DIGITAL SPHYGMOMANOMETER DM-500

INSTRUCTIONS *<ENGLISH>*

This manual is intended to assist you in the safe and efficient operation of DIGITAL SPHYGMOMANOMETER DM-500. 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.

GENERAL PRODUCT INFORMATION

DIGITAL SPHYGMOMANOMETER DM-500 is intended for non-invasive measurement of blood pressure using auscultatory method. The device consists of pressure gauge, inflatable cuff and inflation bulb.
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 designed for proficient medical staff use in medical institutions. The product is not intended to be used either outside the healthcare facility, during professional transportation of a patient outside the healthcare facility or home healthcare environment.

PRODUCT SPECIFICATIONS

Pressure indication range : 20~280 mmHg
Accuracy of cuff pressure display
: ±3mmHg
Operating Environment : +10˚C to +40˚C, 85% relative humidity or below
Storage Environment : -5˚C to +50˚C, 85% relative humidity or below
Protection against electric shock
: Internally powered equipment, Type BF applied part (cuff)
Power source : 2 AA batteries
Voltage : DC3V
Power consumption : 0.5 W (max.)
Size : 122.7×310.5×86.3 mm, closed
Weight : Approximately 780 g, not including batteries

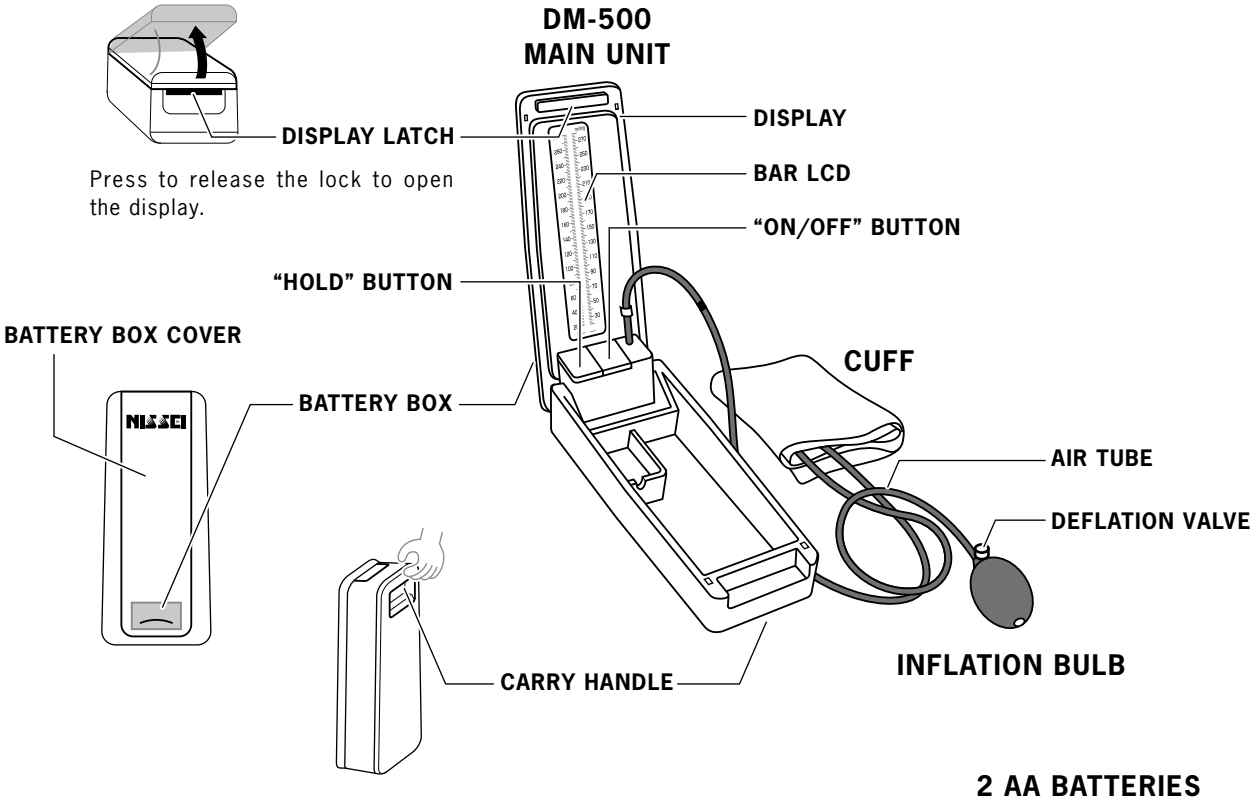
Applicable arm circumference of the Standard cuff
: 23 to 32 cm
Optional Small size cuff (for arms 17 to 25 cm) and Large size cuff (for arms 32 to 42 cm) available
Protection against harmful ingress of water
: IPX0
This device complies with EMC (IEC60601-1-2).
Specifications are subject to change without notice due to improvements in performance.

