NISSEI

PULSE-OXIMETER

Pulsefit®

BO-750/BO-750BT

Instructions

Table of contents

General information

BO-750 is designed to measure %SpO_2 and pulse rate accurately, quickly and simply at a fingertip using high precision optical components and sophisticated analogue-digital circuits.

Haemoglobin in blood turns to oxyhaemoglobin in the lungs to carry oxygen to body cells and turn itself to deoxyhaemoglobin after transferring oxygen to the body cells and returning to the lungs. These oxyhaemoglobin and deoxyhaemoglobin are well known to absorb specific wavelength of lights, infrared and visible red, respectively. BO-750 is calibrated to display functional oxygen saturation analyzed from pulse wave length detected with two high-precision light emitting diodes (LED) emitting infrared and visible red lights individually from one side and a photo diode receiving these lights passing through fingertip at the other side.

This device is for medical staff use.

Warning and precaution

Do not use BO-750 along with, near, in, or for,

- **MRI (MR), electrosurgical unit, defibrillator, mobile phone, RF communication equipment, or hyperbaric oxygen treatment devices**
- **an explosive environment such as where flammable anaesthetics exist or inside oxygen chamber**
- **infant or neonate (BO-750 is designed for adults.)**

Measurement can be affected by or unreliable readings may result from

- **lotions, nail polish and unclean fingertip**
- **stain or scratch of surfaces of LED or photo sensor**
- **strong lights, e.g., sun light or surgical light**
- **improper positioning of the device: fingertip not correctly placed on LED and under photo sensor**
- **movement of fingertip during measurement**
- **radiocontrast agent, methylene blue, indocyanine green, indigo carmine or intravascular dye**
- **CPR treatment**
- **high level of methemoglobin or carboxyhemoglobin**
- **weak pulse signal**
- **restricted circulation of blood or congestion of blood**

BO-750 is not designed to be used at a single spot for an extended time period. Switch fingers periodically if measurement is conducted for over 30 minutes. Change of application spot is also required under such conditions as high fever or peripheral circulatory insufficiency for application of the device could result in sectional rise in temperature.
Do not fix BO-750 to finger with cables or tapes.

Before starting measurement, make sure that

- **both LED and photo sensor surfaces are clean and clear.**
- **finger is clean. Do not use BO-750 on injured or wounded fingers.**
- **batteries have enough power for long term measurement. Exhausted batteries may cause unexpected interruption of measurement during operation.**

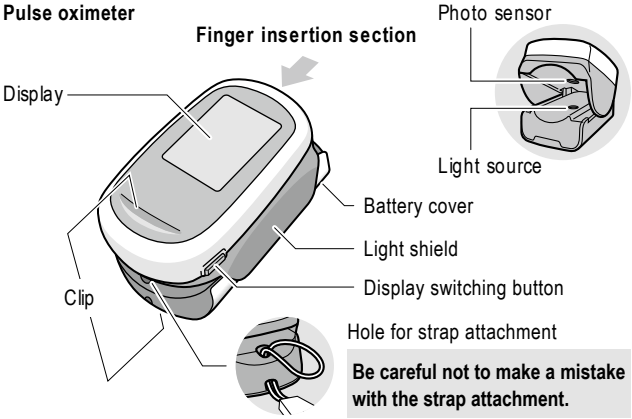
Judgment such as change of dosage of a drug based on measurement results should not be made without professional consultation.

Do not disassemble or modify the device.

Are the following items included?

Check if the following items are included. If anything is missing, contact your distributor.

Pulse oximeter

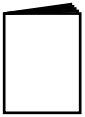


Be careful not to make a mistake with the strap attachment.

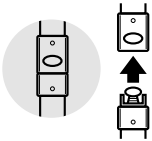
Single AAA alkaline battery
(for testing)

*Enclosed battery is for testing purposes.
Its life may be shorter than those sold commercially.

