TM-2430

Recorder for Ambulatory blood pressure monitor

INSTRUCTION MANUAL

Ambulatory Blood Pressure Monitor

A&D Company, Limited

1WMPD4000136H

The contents of this manual and the specifications of the instruments covered by this manual are subject to change without notice.

Contents

Before use

Compliance

Compliance with European Directive 93/42 EEC for Medical Products

The device conforms to the following requirements: European Directive 93/42 EEC for Medical Products; Medical Products Act; European Standards for Electrical Medical Equipment EN60601-1 (General Safety Provisions), EN60601-2-30 (Particular Requirements for the Safety of Automatic Cycling Indirect Blood Pressure Monitoring Equipment), EN60601-1-2 and EN55011 (Electromagnetic Compatibility); European Standards pertaining to Non Invasive Blood Pressure Instruments EN1060-1 (General Requirements), EN1060-3 (Supplementary Requirements for Electromechanical Blood Pressure Measuring Systems). The above is evidenced by the CE mark of conformity accompanied by the reference number of a designated authority. This device is designed for adults only.

Compliance with FCC Rules

Please note that this equipment generates, uses and can radiate radio frequency energy. This equipment has been tested and has been found to comply with the limits of a Class A computing device pursuant to Subpart J of Part 15 of FCC rules. These rules are designed to provide reasonable protection against interference when this equipment is operated in a commercial environment. If this unit is operated in a residential area it might cause some interference and under these circumstances the user would be required to take, at his own expense, whatever measures are necessary to eliminate the interference. (FCC: Federal Communications Commission in the U.S.A.)

Compliance with the Australian EMC Framework

The device conforms to the following requirements: EMC Emission standard for industrial, Scientific & Medical equipment AS/ NZS 2064-1997, EMC Generic Immunity standard AS/ NZS 4252. 1-1994. The above is evidenced by the C-Tick label.

Definitions

SYS	Systolic Blood Pressure
DIA	Diastolic Blood Pressure
DSD	The difference between Systolic Blood Pressure and Diastolic Blood Pressure.
Exhaust	This means "releasing the cuff air as soon as possible".
Constant exhaust	This means "releasing the cuff air at a constant depressurization rate".
Exhaust velocity	This means the rate of depressurizing the cuff air.
During a measurement	This means "a period between the start of cuff inflation and the end of exhausting the air".
Interval	This is called a "block". A block consists of a start time and frequency.
bpm	beats per minute.

Precautions for Use

Precautions

Batteries

- ☐ Use alkaline batteries (LR6 type, AA type, Mignon) or the specified Ni-MH batteries.
- ☐ Do not mix new and used batteries in the recorder.
- ☐ Remove the batteries from the recorder, if it will not be used for a long period of time and unless there is no risk of a SAFETY HAZARD arising.
- ☐ Do not touch the batteries and the patient at the same time. That may result in electrical shock.
- ☐ Should the battery short-circuit, it may become hot and potentially cause burns.

A malfunctioning recorder

- ☐ If the recorder malfunctions, stop the operation, attach a note "Do not use this recorder" and store in a safe place to avoid misuse.

Training

- ☐ Instruct the patient on how to stop the operation if there is an abnormal measurement, and how to remove the cuff if there is excessive arm pain.
- ☐ Advise the patient on how to cope with mis-operation and contingencies.
- ☐ Take care to avoid accidental strangulation of babies or infants with the hose.

Repair

- ☐ Do not open the recorder case. Contact your nearest A&D dealer if you have questions.

Blood pressure measurement

- ☐ Use the recorder on adults.
- ☐ Clinical testing has not conducted on newborn infants and pregnant woman.
- ☐ The recorder may not make a correct measurement when a patient has continuous arrhythmia or the recorder senses noise due to the patient’s movement.
- ☐ Please check measurement values by other methods, if you suspect the values.
- ☐ Do not use this recorder on a person who is using a heartlung machine and a defibrillator.
- ☐ Do not use this recorder on a person who is critical or is in an intensive care unit.
- ☐ Do not twist the air hose during measurement. This may cause injury due to continuous cuff pressure.
- ☐ Measuring blood pressure too frequently may cause harm due to blood flow interference. Check that the operation of the device does not result in prolonged impairment of blood circulation, when using the device repeatedly.
- ☐ If you have had a mastectomy, please consult a doctor before using the device.

Data in memory

- A built-in backup battery keeps the important data in memory while replacing the main batteries. However it works for a short period of time. Perform the battery replacement swiftly, or you may lose measurement data, the clock setting information and automatic measurement condition data. The period varies depending on the battery condition. The backup battery may take 24 hours or more to be fully charged (depending on the battery condition).
- The built-in backup battery (rechargeable) as well as the primary battery (not rechargeable) will deteriorate along use, which causes to decrease its capacity. The built-in backup battery will deteriorate due to repetitive backup operations.
  To prevent the sudden drop of the built-in battery life, observe the following:
  - Before using the monitor for the first time after purchase or after an extended period of no use, charge the battery fully. It takes 24 hours or more with the power switch turned on. Charging can be performed during measurement.
  - After measurement, leave the battery inside and the power switch turned on. Under this condition, the built-in battery will not deteriorate. (This is true with the "**B**" sign displayed.)
  - When the monitor is not to be used for a month or longer, turn the power switch off to prevent the main batteries from leaking. During an extended period of no use, the built-in battery will deteriorate. To prevent the situation, use the monitor regularly.
  - When the power switch is turned on and off after a short period of use, the built-in battery will not be fully charged and the battery life will decrease. Avoid this situation.

Saving power

- Turn off the power switch when not in use.
- The backup battery life is a few days. Please transfer the data as soon as possible.

Cuff

- Close the cuff fastener properly when attaching the cuff to a patient or replacing the cuff cloth. If the fastener is closed incorrectly, the cuff may be damaged during use.
- Avoid tightly folding the cuff or storing the hose tightly twisted for long periods, as such treatment may shorten the life of the components.
- Unusually, the cuff may get hot during measurement, please handle it with care.

Notes on the Blood Pressure Recorder

Storage

- ☐ Do not store the recorder in the following places.
  - ☐ Where the recorder could be splashed with water or other liquids. If the recorder becomes soaked, it needs a repair. (Do not use the recorder.)
  - ☐ Where the temperature and humidity are high, or in direct sunlight.
  - ☐ Where the recorder may be influenced by vibration or shock.
  - ☐ Where there is dust, salt or sulfur vapor.
  - ☐ Where chemicals are stored, or chemicals are evaporating.
  - ☐ The automatic blood pressure monitor's performance may be affected by excessive temperature or humidity, or altitude.
  - ☐ Allow the device to adapt to the surrounding environment before use (about one hour).

Before use

- ☐ Cover the RS-232C terminal using the cap, to avoid dust.
- ☐ Confirm that the recorder works correctly and measurement values are proper.
- ☐ Confirm that the cuff and air hose are connected properly.
- ☐ Confirm parts in direct contact with the patient. Keep these parts clean.
- ☐ Use a clean cuff cover. Because it comes into direct contact with the patient.
- ☐ Delete the old data before starting a new measurement.
- ☐ Avoid strong magnetic field and static electricity.
- ☐ Do not use this recorder while using high frequency surgical equipment.

During use

- ☐ The recorder should be operated by medical personnel who knows it well.
- ☐ Use the recorder only during the time of diagnosis or medical treatment.
- ☐ Stop using the recorder, if the patient feels pain in the arm or the recorder does not measure properly.
- ☐ The measurement cycle may be reduced due to the environment.
- ☐ When an inside part of the recorder becomes soaked (wet), turn off the power switch and request service from your supplier or the A&D service group.

After use

- ☐ Clean the recorder, cuff and accessories for the next use. Do not pull or kink hoses. Do not use organic solvent, antiseptic solution, etc.
- ☐ Turn off the power switch after measurement.
- ☐ Please use the original box for transportation.
- ☐ Do not let children use the device by themselves and do not use the device in a place within the reach of infants. It may cause accidents or damage.

Periodic maintenance

- ☐ The recorder is a precision instrument. Please check all functions periodically (every year). Contact your nearest A&D dealer for the inspection.

Environmental protection

- ☐ If you discard the recorder, remove the Ni-MH batteries and built-in Li battery from the recorder.
- ☐ Dispose of the Ni-MH batteries in the designated container for recycling.
- ☐ Dispose of the Li battery properly as a hazardous waste.
- ☐ Use of accessories not detailed in this manual may compromise safety.

Welcome

Welcome and Intention

Thank you for your Purchase!

The A&D TM-2430 ambulatory blood pressure recorder enables you to accurately take a patient's blood pressure, automatically, at different preset times throughout a 24-hour period.

Recently, in the treatment of patients with hypertension, there has been an increasing need to prescribe medication according to the particular blood pressure fluctuation pattern of the patient. These patterns can be made more evident by using the TM-2430 recorder, and analysis by a physician.

This manual will explain in simple language how this recorder works.

Patient

This blood pressure recorder is designed for an adult patient.

