ALP K2®

Automatic Sphygmomanometer DM-4000

INSTRUCTIONS
<ENGLISH>

This manual is intended to assist the user for the safe and efficient operation of the Automatic Sphygmomanometer DM-4000. The product must be used in accordance with the procedures contained in this manual and must not be used for purposes other than those described herein. It is essential to read and understand the entire manual before use.

A128851-1_2

Contents

General information

Product Features

◇ **AUTO Mode of Measurement**
Perform automatic measurement (AUTO measurement).

◇ **AUTO3 measurement mode**
Perform AUTO measurement three times in a row, calculate the average of the measurement results, and then display the reliable blood pressure value according to AUTO measurements.

◇ **MANUAL Mode of Measurement**
Measurement can be performed using a stethoscope. The following deflation rates can be selected: 2.5, 3.5, 4.5, 5.5, and 6.5 mmHg/s.

◇ **Regular and Large Size Cuffs**
The regular size cuff will accommodate an upper arm circumference range of approximately 22 to 32 centimeters and the large size cuff will accommodate that of approximately 32 to 42 centimeters.

◇ **AC adaptor and built-in rechargeable battery**
The device can be powered by either an AC adaptor or built-in rechargeable nickel metal hybrid (NiMH) battery.

◇ **Backlight function**
If the buttons of this device are operated, the backlight switches on.

◇ **Automatic re-inflation**
During measurement, the cuff is automatically inflated to the set preset pressure value. If the set preset pressure value was low and insufficient for the measurement, deflation of the cuff starts, and then inflation is carried out again to a pressure higher than the preset value.

◇ **Memory function**
If measurement ends in AUTO measurement mode or AUTO3 measurement mode, the measurement result is saved to memory automatically. The memory can store up to 30 measurement results.

◇ **Irregular pulse wave rhythm mark**
If the pulse wave interval is not constant, the Irregular pulse wave rhythm mark [] appears.
The Irregular pulse wave rhythm mark may appear regularly even when the patient is measured in a calm condition.
Further investigation may be necessary for the determination of the actual cause.

Operation principles

This device is equipped with two types of measurement. AUTO measurement measures the systolic blood pressure, diastolic blood pressure, and pulse rate automatically using the oscillometric method. With MANUAL measurement, an operator uses a stethoscope to measure blood pressure using auscultation. If the artery is compressed by the pressure of a tourniquet (cuff), the artery causes a pulsation that matches the pulse, which becomes the pulsation of the internal pressure of the cuff. The size of the pulsation changes in accordance with the magnitude correlation of the blood pressure and the cuff pressure. An oscillometric blood pressure monitor determines systolic and diastolic blood pressures based on the change pattern of the size of the pulsation that appears when the cuff interior pressure has been gradually changed. Furthermore, with auscultation, a stethoscope is used to detect the Korotkov sounds generated when the cuff interior pressure is gradually changed and measure the blood pressure.

Indication for use

This product is intended for noninvasive measurement of systolic and diastolic blood pressure, determination of pulse rate in adults in a hospital. The product is not designed for neonatal use. Please consult with the doctor or physician to use this product to take blood pressure of child or person in pregnancy or under pre-eclamptic condition. This device is for medical staff use.

Product specifications

Model	: DM-4000
Operating Principle	: Oscillometric method (AUTO measurement) / auscultation (MANUAL measurement)
Indicator	: 12-digit LCD
Pressure Indicating Range	: 3 to 300 mmHg (cuff pressure)
Measuring Range	: 50 to 250 mmHg (systolic) 40 to 180 mmHg (diastolic) 40 to 160 bpm (pulse rate)
Memory	: Results of 30 measurements and the average value
Accuracy*	: ±3 mmHg (cuff air pressure) ±5% of reading (pulse rate)
Quick Exhaust	: 10 seconds or less during quick exhaust from 260 to 15 mmHg
Inflation	: Automatic (air pump)
Inflation Setting Value	: 130 to 280 mmHg
Deflation	: Electronic control valve
Deflation Rate Setting Value	: 2.5, 3.5, 4.5, 5.5, or 6.5 mmHg/s (during MANUAL measurement)
Exhaust	: Automatic exhaust valve
Power Supply	: AC adaptor (model: UM312-7516) or rechargeable nickel metal hybrid (NiMH) battery (model: GP170AAH)
Electrical Rating	: Rated voltage: 4.8 V, AC adaptor: 7.5 V Power consumption: 14 W (maximum)
Operating Environment	: 10 to 40 °C / relative humidity 15 to 85% (no condensation) / Atmospheric pressure 700hPa to 1060hPa
Storage Environment	: -20 to 60 °C / relative humidity 10 to 95% (no condensation)
Coverage Arm Circumference	: Regular size cuff: 22 to 32 cm Large size cuff: 32 to 42 cm
Main Unit Size	: 228 × 134.3 × 206 mm (L x W x D)
Main Unit Weight	: Approx. 925 g (not including accessories and battery)
Protection class IP	: IP 20; Protected against solid foreign particles with a diameter of more than 12.5 mm, no protection against water.
Electric-shock Protection	: Internal power supply device / Class II device
	: Type BF equipment
	: Class II device
	: Important: Read operating instructions.
	: Keep dry
	: The used electrical and electronic products are not household waste. Follow your national/ local recycling rules to dispose of them properly. In the EU countries, please refer to waste management symbol(s) marked on the package or the instrument.

This device complies with EN1060-1:1995+A2:2009 Non-invasive sphygmomanometers

Part 1: General requirements, EN1060-3:1997+A2:2009 Non-invasive sphygmomanometers

Part 3: Supplementary requirements for electro-mechanical blood pressure measuring system and EMC (IEC60601-1-2:2007).

*Accuracy is guaranteed with the measured values that are within the measuring range.

Specifications are subject to change without notice due to improvements in performance.

