

NISSEI WSK-1011



**INSTRUCTOIN MANUAL
DIGITAL BLOOD PRESSURE MONITOR WSK-1011**

**INSTRUKCJA OBSŁUGI
CIŚNIENIOMIERZA CYFROWEGO WSK-1011**

**РЪКОВОДСТВО ЗА ЕКСПЛОАТАЦИЯ
НА ЦИФРОВ ТОНОМЕТЪР WSK-1011**

**UŽIVATELSKÝ NÁVOD
K DIGITÁLNÍMU TONOMETRU WSK-1011**

**A WSK-1011 TÍPUSÚ DIGITÁLIS TONOMÉTER
HASZNÁLATI UTASÍTÁSA**

**MANUAL DE UTILIZARE
A TENSIOMETRULUI DIGITAL WSK-1011**

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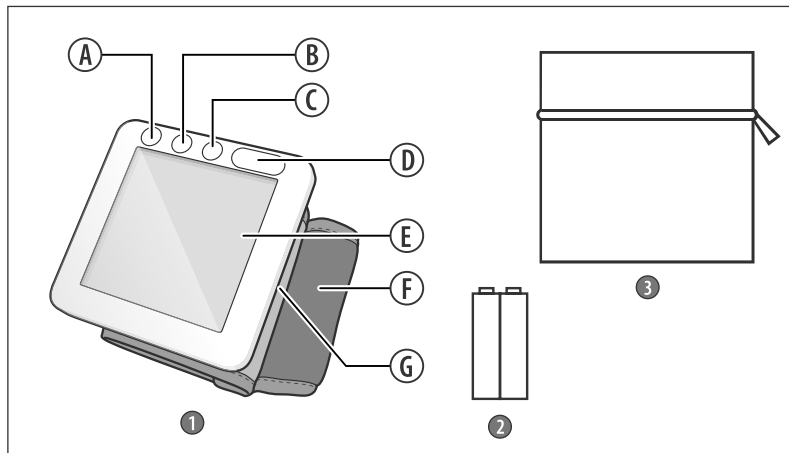
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This manual contains information useful for safe and efficient operation of digital blood pressure monitor model WSK-1011 (hereinafter "Device"). Do not use this device in any manner other than that specified in this manual. Please look thoroughly through this manual and particularly "Recommendations for Correct Measurement".

PARTS AND COMPONENTS



1. ELECTRONIC UNIT
2. BATTERIES
3. BAG

- A. SET BUTTON (SETTINGS)
- B. BUTTON  (MEMORY 1)
- C. BUTTON  (MEMORY 2)
- D. START/STOP BUTTON (START/STOP)
- E. LCD DISPLAY
- F. CUFF
- G. BATTERY COMPARTMENT

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 wrist with a circumference of about 12,5 - 22,5 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.

OPERATION PRINCIPLES

The device uses the oscillometric method of measurement. Connect a cuff to an electronic unit and wrap it around your wrist. When you press the START/STOP button, the device starts the automatic inflation, which is followed by the blood pressure measurement. The sensor element of the device detects slight pressure oscillations in the cuff produced by the expansion and contraction of the brachial artery in response to each heartbeat. Rhythm and amplitude of the pressure waves are measured and displayed on the LC display as a numerical value in millimeters of mercury. The device has an irregular pulse rhythm indicator, as well as two memories with 60 cells in each calculating the average value.

NISSEI New Technologies



Fuzzy Inflation Algorithm – is an algorithm for automatic selection of the cuff inflation pressure. Using this algorithm, the device by itself determines the pressure level to which it is necessary to inflate the cuff based on the patient's systolic pressure. Owing to the Fuzzy Inflation algorithm the device becomes easier to use, while the measurement gets more comfortable and more accurate.



Irregular Pulse Rhythm indicator is a special icon on the display that informs on the irregular heartbeat, while the measurement result is correct.



Touch control – is control of the device by slight touching it.



Body motion indicator – indicator informs the occurrence of possible body motion that can affect the measurement result.



Pulse pressure – along with the measurement result the device displays the pulse pressure value. Pulse pressure is a difference between systolic and diastolic pressure.



M-Cuff series is a unique cuff unit designed and patented by NISSEI. M-shaped cuff can read pulse wave simultaneously from two arteries.