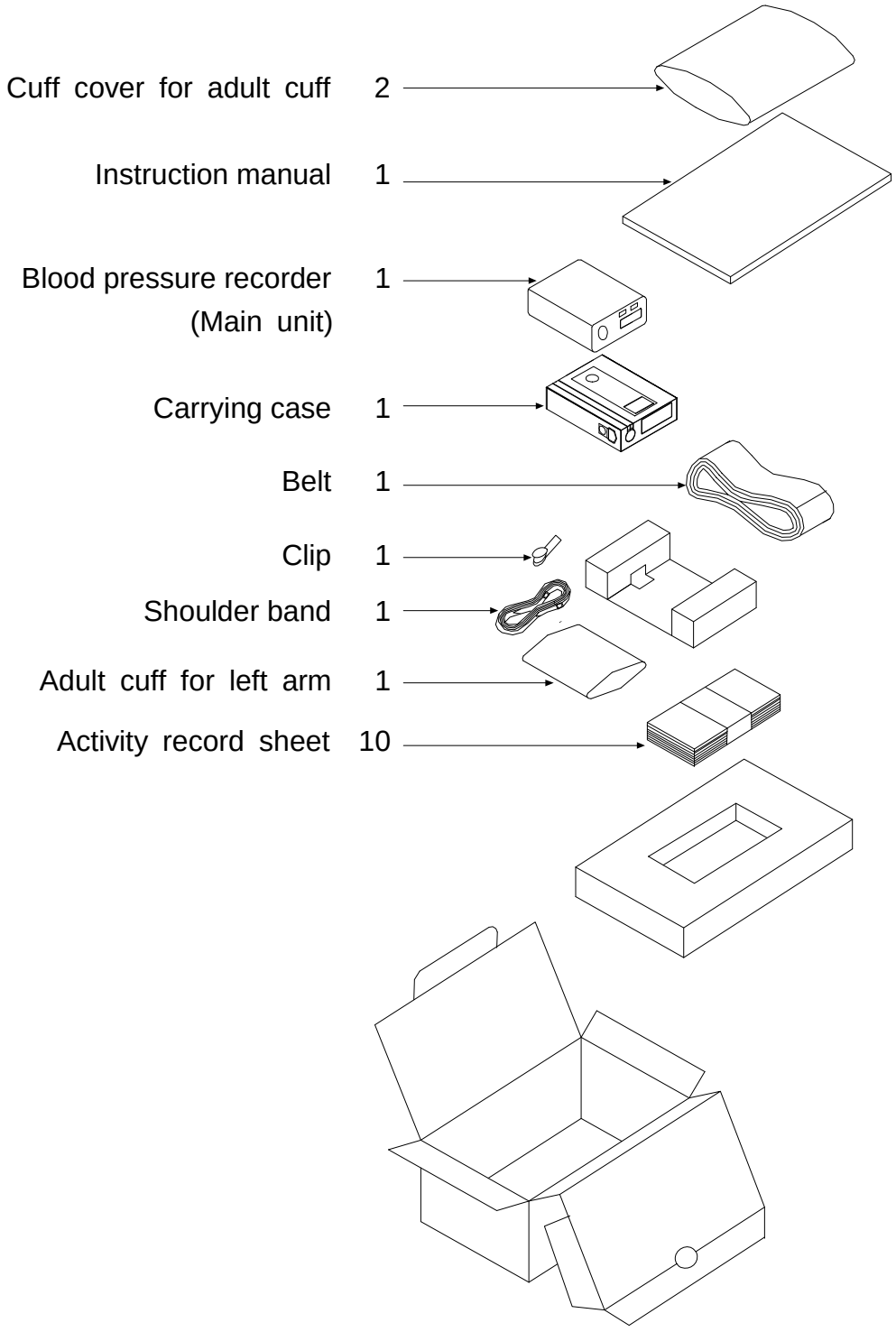
Environment

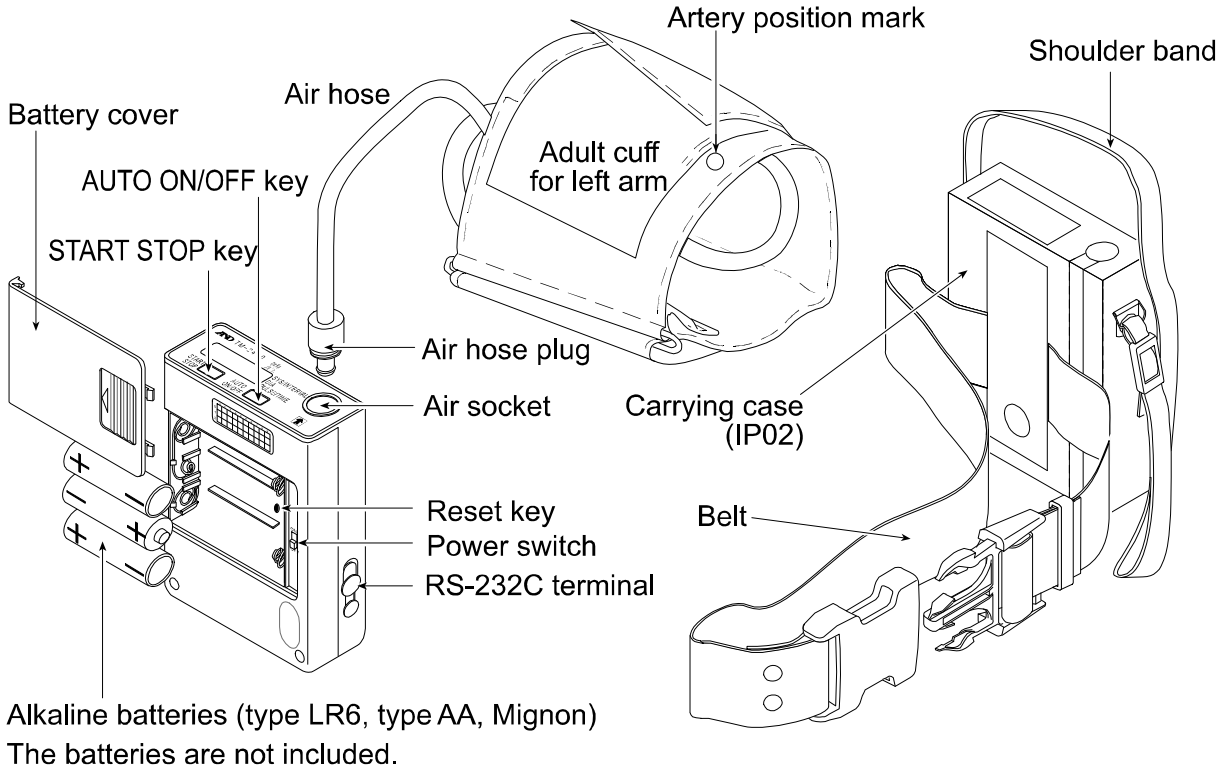
This blood pressure recorder is used in a hospital and / or patient’s home.

Product overview

Packing List and Component Names

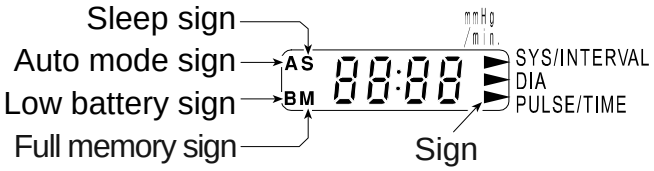
When you open this box, make sure you have everything as shown below:

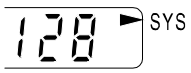




Name	Functions
Power switch	This is the main power switch. At the OFF state, all data and parameters are stored by a backup battery. This backup battery life is approximately 10 days with the power off.
AUTO ON/OFF key	・When you press and hold the AUTO ON/OFF key, the automatic measurement is started or stopped alternately. ・When you press the AUTO ON/OFF key at mode II of the automatic measurement, "**S**" is displayed or turned off alternately. This sign changes the interval for sleep.
START STOP key	・When you press the START STOP key, a blood pressure measurement is started. ・When you press and hold the START STOP key for approx. 3 seconds, the recorder proceeds to "Selection for the automatic measurement". ・When you press and hold the START STOP key for approx. 6 seconds, the recorder proceeds to "Parameters for the display and clock". ・When you press and hold the START STOP key for approx. 9 seconds, the recorder proceeds to "Deleting old data".
RS-232C terminal	This terminal is used for data output to a printer or computer. The optional RS-232C cable is necessary to output the data.
Reset key	All data and parameters are deleted.

Display

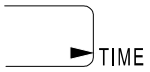




Systolic Blood Pressure display

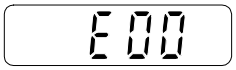
Setup sign of automatic measurement

Diastolic Blood Pressure display



Setup sign of display and clock

Pulse display



Error display ex. "Set the clock"

Clock display

Sign	Name	Functions
►	Arrow	The arrow points to the kind of current display in the measurement result and function mode.
A	Automatic measurement	"**A**" is displayed when the automatic measurement is selected. When you press and hold the AUTO ON/OFF key, this sign is turned on or off alternately.
S	Sleep	When you press the AUTO ON/OFF key while in mode II of the automatic measurement, "**S**" is displayed or turned off alternately. With "**S**" turned off, the time interval is 15 minutes. With "**S**" turned on, the time interval is 30 minutes.
B	Low battery	When the recorder cannot operate all functions due to low battery, this sign is displayed. The clock is still displayed. Please replace the batteries immediately.
M	Full memory	When data memory is at full capacity, this sign is displayed. In this case, you cannot perform another measurement. Transfer the data, save in other media and delete. Then "**M**" turns off.

Symbols

I	Turning on the recorder.
○	Turning off the recorder.
⊕▭⊖	Direction guide to install batteries.
⎓	Direct current.
SN	Serial number.
2014	Date of manufacture.
⚠	Attention symbol. "See instruction for use."
	Recorder, Cuff and tubing are designed to have special protection against electric shocks.
	Operating instructions
	Refer to instruction manual/booklet Note: On ME equipment “Follow instruction for use”
	WEEE symbol

Specifications

Features

Portability

- ☐ The recorder weighs approx. 215 g (including batteries) and is palm top size, because a micro-pump is used.
- ☐ The recorder is powered by LR6 type (Mignon) alkaline batteries. It is possible to replace the LR6 type batteries with Ni-MH rechargeable batteries.

Operation & management

- ☐ Clock and automatic measurement parameters may be set as needed.
- ☐ If you connect to a computer and use the optional software, clock and automatic measurement parameters can be set easily.
- ☐ There are three modes for automatic measurement.
- ☐ The recorder can transmit data to a printer directly. (An adaptable printer is necessary to print the data. Refer to "Data Transmission to a Printer" for specifications of the printer.)
- ☐ The recorder has the built-in rechargeable coin Li battery to keep the clock and automatic measurement parameters.
- ☐ Charge the rechargeable battery using a charger with CE Marking.
  The battery cannot be charged using the recorder.

Analysis

- ☐ The time interval may be changed as needed.
- ☐ The patient's blood pressure can be measured immediately at any time.
- ☐ If you use the optional software, you can analyze the data widely.

Smart measurement

- ☐ The measurement time is shortened by proper exhaust velocity control.
- ☐ The exhaust velocity adjustment is unnecessary, because the constant exhaust is properly controlled.
- ☐ In the automatic measurement, the inflation value and stop value at exhaust is managed to reduce the measurement time.

Functions and Specifications

Blood pressure measurement

- ☐ There are two ways of blood pressure measurement.

  Automatic measurement----- This automatic measurement works in accordance with internal clock, preset time intervals and preset mode. The measurement data is saved in memory.

  Manual measurement -------- Any time you press the START STOP key, a blood pressure measurement is performed immediately. The measurement data is saved in memory.

Automatic measurement

- ☐ The measurement starts or stops using the AUTO ON/OFF key. When the measurement is started, the recorder begins to work in accordance with preset time intervals from the preset time of the internal clock. Refer to "Selection for the Automatic Measurement".
- ☐ In the automatic measurement, "**A**" appears in the upper left of the display.
- ☐ The recorder automatically measures the patient's blood pressure at the time that is pointed out by "the frequency" and "the start time" (by the programmed time intervals).
- ☐ When a measurement error occurs and there is 8 minutes until the next measurement, the measurement is retried after approx. 30 seconds.
- ☐ If a measurement is retried, only the data from the retry is saved.
- ☐ The recorder automatically adjusts the proper pressure, exhaust velocity and end of measurement.
- ☐ Refer to "Selection for the Automatic Measurement" and "Automatic Measurement (by Programmed Time Intervals)" about operation and entering parameters.

Stopping a measurement

- ☐ If you press the START STOP key during a measurement, the recorder exhausts the air and stops the measurement.

Concealing the measurement value

- ☐ This function works only while using automatic measurement.
- ☐ This function does not display the SYS, DIA or pulse rate for the automatic measurement, but the data is saved in memory.
- ☐ This function can select "reveal" or "conceal" at "Parameters for the Display and Clock". Refer to this section.
- ☐ If you select "conceal", the recorder displays the clock during a measurement.
- ☐ If you reset the recorder, this parameter is set to "reveal".

Pressurization

- ☐ The pressure is automatically selected by the recorder while in the automatic measurement mode.
- ☐ The first pressure is set to approx. 185 mmHg. This value automatically varies to the proper value after first measurement. If the first inflation is not successful, the recorder retries twice.
- ☐ If you reset the recorder, the first inflation value is set to 185 mmHg.

Memory

- ☐ The recorder can store 350 sets of data (the memory capacity is 350).
  A data set consists of the SYS, DIA and pulse rate.
- ☐ When memory becomes full, the recorder displays an "**M**". Until you delete the data, you cannot measure blood pressure.

