

DS-1011



NISSEI  
JAPAN

Прибор для измерения артериального  
давления и частоты пульса цифровой DS

*Руководство по эксплуатации*

Вимірювач артеріального тиску та частоти серцевих  
скорочень (Digital blood pressure monitor DS-1011)

*Інструкція з експлуатації*

Күретамырдың қан қысымы мен тамырдың соғу  
жиілігін өлшеуге арналған сандық DS аспабы

*Пайдалану жөніндегі басшылық құжат*

Digital Blood Pressure Monitor

*Instruction Manual*



RUS

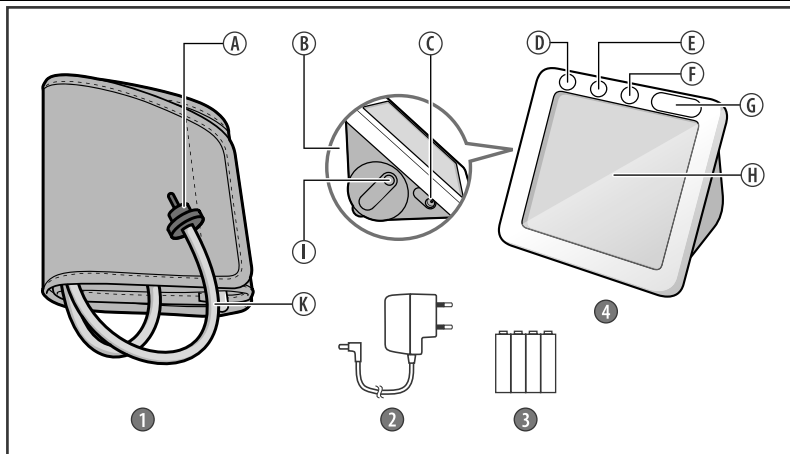
UKR

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ENG

This manual is intended to assist you in the safe and efficient operation of BLOOD PRESSURE MONITOR DS-1011. 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 important to read and understand the entire manual. In particular, please read carefully and become familiar with the section entitled "TIPS ON TAKING YOUR BLOOD PRESSURE".

## PART NAMES AND PRODUCT COMPONENTS



1. Cuff
2. Power Adapter
3. Batteries
4. Monitor

- A. Air plug
- B. Battery Compartment
- C. AC Connector
- D. "Set" Key
- E. Memory Key **1**
- F. Memory Key **2**
- G. "Start/Stop" Key
- H. Display
- I. Air connector
- K. Air hose

## GENERAL INFORMATION

### Indications for use

The device is designed to measure systolic and diastolic blood pressure and heart rate reading in patients aged 13 years and older. This device should not be used for neonate or infant. Consult your doctor for blood pressure measurement in children or person in pregnancy or under pre-eclamptic condition. The device is recommended for use in patients with unstable (nonpermanent) blood pressure or hypertension at home as a supplement to medical surveillance. The cuff is suitable for a upper arm with a circumference of about 22 - 32 cm. Blood pressure is measured in the range from 50 to 250 mmHg for systolic and 40 to 180 mmHg for diastolic, in the range from 40 to 160 heartbeats per minute.

### Method Of Measurement

This product employs the oscillometric method for measurement of blood pressure and pulse rate. The cuff is connected to the main unit and wrapped around the arm. Circuits within the cuff sense the small oscillations in pressure against the cuff produced by the expansion and contraction of the arteries in the arm in response to each heart beat. The amplitude of each pressure waves is measured, converted to millimeters of mercury, and displayed on the LCD as a digital value.

### Used new NISSEI Technologies



**Measurement on Inflation** – is a technology that makes it possible to define the pressure in the course of the cuff inflation.



**Irregular Pulse Rhythm indicator** – displays when the pulse rhythm detected during measurement was irregular. Pulse rhythm can be disturbed from talking, moving or arrhythmias.



**Personal Mode** – the inflation is adjusted based on the latest three readings.



**Touch Control** – touch-sensor operation.



**Interference detection** – is a symbol that informs about the presence of external noise that could affect the measurement result.



**Pulse Pressure Display** – calculates and displays pulse pressure. Pulse pressure is value subtract diastolic value from systolic value and therefore pulse pressure tends to increase with age.