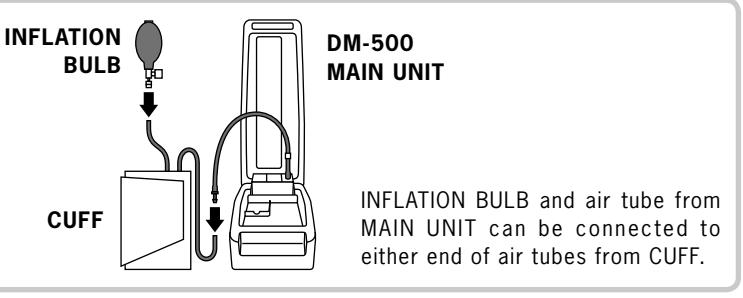
Important; read operating instructions.
Type BF applied part
The used electrical and electronic products are not household waste. Follow your national/local recycling rules to dispose of them properly. In the EU countries, please refer to waste management symbol(s) marked on the package or the instrument.

WARNING AND PRECAUTION

- **Do not use DM-500 in**
  - **an explosive environment such as where flammable anaesthetics exist or inside oxygen chamber**
  - **strong electrostatic and electromagnetic field e.g., mobile phones**
- **Do not use the device in combination with other medical electrical equipments, e.g., pacemaker, implantable defibrillator, ECG.**
- **Do not use cuff or inflation bulb other than those supplied with this product or replacement parts supplied by the manufacturer. Use accessories included in the product or specified in this manual only.**
- **The system may fail to yield specified accuracy if operated or stored in temperature or humidity conditions outside the limits stated in the specifications section of this manual.**
- **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.**
- **Do not inflate the cuff when it is not wrapped around an arm.**
- **Do not disassemble or modify the device.**
- **When replacing the battery do not touch the battery or battery terminal and another person at the same time.**
- **Do not apply the cuff on the limb which the intravenous drip infusion is implemented.**

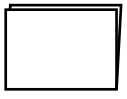
PRODUCT COMPONENTS AND PART NAMES





2 AA BATTERIES

INSTRUCTIONS



** Stethoscope is not included in the product.*

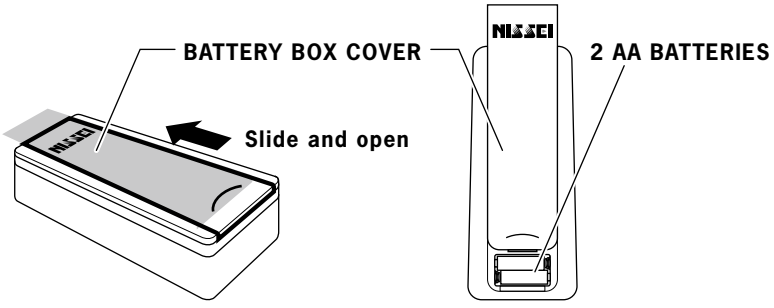
BATTERY INSTALLATION

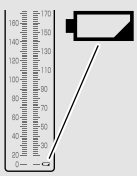
Open BATTERY BOX by sliding the box cover.

Install two AA batteries as indicated inside the box.

Slide back the box cover.

Batteries should be installed or removed as their (-) ends are pushed against the spring.





BATTERY MARK indicates low battery power. As it starts flashing, the device can be used for another several measurements before the batteries are completely depleted. When the mark stops flashing and stays in BAR LCD, the device cannot be operated. Replace both batteries with new ones when the mark is displayed. Do not use new and old batteries mixed.

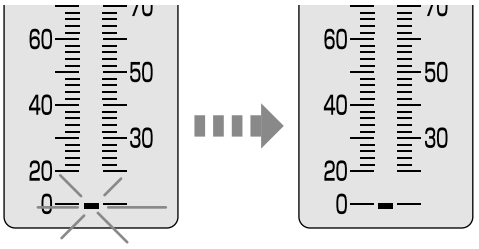
The mark appearing at the LCD test which is performed as the device is turned on does not indicate low battery power.

USING THE DEVICE

Attach the cuff to the patient's upper arm by choosing the suitable cuff size according to patient's arm circumference.

Press "ON/OFF" BUTTON to turn on the device.

As the device is turned on, it starts the zero setting after the LCD test. The flashing dot at "0" in BAR LCD indicates that the zero setting is being conducted. Wait until the dot stops flashing to begin inflation of the cuff.



ZERO setting being performed

ZERO setting completed

Make measurement after the zero setting.

The cuff is pressurized by pumping the inflation bulb and depressurized by operating the deflation valve. The pressure reduction rate is controlled by adjusting the deflation valve.

Turn off the device by pressing "ON/OFF" BUTTON.

The device will be turned off when the cuff pressure remains zero for approximately 3 minutes.