When the recorder saves data for more than one patient, data management becomes complicated. We encourage that each patient's data is recorded, transferred and is deleted from memory.

When "**B**" is displayed, the backup battery that stores a patient’s data is weak. Please transfer the data and save it in other media as soon as possible.

ID number

☐ If you reset the recorder, the ID number is set to "1".

☐ The ID number can be set using the optional software.

Performance specifications

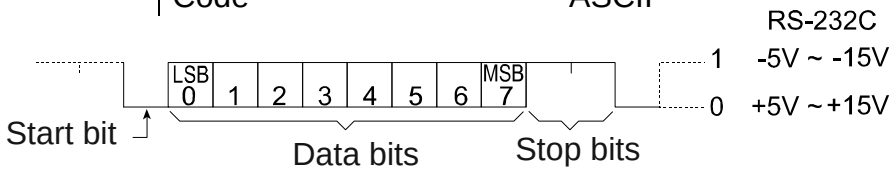
Measurement method	Oscillometric	
Pressurization	Micro-pump Display range 0 ~ 320 mmHg Automatic measurement 85 ~ 300 mmHg (Fitted) Manual measurement 185 mmHg (Fixed)	
Measurement range	Systolic Blood Pressure 60 ~ 280 mmHg Diastolic Blood Pressure 40 ~ 160 mmHg Pulse rate 30 ~ 200 bpm	
Accuracy	Pressure ±3 mmHg Blood pressure Conforming to 1992 AAMI standard Pulse rate ±5 %	
Minimum display division	Pressure 1 mmHg Pulse rate 1 bpm	
Depressurization	Constant exhaust Controlled ceramic valve Exhaust Ceramic valve	
Measurement	Automatic measurement Manual measurement	
Number of measurement	Approx. 200 times (Varies depending on the environment and the condition of the Ni-MH batteries)	
Memory	Up to 350 sets of data	
Display	Normal Clock During a measurement Pressure value After a measurement SYS, DIA and pulse rate Error code, function of concealing the measurement data	
Clock	24-hour (1997-2096, automatic leap year setting)	
Batteries	3 x Alkaline battery (type LR6, type AA, Mignon) or 3 x Ni-MH battery (type AA, Mignon)	
Type of protecting against electric shock	Internally powered equipment type BF 	
CE Marking	The label of the medical device by the EC directive. CE 0123	
C-Tick Marking	The certification trade mark registered to the ACA by the Trademark office. 	
Useful life	Recorder: 5 years. Self-authorization value when proper operation and maintenance are achieved in the best condition. It varies due to usage condition.	
Protection against water and dust	Recorder: IP20 Carrying case (IP02): IP02	IP22 (when both are used)

AAMI: Association for the Advancement of Medical Instrumentation

ACA: the Australian Communications Authority

CE marking and C-Tick marking are labeled only for the countries where they are required.

Interface	Connected to a computer, you can output the data and enter parameters. Connected to a printer, you can print the data. EIA RS-232C, Asynchronous, bi-directional, half duplex Baud rate 9600 bps Data bits 8 bits Stop bits 2 bits X parameter Used (for computer) Not used (for printer) Parity None Code ASCII



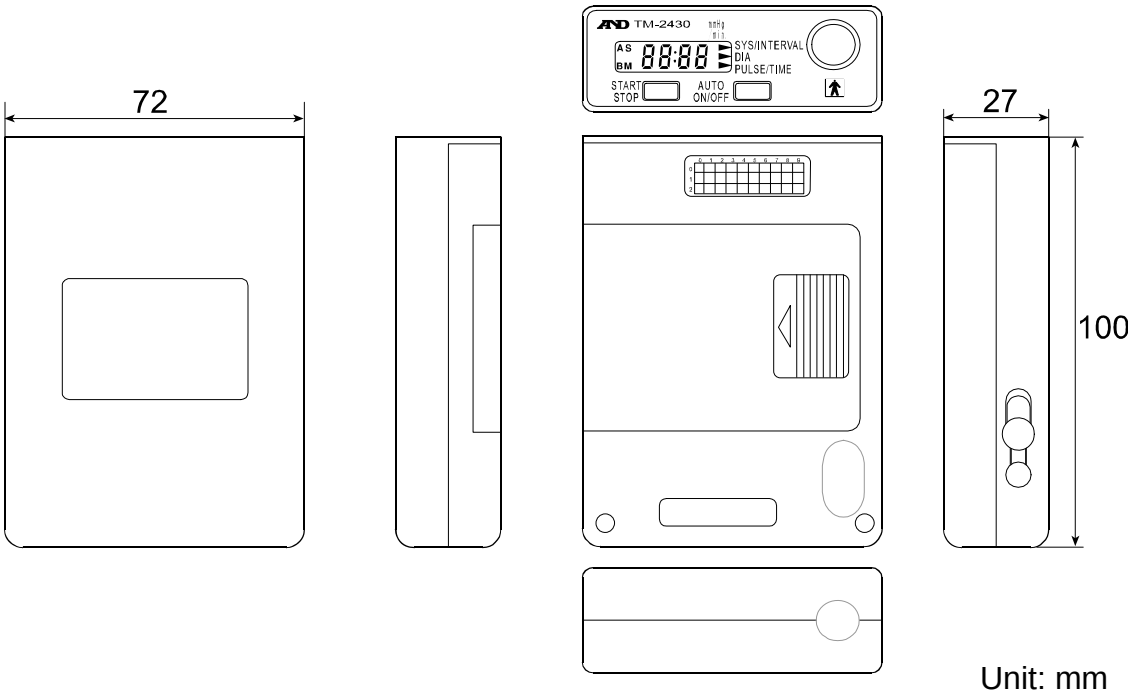
Environment specifications

Operating environment	+ 10° C ~ +40° C (+50° F ~ +104° F), 10 ~ 85%RH *
Transport and Storage	- 20° C ~ +55° C (-4° F ~ +131° F), 10 ~ 95%RH *
Atmospheric pressure (Both for operation and storage)	700 ~ 1060 hpa

* Non Condensing

Physical specifications

Dimensions	72(W) x 100(D) x 27(H) mm 2.8(W) x 3.9(D) x 1.0(H) in.
Weight	Approx. 215 g (0.47lb) excluding cuff



Unit: mm

The complete procedure for use

Step by Step Procedure

Step 1 Battery replacement.
Replace with new alkaline batteries (note direction).
Refer to "Replacing the Batteries" on page 16.

Step 2 Turn on the recorder using the power switch.

Step 3 Follow the procedure, depending on the recorder state.

Case 1 Normal state

The buzzer sounds once and the clock is displayed. The recorder is ready for use. The recorder stores parameters for "display and clock" and "automatic measurement". Please proceed to Step 5.

Case 2 Error state

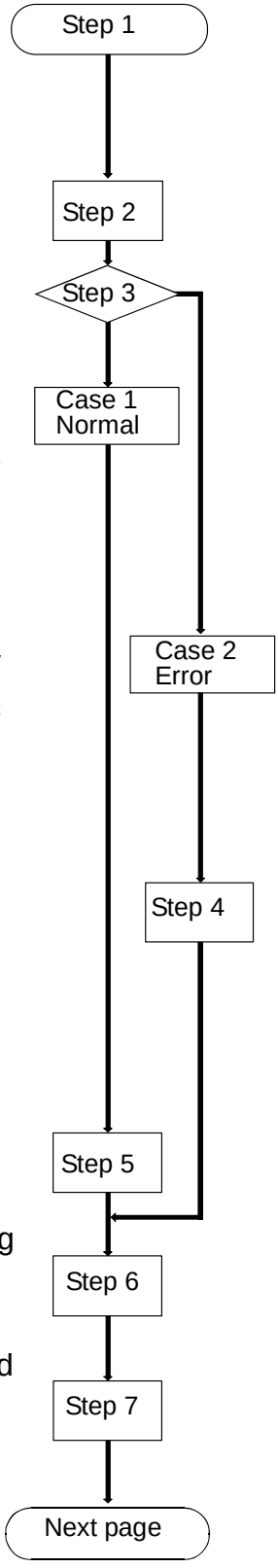
When the recorder displays the E00 error code, it is necessary to set parameters for "display and clock" and "automatic measurement". Please proceed to the next step.

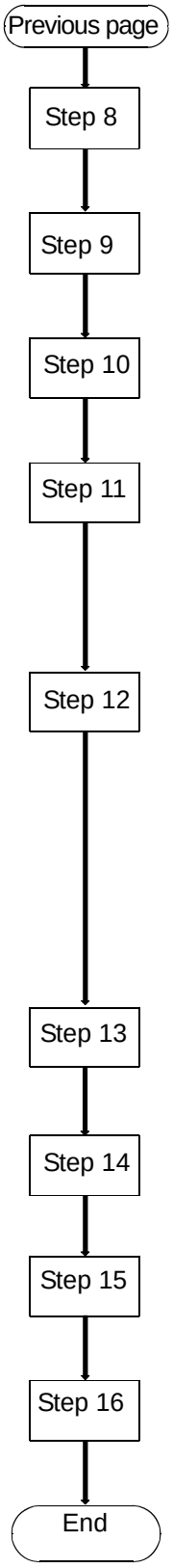
Step 4 Set parameters for "display and clock". When you use automatic measurement, set parameters for automatic measurement. Refer to "Parameters for the Display and Clock" and "Selection for the Automatic Measurement". Please proceed to Step 6.

Step 5 Set new parameters for "display and clock" and "automatic measurement", if necessary.

Step 6 Delete the old data stored in the recorder. Refer to "Deleting Old Data".

Step 7 Explain "Patient Instructions" and " Notes on the Blood Pressure Recorder "to the patient.





Step 8 Attach the cuff to the patient. Refer to "Attaching the Cuff and Recorder".

Step 9 Attach the carrying case to the patient and insert the recorder. Refer to "Attaching the Cuff and Recorder".

Step10 Check the recorder using the manual measurement with relaxed, but correct posture. Refer to "Manual Measurement".

Step11 Start the automatic measurement. The recorder displays "**A**" and starts the automatic measurement sequence.
Refer to "Automatic Measurement".

Step12 When using automatic measurement, consider the following.

- ☐ Consider the sections "Patient instructions" and "Notes on the Blood Pressure Recorder".
- ☐ When the patient uses mode II of automatic measurement, press the AUTO ON/OFF key with each rising and going to bed.

Step13 When the automatic measurement sequence is finished, the "**A**" sign turns off. Refer to "Automatic Measurement".

Step14 Remove the cuff and recorder from the patient.

Step15 Transfer the patient's data and save it in other media. Refer to "Data transfer".

Step16 Clean the cuff and recorder and place them in storage. Refer to "Before use" and "Maintenance".

Initializing the recorder

Replacing the Batteries

Caution

- ☐ When "**B**" is displayed before a measurement, the recorder cannot make a measurement. Please replace with new batteries before using.
- ☐ If "**B**" is displayed during the measurement, stop the measurement and replace with new batteries immediately.
- ☐ Use alkaline batteries or the specified rechargeable batteries for the recorder.
- ☐ Do not use new and used batteries at the same time.