COMPLETE SET

The complete set WSK-1011 includes:

- Electronic unit with cuff – 1 pc.
- Batteries – 2 pcs.
- Bag – 1 pc.
- Instruction Manual – 1 pc.
- Packaging – 1 pc.

RECOMMENDATIONS ON CORRECT MEASUREMENTS

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). 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. 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.

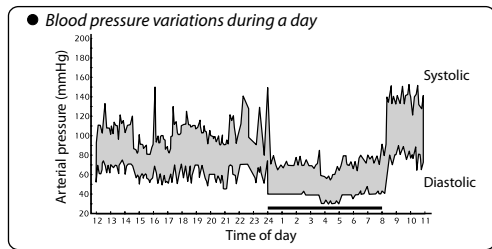


Fig.1

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.
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 wrist. 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 wrist, wrist of which side is under an intravascular access or therapy or an arterio-venous shunt, or wrist 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. Do not inflate the cuff when it is not wrapped around your wrist.
15. Do not apply the cuff on the limb which the intravenous drip infusion is implemented.

POWER SUPPLY OF THE DEVICE

1. Disconnect the battery compartment (Fig.2).
2. Install two "AA" batteries in the compartment.
Make sure that polarity corresponds to signs (+) and (-) shown inside the compartment (Fig. 3).
Batteries are readily installed by pressing the end "-" on the spring.
3. Close the battery compartment.

Do not use excessive force when removing the cover.

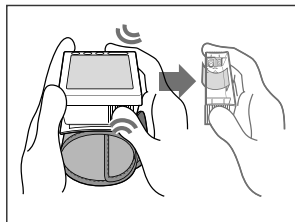


Fig.2

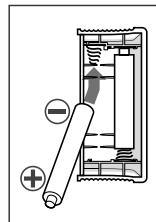


Fig.3

Battery Replacement Indicator

Replace all the batteries when the battery replacement indicator is flashing on the display during the measurement. If upon the device turning on the indicator is steadily flashing, the measurement will not be possible until all the batteries are replaced. The battery replacement indicator does not show a discharge degree.

Use alkaline batteries to increase the device operation duration. Ordinary zinc-carbon batteries require more frequent replacement. The enclosed batteries are meant for testing the sold device, and their operation period can be less than that of batteries acquired in the trade network.



Since neither the device nor the batteries are the waste that can be utilized at home, follow your national/local regulations for waste recycling and take them to corresponding collection facilities

SETTING DATE AND TIME

Date and time can be set after installing batteries. Setting the date and time guarantees the preservation of measurement results with indicated correct date and time. The device can be used without setting the date and time.

Press and hold the SET button until the display flashes the value of the year. Date and time are set in the following order: year, month, day, hour and minute.

1. Setting the Year

Use the **1** button to increase and **2** button to decrease the year value. Press the SET button to confirm and to pass to the next step.

2. Setting the Month

Use the **1** button to increase and **2** button to decrease the month value. Press the SET button to confirm and to pass to the next step.

3. Setting the Day

Use the **1** button to increase and **2** button to decrease the day value. Press the SET button to confirm and to pass to the next step.

4. Setting the Time

Watch uses a 12-hour time format of day. Use the **1** button to increase and **2** button to decrease the hour or minute value. Press the SET button to confirm the settings. To stop the setting, press the «START/STOP» button.

IMPORTANT! If the date and time are set, then when turned off the device display will show the current time.

CUFF PREPARATION

1. Holding your left arm with the palm facing up place a cuff on a wrist so that the meter display is on the palm side. Should you fail to put the cuff on your left wrist, place it on the right one
 2. Place the cuff on your wrist so that its edge is spaced by 5-10 mm off the palm end. Place the meter on the center of your wrist (Fig.4).
 3. Snugly wrap the cuff on your wrist without leaving any space between the cuff and the wrist. Make sure that the cuff comfortably fits your wrist.
- Put the cuff on a bare wrist only. Be careful to prevent your cloth being caught by the cuff.

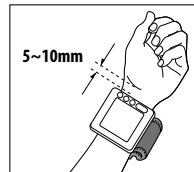


Fig.4

CORRECT POSITION DURING MEASUREMENT

Measurement in the sitting position

1. Sit down on a chair that you can be comfortably seated with your legs uncrossed, feet flat on the floor and back supported. Your forearm should also be supported on the table.
2. Lightly raise your left hand with the palm facing up and put your elbow on the table.
3. Bring the cuff to the heart level placing your arm on a case or folded towel (Fig.5).