**ATTENTION!** Do not use cuffs other than the original cuff included with this product.

## COMPLETE SET

1. Main body – 1 pcs.
2. Cuff – 1 pcs.
3. Battery – 4 pcs.
4. AC Adapter – 1 pcs.
5. Carrying bag – 1 pcs.
6. Instruction manual – 1 pcs.
7. Warranty card – 1 pcs.
8. Packing – 1 pcs.

## TIPS ON TAKING YOUR BLOOD PRESSURE

1. If treated with hemodialysis or anticoagulants, antiplatelets or steroids, refer to your doctor about the blood pressure measurement.
2. Malfunctions are possible when the device is used near working mobile phones, microwave ovens and other equipment generating electromagnetic radiation.
3. For correct measurement it is necessary to know that the BLOOD PRESSURE IS SUBJECT TO SHARP FLUCTUATIONS EVEN IN SHORT TIME INTERVALS. The blood pressure level depends on many factors. It is commonly lower in summer and higher in winter. Blood pressure varies along with atmospheric pressure and depends on the physical exertion, emotional excitability, stress and diet. Medical drugs, alcohol and smoking exert great influence as well. Occasionally, measurements in the clinic cause an increase in pressure values. Therefore, blood pressure measured at home is often different from that measured in the clinic. Since blood pressure increases at low temperatures, measurements should be made at room temperature (about 20°C). If the device was stored at low or high temperature outside the operational temperature range prior to using, it should be kept for at least 2 hours at room temperature. Otherwise the measurement result can be erroneous. During the day, the difference in the readings in healthy people may attain 30-50 mm Hg for systolic (upper) pressure and up to 10 mm Hg for diastolic (lower) pressure. Dependence of blood pressure on various factors is individual for each person. Therefore it is recommended to keep a special recording of blood pressure readings. **ONLY A DOCTOR MAY ANALYZE TRENDS IN CHANGING YOUR BLOOD PRESSURE BASED ON CORRESPONDING RECORDINGS.**
- 4 In case of cardiovascular diseases and a number of other diseases that require the blood pressure monitoring, measurements should be carried out in the hours specified by a doctor. **REMEMBER THAT THE DIAGNOSTICS AND ANY TREATMENT OF ARTERIAL HYPERTENSION SHOULD BE CARRIED OUT ONLY BY A DOCTOR BASED ON BLOOD PRESSURE READINGS OBTAINED BY A DOCTOR. MEDICAL DRUG ADMINISTRATION OR CHANGE OF DOSAGES SHOULD BE MADE ONLY BY PRESCRIPTION OF AN ATTENDING DOCTOR.**

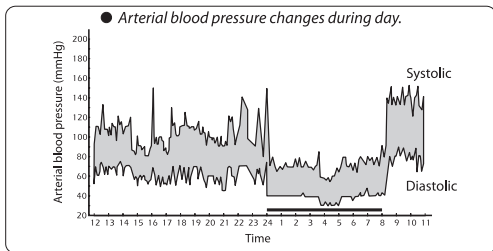


Fig.1

5 In case of disorders such as deep vascular sclerosis, weak pulse wave and break in rhythm of heart contractions, the correct blood pressure measurement can be complicated. IN THIS CASE, A DOCTOR SHALL PROVIDE RECOMMENDATIONS IN RELATION TO USE OF THIS DEVICE.

6 KEEP QUIET DURING THE MEASUREMENT TO OBTAIN THE CORRECT BLOOD PRESSURE READING WHEN USING THE ELECTRONIC DEVICE. The blood pressure measurement should be carried out in a quiet comfortable atmosphere at room temperature. Exclude meal an hour before the measurement, and exclude smoking, soft drinks, and alcohol 1.5-2 hours before the measurement.

7 Accuracy of the blood pressure measurement depends on matching the device cuff and size of your arm. THE CUFF SHOULD NOT BE TOO SMALL OR TOO BIG.

8 Repeated measurements are carried out at 5-minute intervals to recover the blood circulation. However, persons suffering from severe atherosclerosis, due to a significant loss of elasticity of blood vessels, need longer intervals between measurements (10-15 minutes).

This also concerns patients suffering from long-term diabetes. For more accurate determination of blood pressure it is recommended to carry out a series of three consecutive measurements and to calculate the average value of measurement results.

9 Do not use this device in an explosive environment such as near flammable anesthetics or inside oxygen chamber.

10 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.

11 Do not use cuffs or accessories other than those specified by the manufacturer. Otherwise, correct measurement readings cannot be obtained.

