

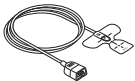
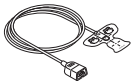
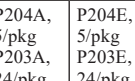
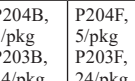

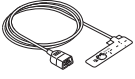
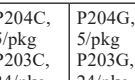
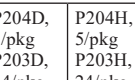
OPERATOR'S MANUAL
SpO₂ Probe
**TL-271T, TL-271T3, TL-272T, TL-272T3,
TL-273T, TL-273T3, TL-274T, TL-274T3**

本品は、出荷される国や地域により仕様等が異なることがあります。
※ 日本向け製品については、日本語で記載しています。
英語などその他の言語で記載されている内容は、日本以外に出荷される製品の説明です。

Some specifications of this product may differ depending on the destination country or region. Therefore descriptions in the Japanese manual and English and other language manuals may also differ.

General

This probe is a disposable probe for single patient use. The probe can be used multiple times with the same patient until the adhesive tape loses its adhesion. It is a one piece probe with adhesive tape that is easy to attach on the patient skin. The probe is not sterilized and is not made with natural rubber latex. The probe can be used with a Nihon Kohden device with SpO₂ measurement. Some devices require a connection cable to connect the probe.

Model	TL-271T	TL-271T3	TL-272T	TL-272T3
				
Supply Code, Qty	P204A, 5/pkg P203A, 24/pkg	P204E, 5/pkg P203E, 24/pkg	P204B, 5/pkg P203B, 24/pkg	P204F, 5/pkg P203F, 24/pkg
Suitable Weight (Reference)	30 kg or more, adult		10 to 50 kg, child	
Attachment Site	Finger or toe		Finger or toe	
Model	TL-273T	TL-273T3	TL-274T	TL-274T3
				
Supply Code, Qty	P204C, 5/pkg P203C, 24/pkg	P204G, 5/pkg P203G, 24/pkg	P204D, 5/pkg P203D, 24/pkg	P204H, 5/pkg P203H, 24/pkg
Suitable Weight (Reference)	3 kg or less, neonate 40 kg or more, adult		3 to 20 kg, infant	
Attachment Site	Neonate: instep and sole Adult: finger or toe		Finger or toe	
Cable Length	TL-271T, TL-272T, TL-273T and TL-274T: approx. 80 cm TL-271T3, TL-272T3, TL-273T3 and TL-274T3: approx. 160 cm			
















Recommended Maximum Attachment Time at One Measurement Site

8 hours



For details, refer to the "Monitoring" section.

Symbols

The following symbols are used with the SpO₂ probe. The names and descriptions of each symbol are as shown in the table below.

Symbol	Description	Symbol	Description
	Caution		Do not reuse
	Date of manufacture		Manufacturer
 (Background color: Blue)	Follow instructions for use		European representative
	Atmospheric pressure limits		Keep away from rain
	Humidity limits		Temperature limits
	Fragile		Lot number
	CAUTION: United States law restricts this product to sale by or on the order of a physician.		
	The CE mark is a protected conformity mark of the European Community. The four digits after the CE mark indicate the identification number of the Notified Body involved in assessing the product's conformity as a medical device.		
	Products marked with this symbol comply with the European WEEE directive 2012/19/EU and require separate waste collection. For Nihon Kohden products marked with this symbol, contact your Nihon Kohden representative for disposal.		

Safety Information

-  **WARNING** A warning alerts the user to possible injury or death associated with the use or misuse of the instrument.
-  **CAUTION** A caution alerts the user to possible injury or problems with the instrument associated with its use or misuse such as instrument malfunction, instrument failure, damage to the instrument, or damage to other property.

Pay attention to all safety information in this operator's manual.

General
 **WARNING**

When performing MRI test, remove this probe from the patient. Failure to follow this warning may cause skin burn on the patient. For details, refer to the MRI manual.