Fig.5

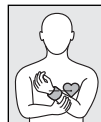


Fig.6



Fig.7

In case of unavailability of a table

1. Sit down on a chair. that you can be comfortably seated with your legs uncrossed, feet flat on the floor and back supported.
2. Bring the cuff to the heart level lightly pressing your left hand to the chest (Fig.6).
3. While measuring lightly support your left arm by the right hand.

Measurement in the lying position

1. Lie on your back.
2. Bring the cuff to the heart level using a case and folded towel (Fig.7).

Try to use the same wrist and position for measurement.

If the cuff is positioned above/below the heart, resulting reading may be incorrect (lower/higher).

MEASUREMENT PROCEDURE

IMPORTANT! The device has touch-sensitive buttons that are pressed by slight touching. Moisture, dirt and extraneous objects between the finger and the device panel can affect the ability of buttons to respond to touching.

Before measurement, take a few breaths and relax. During the measurement, do not talk and do not move.

1. Press the START/STOP button. The deflating symbol «**∇**» will flash on the display, and the device will release the remaining air from the cuff (Fig.8).
2. Beep will be heard, and air will be pumped into the cuff. The symbol «**▲**» will flash, and the displayed value will increase (Fig.9). Inflation will stop at optimum level owing to the Fuzzy Inflation algorithm.
3. The symbol «**▲**» will disappear and measurement will start up. The pressure cuff will slowly deflate.



Body Motion Indication

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. «**⚠**» indicates the results might be affected by body movement.

Press the START/STOP button to stop forcibly the measurement: the device will stop inflation and quickly release the air.

4. Symbol «**♥**» will start flashing simultaneously with the beep immediately after the pulse rate is detected (Fig.10).

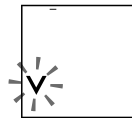


Fig.8

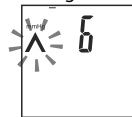


Fig.9



Fig.10

5. When the measurement is completed, the display will show the values of blood pressure, pulse pressure, WHO scale and heart rate (Fig.11). The device will automatically release the air from the cuff.
6. Press the **1** button or **2** button and the result will remain in the selected memory unit.
7. Press the START/STOP button to turn off the device.

If you forget to turn off the device, it will do so automatically after 3 minutes.

Do not perform several measurements in a row.

This will cause numbing the arm and can affect the measurement result. Give your wrist a break for at least 5 minutes.

INDICATION OF IRREGULAR PULSE RHYTHM

The flashing symbol «⊕», appeared on the display reports on an irregular heartbeat rhythm (Fig.12). If this symbol appears from time to time, refer to your doctor. The irregular pulse rhythm indicator occurrence can be also caused by body movements in the course of the measurement.

INDICATION OF READINGS BY THE WHO SCALE

In addition to pressure numerical values, the result is also displayed as a graphic scale. This scale makes it possible to classify the obtained blood pressure value in accordance with the World Health Organization recommendations. The scale appears along with the numerical value of blood pressure in the lower right corner of the display (Fig.13).

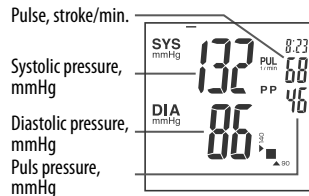
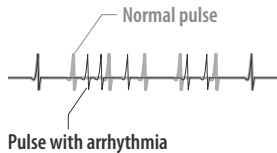


Fig.11



Normal pulse

Pulse with arrhythmia

Fig.12

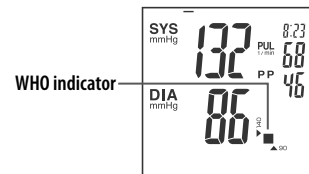


Fig.13

Table of Results by the WHO Scale

Indication	WHO Classification	SYS	DIA
	Hypertension (severe)	>180	>110
	Hypertension (moderate)	160-179	100-109
	Hypertension (slight)	140-159	90-99
	Increased normal pressure	130-139	85-89
	Normal pressure	120-129	80-84
	Optimal	<120	<80

Indication of Pulse Pressure

This device calculates and displays the pulse pressure value (Fig. 14). Pulse pressure – a difference between the systolic and diastolic pressures – tends to increase with aging.