Instruction manual



Strap



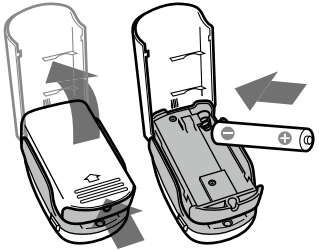
The strap is designed to be safely detachable e.g. when a strong force is applied.
If it is detached, align the protruding side to the side with the opening to fix it back.

Inserting battery

Slide the battery cover at the back of the device in the direction of the arrow to open.

Put in the single AAA alkaline battery (LR03) as shown on the device and close the battery cover.

When inserting or removing the battery, push the negative side of the battery against the spring.



Regarding the use of rechargeable batteries

Although this device can also be used with a rechargeable battery, the battery mark may not appear correctly.

All indicators will appear and the initial test will be carried out if the battery is inserted correctly.

Do not start the measurement during the initial test.

* The display value may vary.

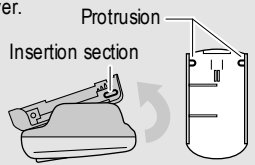
All indicators (approximately 2 sec)

Initial test*

When the battery cover is detached

Open the finger insertion section and insert the protrusions on the cover into the side of the device to install the cover.

Insert the protrusion on one side first and open the cover a little to insert the other side. Be careful not to forcefully widen the cover too much or insert the protrusion forcibly.



About the battery

Replace the battery when the battery mark ( ) appears. Measurement cannot be taken when the indicator changes from flashing to lit.

The battery mark which appears when all indicators are lit does not mean that the battery is due for replacement.

- Dispose used batteries in a proper manner in accordance with the regulations of each municipality.
- Check the expiry date of the battery. Using expired batteries will result in a malfunction or failure.
- Take out and store the battery when not using the product for an extended period of time. The battery liquid may leak and damage the product.

Making measurement

Measurements cannot be taken correctly in the following situations

Hand and device are cold

When cold, blood vessels constrict and blood flow deteriorates, making measurement impossible.

- If your fingertip is cold, warm your finger by massaging it to improve blood flow first before measuring.
- If the device is cold, the fingertip to be measured may become chilled. Warm up the device a little first before measuring in a warm place.

Moving

Measurement is not possible if the pulse wave cannot be detected normally.

- Do not move your fingertips or body during measurement.
- Your pulse will be disturbed by your physical and mental condition when you are surprised or when you walk. Rest for a while first before measuring.

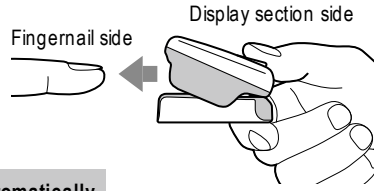
Light does not reach the finger

Measurement is not possible if your finger does not touch the light source and photo sensor inside the device.

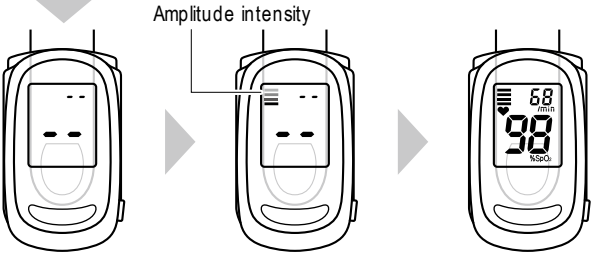
- Insert your finger fully all the way in so that it contacts the light source and photo sensor. In addition, take note that your finger may not reach the light source and photo sensor e.g. when your fingernail is long.

Hold the clip on the device, open the finger insertion section, and fit it on your finger so that the **display is on the fingernail side**.

Insert your finger fully all the way in **so that it contacts the light source and photo sensor on the inside of the device**.



Measurement starts automatically when you put on the device



When measurement starts, the pulse wave is detected and the amplitude intensity is displayed.

Measurement results are displayed about 8 sec after measurement starts. Read the measurement value after the value stabilizes. (after approximately 8 beats)

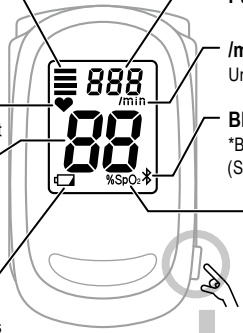
See page 10 for the display of the measurement results.

