NISSEI

PULSE-OXIMETER

pulsfit

BO-750/BO-750BT

User manual <English>

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General information

Intended Use

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.

The product is a designed for the professional 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.

Operating Principles

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.

Peak wavelength range *

Red light : 655~665nm (typical value: 660nm)

Infrared light : 880~910nm (typical value: 900nm)

Maximum optical output power

Red light : 29.0mW

Infrared light : 10.5mW

(component spec. under the condition of IF=20mA)

* Information of the peak wavelength range is provided for the utility of clinicians performing photodynamic therapy etc.

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**
- **low amplitude intensity or PI value**
- **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.

No materials which have toxicity or the effect on tissues are used for the device. However please consult a doctor in case a rash, inflammation or similar appears on the finger during the use.

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.

Displayed Symbols


Type BF applied part


Refer to instruction manual/booklet.

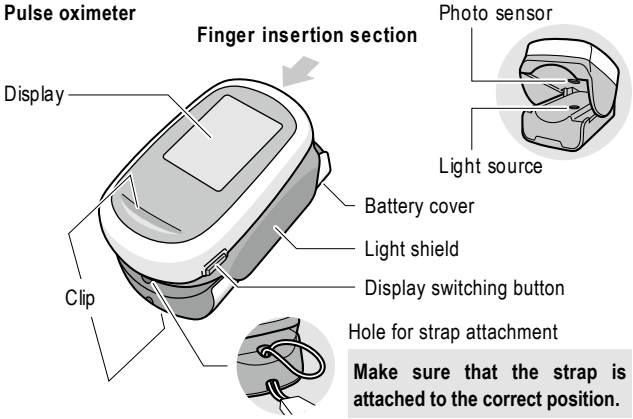
No SpO_2 alarms


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.

Are the following items included?

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

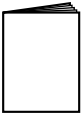
Pulse oximeter



Make sure that the strap is attached to the correct position.

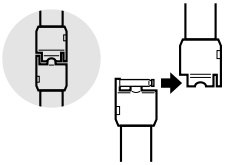
AAA alkaline battery
(for test use)

User manual



Strap

*Enclosed battery is for test use purpose.
The life may be shorter than that of commercial batteries.



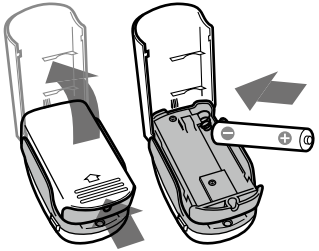
The strap is designed to come apart for safety reasons if subjected to strong forces. If it comes apart, please insert the male side connector by sliding it sideway to the female side connector as shown in the picture.

Inserting battery

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

Put in one 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.

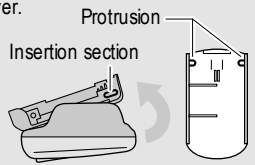
All indicators (approximately 2 sec)

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 mark changes from blinking to remaining indication.

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

- Dispose used batteries in a proper manner in accordance with the local regulations.
- Check the expiry date of the battery. Using expired batteries will result in a malfunction or failure.
- Take out 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 they are cold, blood vessels are constricted and blood flow is deteriorated. It causes the disturbance of measurement.

- If your fingertip is cold, warm your finger by massaging etc. to improve the blood flow before making a measurement.
- If the device is cold, fingertip may also be cooled during the measurement. Warm up the device a little and make a measurement in a warm place.

Moving

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

- Do not move your fingertips or body during measurement.
- The pulse will be disturbed by the physical and mental conditions such as feeling stresses and walking. Rest for a while before making a measurement.

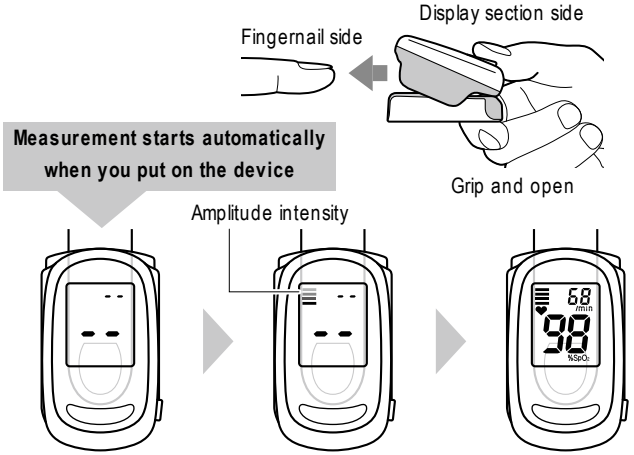
Light does not reach the finger

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

- Make sure that the finger is inserted to the end of opened device and that the fingertip is centered at the light source and photo sensor. Please be aware that the finger may not reach the light source and photo sensor if the fingernail is long.

Hold the device and pinch it like shown in the picture to open the finger insertion part and fit it on your finger with **the display side of the device on the fingernail side.**

Insert your finger to the end so that **the fingertip is centered at the light source and photo sensor inside the device.**



The pulse detection and the indication of amplitude intensity will soon be shown in the display.