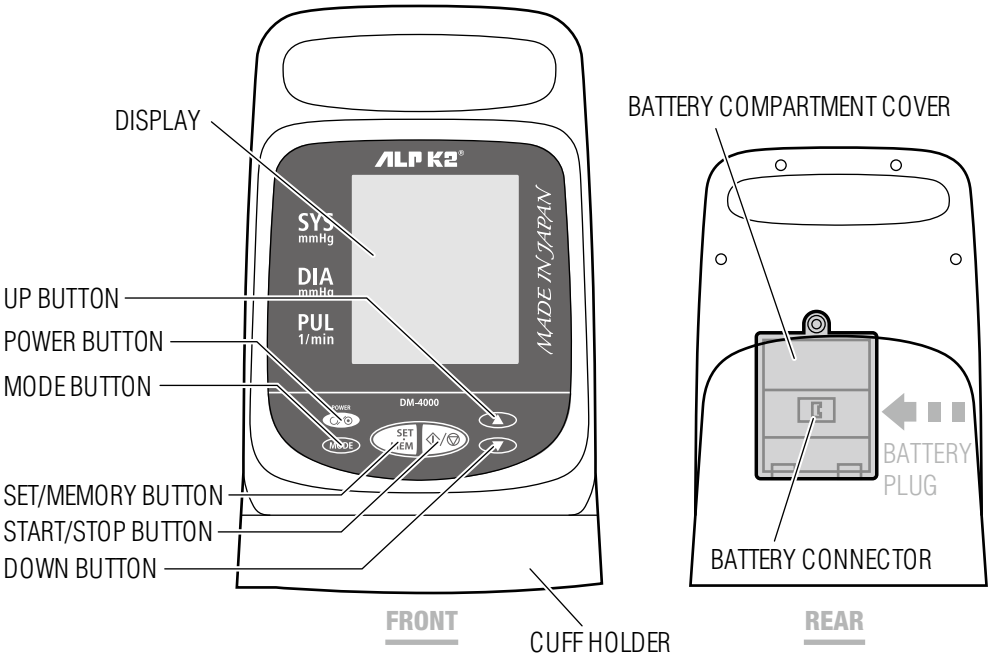
Precaution and contraindication

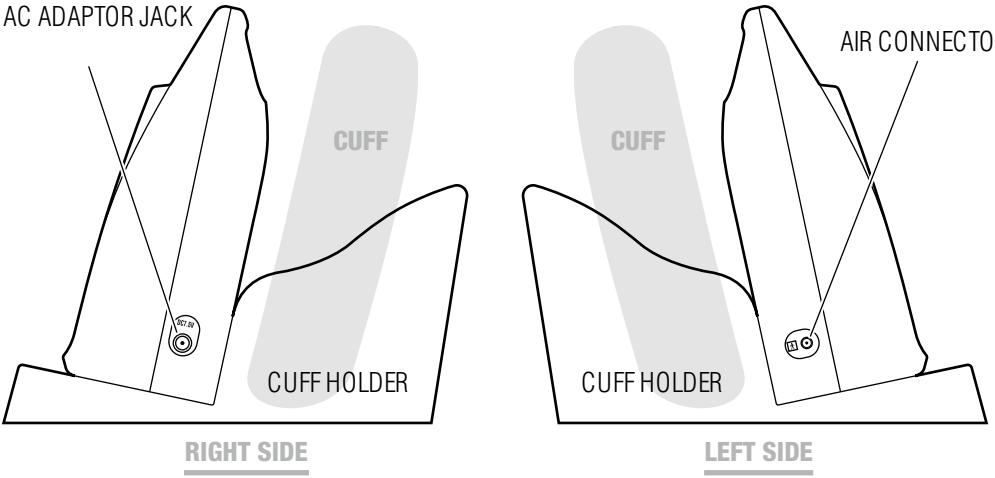
- **Please carefully check patient's conditions in advance to the measurement if he / she is under dialysis therapy or on anticoagulants, antiplatelets or steroids. Use of this instrument under such conditions could cause internal bleeding.**
- **Do not use this product along with implantable and wearable medical electrical equipment such as pacemaker, defibrillator, or electrocardiographic monitor.**
- **This product is not also intended to be used with HF surgical equipment.**
- **Do not use this product in an explosive environment such as near flammable anesthetics or inside oxygen chamber.**
- **The system may fail to yield specified measurement accuracy if operated or stored in temperature or humidity conditions outside the limits stated in the specifications section of this manual.**
- **Do not use cuffs or accessories other than those specified by the manufacturer. Otherwise, correct measurement readings cannot be obtained.**
- **Use of this product in areas near mobile phones, microwave ovens or other devices with strong electromagnetic field may cause malfunctions.**
- **Do not apply the cuff over wounded arm, arm under an intravascular access or therapy or an arterio-venous shunt, or arm on the side of a mastectomy. Otherwise injury may be resulted.**
- **Make sure that inflation of the cuff is not causing prolonged impairment of blood circulation. Also, be cautious about temporary loss of the functions of any other medical equipment if any monitoring equipment is used on the same limb with the blood pressure measuring cuff.**
- **To avoid harmful injury due to interfered blood flow from cuff inflation,**
  - **Make sure that AIR TUBE is not kinking before measurement. Otherwise, cuff inflation may not be conducted properly and prolonged, and**
  - **Do not make measurements repeatedly.**
- **To avoid any possibility of accidental strangulation, keep this product away from children and do not drape AIR TUBE around your neck.**
- **Because the product includes precision parts, avoid extreme temperature variations, humidity, shock, dust, and direct sunlight. Do not drop or strike the product. Make sure not to expose it to moisture. This product is not water resistant.**

- **The performance of this product may be affected by extremes of temperature, humidity and altitude.**
- **Do not press the display or place the monitor with display face down.**
- **Do not take out batteries or unplug the AC adaptor when the monitor is turned on. Make sure to switch off the monitor before removing batteries or AC adaptor.**
- **Do not touch the output plug of AC adaptor during measurement.**
- **Do not disassemble or modify the product.**
- **Do not inflate the cuff when it is not wrapped around patient's arm.**
- **Carefully monitor the patient's condition during measurement.**