Steps for replacing the batteries

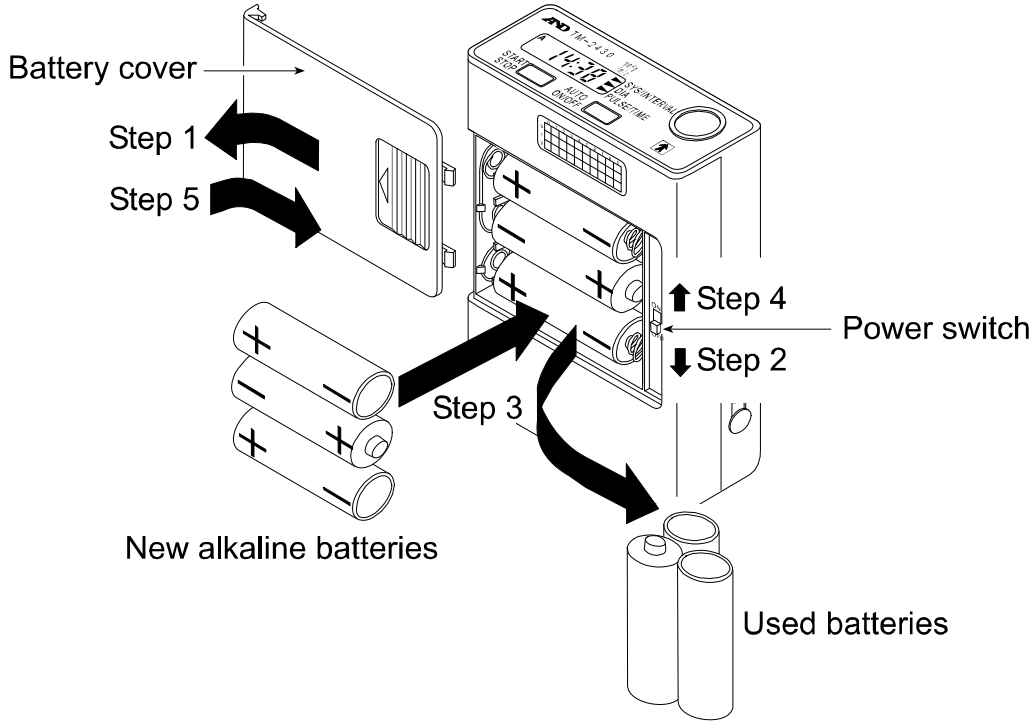
Step 1 Open the battery cover.

Step 2 Turn off the power switch.

Step 3 Replace with new batteries. (Note the direction, "+" and "-".)

Step 4 Turn on the power switch.

Step 5 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.

The State of Turning on the Recorder

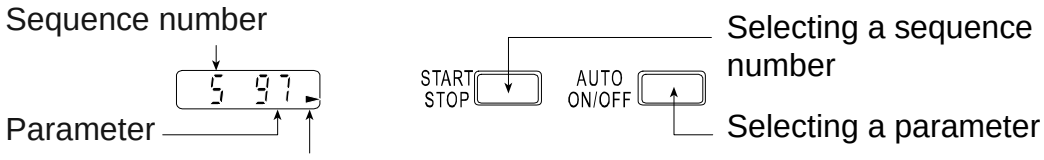
There are three types of state when the recorder is turned on. Select an operation. Refer to "The complete procedure for use" about use.

Action when the recorder is turned on.	State of recorder	Treatment (Operation)
The buzzer sounds once and the clock is displayed. (Normal state)	The recorder stores parameters for "display and clock" and "automatic measurement".	The recorder is ready for use.
The buzzer sounds once and E00 is displayed blinking.	All parameters are lost.	Set parameters for "display and clock" and "Automatic measurement".
The buzzer sounds four times and E00 is displayed blinking.	The state after reset. All parameters are lost.	

Parameters for the Display and Clock

This setting selects the display during automatic measurement sequence and adjusts the clock parameters. The sequence number tells you which parameter you are adjusting.

Display & key



Sign of setting parameters for display and clock

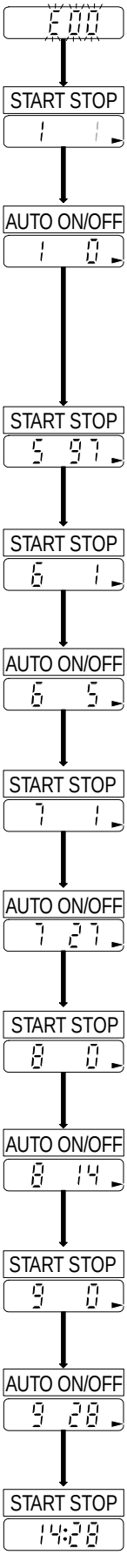
Items

Sequence number	Value & range	Meaning of parameters	
1	0	Displaying clock only in automatic measurement	1 1
	1	Displaying pressure and result in automatic measurement	
5	00 ~ 99	Year (1997 ~ 2096)	5 97
6	01 ~ 12	Month	6 1
7	01 ~ 31	Day	7 1
8	00 ~ 23	Hour	8 0
9	00 ~ 59	Minute	9 00

Steps for setting the display and clock

This explanation uses the following examples.

ex. After reset, the measurement value is not displayed.
The clock is adjusted to 1997/ 05/ 27 14:28.



Step 1 Press and hold the START STOP key for approx. 6 seconds. The recorder displays 1 1 for adjusting the display and clock.

Step 2 Press the AUTO ON/OFF key to display 1 0.
(A selection to display the clock only in automatic measurement)

Step 3 Press the START STOP key. The current year is displayed.

Step 4 Press the START STOP key. The current month is displayed.

Step 5 Press the AUTO ON/OFF key to display 5 (for May).

Step 6 Press the START STOP key. The current day is displayed.

Step 7 Press the AUTO ON/OFF key to display 27 (27th day).

Step 8 Press the START STOP key. The current hour is displayed.

Step 9 Press the AUTO ON/OFF key to display 14 (14th hour).

Step10 Press the START STOP key. The current minute is displayed.

Step11 Press the AUTO ON/OFF key to display 28 (28th minute).

Step12 Press the START STOP key to save these parameters. Then the recorder displays the clock.

Selection for the Automatic Measurement

This setting initializes measurement intervals that are based on the internal 24-hour clock.

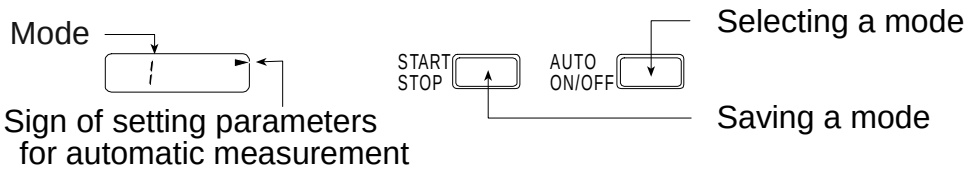
Mode

mode I 07:00 ~ 21:59 The measurement is performed every quarter hour.
22:00 ~ 06:59 The measurement is performed every half hour.

mode II The AUTO ON/OFF key is pressed at rising and going to bed so that the measurement intervals are changed and the time during sleep can be distinguished on the data.
When "**S**" is off, the measurement is performed every quarter hour.
When "**S**" is displayed, the measurement is performed every half hour.

mode III The measurement interval can be changed six times within a maximum of 24 hours. (The recorder can store six measurement intervals (blocks) in 24 hours. A block consists of a start time and frequency.)

Display & key



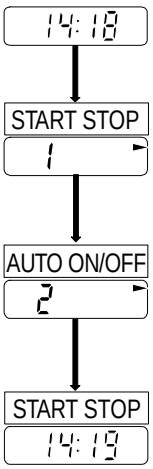
Steps for selecting a mode

ex. Mode II is selected.

Step 1 Press and hold the START STOP key for about 3 seconds. The current mode is displayed.

Step 2 Press the AUTO ON/OFF key to display 2 for mode II.

Step 3 Press the START STOP key. The recorder stores the mode and displays the clock.



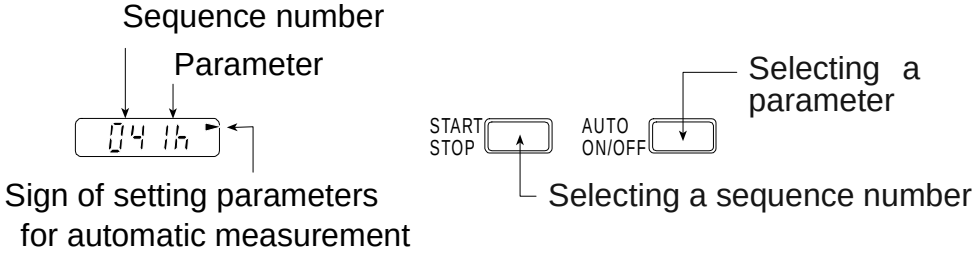
Mode III Settings

Setup procedure

Before you enter into mode III, read the procedure below. Also, refer to the example on the next page for the setting procedure.

- ☐ Each block's finish time is the next block's start time.
- ☐ The end of block 6 automatically becomes the start time of block 1.
- ☐ If you enter the block 1 start time in any other block, these parameters are saved and this sequence is finished.
- ☐ When selecting 120 minutes for the current frequency, you must adjust the start time of the next block so that the current block fits a multiple of 120 minutes. If not, an error code is displayed.
- ☐ The recorder displays 1h as 60 minutes and 2h as 120 minutes.
- ☐ When you enter the sequence of mode III settings, the recorder initializes each start time to the start time of block 1 and each frequency to "-" (not used).
  To read the current settings, press the START STOP key in this sequence.

Display & key



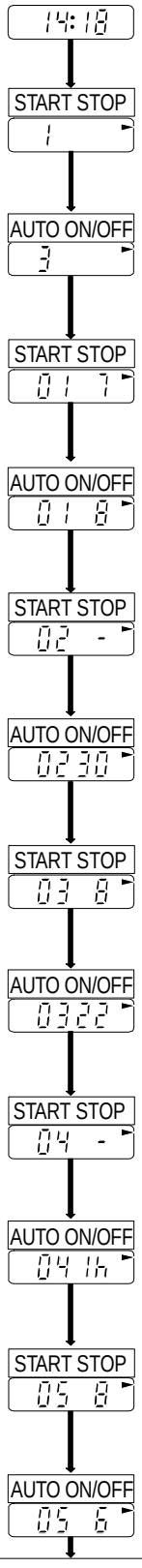
Items

Sequence number	Parameters (monitor)	Meaning	Initial value
01	0 ~ 23 o'clock	Start time of first block	01 7
02	-, 5, 10, 15, 20, 30, 60, 120 minutes	Frequency of first block	02 15
03	0 ~ 23 o'clock	Start time of second block	03 22
04	-, 5, 10, 15, 20, 30, 60, 120 minutes	Frequency of second block	04 30
05	0 ~ 23 o'clock	Start time of third block	05 7
06	-, 5, 10, 15, 20, 30, 60, 120 minutes	Frequency of third block	06 -
07	0 ~ 23 o'clock	Start time of fourth block	07 -
08	-, 5, 10, 15, 20, 30, 60, 120 minutes	Frequency of fourth block	08 -
09	0 ~ 23 o'clock	Start time of fifth block	09 -
10	-, 5, 10, 15, 20, 30, 60, 120 minutes	Frequency of fifth block	10 -
11	0 ~ 23 o'clock	Start time of sixth block	11 -
12	-, 5, 10, 15, 20, 30, 60, 120 minutes	Frequency of sixth block	12 -
13	0 ~ 23 o'clock	End of sixth block	13 -

"-" means "not used".