12 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 or lymph node clearance. Otherwise injury may be resulted.

13 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.

14 To avoid harmful injury due to interfered blood flow from cuff inflation, make sure that AIR HOSE is not kinking before measurement. Otherwise, cuff inflation may not be conducted properly and prolonged.

15 Do not take out batteries or unplug the AC adaptor when the device is turned on. Make sure to switch off the device before removing batteries or AC adaptor.

16 Do not touch the output plug of AC adaptor during measurement.

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

18 Do not apply the cuff on the limb which the intravenous drip infusion is implemented.

## BATTERY INSTALLATION

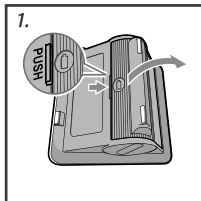


Fig.2

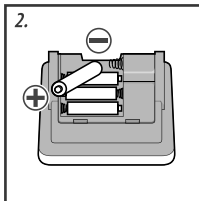


Fig.3


1. Open the battery compartment cover (fig.2).
2. Install four "AA" type batteries into the compartment. Make sure that the polarities correspond to the (+) and (-) marks inside the battery compartment (fig.3). Batteries can be easily installed or removed as their (-) ends are pushed against the spring.

You may use nickel hydride rechargeable batteries. These batteries can not be charged with this product. Use the designated battery charger.

3. Close the battery compartment cover.  
Do not force the battery cover into position.

### Operation With AC Adaptor

AC Adapter socket is located at the side of the device. Connect the AC Adapter jack to the device firstly and after supply AC Adapter plug into the power outlet, press «START / STOP». To switch off the device after finishing the measurement press «START / STOP», unplug the AC Adapter from the power outlet and disconnect AC Adapter from the device.

 **Battery symbol** will flash when battery power is low. Measurement can not be made while the symbol is displayed. Replace the batteries. All four batteries need to be replaced with new ones; do not mix new and old batteries or different batteries.

The symbol might appear only during measurement although you can review readings in memory. This is because more battery power is required for conducting a measurement, e.g. inflating the cuff, than displaying the readings in memory. Please have the batteries replaced. The enclosed batteries are for monitoring, and their life may be shorter than that of commercial batteries.



The used electrical and electronic products are not household waste. Follow your national/local recycling rules to dispose of them properly.

### WARNING!

If you will switch off AC Adapter without batteries in the device all information stored in memory (results of measurements, date and time) will be erased. If you want to save this information, do not remove batteries from the device when using the AC Adapter.

## ADJUST DATE AND TIME AND ACTIVATE THE CLOCK

Date and time can be set after installing the batteries. Set the time guarantees the preservation of the measurement results with the correct date and time. There is a possibility of measurement of pressure and pulse rate without setting date and time.

Press "SET" KEY until "2011" starts flashing.

Clock is set in the order of year, month, day, hour and minute.

The flashing number increases with [1] and decreases with [2]. The number will be fast-forwarded if you keep your finger on the key. Pressing "SET" will fix the number and the next article will flash. Pressing "START/STOP" will terminate the setting.

**IMPORTANT!** If the date and time have been set, current time will be shown on the display when the device is turned off.

## CORRECT MEASURING POSTURE

Sit down at the table with your back supported and feet flat on the floor so that during the blood pressure measurement your forearm and hand are on its surface. Make sure that the place where the cuff is put on the upper arm is about the same level as the heart and the forearm and hand freely lie on the table and does not move (fig.4).

Pressure measurement while lying. Place the cuff at heart level, using a case or a folded towel (fig.6).

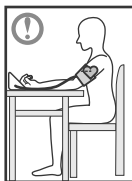


Fig.4



Fig.5

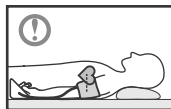


Fig.6

The results of measurements can vary slightly depending on the posture during the measurement. If the cuff is below (above) in relation to the heart, the measurements will be overstated (understated).

## WRAPPING THE CUFF

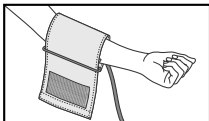


Fig.7

1 Put the cuff on your left arm with AIR HOSE positioned toward your arm. (fig.7). You may use your right upper arm for measurement (the results of measurements can slightly).