Parts and product components

MAIN UNIT



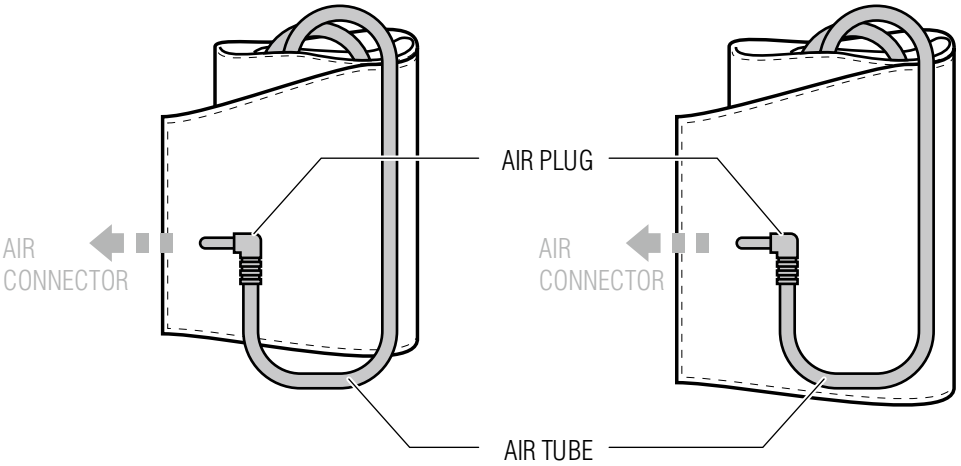


REGULAR SIZE CUFF

For arm circumference of 22 to 32 cm

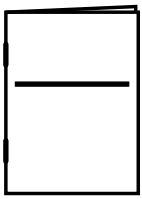
LARGE SIZE CUFF

For arm circumference of 32 to 42 cm



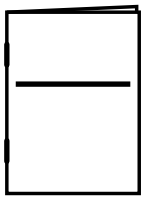
INSTRUCTION MANUAL

(English)



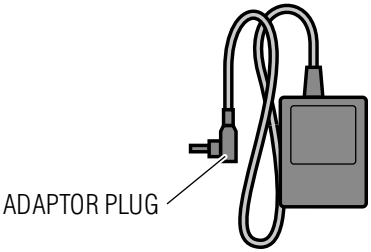
INSTRUCTION MANUAL

(Spanish)



AC ADAPTOR

Model: UM312-7516



Please check that all of the items above are included.
When you purchase consumables or options, contact a dealer.

Taking blood pressure -AUTO measurement-

To allow the patient to relax, have a five-minute rest before starting measurement. Furthermore, make sure the patient does not talk or move during measurement.

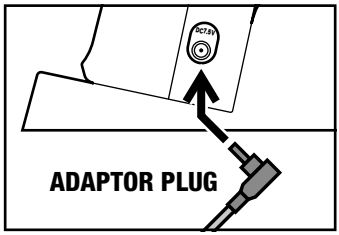
Ensure that the cuff is kept at the height of patient's heart during measurement.

To stop measurement, press the START/STOP BUTTON.
Air is exhausted quickly from the cuff.

1. Connect the AC adaptor

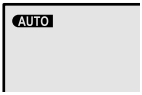
The AC adaptor jack is on the right side of the main unit.
When the AC adaptor is connected correctly, the AC adaptor mark switches on.

To use the rechargeable battery, see page 22.



2. Push the POWER BUTTON to turn on the power

3. After 0 appears in the display, press the MODE BUTTON to set [AUTO]

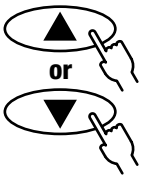


4. Set the preset pressure value using the UP or DOWN BUTTON

If the UP or DOWN BUTTON is pressed, the preset pressure value can be changed. The following pressures can be set: 130, 160, 190, 220, 250, and 280 mmHg.
Select a pressure approximately 30 to 40 mmHg above the expected systolic pressure.
Set the pressure at 190 mmHg if patient's systolic pressure is difficult to predict. By default, the inflation value is set to 190 mmHg.

If the preset pressure value was insufficient for the measurement, inflation is carried out again automatically.

For information about re-inflation, see page 3.

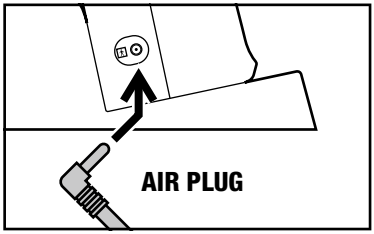


5. Connect the cuff

Measure the patient's arm circumference, and then use an appropriate cuff based on the table on the right.

ARM CIRCUMFERENCE	CUFF SIZE
22-32 cm	REGULAR
32-42 cm	LARGE

Securely insert the air plug of the cuff into the air connector on the left side of the main unit.

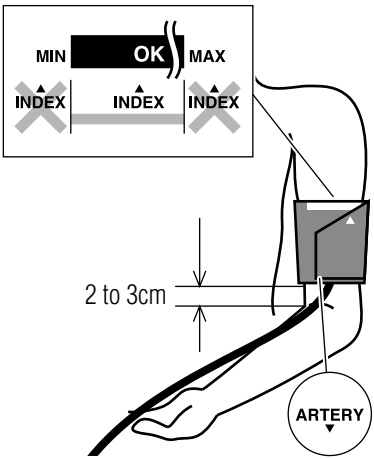


6. Apply the cuff to the patient's arm.

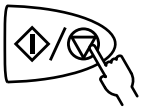
Find a chair and a table so that the patient can be comfortably seated with patient's back and arm supported. Legs should not be crossed and feet kept flat on the floor.

Measure the left arm during AUTO measurement. If the right arm is measured, it may not be possible to measure normally due to the attachment state of the cuff.

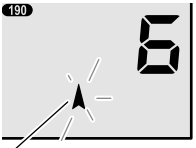
When applying the cuff, make sure that the ARTERY mark "ARTERY" aligns with the brachial artery and the INDEX mark "INDEX" is within the OK line.