Steps for automatic measurement

ex. First block 08:00 ~ 21:59 frequency 30 minutes
Second block 22:00 ~ 05:59 frequency 60 minutes
Third block 06:00 ~ 07:59 frequency 10 minutes



Step 1 Press and hold the START STOP key for approx. 3 seconds. The current mode is displayed.

Step 2 Press the AUTO ON/OFF key to display 3 for mode III.

Step 3 Press the START STOP key. The mode is stored and the current start time of the first block is displayed.

Step 4 Press the AUTO ON/OFF key to display "8" for 8:00 hours as the start time of the first block.

Step 5 Press the START STOP key. The current frequency for the first block is displayed.

Step 6 Press the AUTO ON/OFF key to display "30" for 30 minutes as the frequency for the first block.

Step 7 Press the START STOP key. The current start time of the second block is displayed.

Step 8 Press the AUTO ON/OFF key to display "22" for 22:00 hours as the start time for the second block.

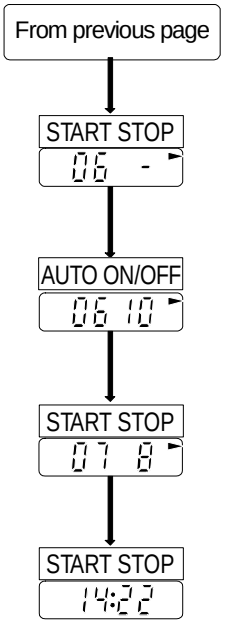
Step 9 Press the START STOP key. The current frequency for the second block is displayed.

Step10 Press the AUTO ON/OFF key to display "1h" for 60 minutes as the frequency of the second block.

Step11 Press the START STOP key. The current start time of the third block is displayed.

Step12 Press the AUTO ON/OFF key to display "6" for 6:00 hours as the start time of the third block.

To next page



Step13 Press the START STOP key. The current frequency of the third block is displayed.

Step14 Press the AUTO ON/OFF key to display "10" for 10 minutes as the frequency of the third block.

Step15 Press the START STOP key. The current start time of the fourth block is displayed.

Step16 Press the AUTO ON/OFF key. The recorder stores these parameters and displays the clock, (because the current start time of the fourth block is the same as the start time of the first block).

Deleting Old Data

Caution ☐ Confirm that the data has already been transferred and saved, when the data is to be deleted. It is not possible to recover data that was deleted.

☐ It is not possible to delete data completely, if the START STOP key is released while the buzzer sounds at Step 2.

Steps for deleting old data

Step 1 Press and hold the START STOP key for approx. 9 seconds. CL is displayed. If you want to cancel this process, press the AUTO ON/OFF key.

Step 2 Press and hold the START STOP key once more until the buzzer stops.

Resetting the Recorder

If the recorder does not work correctly, press the reset key. The recorder deletes all data and parameters. The internal system is initialized.

Caution ☐ By resetting, all data and parameters are deleted and the internal system is initialized.

☐ Do not press the reset key too intensely. Press the key gently so as not to damage the components inside.

☐ Keep the reset key hole free of foreign materials.

Steps for resetting the recorder

Step 1 Open the battery cover.

Step 2 Turn off the power switch.

Step 3 Remove the batteries from the recorder.

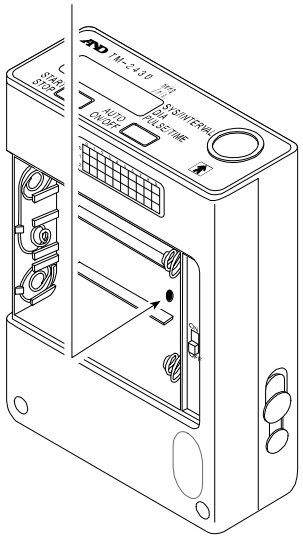
Step 4 Press the reset key gently.

Step 5 Place new batteries in the recorder.

Step 6 Turn on the power switch. The recorder sounds the buzzer four times and E00 is displayed blinking.

Step 7 Set the parameters for the display and clock. Also, adjust the parameters for automatic measurement.

Reset key



Preparing the patient

Patient Instructions

Advise the patient on how to cope with mis-operation and contingencies.

Precautions during automatic measurement

- ☐ Relax and be quiet, when the recorder starts inflating the cuff.
- ☐ Maintain the same posture during measurement.
- ☐ Avoid noises and vibrations during measurement.
- ☐ After inflation, the recorder deflates the cuff and measures the patient's blood pressure. The maximum measurement time is 90 seconds. Relax and be quiet during measurement.
- ☐ If you move your body during measurement, the recorder may start inflation during the deflation process for reevaluating the blood pressure.
- ☐ If the recorder did not acquire usable data due to the patient's body movement and the frequency of the interval is 8 minutes or more, the recorder may start measurement again approx. 30 seconds after measurement.. Do not move and try to relax during measurement.
- ☐ Stop using the recorder, if the patient feels pain in the arm.

Stopping or canceling an automatic measurement

- ☐ To stop the measurement, press the START STOP key. The recorder beeps, releases the cuff air and an error is displayed. The recorder will inflate the cuff for the next time period automatically.
- ☐ To cancel automatic measurement, press and hold the AUTO ON/OFF for approx. 3 seconds. Automatic measurement is canceled and "**A**" turns off.
  To restart automatic measurement after cancellation, press and hold the AUTO ON/OFF for approx. 3 seconds. "**A**" appears and the recorder resumes measurement and records data except the cancelled block.

Manual measurement

- ☐ To start a measurement, press the START STOP key.
- ☐ To stop the measurement, press the START STOP key.

Precautions for attaching the cuff and recorder

- ☐ Do not drop or apply shock to the recorder.
- ☐ The recorder and cuff are not water resistant. Prevent rain, sweat and water from wetting the recorder and cuff.
- ☐ Do not place anything on the recorder.
- ☐ Re-attach the cuff if the cuff is slipped from the proper position due to the patient's movement.
- ☐ Use caution not to break the air hose or not to entangle around the patient's neck or body during sleep. Attach the air hose to the patient's body only as shown on page 27.

Replacing the batteries

- ☐ Replace with new batteries immediately, when "**B**" is displayed.

Notes on Cuff Use

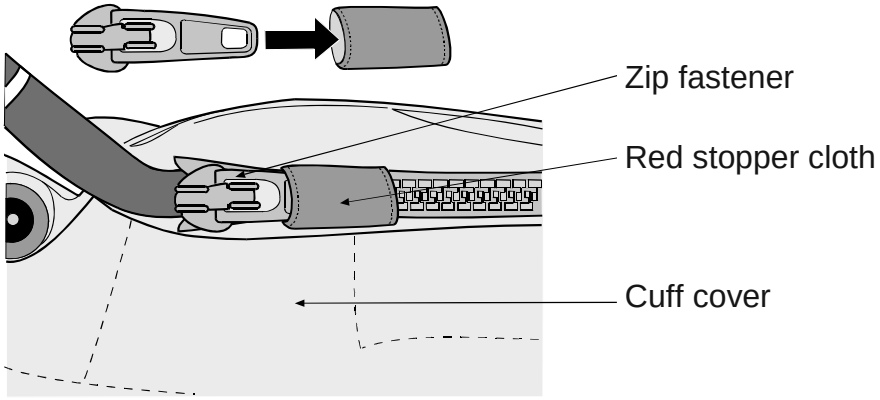
Note: A cuff is a consumable item and may need replacing if worn or damaged. Please check the cuff conditions before use.

In the following cases, replace the used cuff with a new one immediately.

- ☐ When there is a crack or stickiness in the joint of the cuff's bladder or the tube.
- ☐ When the tube is not flexible or has stiffened.
- ☐ When the surface of the tube is coated with an oil-like substance.
- ☐ When there is a defined crease in the bladder.

Confirm the following before use.

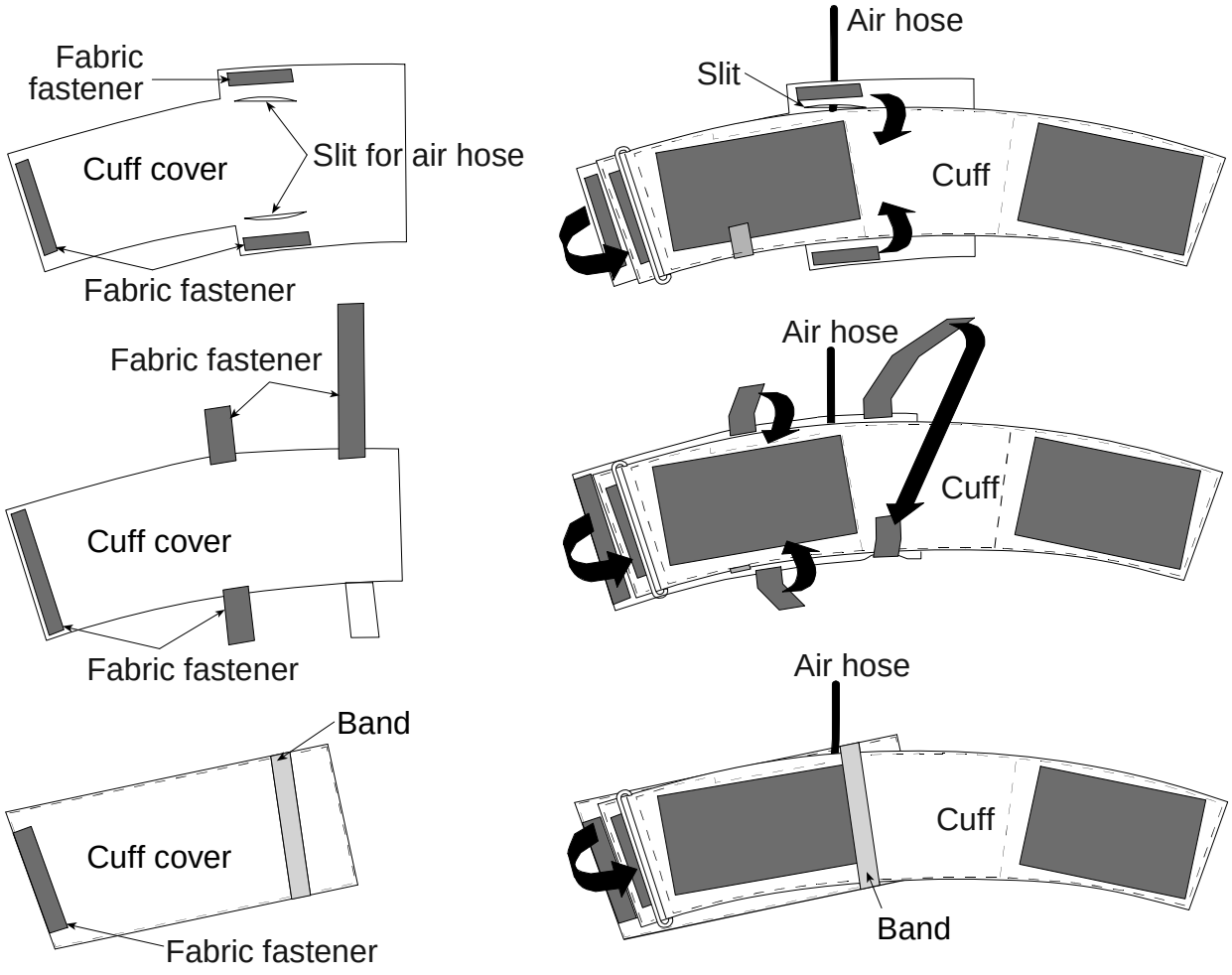
- ☐ Confirm that the zip fastener, for the cuff cover, is closed completely, to the red stopper cloth, as shown in the illustration below.
  If the zip fastener is not closed completely, the internal bladder may escape from the cuff cover and explode or otherwise be damaged.