Systolic blood pressure continues to increase with aging, while diastolic blood pressure tends to decrease since the age of about 50 years.

It is considered that a high pulse pressure is related to poor elasticity of arteries and is one of the risk factors for circulatory diseases. Pulse pressure is considered to be normal when it attains 35 ± 10 mm Hg.

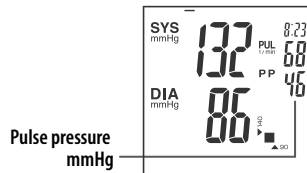


Fig.14

MEMORY FUNCTOIN

The measured values are automatically saved for later viewing in the selected memory unit. These memory units can be used to save separately the measurement results of two different persons or to save separately the results of morning and evening measurements.

Each unit can keep up to 60 measurement results and the average value thereof. When the number of kept values exceeds 60, the oldest readings are deleted to record new values.

Saved values are kept with the measurement date and time, if set. If you want to save time and date together with the measurement values,

date and time should be set before the measurement. When an error occurs (ERR), the measurement results are not saved.

Viewing the Saved Data

1. Turn off the device by pressing the START/STOP button. To view the results stored in the memory unit 1, press **[1]**, and to view the results stored in the memory unit 2, press **[2]**. The selected memory unit will be underlined on the display. The display shows the average value of stored results indicated with index «**1**» (Fig.15). Average value is displayed when the selected memory unit contains two or more saved measurement results.
2. Each time you press the **[1]** button or **[2]** button, saved measurement results will be displayed in a sequential manner.
3. Memory unit number, measurement date and time will be displayed one by one in the upper right corner of the display.
4. The result saved in the memory unit 1 is the most recent among the saved data in the selected memory. The higher memory number, the older the result. The memory data are displayed for about 30 seconds and after that, if no button is pressed, the device is automatically turned off. Pressing the **[2]** button switches the display from records in the memory unit 1 to records in the memory unit 2, while pressing the **[1]** button results in returning to data recorded in the memory unit 1.
5. Press the START/STOP button to turn off the device.

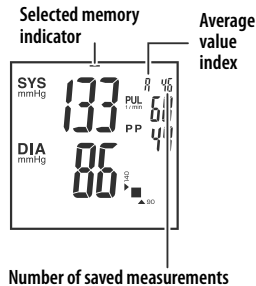


Fig.15


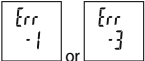
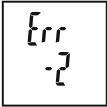

Deletion of Saved Data


Readings can be deleted unit by unit: all together or separately. The memory may be cleared when the selected memory unit contains two or more results.

1. Select a value from the memory unit to be deleted or the average value (unit with index «**1**») to clear the whole memory unit.
2. Press and hold the **[1]** button or **[2]** until the sign «---» appears on the display.

INFORMATION ABOUT ERRORS

INDICATION	LIKELY CAUSE	METHODS OF CORRECTION
Blood pressure is too low or too high.	The cuff is not at the heart level. The cuff is put on incorrectly. During the measurement, a person was talking or moving.	Put on the cuff at the heart level. Check the cuff position on the wrist. Be calm and quiet during the measurement.

Measurement results are different each time.	Effect of measurement conditions, physical or mental state.	Take measurements under the same conditions.
Measurement results are different in clinic and at home.	Effect of relaxed state at home and tension in clinic.	Show the pressure records made at home to your doctor for advice.
Inflation is repeated.	If the initial pressure is insufficient, inflate the cuff again. Inflate the cuff till your pressure will be successfully measured.	Re-inflation is not a malfunction of the device. Do not talk and do not move during the measurement.
	Maximum allowable pressure: pressure can not be measured due to movement or talking during the measurement, in spite of the fact that the cuff was pumped at maximum.	Do not talk and do not move during the measurement.
	Pressure can not be measured due to movement or talking.	Do not talk and do not move during the measurement.
	Cuff is not securely connected to the device. Cuff is not put on properly.	Check the connection. Make sure that the cuff is put on correctly.
	Batteries are discharged.	Replace all batteries with new ones.
No time indication on the display.	Time was not set. Note: there is no time indication when batteries and/or power source are not provided.	Set time and date. Install batteries and connect the power source.
Date and time are displayed as «--/--».	Time was not set or measurements were carried out before setting the time.	Set date and time. Date and time can not be saved without setting.