7. Press the START/STOP BUTTON to start measurement

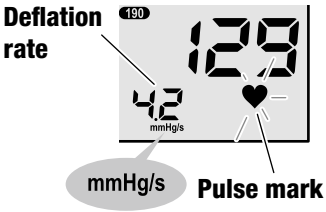


Automatic inflation of the cuff starts.
Pressurization stops when the cuff pressure reaches the preset pressure value, and then the pressure starts to descend.



Inflation mark

When a pulse wave is detected, the pulse mark flashes in the display.



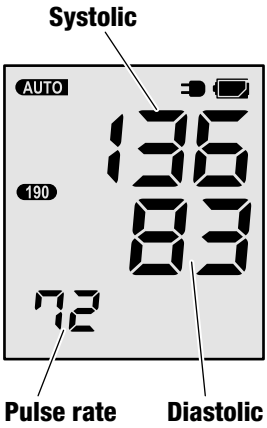
When measurement ends, air is rapidly exhausted, and then the measurement result is displayed.

The measurement result is saved to memory automatically.

For information about the memory function, see page 20.

Error results are not saved.

For information about the error display, see page 24.



8. Push the POWER BUTTON to turn off the power

Even if you forget to switch off the power, the power switches off automatically after about three minutes.

Taking blood pressure -AUTO3 measurement-

This device is equipped with an average mode function. This function performs blood pressure measurement three times in a row, calculates the average of these measurement results, and then displays the reliable blood pressure value according to AUTO measurements.

To allow the patient to relax, have a five-minute rest before starting measurement. Furthermore, make sure the patient does not talk or move during measurement.

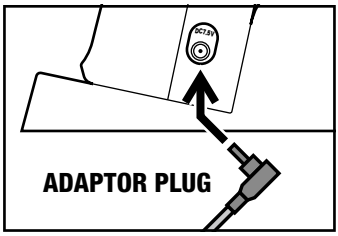
Ensure that the cuff is kept at the height of patient's heart during measurement.

To stop measurement, press the START/STOP BUTTON.
Air is exhausted quickly from the cuff.

1. Connect the AC adaptor

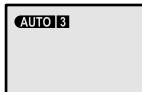
The AC adaptor jack is on the right side of the main unit.
When the AC adaptor is connected correctly, the AC adaptor mark switches on.

To use the rechargeable battery, see page 22.



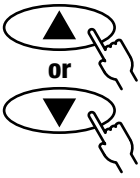
2. Push the POWER BUTTON to turn on the power

3. After 0 appears in the display, press the MODE BUTTON to set [AUTO3]



4. Set the preset pressure value using the UP or DOWN BUTTON

If the UP or DOWN BUTTON is pressed, the preset pressure value can be changed. The following pressures can be set: 130, 160, 190, 220, 250, and 280 mmHg.
Select a pressure approximately 30 to 40 mmHg above the expected systolic pressure.
Set the pressure at 190 mmHg if patient's systolic pressure is difficult to predict. By default, the inflation value is set to 190 mmHg.



If the preset pressure value was insufficient for the measurement, inflation is carried out again automatically.

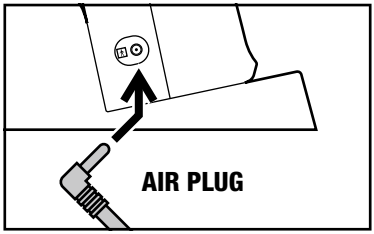
For information about re-inflation, see page 3.

5. Connect the cuff

Measure the patient's arm circumference, and then use an appropriate cuff based on the table on the right.

ARM CIRCUMFERENCE	CUFF SIZE
22-32 cm	REGULAR
32-42 cm	LARGE

Securely insert the air plug of the cuff into the air connector on the left side of the main unit.

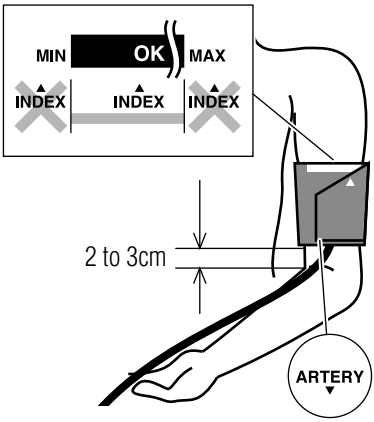


6. Apply the cuff to the patient's arm.

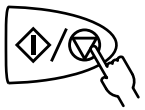
Find a chair and a table so that the patient can be comfortably seated with patient's back and arm supported. Legs should not be crossed and feet kept flat on the floor.

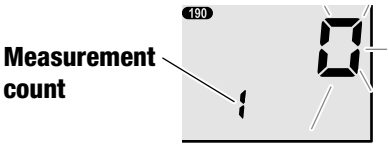
Measure the left arm during AUTO measurement. If the right arm is measured, it may not be possible to measure normally due to the attachment state of the cuff.

When applying the cuff, make sure that the ARTERY mark "ARTERY" aligns with the brachial artery and the INDEX mark "INDEX" is within the OK line.

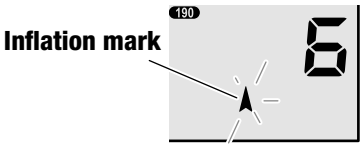


7. Press the START/STOP BUTTON to start measurement

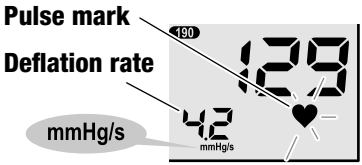




Automatic inflation of the cuff starts.
Pressurization stops when the cuff pressure reaches the preset pressure value, and then the pressure starts to descend.

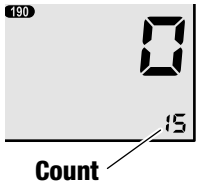


When a pulse wave is detected, the pulse mark flashes in the display.



When measurement ends, air is quickly exhausted, and then a countdown (15 seconds) starts.