Use of the Cuff Cover

Step 1 Place the cuff on the cuff cover as shown.
When the cuff cover with slits is used, pass the air hose through a slit.

Step 2 Secure the cuff cover to the cuff using the fabric fasteners.



Attaching the Cuff and Recorder

Caution

- ☐ If the cuff is not attached at the proper position, the recorder may not measure the blood pressure correctly and an error may occur.
- ☐ The cuff accessory is for use on the left arm, of about 20cm ~ 31cm. If you need a different cuff, purchase a cuff of the proper size and arm position. Refer to "Option and accessories".
- ☐ Do not attach the cuff to an arm with an unhealed wound, dermatitis, etc.

Keep the cuff clean. Change the cuff cover for each patient. The cuff cover may be used for either right or left arm cuff.

Steps for attaching the cuff and recorder

Step 1 Make a circle where the end of the cuff is passed through the ring.

Step 2 Search for the brachial artery using palpation.

Step 3 Attach the cuff directly against the skin so that the artery position mark is directly over the brachial artery and the lower edge of the cuff is placed one inch above the inside of the elbow.

Step 4 Wrap the cuff so that the ring is within the slide range, evenly and tight enough not to slip down but loose enough to insert two fingers. (If the ring is not within the slide range, you need a proper cuff.)

Step 5 Position the air hose over the shoulder and affix it on the patient using the clip.

Step 6 Assemble the belt and carrying case.

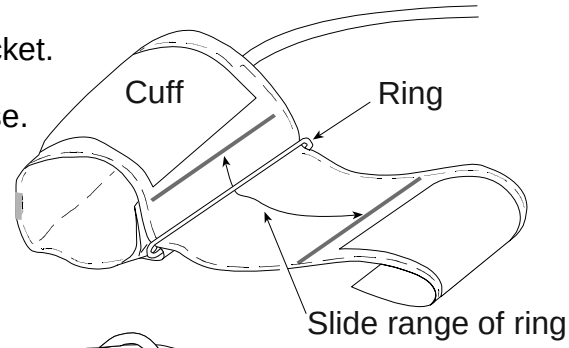
Step 7 Position the belt so that the carrying case is on the right (left) side of the patient, when a patient attaches the left (right) arm cuff.

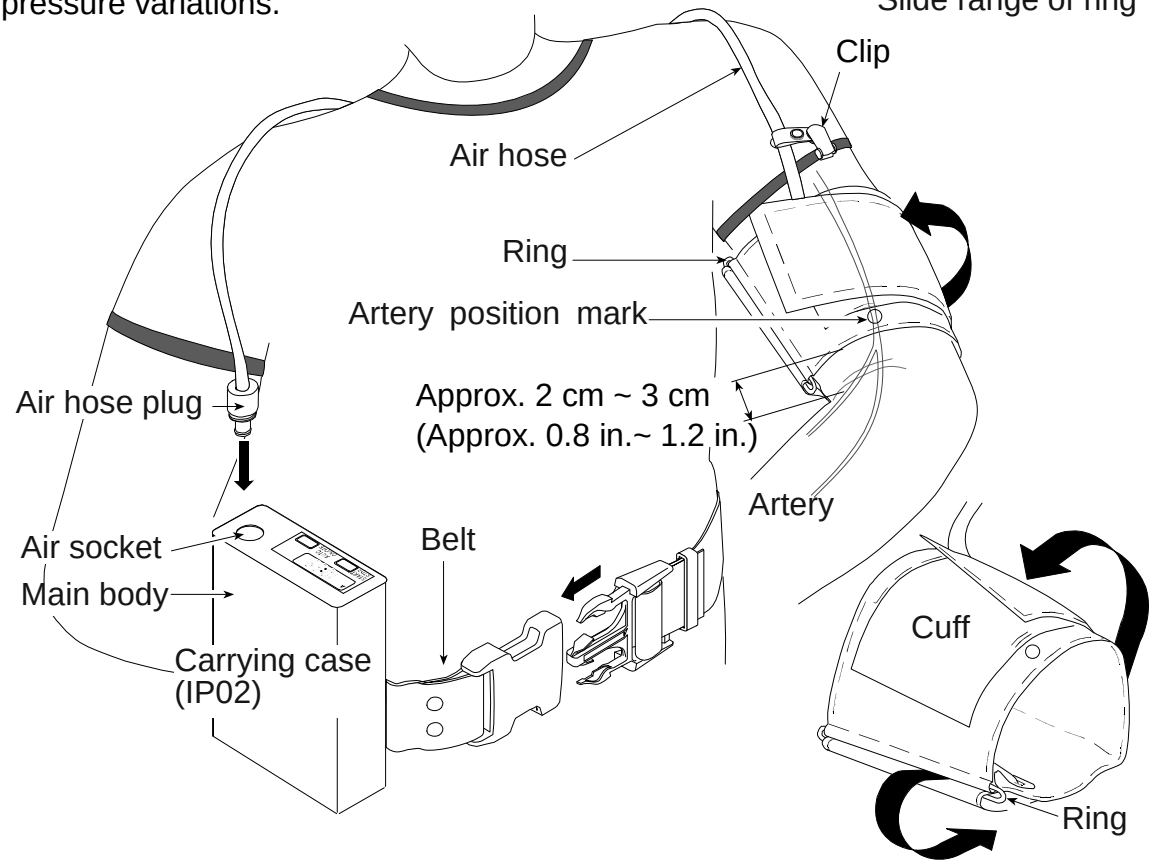
Step 8 Connect the air hose plug to the air socket.

Step 9 Place the recorder into the carrying case.

Caution

☐ Do not disturb the cuff or air hose during the measurement because the recorder measures small pressure variations.





Preparation of the Carrying Case

- ☐ Use the belt or shoulder band to attach the carrying case.
- ☐ We recommend the belt so that the carrying case is not worn out of shape on the patient.

Using the belt

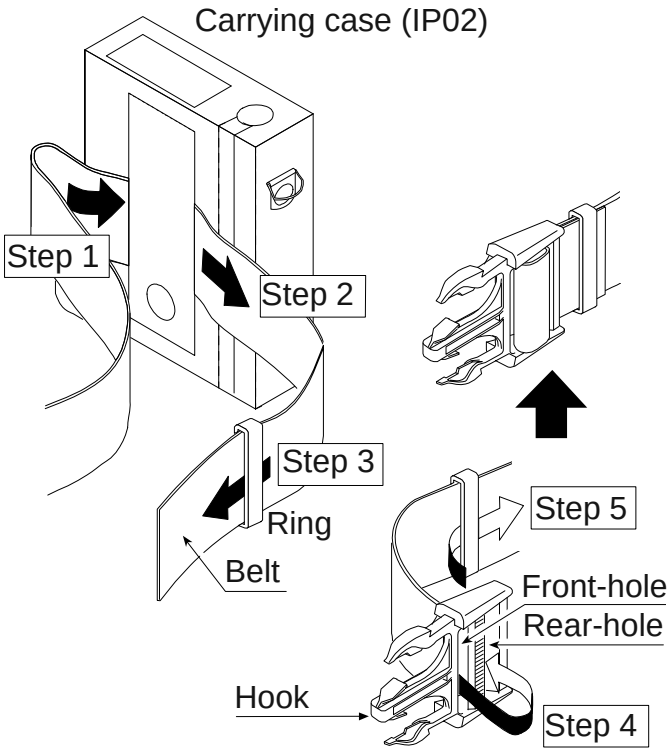
Step 1 Insert the belt through the strap located on the rear of the carrying case.

Step 2 Pull the belt through the strap.

Step 3 Pass the belt through the ring.

Step 4 Pass the belt through the front-hole and the rear-hole of the hook.

Step 5 Insert the belt into the ring again.

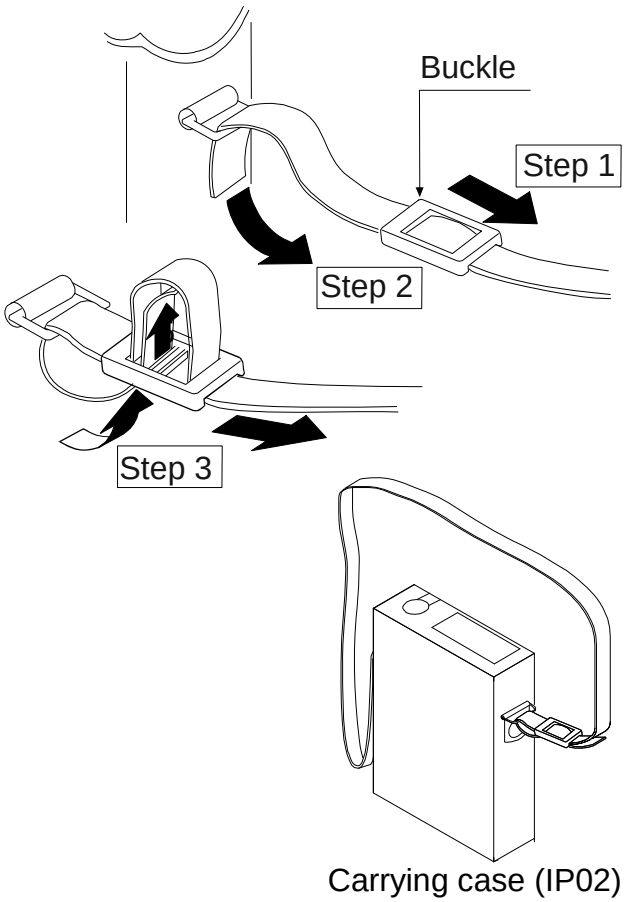


Using the shoulder band

Step 1 Insert the band into the buckle.

Step 2 Pass the band through the ring.

Step 3 Pass the band through the buckle as shown in the right illustration.



Operation

Automatic Measurement

Caution

- ☐ Automatic measurement uses the internal clock and parameters for automatic measurement. Refer to "Parameters for the Display and Clock" and "Selection for the Automatic Measurement" for setting these parameters.
- ☐ When the patient stops the automatic measurement or removes the cuff, press and hold the AUTO ON/OFF key for approx. 3 seconds to turn off the "**A**" sign. If the "**A**" sign is left turned on, the recorder may start the next automatic measurement and cause damage to the cuff.

Starting or re-starting automatic measurement

Step 1 Confirm the parameters for automatic measurement. Refer to "Selection for the Automatic Measurement".

Step 2 Press and hold the AUTO ON/OFF key for about 3 seconds. Then "**A**" is displayed and the recorder starts an automatic measurement based on the internal clock and the parameters for automatic measurement.

Operation using mode II

Step 1 Press the AUTO ON/OFF key to turn off "**S**" when the patient wakes up.