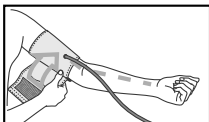


Fig.8

2 Attach the cuff with hook and loop fastener with the lower edge of the cuff approximately 2 to 3 cm above the inner elbow. Adjust the position of the cuff so that AIR HOSE is over the inner part of your arm over the brachial artery (fig.8).

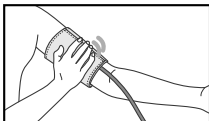


Fig.9

3 Press the surface of the cuff to make sure that the hook & loop fastens securely (fig.9). If the cuff is wrapped tightly or loosely, inaccurate blood pressure readings may result.

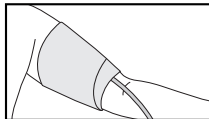


Fig.10

4 If the arm has taper form, it is recommended to put the cuff on "spiral way", as shown in the figure (fig. 10).

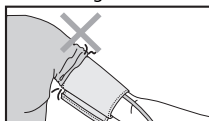


Fig.11

5 If you are wearing a shirt that might restrict circulation in your upper arm or you roll your sleeve up over the upper arm, the blood flow will be restricted, preventing accurate measurement (fig.11).

## PROCEDURE FOR THE MEASUREMENT

**IMPORTANT!** The device has sensor keys and clicking is a slight touch of a finger.

Moisture, dirt and other objects between the finger and panel of the device can affect the ability to respond to the touching keys.

1. Insert AIR PLUG into AIR CONNECTOR before starting a blood pressure measurement.

*Take deep breaths and relax. Do not move, chat or strain your arm or arm during measurement.*

2. Press "START/STOP". Air is exhausted from the cuff (fig.12).



3. Automatic inflation starts (fig.13).

4. Inflation stops when the pressure, that is, the displayed value, reaches the designated value.



### Noise Interference Detection

Blood pressure value taken while moving cannot be said to be the correct value because body movement can affect blood pressure.

This product analyzes pulse wave and displays «» when body motion is detected. Symbol «» indicates the results might be affected by body movement.

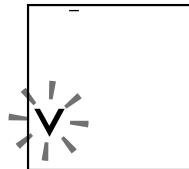


Fig.12

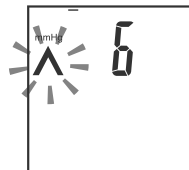


Fig.13



Press "START/STOP" again to cancel measurement. The monitor will exhaust air from the cuff and turn off .

5. Pulse Symbol «♥» is displayed as pulse is detected (fig.14).
6. Air is released from the cuff and measured values are displayed as measurement completes (fig.15).
7. Pressing **1** or will **2** switch the bank.
8. Press "START/STOP".

The monitor will be turned off. Even if you do not turn off the monitor, it turns off automatically after 3 minutes.

Do not execute repeated measurements for congestion of blood could result in false measurement.  
Let your wrist rest for at least 5 minutes.

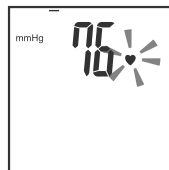


Fig.14

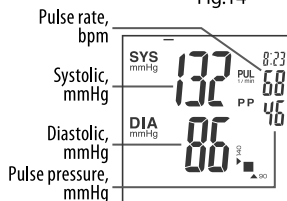
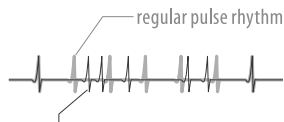


Fig.15

### Irregular Pulse Rhythm Symbol

Pulse rhythm can be disturbed from talking, moving or arrhythmias. This product displays «**HR**» when the pulse rhythm detected during measurement was irregular (fig.16).



An example of irregular pulse rhythm compared to regular pulse rhythm

Fig.16





### WHO Classification Symbol

Measured blood pressure values are classified against WHO guideline. Scale, being lower right on display, allows us to estimate the obtained figures according to the classification (fig.17).



Fig.17

## WHO scale is the scale classification derived values of blood pressure

Display	WHO Classification	SYS	DIA
	<b>Hypertension (severe)</b>	<b>≥180</b>	<b>≥110</b>
	<b>Hypertension (moderate)</b>	<b>160-179</b>	<b>100-109</b>
	<b>Hypertension (mild)</b>	<b>140-159</b>	<b>90-99</b>
	<b>High Normal</b>	<b>130-139</b>	<b>85-89</b>
	<b>Normal</b>	<b>120-129</b>	<b>80-84</b>
	<b>Optimal</b>	<b>&lt;120</b>	<b>&lt;80</b>

## Pulse Pressure Display

This product calculates and displays pulse pressure (fig.18).