After the countdown ends, inflation starts automatically, and then the next measurement starts.



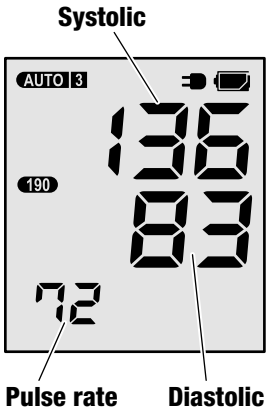
When three measurements end, the measurement result is displayed.

The measurement result is saved to memory automatically.

For information about the memory function, see page 20.

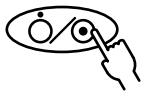
Error results are not saved.

For information about the error display, see page 24.



8. Push the POWER BUTTON to turn off the power

Even if you forget to switch off the power, the power switches off automatically after about three minutes.



Taking blood pressure -MANUAL (auscultation) measurement-

In MANUAL measurement mode, this device inflates the cuff automatically, and then blood pressure is measured using auscultation. A stethoscope is not included in the product. Please prepare your own stethoscope.

To allow the patient to relax, have a five-minute rest before starting measurement. Furthermore, make sure the patient does not talk or move during measurement.

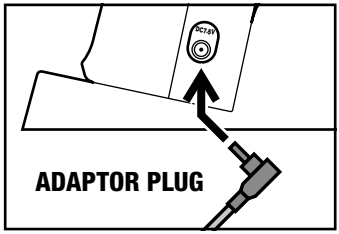
Ensure that the cuff is kept at the height of patient's heart during measurement.

To stop measurement, press the START/STOP BUTTON.
Air is exhausted quickly from the cuff.

1. Connect the AC adaptor

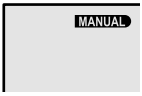
The AC adaptor jack is on the right side of the main unit.
When the AC adaptor is connected correctly, the AC adaptor mark switches on.

To use the rechargeable battery, see page 22.



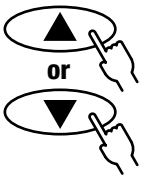
2. Push the POWER BUTTON to turn on the power

3. After 0 appears in the display, press the MODE BUTTON to set [MANUAL]



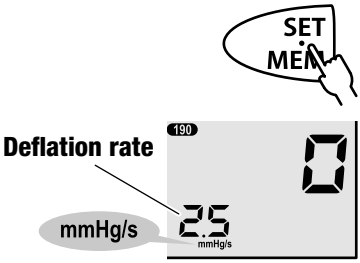
4. Use the up or down button to set the preset pressure value

If the UP or DOWN BUTTON is pressed, the preset pressure value can be changed. The following pressures can be set: 130, 160, 190, 220, 250, and 280 mmHg.
Select a pressure approximately 30 to 40 mmHg above the expected systolic pressure.
Set the pressure at 190 mmHg if patient's systolic pressure is difficult to predict. By default, the inflation value is set to 190 mmHg.



5. Press the SET/MEMORY BUTTON to set the deflation rate

The deflation rate displayed in the bottom left of the display area changes each time the SET/MEMORY BUTTON is pressed.
Select from one of the following: 2.5, 3.5, 4.5, 5.5, or 6.5 mmHg/s.

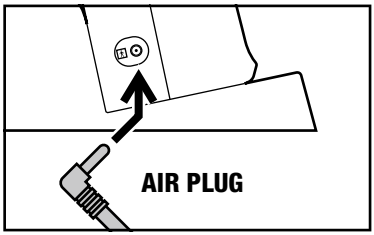


6. Connect the cuff

Measure the patient's arm circumference, and then use an appropriate cuff based on the table on the right.

ARM CIRCUMFERENCE	CUFF SIZE
22-32 cm	REGULAR
32-42 cm	LARGE

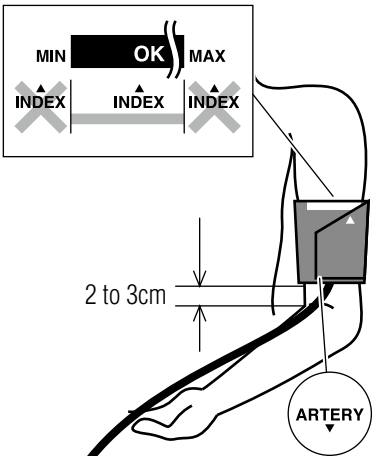
Securely insert the air plug of the cuff into the air connector on the left side of the main unit.



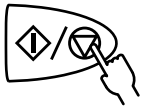
7. Apply the cuff to the patient's arm.

Find a chair and a table so that the patient can be comfortably seated with patient's back and arm supported. Legs should not be crossed and feet kept flat on the floor.

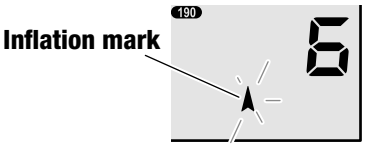
As when measuring with a standard column of mercury, apply the cuff, and then apply the stethoscope.
When applying the cuff, make sure the INDEX mark "INDEX" is within the OK line.



8. Press the START/STOP BUTTON to start measurement

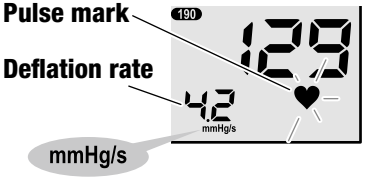


Automatic inflation of the cuff starts.
Pressurization stops when the cuff pressure reaches the preset pressure value, and then the pressure starts to descend.



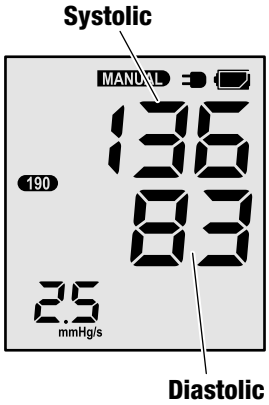
If the preset pressure value was insufficient for measurement, wait until inflation stops and deflation starts, and then press and hold the START/STOP BUTTON. Inflation will continue while the button is pressed. Pressure does not exceed 280 mmHg.

