
	Cushion	Air cushion, special case
	Bag	Vinyl
Inside the recorder	Case	ABS + PC resin
	Internal parts	General parts
	Chassis	Iron
	Backup battery on the board	Lithium rechargeable coin cell battery : ML2016H
	Battery	Alkaline battery : 1.5V LR6 or AA size Rechargeable battery : AA size Ni-MH batteries, 1900 mAh or more

9.5. Troubleshooting

Consult the following checklist and error code list before contacting your local dealer.

If this measures do not improve the problem or the problem occurs again, contact your local dealer.

Problem	Main cause	Treatment
No display after pressing any switches.	Battery power has been consumed.	Replace to new batteries.
No OLED during A-BPM.	OLED may disappear by the electrostatic effect.	Remove batteries and reinstall them again.
Frequent clock reset.	The backup battery does not charge. #1	Charge it for 48 hours using new batteries.
No pressurization	Cuff is not exactly connected.	Check the cuff and air hose concerning folding, kink and connection.
No USB communication #2	Communication cable is removed.	Confirm the cable to be connected correctly.
Battery cover cannot be opened	Non-standard size batteries were used.	Contact your local dealer.

#1 : Users (unauthorized maintenance personnel) cannot replace the backup battery (lithium battery) placed on the electronic board inside the recorder. The backup battery is charged from the batteries (LR6 or AA size) for the measurement.

#2 : **Dedicated peripheral** is required.

Caution



Do not disassemble or modify the recorder. It may be damaged.

9.6. Error Codes

Measurement error codes

Code	Meaning	Cause and treatment
E03	Pressure zero error	Release the air left in the cuff.
E04	Low battery	Replace with new batteries.
E05	Failure of pressurization	<ul style="list-style-type: none">□ Inflation does not reach the target pressure.□ Confirm the cuff connection.□ If there are no problems with the cuff connection, the recorder may have malfunctioned and requires inspection.
E06	Pressure exceeds 299 mmHg	Body motion may be occurred in the pressurization. Relax and keep the silence during measurement. If the treatment is not enough, inspect the recorder.
E07	Force stop using START/STOP switch.	Press the START/STOP switch only when necessary.
E08	Blood pressure cannot be measured.	<ul style="list-style-type: none">□ The heartbeat cannot be detected due to body motion or noise from clothes.□ Relax and do not move.□ Confirm the position of the cuff.□ If this failure occurs even when relaxed, contact your dealer to inspect and repair the recorder.
E10	Excessive body motion.	Relax and keep silent during the measurement.

Code	Meaning	Cause and treatment
E20	Out of range, $30 \leq \text{PUL} \leq 200$	<p>If these errors occur multiple times, try another blood pressure measurement.</p> <p>#1 PP = SYS - DIA</p> <p>SYS : Systolic blood pressure DIA : Diastolic blood pressure PP : Pulse pressure</p>
E21	Out of range, $30 \leq \text{DIA} \leq 160$	
E22	Out of range, $60 \leq \text{SYS} \leq 280$	
E23	Out of range, $10 \leq \text{PP} \leq 150$ #1	
E30	Measurement is above 180 seconds.	If the inflation speed or exhaust speed is slow, an inspection is necessary.
E31	Exhaust is above 90 seconds.	The exhaust speed may be slow, an inspection is necessary.
E48	Heartbeat cannot be detected.	Heartbeat cannot be detected because of body motion, etc. Measure the blood pressure while relaxed and do not moving.
E60	The settings of the interval time are incorrect.	If the interval time is set to 120 minutes, the difference between last start time and next start time cannot divide into two hours perfectly.
E90	Zero pressure error for safety circuit.	<ul style="list-style-type: none"> □ Displays at the measurement start time. □ Release the air remaining in the cuff completely.

Code	Meaning	Cause and treatment
E91	Safety circuit detects over load pressure.	<ul style="list-style-type: none"> □ Body motion may be detected at the pressurization. Relax and do not move while the measurement. □ If this error occurs even when relaxed and not moving, contact your dealer for inspection.