Measurement results are displayed about 8 sec. after the measurement starts. The measurement value should be read and recorded after the values are stabilized. (approx. 8 beats after the measurement results are displayed)

See page 10 for the display of the measurement results.

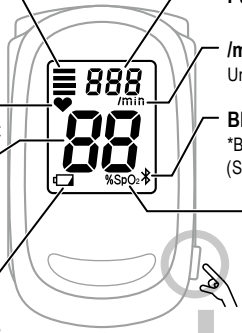
For BO-750BT, once the measurement results appear, the Bluetooth mark will start blinking and the mode will switch to the communication mode.
See page 12 for details on data communications.

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

Stability mark
Indicates that the measurement condition is favorable

Blood oxygen saturation level
Backlight turns to 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 while the measurement results are shown to display the connection ID.
If data communication is not carried out, the display will return to the measurement results automatically after about 60 sec.

BO-750BT only

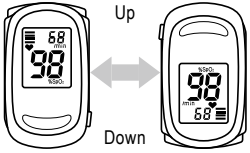
* Communication mode is available for BO-750BT only.
There is no communication function in BO-750.

Measurement is not possible if the backlight turns to 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 while the device is turned off to display the measurement results at the end of the last measurement.

1.5 sec display 1.5 sec display

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

Performing data communication (BO-750BT)

Installing the app

1. Get ready a Smartphone etc.

Compatible OS

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

*Please make sure that the mobile computing platform (Smartphone etc.) connected to BO-750BT conforms to applied safety, EMC, and Wireless communication standards.

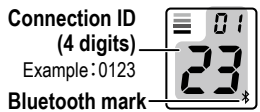
2. Download **NISSEI HealStyle** from the Apple **App Store** or Google **Play Store**.
3. Start NISSEI HealStyle and register the user information.

NISSEI HealStyle

Starting the data communication

1. Tap the pulse oximeter on the app screen.

2. Wear the pulse oximeter on your finger and start the measurement.
   Once the measurement results appear on the display, the device will automatically switch to the communication mode.
3. Press and hold the display switching button on the main unit for 3 sec or longer. (If the connection ID is registered in the app, this step is not required.)
   The connection ID will appear.
   If data communication is not carried out, the display will return to the measurement results automatically after about 60 sec.



4. Tap Reception 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. (If the connection ID is registered in the app, this step is not required.)

6. Start the data communication.

   The management of the measurement results with Smartphone is possible for BO-750BT by using the app.
   See the NISSEI website for more information on how to run the app.
   http://www.nissei-kk.co.jp/english/

- If you register the connection ID in the app, you will not need to enter the connection ID the next time you want to perform data communication.
- If the connection is not stable, 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 displayed value may vary.)

Indication	Cause	Countermeasure
	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.
	Sensor is not working properly.	Contact your distributor.

* When the measurement of %SpO_2 or pulse rate is not possible for more than 20 seconds, Err is displayed. In case of the pulse rate measurement error, %SpO_2 also becomes error automatically.

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 result display	Average of 4 pulses (automatic update at every pulse)	
Measurement Range	$\%SpO_2$	0 - 100%
	Pulse rate	30 - 240bpm
Accuracy	$\%SpO_2$	±2% (70%≤SpO_2≤100%) *1
	Pulse rate	±3%/±1 digit (30 - 240bpm) *2
Power source	One AAA alkaline (LR03) battery	
Rated voltage	DC 1.5V	
Rated power consumption	0.09W	
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 37g (without battery)	
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 12.5mm, and dripping water when tilted up to 15 degrees.	
Mode of operation	Continuous operation	

The device conforms to the particular standard, ISO 80601-2-61:2011 Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.

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

*1 The $\%SpO_2$ measurements are statistically distributed and approximately two-third of the measurement results are expected to fall within the designated measurement accuracy against $\%SaO_2$ values.
The validation of the measurement accuracy was conducted by the clinical test with comparison against $\%SaO_2$ for healthy, xanthous, male adult subjects.
Functional tester cannot be used to assess the $\%SpO_2$ accuracy of the device.

*2 Pulse rate accuracy was validated with an electronic pulse simulator.

Contact Nissei Healthcare (UK) Ltd., our EC representative for any further information.

Technical description

BO-750/BO-750BT complies with the EMD, electromagnetic disturbance, standard, IEC60601-1-2:2014.
Please refer to the following tables for specific information regarding the compliance to the standard.

BO-750/BO-750BT, as a medical electrical equipment, needs special precautions regarding EMD and needs to be installed and put into service 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 this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm to any part of the device. Otherwise, degradation of the performance of this equipment could result.

Electromagnetic emissions

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	BO-750/BO-750BT 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	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Electromagnetic immunity

ENCLOSURE PORT

Phenomenon	Basic EMC standard or test method	IMMUNITY TEST LEVELS
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM fields	IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
RATED power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz

PATIENT coupling PORT

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation 18 Hz	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28
710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	9
745				
780				
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28
870				
930				
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28
1845				
1970				
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9
5500				
5785				

Declaration for Directive 2014/53/EU:

Hereby, NIHON SEIMITSU SOKKI CO., LTD. declares that BO-750BT is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address:
http://www.nissei-kk.co.jp/english/medical/pulse/

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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