Step 2 Press the AUTO ON/OFF key to turn on "**S**" when the patient goes to bed.

Stopping or canceling automatic measurement

Step 1 Press and hold the AUTO ON/OFF key for about 3 seconds. "**A**" turns off and the recorder stops automatic measurement.

Manual Measurement

Step 1 Press the START STOP key. The recorder starts a measurement. The results are displayed and stored in memory.

To Stop the Current Measurement

Step 1 Press the START STOP key during measurement. The recorder will stop the measurement and releases the air from the cuff.

Data transfer

- ☐ The recorder transfers data to a printer or computer using the RS-232C terminal.
- ☐ We recommend analysis of the data using the optional analysis software.

Caution

- ☐ Cover the RS-232C terminal using the cap, to prevent dust and foreign materials from entering when this terminal is not in use.
- ☐ Remove the recorder and cuff from the patient, when the recorder is connected to a printer or computer.
- ☐ The personal computer must comply with EN60601-1.

Data Transmission to a Printer

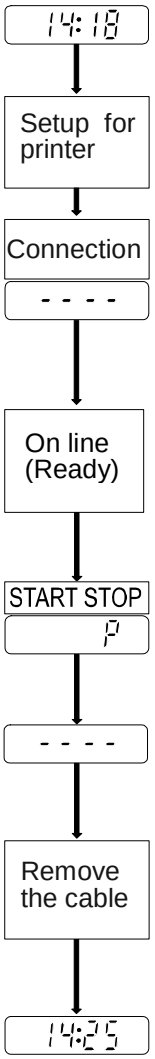
Caution

- ☐ The recorder intensely consumes the battery power while connected to the RS-232C cable. Disconnect the cable when not actually transferring data.
- ☐ Maintain the power-on state while transmitting the data so that the data is not damaged.
- ☐ The optional RS-232C cable is required when connecting to a printer.
- ☐ The printer (to print the data) must have a serial interface and adapt to the RS-232C protocol of the recorder.
- ☐ The printer must comply with EN60601-1.

Specifications for an adaptable printer

Transmission	EIA RS-232C	
	Asynchronous, bi-directional, half duplex	
	Baud rate	9600 bps
	Start bits	1 bit
	Data bits	8 bits
	Parity bit	None
	Stop bits	2 bits
	X parameter	Not used
	ETX/ACK	Not used
	DSR	Not used
	Code	ASCII
Command	Carriage return	0Dh
	Next line	0Dh 0Ah
	Next page	0Ch 0Dh
Printer parameters	Next page	Automatic
	Characters per line	72 min.
	Buffer size	approx. 32Kbytes

Steps for data transmission



Step 1 Enter the parameters into the printer so that the data can be transmitted.

Step 2 Connect the cable to both the recorder and printer. Then the recorder displays [- - - -]. Refer to "Analysis Software and Communication Cables" about the cable.

Step 3 Set the printer to "ON LINE".

Step 4 Press the START STOP key. Then [P] is displayed and the data is transmitted.

Step 5 When the transmission is finished, [- - - -] is displayed.

Step 6 Remove the cable. The clock is displayed.

Print sample

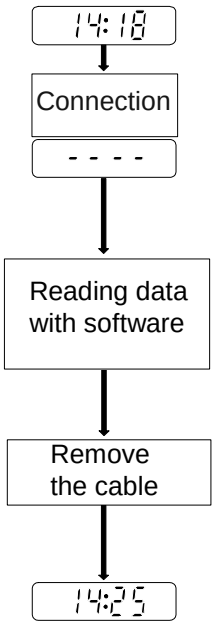
```
====================== ABPM DATA TABLE ======================
 No.      Date       Time  |  SYS(mmHg)   DIA(mmHg)   PUL(bpm)   ERR
-------------------------------------------------------------------
  1    `97/ 5/17     7:43  |      103          65          55       -
  2    `97/ 5/17     8:00  |      119          79          65       -
  3    `97/ 5/17     8:30  |      125          88         132       -
  4    `97/ 5/17     9:00  |      122          84         116       -
  5    `97/ 5/17     9:30  |      115          87          63       -
  6    `97/ 5/17    10:00  |      118          76          61       -
  7    `97/ 5/17    10:30  |        -           -           -      08
  8    `97/ 5/17    10:35  |      116          82          68       -
  9    `97/ 5/17    11:00  |      114          75          62       -
 10    `97/ 5/17    11:30  |      122          81          94       -
 11    `97/ 5/17    12:00  |      123                              -
 12    `97/ 5/17    12:30  |      11
```

Data Transmission to a Computer Using Analysis Software

Caution

- ☐ The recorder intensely consumes the battery power while connected to the RS-232C cable. Disconnect the cable when not actually transferring data.
- ☐ Maintain the power-on state while transmitting the data so that the data is not damaged.

Steps for data transmission



Step 1 Connect the cable to both the recorder and printer. The recorder displays - - - -. Refer to "Analysis Software and Communication Cables" about the cable.

Step 2 Read the data using the optional analysis software. Refer to the software instruction manual.

Step 3 Remove the cable. The clock is displayed.

Options and accessories

Analysis Software and Communication Cables

The analysis software has functions as follows:

- ☐ Maximum value, minimum value and average are calculated in an arbitrary period of time. (Partial analysis)
- ☐ Correlation graph, trend graphis and histogram are displayed.
- ☐ The patient's data and information are managed.
- ☐ Data can be saved.
- ☐ Data can be deleted or copied.
- ☐ A saved data file can be exported into CSV format so that EXCEL can read it.
- ☐ Data can be output as a report.
- ☐ Data is input from the recorder and parameters are written to the recorder.

Name	Order code
Windows-based analysis software	TM2430-13
Communication cable, D-SUB 9pin socket type	AX-KO1502
Communication cable, D-SUB 25pin socket type	AX-KO1503
Communication cable, D-SUB 25pin plug type	AX-KO1504

Cuffs and Other Accessories

Cuff

Name	Order code
Large cuff for left arm, 28 ~ 36 cm (11 ~ 14 inches)	TM2430-02B
Adult cuff for left arm, 20 ~ 31 cm (8 ~ 12 inches)	TM2430-06B
Small cuff for left arm, 15 ~ 22 cm (6 ~ 8 inches)	TM2430-07B
Adult cuff for right arm, 20 ~ 31 cm (8 ~ 12 inches)	TM2430-09B

Cuff cover

Name		Order code
Large cuff cover	10 sheets	AX-133002066-S
Adult cuff cover	10 sheets	AX-1133011576-S
Small cuff cover	10 sheets	AX-13A37410-S

Others

Name		Order code
TM-2430 Accuracy Diagnostic Kit		TM2430-90
Activity record sheet	10 sheets	AX-PP174-S
Carrying case (IP02)		AX-133012212

Maintenance

Checking Accuracy

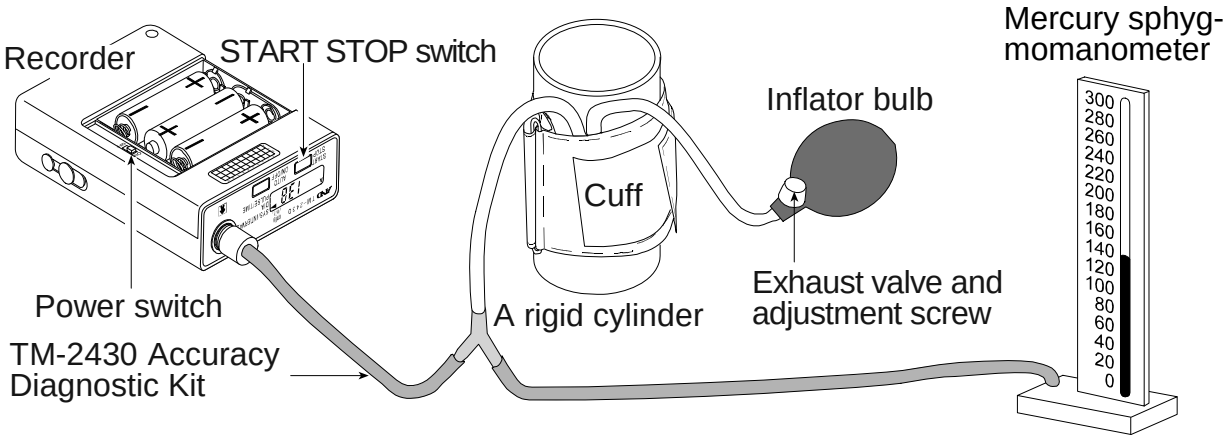
Required equipment

- ☐ Accurate office mercury sphygmomanometer or aneroid gauge with inflation system.
- ☐ TM-2430 Accuracy Diagnostic Kit (TM2430-90).
- ☐ A rigid cylinder sized to fit the cuff pressured.

Steps for checking accuracy

Step 1 Turn off the TM-2430 and remove the air hose from the unit.

Step 2 Construct the check system as shown below



Step 3 Keep the pressure at the air socket to atmospheric pressure.

Step 4 While holding the START STOP key, turn on the power switch. "0" blinks. Release the START STOP key. "0" stops blinking.

Step 5 Squeeze the inflator bulb until the cuff pressure reaches 50 mmHg. Check the difference between the blinking display of TM-2430 and mercury sphygmomanometer is within ±3 mmHg.

Step 6 Squeeze the inflator bulb until cuff pressure reaches 150 mmHg. Check the difference is within ±3 mmHg.

Step 7 Squeeze the inflator bulb until cuff pressure reaches 250 mmHg. Check the difference is within ±3 mmHg.

Step 8 Release the cuff air, turn off the TM-2430 and disassemble the check system. The blood pressure recorder is a precision instrument. Contact your nearest A&D dealer, if you need repair.

Cleaning the Cuff and Recorder

- ☐ Before cleaning the recorder, remove the battery cover, turn the power switch off and remove the batteries.
- ☐ The recorder is not water resistant. Do not allow liquids to splash on or get into the case while cleaning.
- ☐ After each use, wipe the case of the recorder with a clean lint free cloth, moistened with water and a mild detergent.
- ☐ Do not use antiseptic solutions, Alcohol, etc., to clean the recorder, hose or cuff.
- ☐ Clean the cuff cloth and cuff cover by washing in water with a mild detergent. Do not scrub or wring them by hand. If the cuff cloth and cuff cover become contaminated, replace them with new ones.

Periodical Inspection

- ☐ This blood pressure recorder is a precision instrument. Please inspect the functions (once a year) periodically. Contact your nearest A&D dealer for the inspection.
- ☐ Confirm the accuracy of the blood pressure monitor once a year.

Disposal

Conceming 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	
	Remove and properly dispose of the lithium battery inside the recorder when the recorder is disposed.

Others

Name	Part	Material
Package	Case	Cardboard
	Cushion	Cardboard
	Bag	Vinyl
Inside the recorder	Case	ABS resin
	Internal parts	General parts
	Chassis	Iron
	Backup battery on the board	Lithium rechargeable coin cell battery
	Battery	Alkaline battery: 1.5V LR6 or AA size Rechargeable battery: AA size Ni-MH batteries, 600 mAh or more

Troubleshooting

Caution

- ☐ Do not open the case of the recorder because it uses delicate electrical components and intricate air unit that could be damaged.
- ☐ If you cannot locate and fix the problem, request service from your nearest A&D dealer, or from the A&D service group.
- ☐ A&D service group will support authorized suppliers about technical information, spare parts and units.