Amplitude intensity
The intensity of the amplitude of the detected pulse is indicated in 4 levels.

Stability mark
Indicates that the measurement condition is favorable

Blood oxygen saturation level
Backlight turns orange when the level is less than 90%.

Battery mark
Indicates that the battery is depleted
(See page 7)



Pulse rate

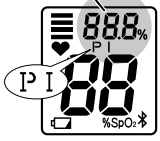
/min
Unit of pulse rate (bpm)

Bluetooth mark
*BO-750BT only
(See page 12)

%SpO2
Unit of blood oxygen saturation level

PI value
(PI：Perfusion Index Unit：%)

Press the display switching button to switch the pulse rate display and PI value display.
PI value display returns to the pulse rate display automatically after about 30 sec.



Display for about 30 sec

Press and hold for 3 sec

Connection ID
(example：0123)

Press and hold the display switching button for 3 sec or longer to switch to the communication mode, upon which the Bluetooth mark will flash.
If there is no connection, the display will return to the measurement results automatically after about 60 sec.

BO-750BT only

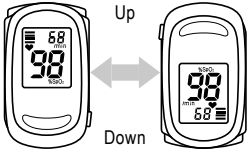
* Communication mode is available for the BO-750BT only.
There is no communication function in the BO-750.

Measurement is not possible if the backlight turns orange and Er appears.
For information about the error display, see page 14.

When the device is removed, the measurement ends automatically and the power supply is switched off after about 8 sec.

Auto display switching

Invert the device to automatically switch the display.
If the top and bottom of the display cannot be determined, read in the direction that SpO_2 can be read correctly.



Memory function

Press the display switching button with the power supply turned off to display the value which appeared when the last measurement ended.

1.5 sec display 1.5 sec display

The memory is erased when the battery is removed.
Er is not recorded.

Performing data communication (BO-750BT)

Installing the app

1. Get ready a smart phone etc.

Compatible OS

- iOS8 or higher
  (Compatible with only iPhone 4s or higher and 5th generation iPod touch)
- Android 4.3 or higher (equipped with Bluetooth 4.0 or higher)

2. Download **NISSEI HealStyle** from the Apple **App Store** or Google **Play Store**.

NISSEI HealStyle

3. Start NISSEI HealStyle and perform user registration.

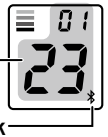
Performing communication

1. Tap the pulse oximeter on the app screen.
2. Wear the pulse oximeter on your finger and start the measurement.

3. Once the measurement results appear, press and hold the display switching button on the main unit for 3 sec or longer.

The Bluetooth mark will flash and the mode will switch to the communication mode.

If there is no connection, the display will return to the measurement results automatically after about 60 sec.



4. Tap Receive at the top right of the app screen.

5. Register the connection ID in the app (if unregistered)
   Register the connection ID (4-digit number) displayed in the main unit of the pulse oximeter in the app.

6. Start the data communication.

   Using the app, the BO-750BT can manage the measurement results with a smart phone.
   See the NISSEI website for more information on how to run the app.
   http://www.nissei-kk.co.jp/english/

- If the connection is not smooth, remove your finger from the main unit to end the measurement once before re-connecting.
- Do not remove the battery from the main unit during data transmission.

Error displays and troubleshooting

Indication	Cause	Countermeasure
	Signal is not detected	Re-install the device so that your finger is in contact with the light source and photo sensor.
	An object is stuck in the finger insertion section	Remove the stuck object.
 	Pulse rate can be measured but the blood oxygen saturation level cannot be measured	More information from the pulse wave detected is required in the measurement of the blood oxygen saturation level. Conduct the checks to ensure correct measurement one more time before measuring. Measure with another finger if the pulse amplitude intensity is small and the signal is weak.
 Nothing appears	Battery is not inserted	Insert the battery.
	Battery is inserted with wrong polarity	Re-insert the battery correctly.
	Battery is depleted	Replace with a new battery.
	Battery terminal (connection section) is stained	Clean with a dry cloth.
	Initial test: Initial test is carried out when the battery is inserted	This is not a malfunction. * The display value may vary.