When a pulse wave is detected, the pulse mark flashes in the display.



9. After checking the blood pressure, press the SET/MEMORY BUTTON

If the SET/MEMORY BUTTON is pressed while monitoring the systolic and diastolic blood pressures, these values are recorded to the device. After measurement, you can check the values on the LCD. (They are not saved to memory.)
If you do not need to check the values on the LCD after measurement, you do not need to press the button.



After the SET/MEMORY BUTTON has been pressed twice, the device soon quickly exhausts the air.
If pressure reaches 30 mmHg, the air is quickly exhausted automatically, even if the SET/MEMORY BUTTON is not pressed.

10. Push the POWER BUTTON to turn off the power

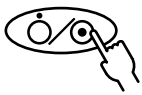
Even if you forget to switch off the power, the power switches off automatically after about three minutes.

Memory function

Measurement results measured using AUTO measurement and AUTO3 measurement are saved to memory automatically after measurement. Measurement results recorded using MANUAL measurement are not saved.
The memory can store up to 30 measurement results.
If the number of saved measurement results reaches 30, the oldest measurement result is deleted, and the latest measurement result is saved after the next measurement.
Furthermore, you can delete unnecessary measurement results from memory.

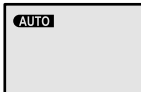
Recalling saved measurement results

1. Push the POWER BUTTON to turn on the power

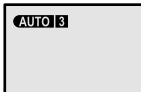


2. After 0 appears in the display, press the MODE BUTTON to set [AUTO] or [AUTO3]

In the [MANUAL] setting, saved results cannot be recalled.



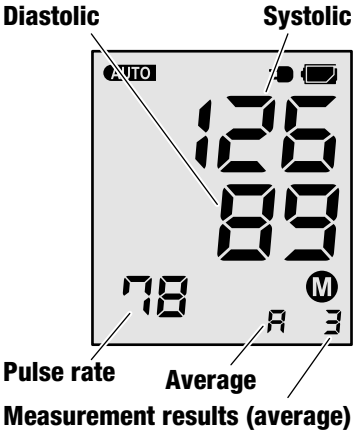
or



3. Press the SET/MEMORY BUTTON

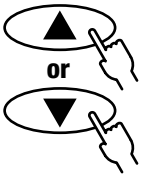
The average value of saved measurement results is displayed.
The average indicates the average of, at most, the last three measurement results from the latest measurement result.
Measurement results (average) indicates the number of measurement results used for the average.

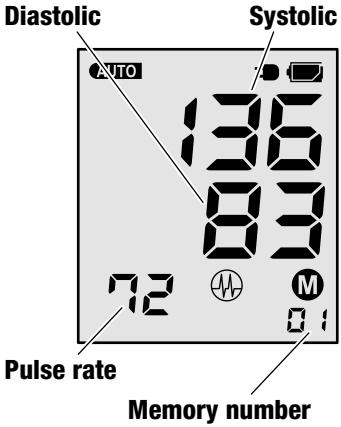
When there is only one saved measurement result, this measurement result is displayed.



4. Use the UP or DOWN BUTTON to change the display

When the UP BUTTON is pressed, the display changes from the latest measurement result to an old measurement result. When the down button is pressed, the display changes from the oldest measurement result to a new measurement result. Higher memory numbers indicate older measurement results.





5. Push the POWER BUTTON to turn off the power

Even if you forget to switch off the power, the power switches off automatically after about three minutes.

Deleting saved measurement results

1. Display the measurement result to be deleted (To delete all measurement results from the memory, display the average)

2. Press and hold the SET/MEMORY BUTTON

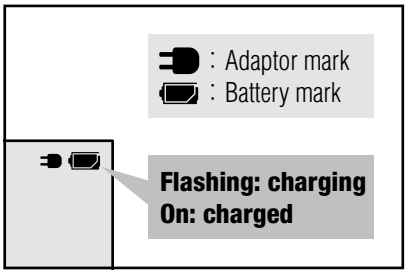
If the button is pressed and held, the display flashes. Soon, the measurement result disappears, and [– – –] is displayed.

Operation with built-in rechargeable battery

If the built-in rechargeable battery has been charged, this product can be used without the AC adapter. Charge for about four hours before use.

Charging the rechargeable battery

If the AC adaptor is connected correctly, the adaptor mark of the display section switches on.
The battery is charged regardless of whether the power of the main unit is on or off.
While the battery is being charged, the battery mark flashes. When the battery is charged, the mark switches to the remaining indication. Charging takes about four hours.



Remaining charge of the rechargeable battery

Flashing

If the remaining charge of the battery is low, the battery mark on the display flashes. This indicates the remaining battery charge for a few measurements.

Remaining

If the battery mark changes from flashing to remaining indication, measurement is not possible. Charge the battery.

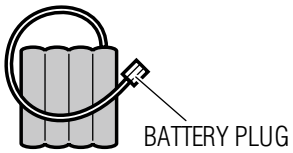
About the rechargeable battery

- The rechargeable battery may not be charged sufficiently the first time you use it or if you do not use it for a long time.
  This is due to the characteristics of rechargeable batteries. This is resolved by using the rechargeable battery (with electrical charging and discharging) several times.
- While it depends on the operating environment and conditions, the life of the rechargeable battery is about two years.
  To ensure extended use of the rechargeable battery, we recommend charging the rechargeable battery after it has completely run out.
  If the battery mark flashes frequently or charging is necessary frequently, replace the rechargeable battery.

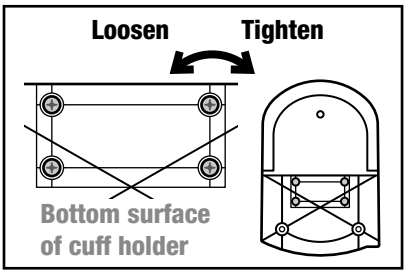
When you purchase consumables, contact a dealer.