While systolic blood pressure keeps increasing with age, diastolic blood pressure tends to start decreasing at around age 50. Pulse pressure is value subtract diastolic value from systolic value and therefore pulse pressure tends to increase with age. Pulse pressure has been considered to be related to stiffness of artery and has been studied as one of circulatory risk factors. It is sometimes said that 45 mmHg of pulse pressure is normal value. Pulse pressure only does not represent arterial sclerosis. However, observation of pulse pressure in long term will be important.

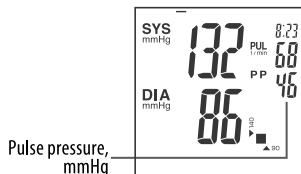




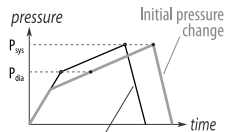
Fig.18

## Personal mode

The inflation is adjusted based on the latest three readings in the selected bank, either  or , to shorten the measurement time and to improve comfort (fig.19).

For example, high diastolic blood pressure values from past three measurements will lead to inflation to higher pressure value than the default value. In the event that this value is too high for your current blood pressure, the cuff will rapidly deflate and measurement will restart.

To use the personal mode effectively, chose the memory bank before starting a measurement. This monitor remembers the last memory bank that was displayed. To choose the memory bank before starting a measurement, display a reading saved in the desired memory bank, turn off the monitor once and then start measurement.



An example of pressure change determined with "personal mode"

Fig.19

## MEMORY FUNCTION

The measured values are automatically saved for later review in either one of two memory banks. These two memory banks can be used to save readings of two persons separately or to save morning readings and evening readings separately.

Each bank can save up to 60 readings. When the number of stored readings reaches 60, the oldest reading will be deleted to record new reading.

Saved readings are recalled with measurement date and time when clock function is activated. \*The clock needs to be activated before measurement for date and time to be saved with the measured value.

[Err] results are not saved.

1 Turn off the monitor once with "START/STOP" when the results are displayed after a measurement. Press **[1]** to review readings saved in memory 1 and **[2]** to review those in memory 2.

The average of the saved readings are displayed (fig. 20).

Average will not be displayed unless there are two or more readings saved.

2 Press the same memory key again. The latest reading saved in the selected bank is displayed.

3 The display at the top shows memory number, measurement date and time alternately.

4 The latest reading is displayed as memory "No. 1". The bigger memory number indicates the older number.

Even if you do not turn off the monitor, it displays the result for approximately 30 seconds and will turn off automatically.

Pressing **[2]** at display of reading in the bank M1 will switch the display to reading in bank M2 and pressing **[1]** side again will return to the display of result in the bank M1.

5 Press "START/STOP".

### Deleting saved readings

The readings can be deleted from the memory. The memory can be initialized only when two or more results are saved in the bank.

1 Press **[1]** to delete reading in MEMORY 1 or **[2]** to delete reading in MEMORY 2. Display the average reading of to delete entire readings in the memory.

2 The display will start flashing. Keep your finger on the key until the reading is replaced with «---».

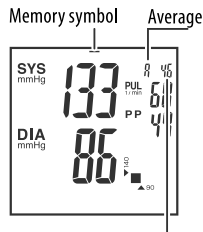

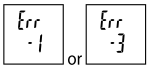





Fig.20

## TROUBLESHOOTING

SYMPTOM	PROBABLE CAUSE	Remedies
Blood pressure is extremely high or low.	The cuff is not adjusted to your heart. The cuff is not wrapped appropriately. Movement or speaking was detected.	Adjust the cuff to the height of your heart. Reconfirm how to put the cuff on your arm. Do not move or speak during measurement.
Measured values vary all the time.	Mental and physical condition or measurement condition is influencing blood pressure.	Make measurement under the same condition.
Measured value is different from that taken at a hospital.	Mental condition such as nervousness at a hospital or relaxed feeling at home is influencing blood pressure.	Take records of blood pressure taken at home and consult with your doctor.
Inflation is repeated.	The cuff is inflated again when the initial pressure was insufficient for blood pressure to be taken or movement was detected. Inflation is repeated until blood pressure is taken.	Repeated inflation is not a malfunction of the monitor. Do not move or speak during measurement.
	Over pressure: blood pressure could not be taken due to moving or speaking although the cuff was inflated to the maximum pressure.	Do not move or speak during measurement.
	Blood pressure could not be taken due to moving or speaking.	Do not move or speak during measurement.
	The cuff is not wrapped appropriately.	Reconfirm how to put the cuff on your arm.
	Batteries are weak.	Replace all batteries with new ones.
Clock is not displayed.	Batteries are deleted. Batteries are inserted incorrectly. Battery terminals are not clean.	Replace all batteries with new ones. Reinsert the batteries correctly. Clean the terminals with dry cloth.
Measurement date and time are displayed with «--/--».	The clock is not activated. Measurement was taken before the clock was activated.	Adjust date and time and activate the clock. Measurement date and time can not be saved without clock being activated.