Hardware error codes of the recorder

Code	Meaning	Cause and treatment
E52	Memory error	<ul style="list-style-type: none"> □ It may record in case of catching strong impact like a dropping down the recorder. □ If this code displays frequently, malfunction of the built-in memory may cause. Contact your dealer for inspection.

Note

The error codes may be changed without any notice.

10. Optional Items (requiring order)

Cuffs

Name	Description	Order code
Small cuff for left arm	Arm circumference 15 to 22 cm 5.9" to 8.7"	TM-CF202A
Adult cuff for left arm	Arm circumference 20 to 31 cm 7.8" to 12.2"	TM-CF302A
Large cuff for left arm	Arm circumference 28 to 38 cm 11.0" to 15.0"	TM-CF402A
Extra large cuff for left arm	Arm circumference 36 to 50 cm 14.2" to 19.7"	TM-CF502A
Adult cuff for right arm	Arm circumference 20 to 31 cm 7.8" to 12.2"	TM-CF802A
Disposable cuff	10 sheets	TM-CF306A
Small cuff cover	for left arm 10 sheets	AX-133024667-S
Adult cuff cover	for left arm 10 sheets	AX-133024500-S
Large cuff cover	for left arm 10 sheets	AX-133024663-S
Extra large cuff cover	for left arm 10 sheets	AX-133024503-S
Adult cuff cover	for right arm 10 sheets	AX-133024353-S
Small cuff cloth	for left arm 2 sheets	AX-133025101-S
Adult cuff cloth	for left arm 2 sheets	AX-133024487-S
Large cuff cloth	for left arm 2 sheets	AX-133025102-S
Extra large cloth	for left arm 2 sheets	AX-133025103-S
Adult cuff cloth	for right arm 2 sheets	AX-133025104-S
Air hose adaptor	—	TM-CT200-110

Data analysis

Name	Description	Order code
USB cable	—	AX-KOUSB4C

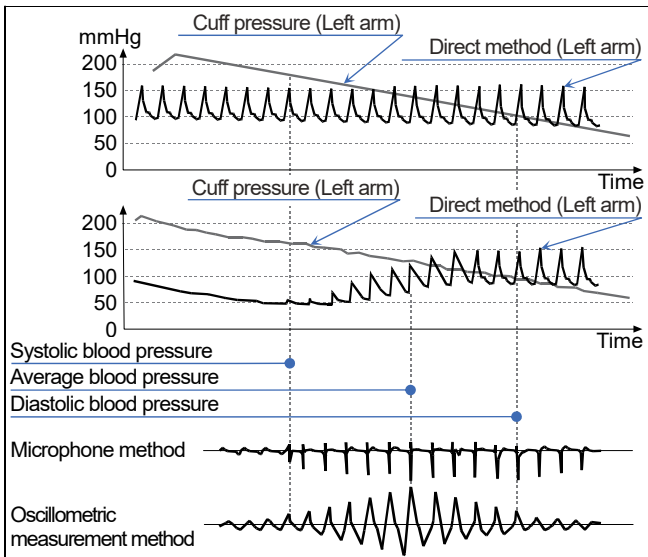
Others

Name	Description	Order code
Activity record sheet	10 sheets	AX-PP181-S
Carrying holder	—	AX-133025995
Belt	—	AX-00U44189
Clips	5 pieces	AX-110B-20-S