RECHARGEABLE NICKEL METAL HYBRID (NiMH) BATTERY

Model: GP170AAH



Replacing the rechargeable battery

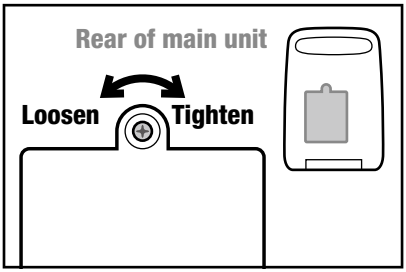


1. Remove the cuff holder

Use a Phillips head screwdriver to remove the 4 screws on the bottom surface of the cuff holder.

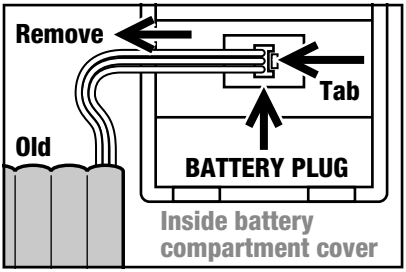
2. Open the battery compartment cover

Use a Phillips head screwdriver to remove the screw of the battery compartment cover.



3. Remove the battery plug

While pressing the tab of the battery plug, remove the battery plug.

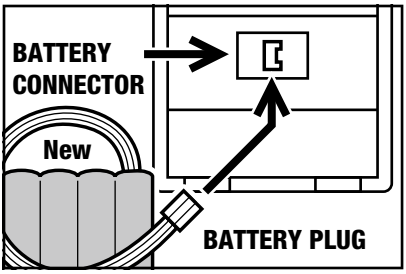


4. Connect a new rechargeable battery

Insert the battery connector into the battery plug firmly until you hear a click.

5. Close the battery compartment cover

Use a Phillips head screwdriver to secure the screw of the battery compartment cover.



6. Attach the cuff holder

Use a Phillips head screwdriver to secure the screws of the cuff holder.

When you unplug the rechargeable battery, do not forcibly pull the cord. Hold the plug section, press the tab, and then remove the cord.

Use the designated rechargeable battery.

Error displays and troubleshooting

appears (over-pressurization)

Because the patient moved, inflation reached the maximum pressure value, but measurement was not possible.

Make sure that the patient stays still during measurement.

appears (measurement error)

The patient moved or talked during measurement.

Make sure the patient does not move or talk during measurement.

appears (inflation error)

Either the air plug is not inserted correctly or noise was detected.

Check the air plug connection and make sure the patient does not move or talk during measurement.

appears (deflation error)

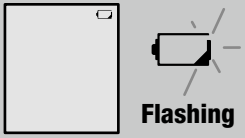
Because the patient moved during measurement, a sudden pressure change occurred.

Make sure the patient does not move or strain their arm during measurement.

appears (checking mode)

A button was pressed during AC adaptor or rechargeable battery connection.

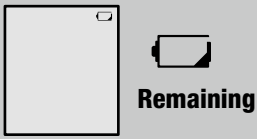
When you perform measurement, turn the power on and off before starting.



Flashing

Low charge remaining.
This indicates the remaining battery charge for a few measurements.

The battery mark is displayed when a full LCD display occurs when the power switched on. The display at this time does not indicate that the remaining charge is insufficient.



Remaining

No charge remaining.
The device must be charged for measurements to be possible.

? Inflation of the cuff started again during deflation (during measurement)

When, for example, the set inflation value is insufficient for blood pressure measurement, the patient moves during measurement, or noise is detected, inflation occurs again until the cuff reaches a value higher than the preset pressure value after deflation starts.
This does not indicate a problem. Automatic re-inflation: See page 3
Make sure that the patient stays still during measurement.

? Blood pressure is different each time or extremely high (low)

The measurement posture is different or the measurement position does not match the height of the heart.
Make sure the patient is in the correct posture for measurement.
Make sure that the measurement position matches the height of the heart.
Blood pressure values differ by psychosomatic states.
Measure under the same conditions.

? The pulse rate is unusually low (high)

The patient moved during measurement.
Make sure that the patient stays still during measurement.
The patient did not rest sufficiently before measurement.
Allow the patient to rest for about five minutes so that they can relax before measurement.

? Saved measurement values are not displayed

The device is set to [MANUAL].
Press the MODE BUTTON to set [AUTO] or [AUTO3].
Furthermore, measurement results recorded using MANUAL measurement are not saved.

? The cuff is not inflated

No charge remaining
When the battery mark is on, measurement is not possible.
Charge the battery.

? The battery mark is on, even though the power is off

The battery mark indicates the charge status of the rechargeable battery.
(Flashing: charging / Remaining: charged)

Nothing is displayed even when the POWER BUTTON is pushed.

The adaptor is not connected correctly.
Check the connection of the adaptor.
No remaining charge in the rechargeable battery.
Either use the adaptor or charge the rechargeable battery.
The device was left for one hour or more.

If measurement cannot be completed normally even after using the above-mentioned methods, contact Nissei or a dealer.

Tips on taking blood pressure

Blood pressure is the force exerted by the heart in pumping the blood through the arteries and the resistance by the veins to this flow.

Blood pressure varies all the time, influenced by mental and physical factors and is never constant.

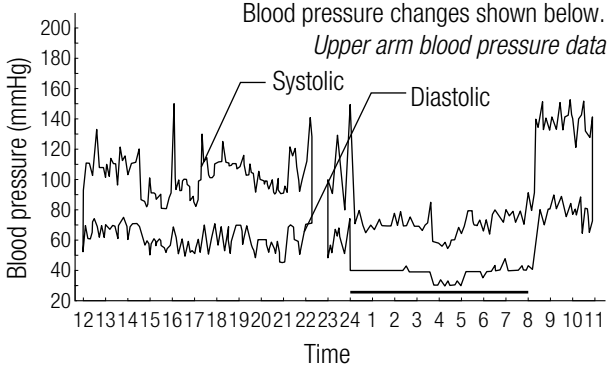
In general, blood pressure is highest during the working hours and gradually decreases during the afternoon and evening hours. It is low during sleep and increases at a relatively fast rate after arising from bed.