Nothing is displayed.	Batteries are deleted. Batteries are inserted incorrectly. Battery terminals are not clean.	Replace all batteries with new ones. Reinsert the batteries correctly. Clean the terminals with dry cloth.
	START/STOP was being pressed at installation of batteries.	Turn off the monitor once with "START/STOP" and make measurement.

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

## WARRANTY

- 1 Warrantee period for the electronic unit is 5 years from the date of sale. The warranty period for the cuff and power adapter is 12 months from the date of sale.
- 2 The warranty obligations are prescribed by warranty certificate for buyer. This warranty does not cover damage or malfunctions caused by improper armling or use contrary to the instructions in this manual.
- 3 The addresses of organizations for guarantee maintenance are present in the warranty certificate.

## SPECIFICATIONS

Operating Principle	Oscillometric
Indicator	15 digits liquid crystal display
Pressure Indicating Range: cuff pressure, mmHg	0-300
Measuring Range: cuff pressure, mmHg. pulse rate, bpm.	40-250 40-160
Accuracy: cuff pressure, mmHg. pulse rate, %	±3 ±5
Inflation	Automatic inflation (Measurement on inflation)
Deflation	Automatic (electric control valve)
Power supply	6V, 4 x AA (dry alkaline elements) or AC Adapter
Memory	2 x (60 + average)
<b>AC Adapter ADP-W5</b>	
Output voltage, V	6
Maximum electric load, A	0,5
Input voltage range, V/Hz	100-240/50
Operating Environment temperature, °C relative humidity, % Rh	from 10 to 40 85 or below
Environment temperature, °C relative humidity, % Rh	from -20 to 50 85 or below
Cuff Model	Cuff DS-1011
Cuff Size	adult (circumference of the upper arm 22-32 cm)
Overall dimensions: Size (without cuff), mm Weight (without package, case, battery and power adapter), g	115 x 115 x 65 406
The service life: Unit (without cuffs), years Cuff, years	7 3
Year of manufacture:	Year of manufacture is indicated in the serial number after the letters «SN» on the case of the device
Protection class IP	IP20: Protected against solid foreign particles with a diameter of more than 12.5 mm, no protection against water.
Protection against electric shock	Internally powered equipment/Class II equipment, Type BF applied part
Mode of operation	Continuous operation

Classification

Class II / Internally powered equipment

Key to symbols:



Important: Read the instructions



Sign of type approval of measuring instruments



Type BF



Manufacturer



Environmental Packaging



Protect from moisture

**IP20** IP protection class



Class II



Mark of conformity of Ukraine



19 Sign of type approval of measuring instruments of Ukraine



When utilizing the waste, refer to current rules applicable in your region



CE 0123 Compliance with Directive 93/42 / EEC

\*This device complies with EN1060-1:1995+A2:2009 Non-invasive sphygmomanometers Part 1: General requirements and EN1060-3:1997+A2:2009 Non-invasive sphygmomanometers Part 3: Supplementary requirements for electro-mechanical blood pressure measuring system

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

\*The measurement accuracy of the device has been proven according to ISO 81060-2 protocol. In the clinical study, K5 was used for the determination of diastolic pressure values at all auscultatory measurements.

\*This device is intended for use in the environment with one atmospheric pressure.

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

Revision date of the present Manual is indicated on the last page as IXXX/YYMM/NN, where YY is the year, MM is the month and NN is the number of revision.