Nothing is shown on the display.	Batteries are discharged. Batteries are installed incorrectly. Connecting terminals are contaminated. Power source is not connected.	Replace all batteries with new ones. Install batteries properly. Wipe connecting terminals with a dry cloth. Connect the power source.
	You touched the START/STOP button when installing the batteries.	Turn off the device by pressing the START/STOP button and perform the measurement again.

If, despite the above-given recommendations, you fail to obtain the right measurements, stop the operation and contact the service center (addresses and telephone numbers of authorized organizations are provided in the warranty certificate). Do not attempt to adjust the device internal mechanism on your own.





WARRANTY

1. The manufacturer guarantees the warranty period of 5 years for the device from the sale date provided that the consumer observes operation, transportation and storage requirements. The warranty period for the cuff and the power source is 12 months from the sale date.
2. Warranty liabilities are documented with the warranty certificate upon selling the device to the buyer. The guarantee is valid provided that the device has not been opened or damaged by the buyer.
3. Addresses of organizations engaged in the warranty service are specified in the warranty certificate.

TECHNICAL SPECIFICATIONS

Operating Principle	Oscillometric method
Indicator	15 digits liquid crystal display
Indicating Range: cuff pressure, mmHg	0-300
Measuring Range : cuff pressure, mmHg pulse rate, bpm	50-250 (systolic), 40-180 (diastolic) 40 - 160

Accuracy:	
cuff pressure, mmHg	±3
pulse rate, %	±5
Inflation	Automatic inflation (air pump, Fuzzy Inflation algorithm)
Deflation	Automatic Deflation (electric valve)
Electric supply voltage, V	6
Electric supply type	Two 1.5 volt LR6 (AA alkaline) batteries
Memory	2 units, 60 values per each + average value
Operating Condition	
temperature, °C	+10 to +40
humidity, % Rh	15 to 85
Storage Condition	
temperature, °C	-20 to +60
humidity, % Rh	10 to 95
Cuff Size	adult (circumference of the wrist 12,5-22,5 cm)
Overall dimensions:	
Size (electronic unit), mm	70 x 70 x 27
Weight (without packaging, bags and batteries), g	110
Manufacture year:	specified on the device housing (in the battery compartment) in the device serial number after the letters «SN»
Protection level	IP 20: 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, Type BF applied part
Mode of operation:	Continuous operation
Classification:	Internally Powered Equipment
Expected Service Life:	5 years

-  Type BF applied part
-  Refer to instruction manual/booklet
-  Keep dry
-  When utilizing the waste, refer to current rules applicable in your region

*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 EXXX/YYMM/XX, where YY is the year and MM is the month of revision.

CARE, STORAGE, REPAIR AND DISPOSAL

1. Because the product includes precision parts, avoid extreme temperature variations, humidity, shock, dust, lint, and direct sunlight. Do not drop or strike the product. Make sure not to expose it to moisture. This product is not water resistant.
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 product clean. Inspect its cleanliness after use. To clean, use only a soft dry cloth. Do not use gasoline, paint thinner, or other strong solvents. Since the cuff may absorb perspiration and other fluids, inspect it for stain and discoloration after each use. The cuff is resistant to repeated sanitation. The cuff internal fabric surface (being in contact with a patient' wrist) 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.
13. Stop using the device immediately and contact your dealer or the manufacturer in case any visible damage is found on the device.
14. Do not press the display or place the device with display face down.
15. 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.
16. This device is not designed for self-use by unspecified persons in public areas.
17. 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 such as ISO 9001, ISO 13485, ISO 14001.

The device meets international standards IEC 60601-1:2005+A1:2012 and IEC 60601-1-2:2014.

Complaints and requests should be addressed to:

Little Doctor Europe Sp. z o.o.

57G Zawila Street, 30-390, Krakow, Poland

Tel.: +48 (12) 268-47-46, (12) 268-47-47. Fax: +48 (12) 268-47-53

E-mail: biuro@littledoctor.pl

Produced by Nihon Seimitsu Sokki Co., Ltd.

Manufacturer: NIHON SEIMITSU SOKKI CO., LTD.

2508-13 Nakago Shibukawa Gunma 377-0293 Japan

web site www.nissei.pl

TECHNICAL DESCRIPTION

WSK-1011 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.



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