Problem	Cause	Treatment
No display at turning on.	Batteries are drained.	Replace with new batteries.
Data lost while replacing batteries.	The built-in backup battery is drained	Turn on the recorder and display the clock for 24 hours or more, to fully charge the backup battery.
No pressure.	Air leakage at the connector, hose or cuff.	Confirm the cuff and air hose are not damaged and are connected correctly.

Error Codes

Caution The error code may be updated without prior notice.

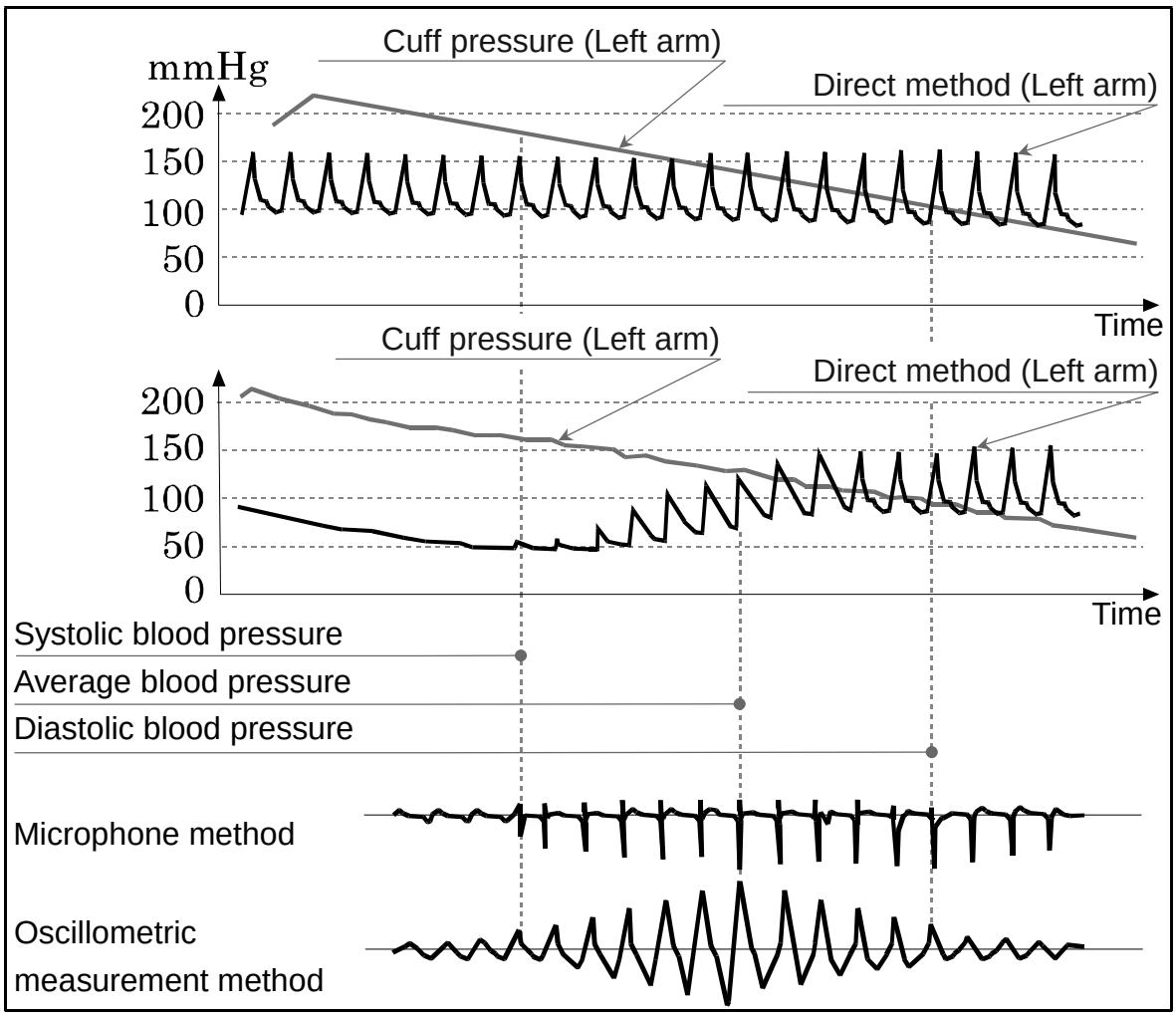
Error code	Meaning	Status	Operation and Treatment
E00	No clock parameter	All parameters are lost. Reset status.	Enter clock parameters. Refer to "Parameters for the Display and Clock"
E03	Pressure zero error	An error code is displayed without cuff inflation.	Release the air from the cuff completely.
E04	Low battery	Measurement is stopped. An error code is displayed. Auto mode is quit.	Replace with new batteries. Restart the auto mode if you use it.
E05	Inflation error	Inflation pressure does not reach the target pressure.	Connect the cuff to the main unit securely. If you cannot clear the error, there may be an air leak and repair is necessary
E06	Above 320 mmHg	An error code is displayed.	Do not move and try to relax during the measurement. If you cannot clear the error, repair is necessary
E07	Controlled stop using STOP key	Air is exhausted. An error code is displayed.	Press the STOP key only when necessary.
E08	Pulsation cannot be measured	Measurable pulsation is searched to 20mmHg in constant exhaust. An error code is displayed.	Do not move and try to relax during the measurement. The error occurs when pulsations are not detected due to thick cloth or quick motion.
E10	Pulsations cannot be detected because the patient may have moved.	In the measurement, quick exhaust is executed. An error code is displayed.	Do not move and try to relax during the measurement.
E20	Pulse rate < 30 200 < Pulse rate	An error code is displayed.	Measure the blood pressure by other methods.
E21	DIA < 40 160 < DIA	DIA : Diastolic Blood Pressure SYS : Systolic Blood Pressure DSD : The Difference between Systolic Blood Pressure and Diastolic Blood Pressure.	
E22	SYS < 60 280 < SYS		
E23	DSD < 10 150 < DSD		

Error code	Meaning	Status	Operation and Treatment
E30	Measurement time exceeds 120 seconds.	Air is exhausted from the cuff, and an error code is displayed.	Repair is necessary because of slow inflation or slow constant exhaust.
E31	The constant exhaust exceeds 60 seconds.	Air is exhausted from the cuff, and an error code is displayed.	Repair is necessary because of slow constant exhaust.
E32	Clock error.	An error code is displayed.	If you cannot clear this error, repair is necessary.
E50	Pressure offset error to measure pulsation.	An error code is displayed at restarting the recorder.	Release the air from the cuff completely, reset the recorder. If you cannot clear this error, repair is necessary.
E52	Memory error.	An error code is displayed at restarting the recorder.	The recorder needs repair.
E53	Battery contact is defective.	The measurement is stopped, air is released from the cuff and an error code is displayed.	Replace batteries correctly. If you cannot clear this error, repair is necessary.
E55 E56 E57	Exhaust error.	An error code is displayed at measurement.	Do not move and try to relax during the measurement. If this error occurs frequently, repair is necessary.
E60	Interval setting error.	Start time is not proper, interval of last block is not set in the unit of 120 min.	Enter parameters for the interval correctly.
E70 E71 E72 E73	RS-232C error.	The error code is displayed during communications.	Re-connect the communication cable. If you cannot clear this error, repair is necessary.
E74	Low battery for communication.		Replace batteries with new ones and restart communication.
E75	Protocol error due to external equipment.		Re-connect the communication cable. If you cannot clear this error, repair is necessary.
E90	Pressure zero error for safety circuit.	This error code is displayed before the measurement.	Release the air from the cuff completely.
E91	Safety circuit detects overload pressure.	Patient moved during the measurement.	Relax and try to be quiet during the measurement. If it occurs while the patient relaxes and is quiet, the recorder needs repair.
Other		Monitor code is displayed.	Reset. Turn on the power switch again.

Appendix

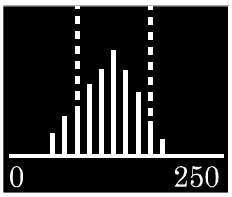
Principle of Blood Pressure Measurement

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.

EMC Information

☐ EMC guidelines and manufacturer's declaration

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the 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 (other than A&D original parts) may result in increased emissions or decreased immunity of the unit.

Guidance and manufacturer's declaration – electromagnetic emissions		
The A&D unit is intended for use in the electromagnetic environment specified below. The customer or the user of the A&D unit should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The A&D unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The A&D unit is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	n.a.	
Voltage fluctuations/flicker emissions IEC 61000-3-3	n.a.	

Recommended separation distances between portable and mobile RF communications equipment and the A&D unit

The A&D unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the A&D unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the A&D unit as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *p* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration – electromagnetic immunity			
The A&D unit is intended for use in the electromagnetic environment specified below. The customer or the user of the A&D unit should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V_{rms} 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 V_{rms} 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the A&D unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the A&D unit is used exceeds the applicable RF compliance level above, the A&D unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the A&D unit. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The A&D unit is intended for use in the electromagnetic environment specified below. The customer or the user of the A&D unit should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	n.a.	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line to line ±2 kV line to earth	n.a.	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 s	n.a.	Mains power quality should be that of a typical commercial or hospital environment. If the user of the A&D unit requires continued operation during power mains interruptions, it is recommended that the A&D unit be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE : U_T is the AC mains voltage prior to application of the test level.			

Index

Symbols

A

B

C

D

E

F

I

L

A&D Company, Limited
1-243 Asahi , Kitamoto-shi, Saitama 364-8585, JAPAN
Telephone: [81] (48) 593-1111 Fax: [81] (48) 593-1119

EC REP **A&D INSTRUMENTS LIMITED**
Unit 24/26 Blacklands Way, Abingdon Business Park, Abingdon, Oxfordshire OX14 1DY United Kingdom
Telephone: [44] (1235) 550420 Fax: [44] (1235) 550485

A&D ENGINEERING, INC.
1756 Automation Parkway, San Jose, California 95131, U.S.A.
Telephone: [1] (408) 263-5333 Fax: [1] (408)263-0119

A&D AUSTRALASIA PTY LTD
32 Dew Street, Thebarton, South Australia 5031, AUSTRALIA
Telephone: [61] (8) 8301-8100 Fax: [61] (8) 8352-7409

OOO A&D RUS ООО "ЭЙ энд ДИ РУС"
121357, Российская Федерация, г.Москва, ул. Верейская, дом 17
(Business-Center "Vereyskaya Plaza-2" 121357, Russian Federation, Moscow, Vereyskaya Street 17)
тел.: [7] (495) 937-33-44 факс: [7] (495) 937-55-66

A&D Technology Trading(Shanghai) Co. Ltd **爱安德技研贸易（上海）有限公司**
中国 上海市浦东新区浦东大道138号永华大厦21楼A室 邮编200120
(21F Room A, Majesty Building, No.138 Pudong Avenue, Pudong New Area, Shanghai, 200120, China)
电话: [86] (21) 3393-2340 传真: [86] (21) 3393-2347

A&D INSTRUMENTS INDIA PRIVATE LIMITED
509, Udyog Vihar, Phase-Ⅴ, Gurgaon - 122 016, Haryana, India
Telephone: 91-124-4715555 Fax: 91-124-4715599