## CARE, STORAGE, REPAIR AND RECYCLING

- 1 This device should be protected from excessive moisture, extreme temperature variations, direct sunlight, strokes, dust, lint and vibration. **THE DEVICE IS NOT WATERPROOF!**
- 2 Do not keep or do not use the device in close proximity to heaters and open flame.
- 3 In case the product is stored in the environment with ambient temperature above 40°C or below 10°C, please leave it for at least 2 hours before taking a measurement.
- 4 If the device has not been used for a long time, remove the batteries. Leaking of batteries can cause damage to the device and terminate the warranty. **KEEP BATTERIES AWAY FROM CHILDREN!**
- 5 Do not contaminate the device and protect it from dust. The device can be cleaned with a dry, soft cloth.
- 6 Do not allow the contact between the device and its parts with water, solvents, alcohol, and gasoline.
- 7 Keep the cuff away from sharp objects, and do not try to pull out the cuff.
- 8 Do not expose the device to strong strokes and do not throw it.
- 9 The device does not contain any adjustment controls for settings. Unauthorized opening of the electronic device is forbidden. If needed, repair the device only in specialized organizations.

- 10 On the expiry of the specified operation term, refer to specialists (specialized repair organizations) on a periodic basis to check the technical condition of the device.
- 11 When utilizing the waste, refer to current rules applicable in your region. No special utilization conditions are specified by the manufacturer for this device
- 12 Keep the device clean. Inspect its cleanliness after use. To clean, use only a soft dry cloth. Do not use gasoline, paint thinner, or other strong solvents. The cuff is resistant to repeated sanitation. The cuff internal fabric surface (being in contact with a patient' arm) can be treated with a cotton swab moistened in a 3% solution of hydrogen peroxide. Partial discoloration of the cuff covering tissue is possible if used for a long time. Do not wash the cuff and do not treat it with a hot iron.
- 13 Do not leave unattended the device plugged into the network.
- 14 Stop using the device immediately and contact your dealer or the manufacturer in case any visible damage is found on the device.
- 15 To avoid any possibility of accidental strangulation, keep this device away from children and do not drape AIR HOSE around your neck.
- 16 Do not press the display or place the device with display face down.
- 17 The device contains small parts and batteries which could be swallowed by children or pets. They should therefore be kept out of the reach of children and pets at all times.
- 18 This device is not designed for self-use by unspecified persons in public areas.
- 19 Any serious incident occurred in relation to the device should be reported to the manufacturer and the competent authority in your country/area. If you have no contact information of such authority, please contact the manufacturer or EU authorized representative whose contact information is indicated in this instruction manual.

## CERTIFICATION AND STATE REGISTRATION

The production of devices is certified pursuant to international standards ISO 9001, ISO 13485, ISO 14001. The device meets international standards IEC 60601-1:2005+A1:2012 and IEC 60601-1-2:2014.

AC Adaptor ADP-W5 meets international standard IEC60601-1 by JQA, class II.

Produced by Nihon Seimitsu Sokki Co., Ltd.

Address: 2508-13 Nakago Shibukawa Gunma 377-0293 Japan

website: [www.nissei.pl](http://www.nissei.pl)

EC-Representative: MDSS GmbH Schiffgraben 41, 30175 Hannover, Germany

## TECHNICAL DESCRIPTION FOR ELECTROMAGNETIC DISTURBANCES

The device complies with the Electromagnetic Disturbances standard, IEC60601-1-2:2014.

As a medical electrical equipment, special precautions regarding the electromagnetic disturbances shall be taken at usage of the device according to the information provided below.

- The device is not intended for use in environments where the intensity of electromagnetic disturbance is high, such as near active HF surgical equipment and MRI (magnetic resonance imaging) equipment etc.



- Use of the device adjacent to or stacked with other equipment must be avoided because it could result in improper operation.
- Use of accessories other than those specified or provided by the manufacturer could result in increased electromagnetic emissions or decreased electromagnetic immunity of the device and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used at least 30cm away from any part of the device, including specified cables. Otherwise, degradation of the performance of this equipment could result.

Please contact your dealer or the manufacturer for specific information regarding the compliance to the standard.



# NIHON SEIMITSU SOKKI CO., LTD.

2508-13 Nakago Shibukawa Gunma 377-0293 Japan

web site: [www.nissei-kk.co.jp/english/](http://www.nissei-kk.co.jp/english/)



MDSS GmbH

Schiffgraben 41, 30175 Hannover, Germany

CE 0123



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