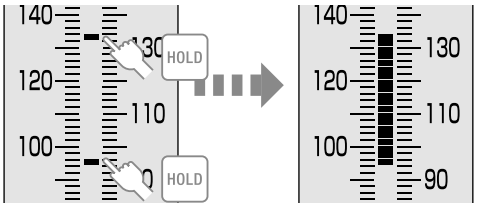
Press "ON/OFF" BUTTON in case of any malfunction of the device or whenever to interrupt measurement. The device will exhaust the air from CUFF.

"HOLD" BUTTON

Blood pressure can be confirmed on BAR LCD after measurement using "HOLD" BUTTON.

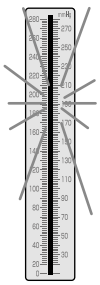
Press "HOLD" BUTTON as you determine systolic blood pressure and a dot stays in BAR LCD. Press again as you determine diastolic blood pressure and the second dot stays in BAR LCD.
If you press "HOLD" BUTTON more than twice, the first dot disappears. Only two dots remains on LCD.

The display of measured blood pressure disappears as the device is turned off.
The change in the cuff pressure, caused by removal of cuff or such, will erase the blood pressure display.



Display after cuff exhaust

TROUBLESHOOTING



FLASHING LCD
Flashing LCD indicates over-pressurization.
Air will be exhausted from CUFF and the device will conduct the zero setting. The device can be used for measurement after the zero setting.

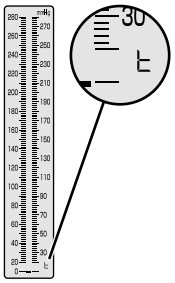
UNABLE TO MEASURE
Confirm the dot display at "0" in BAR LCD. Flashing dot indicates that the zero setting is being performed. Wait to start measurement until the dot stops flashing.

If the dot is not displayed the device is turned off. It automatically turns off if the cuff pressure remains zero for approximately 3 minutes.

If BATTERY MARK is displayed, the battery power is low. Measurement cannot be made when the mark is displayed. Replace the batteries with new ones.

DISPLAYED VALUES ARE DIFFERENT FROM THE ACTUAL BLOOD PRESSURE VALUES
Difference could arise from motion of pressing the button especially when the deflation speed is high.

THE DEVICE DOES NOT TURN ON
Reconfirm the installation of batteries. Make sure they are installed correctly as indicated in the battery box. If they are installed correctly, they may be exhausted. Try new batteries. As the power supply becomes low, BATTERY MARK starts flashing at the bottom of BAR LCD.



DISPLAY OF "ㄷ"
"ON/OFF" BUTTON was pressed during battery installation. Press the button and turn off the device once to use.

If you cannot get correct measurement with the methods above, contact your dealer. Do not disassemble or tamper with the internal mechanism.

CARE AND MAINTENANCE

Remove batteries when cleaning the device. 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 device. Since the cuff may absorb perspiration and other fluids, inspect it for stains and discoloration after each use. The cuff shell is hand/ machine-washable. Take out bladder from inside the cuff shell before washing the cuff shell. Use common detergents. Air dry thoroughly. Please contact the manufacturer or the dealer in case the device needs to be disinfected.

When storing the device, do not place heavy objects on it and do not coil AIR TUBE too tightly. Do not forcefully close the display. When closing the display, check if the finger, cuff or tube is not caught between the display part and the cuff compartment part. Remove the batteries if the device is to be stored for an extended period of time. Keep the batteries out of reach of children. 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.

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-500 complies with the EMC, *electromagnetic compatibility*, standard, IEC60601-1-2. Refer to the tables below for specific information regarding compliance to the standard. DM-500, 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-500 should not be used adjacent to or stacked with other equipment.

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

DM-500 is intended for use in the electromagnetic environment specified below. The customer or the user of DM-500 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	DM-500 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	DM-500 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	

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

DM-500 is intended for use in the electromagnetic environment specified below. The customer or the user of DM-500 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	N/A	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	N/A
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	N/A	N/A
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	N/A	N/A
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-500 is intended for use in the electromagnetic environment specified below. The customer or the user of DM-500 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 Vrms, 150 kHz to 80 MHz 3 V/m, 80 MHz to 2,5 GHz	N/A 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of DM-500, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance N/A d=1.2√P, 80 MHz to 800 MHz d=2.3√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-500 is used exceeds the applicable RF compliance level above, DM-500 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating DM-500.

[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-500 -

DM-500 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of DM-500 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and DM-500 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, N/A	80 MHz to 800 MHz, d=1.2√P	800 MHz to 2,5 GHz, d=2.3√P
0,01	N/A	0,12	0,23
0,1	N/A	0,38	0,73
1	N/A	1,2	2,3
10	N/A	3,8	7,3
100	N/A	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

NISSEI 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 unauthorized 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.
NISSEI is not liable for any consequential damages caused by DM-500, direct or indirect, economically or biologically.

NISSEI CE 0123

Manufacturer: **NIHON SEIMITSU SOKKI CO., LTD.**
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EC-Representative: **Nissei Healthcare (UK) Ltd.** Henfield, BN5 9SJ UK web site http://www.nisseihealthcare.com