Indication	Cause	Countermeasure
	Initial test error: A finger was inserted or an object was stuck in the finger insertion section during the initial test.	Check that there is nothing in the insertion section, and start the measurement after the initial test error display disappears. * Contact your distributor if the initial test error appears even if no finger or object has been inserted.

Care and maintenance

Calibration

No calibration or adjustment is required for the life of the product.

Cleaning

Wipe stain or dirt with soft cloth damped with neutral detergent or isopropyl alcohol. Remove batteries before cleaning.

Handling and Storage

Because the unit includes precision parts, care should be taken to avoid extreme temperature variations, humidity, shock, dust, and direct sunlight. **Do not drop or expose the device to strong shocks. Use strap to prevent accidental fall.** Avoid storing BO-750 in a gaseous atmosphere or places where chemicals are used or they are in the air. Take out batteries to prevent battery solution leakage when BO-750 is not to be used for an extended period of time. **Keep the batteries out of reach of children.**

Disinfection

Autoclaving is not possible.

Water resistance

BO-750 has limited water resistance. Do not immerse the device in liquid, nor expose to excessive moisture.

Specifications

Operating principle	Double wavelength lights absorption method	
Measurement Range	%SpO_2	0 - 100%
	Pulse rate	30 - 240 bpm
Accuracy*	%SpO_2	±2% (70%≤SpO_2≤100%)
	Pulse rate	±3%/±1 digit (30 - 240 bpm)
Power source	One single AAA alkaline (LR03) battery	
Rated voltage	DC 1.5 V	
Rated power consumption	0.09 W	
Bluetooth compatibility standard	Bluetooth Low Energy 4.1	
Operating condition	+10°C to +40°C, 30% to 85% RH (no condensation)	
Transportation/storage condition	-20°C to +60°C, 10% to 95% RH (no condensation)	
Size	Approximately 60 (H) × 35 (W) × 32 (D) mm	
Weight	Approximately 37 g (without batteries)	
Electric-shock Protection	Internally powered equipment, Type BF applied part	
Protection class IP	IP22: Protected against solid foreign particles with a diameter of more than 12.5 mm, no protection against water.	
Mode of operation	Continuous operation	
Key to symbols		Type BF applied part
		Refer to instruction manual/booklet.
		No SpO_2 alarms
		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.

Specifications are subject to change without prior notice due to improvements in performance and quality. *Accuracy for %SpO_2 is a statistical standard deviation and up to 68.3% of reading may fall into this limit and other may fall out of this limit. Information on the range of the peak wavelengths and maximum optical output power of the light emitted by the pulse oximeter can be useful to a clinicians performing photodynamic therapy. Contact Nissei Healthcare (UK) Ltd., our EC representative for any further information.

Technical description

BO-750 complies with the EMC, electromagnetic compatibility, standard, IEC60601-1-2. Refer to the tables below for specific information regarding compliance to the standard. BO-750, 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. BO-750 should not be used adjacent to or stacked with other equipment.

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

BO-750 is intended for use in the electromagnetic environment specified below. The customer or the user of BO-750 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	BO-750 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	BO-750 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 -

BO-750 is intended for use in the electromagnetic environment specified below. The customer or the user of BO-750 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 -

BO-750 is intended for use in the electromagnetic environment specified below. The customer or the user of BO-750 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of BO-750, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	N/A
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d=1.2\sqrt{P}$, 80 MHz to 800 MHz $d=2.3\sqrt{P}$, 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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 BO-750 is used exceeds the applicable RF compliance level above, BO-750 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating BO-750.

[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 BO-750 -

BO-750 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of BO-750 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and BO-750 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, $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz, $d=2.3\sqrt{P}$
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 charge for inspection, adjustment, repair and labour. Evidence of date of purchase is required for warranty. 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. Purchaser shall bear transport or shipping related costs. NISSEI is not liable for any consequential damages caused by BO-750, direct or indirect, economically or biologically.

NISSEI CE 0123

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