11. Appendix

11.1. Principle of Blood Pressure Measurement

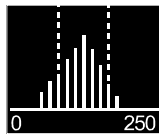
Measurement procedure : Wrap the cuff around the upper arm. Inflate the cuff to a pressure exceeding the systolic blood pressure. Then, exhaust the air from the cuff gradually. While the pressure is detected in the cuff in the air exhaustion stage, the pulse waveform appears in synchronization with the heartbeat. The pulse waveform suddenly increases near the systolic blood pressure. It increases further with exhaustion until it reaches the highest in amplitude, then decreases gradually. The changes in the pulse waveform are illustrated at next page. In the oscillometric blood pressure measurement, the systolic blood pressure is specified as the point where the amplitude increases suddenly after the pulse in the cuff pressure is detected, the mean blood pressure is specified as the point where the amplitude reaches the highest, the diastolic blood pressure is specified as the point where the amplitude decreases gradually and becomes small. Actually, the pressure sensor detects the subtle changes in the cuff pressure with time, stores the pulse waveform in memory, and evaluates the systolic and diastolic blood pressures according to the oscillometric measurement algorithm. The details in the algorithm vary with the blood pressure monitor. Blood pressure values of adults and infants are measured by the oscillometric method and are compared with those measured by the auscultatory method. Diastolic blood pressure is defined to be the end point of phase 4 in the auscultatory method. The pulse waveform of the cuff pressure depends on the characteristics of the cuff material. Therefore, by using the specified cuff and the measurement algorithm, the measurement accuracy is maintained. Air hose length is within 3.5 m because of the damping characteristics due to pulse wave propagation.



Blood pressure measurement Error factors

The pulse graph can be an objective indicator of the reliability of the measurement accuracy.

When noise occurs due to irregular heart beat or physical movements, the amplitude of the graph changes. When the pulse graph is not a smooth outline, check again or use other methods.



Pulse graph

Cuff position at the same height as heart

Wrap the cuff on the arm at the same level as the heart. If the cuff position is incorrect, a measurement error occurs. For example, if the cuff is 10 cm lower than the heart level, the blood pressure is measured 7 mmHg higher.

Proper cuff size

Use a cuff of adequate size. If the size is too small or too big, a measurement error occurs. Measurements with too small a cuff tend to be evaluated as high blood pressure, regardless of the proper blood pressure and normal artery. Measurements with too large a cuff tend to be evaluated as low blood pressure, especially for those who suffer from severe arteriosclerosis or have abnormal arterial valves. The wrong cuff size is a cause of differences between the direct method and oscillometric measurement method. The cuff has the label described range of the arm circumference. Select and attach the proper size cuff for each patient. The accuracy of the blood pressure measurement is guaranteed by the pressure accuracy of the pressure sensor, exhaust characteristics and measurement algorithm, so long as the proper cuff and air hose are used. Inspect the pressure accuracy of the pressure sensor and exhaust characteristics periodically.

11.2. EMD Information

The requirements that apply to medical electronic instruments are described below :

Performance concerning of the EMD guidelines

The use of the recorder require special precautions regarding EMD (Electromagnetic Disturbances). Operate the recorder in accordance with cautions regarding EMD described in this manual. Portable and mobile RF communication equipment (e.g. cell phones) can affect medical electrical equipment.

Accessories compliant with EMD standards

The accessories and options for this recorder accord with the condition of IEC60601-1-2:2014. If not authorized accessory is used, it may cause of increasing emission and lowering noise immunity.

Warning



Use accessories designated by the A&D company.
Unauthorized accessories may be influenced by electromagnetic emission and have reduced immunity against disturbances.

EMISSIONS LIMITS

Phenomenon		Compliance
Radiated RF emission	CISPR11	Group 1、 Class B

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 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)
Rated power frequency magnetic fields IEC 61000-4-8	30 A/m 50 Hz / 60 Hz

IMMUNITY TEST LEVELS : PATIENT COUPLING Port

Phenomenon	Immunity test levels
Electrostatic discharge IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air

IMMUNITY TEST LEVELS : Signal input / output Port

Phenomenon	Immunity test levels
Electrostatic discharge IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Electrical fast transients / bursts IEC 61000-4-4	± 1 kV 100 kHz repetition frequency
Conducted disturbances induced by RF fields IEC 61000-4-8	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

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	704 – 787	LTE Band 13,17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 – 1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1,3,4,25 UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 – 2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						



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