Causes for Changes in Blood Pressure

- Body movement
- Conversation
- Mental Tension
- Nervousness
- Emotions
- Eating
- Drinking Alcohol
- Smoking
- Measurement posture
- Recent Urination or Bowel Movement
- Room temperature
- Changes in the surroundings such as movement or noise, etc.

Blood pressure changes shown below.

Upper arm blood pressure data



Blood pressure measured at hospital or clinics tends to be higher than when it is measured at one's home, this symptom is known as "White Coat Syndrome".

Being in a hospital could cause mental tension and therefore lead to higher blood pressure than that taken under relaxed condition at one's own home.

Judgment such as a change of dosage of a drug based on measurement results should not be made by patients on their own without professional consultation.

Blood pressure classification by WHO (1999)

180~	**(severe)**					
160~179	**(moderate)**					
140~159	**(mild)**					
130~139	**High Normal**					
120~129	**Normal**					
~120	**Optimal**					
SYS mmHg **DIA**	~ 80	80 ~ 84	85 ~ 89	90 ~ 99	100 ~ 109	110 ~

Hypertension

Blood pressure should be taken after approximately five minutes of rest, under relaxed conditions and in a quiet environment.

Exercise, eating, drinking alcohol, smoking and other activities that effect blood pressure should be avoided prior to measurement.

Cuff measurement position should be at the height of the heart to obtain correct measurement results. If the cuff is lower (higher) than the heart, the measured reading tends to become larger (smaller).

There should be no speaking or moving during blood pressure measurement. Otherwise correct measurement results cannot be obtained.

The ambient temperature should be approximately 20˚C for blood pressure measurement.

Any shirt or accessories that might restrict circulation in the upper arm should be taken off for blood pressure measurement.

Sleeves rolled up over the upper arm will restrict the blood flow and lead to inaccurate measurement.

Measurement of blood pressure should not be repeated immediately since congestion of blood could result in inaccurate measurement. There should be at least 5 minutes between measurements.

Care and maintenance

Because the device includes precision parts, care should be taken to avoid extreme temperature variations, humidity, shock, dust, and direct sunlight. Do not drop or strike the device. Make sure not to expose the unit to moisture. This unit is not water resistant.

Use only a soft, dry cloth to clean the device. Do not use gasoline, paint thinner, chemicals such as strong soda, strong acids, oxidizing agents and reducing agents, or other strong solvents on the unit. Since the cuffs may absorb perspiration and other fluids, inspect them for stains and discoloration after each use. Cotton cuff shells are hand/machine-washable. Take out bladders from inside the cuffs before washing cotton shells. Use common detergents. Air dry thoroughly.

When storing the device, do not place heavy objects on it and do not coil AIR TUBE too tightly. When the unit has been stored at a temperature below the freezing point, keep it for at least 1 hour in a warm place before using. Keep the batteries out of reach of children.

Do not inflate the cuff when it is not wrapped around an arm.

Do not disassemble or modify the device.

We suggest that the device be checked every 2 years. This operation may only be performed by the manufacturer or by authorized agents of the manufacturer.

Technical description

DM-4000 complies with the EMC, electromagnetic compatibility, standard, IEC60601-1-2. Refer to the tables below for specific information regarding compliance to the standard.
DM-4000, as a medical electrical equipment, needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.
Portable and mobile RF communications equipments can affect the device.
The use of accessories other than those specified in this manual may result in increased emissions or decreased immunity of the device.
DM-4000 should not be used adjacent to or stacked with other equipment.

Table 1 - Guidance and manufacturer's declaration - electromagnetic emissions -

DM-4000 is intended for use in the electromagnetic environment specified below. The customer or the user of DM-4000 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	DM-4000 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 A	DM-4000 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	Complies	

Table 2 - Guidance and manufacturer's declaration - electromagnetic immunity -

DM-4000 is intended for use in the electromagnetic environment specified below. The customer or the user of DM-4000 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	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage 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 sec	<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 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of DM-4000 requires continued operation during power mains interruptions, it is recommended that DM-4000 is 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 a.c. mains voltage prior to application of the test level.			

Table 4 - Guidance and manufacturer's declaration - electromagnetic immunity -

DM-4000 is intended for use in the electromagnetic environment specified below. The customer or the user of DM-4000 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	3 Vrms 150 kHz to 80 MHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of DM-4000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=[3.5/V1]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d=[3.5/E1]\sqrt{P}$ 80 MHz to 800 MHz $d=[7/E1]\sqrt{P}$ 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: 

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radios 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 DM-4000 is used exceeds the applicable RF compliance level above, DM-4000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating DM-4000.

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

Table 6 - Recommended separation distances between portable and mobile RF communications equipment and DM-4000 -

DM-4000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of DM-4000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and DM-4000 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, $d=[3.5/V1]\sqrt{P}$	80 MHz to 800 MHz, $d=[3.5/E1]\sqrt{P}$	800 MHz to 2.5 GHz, $d=[7/E1]\sqrt{P}$
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.

NOTE1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Warranty and service

ALP K2 warrants the product for two years from the date of purchase for functionality and accuracy without charging cost for inspection, adjustment, repair and labour. Evidence of date of purchase is required for warranty claims.

However, this warranty does not cover defects resulting from,

- damage caused by wear or misuse,
- damage caused by unauthorised repair or modification or
- damage caused by natural disaster, violent action or war.

Also, cuffs, including cuff shells, bladders, tubes and plugs, are not covered by this warranty except for defects in manufacture.

Purchaser shall bear transport or shipping related costs.

ALP K2 is not liable for any consequential damages caused by DM-4000, direct or indirect, economically or biologically.

ALP K2® CE 0123

Manufacturer
TANAKA SANGYO CO., LTD. 3-16-3, Hongo, Bunkyo-ku, Tokyo 113-0033, JAPAN
EC Representative
FLEMING COMERCIAL, S. A. Can Bruixa, 20-22 08028 Barcelona, SPAIN