⚠ CAUTION

- Use this probe only with the specified instruments. If this probe is connected to an unspecified instrument, pulse signals may not be detected, measured values may be incorrect, or the patient may get skin burn.
- Do not use a damaged, disassembled, modified or faulty probe. It causes incorrect measurement and may injure the patient.
- Handle the probe cable according to the following cautions. Failure to follow these cautions may cause cable discontinuity or short circuit of the probe cable which may cause incorrect measurement data or inability to perform measurement. Also in rare cases, the probe temperature may increase and cause skin burn on the patient. If the probe cable is damaged, replace the probe with a new one.
 - Do not pull or bend the probe cable.
 - Do not let caster feet run over the probe cable.
- The disposable probe is not sterilized. Use the disposable probe only for a single patient. Never reuse the disposable probe for another patient because it may cause cross infection.
- Do not use a probe which is deteriorated by aging. Accurate measurement cannot be performed.
- Do not immerse the probe in water or disinfectant.
- Take extreme care to prevent the patient from swallowing or biting the probe. Probe pieces may cause inability to eat or drink, stomach ache or diarrhea.
- Always check the probe appearance (such as a change in appearance or a loss of part) and make sure that the patient does not swallow the probe or pieces.
- Do not fasten the probe to the finger by wrapping with tape over the attachment tape. It may cause burn and skin problems from poor blood circulation even for short-term monitoring. Accurate measurement cannot be performed on a site with poor peripheral circulation.
- Attach the probe to the part such as a finger or toe where there is no change in peripheral blood circulation. If the probe is attached to a finger or toe where there is an NIBP cuff or an IBP catheter on the arm or leg, the blood circulation at the probe attachment site is affected and measurement may be inaccurate.
- United States law restricts this product to sale by or on the order of a physician.

- When monitoring SpO₂ of a patient who is receiving photodynamic therapy, the light from the finger probe sensor may cause a burn. Photodynamic therapy uses a photosensitizing agent that has a side effect of photosensitivity. The SpO₂ probe manufactured by Nihon Kohden have two wavelengths with peaks in the range of 650 and 950 nm. The maximum light intensity is less than 5.5 mW/sr.
- When using a disposable probe, change the measurement site at least every 8 hours by checking the skin condition. The skin temperature may increase at the attached site by 2 or 3°C (4 or 5°F) and cause a burn or pressure necrosis. When using the probe on the following patients, take extreme care and change the measurement site more frequently according to symptoms and degree.
 - Neonate
 - Elderly patient
 - Unconscious patient
 - Patient with insufficient peripheral circulation
 - Patient with a fever

⚠ CAUTION

- When the probe is attached on an appropriate site with sufficient thickness and the error message confirming the probe attachment repeatedly appears, the probe may be deteriorated. Replace it with a new one.
- When the probe is off or not attached to the patient properly, a message other than “Check Probe” may appear and an incorrect measurement value may be displayed.
- Normal external light does not affect measuring accuracy but strong light such as a surgical light or sunlight may affect measuring accuracy. If affected, cover the measuring site with a blanket.
- If the skin gets irritated or redness appears on the skin from the probe, change the attachment site or stop using the probe. Take extreme care for the patients with delicate skin.

Selecting a Probe Attachment Site

For proper light transmission and measurement, attach the probe to a site with the recommended thickness (finger, toe or instep and sole).

Connected Devices or Connection Cable	Recommended Thickness
Devices (BSM-6000 series or other) or connection cables other than below	6 to 18 mm
Bedside Monitor: BSM-7100 series, BSM-3101J/K Head Amplifier: AL-801P	6 to 14 mm
Bedside Monitor: BSM-2101A/K, BSM-2102A/K Pulse Oximeter: OLV-1100 series, OLV-1200 series Head Amplifier: AL-800PA	9 to 14 mm ¹

¹ If the patient’s finger is thin, a “Check probe” or “probe off” message may appear on the device and SpO₂ measurement may fail.

Monitoring

⚠ WARNING

- SpO₂ measurement may be incorrect in the following situations.
 - When the patient’s carboxyhemoglobin or methemoglobin increases abnormally.
 - When dye is injected in the blood.
 - When using an electrosurgical unit.
 - During CPR.
 - When measuring at a site with venous pulse.
 - When there is body movement.
 - When the pulse wave is small (insufficient peripheral circulation).

Attaching the Probe

⚠ WARNING

To avoid poor circulation, do not wrap the tape too tight. Check the blood circulation condition by observing the skin color and congestion at the skin peripheral to the probe attachment site. Even for short-term monitoring, there may be burn and skin problems from poor blood circulation, especially on neonates or low birth weight infants whose skin is delicate. Accurate measurement cannot be performed on a site with poor peripheral circulation.

⚠ CAUTION

- Keep the patient away from the cable as much as possible. Otherwise the patient may get tangled in the cable and get injured. If the cable coils around the patient, remove the cable promptly.
- If the attachment site is dirty with blood or bodily fluids, clean the attachment site before attaching the probe. If there is nail polish on the attachment site, remove the polish. Otherwise, the amount of transmitted light decreases, and measured value may be incorrect or measurement cannot be performed.

1. Clean the attachment site.

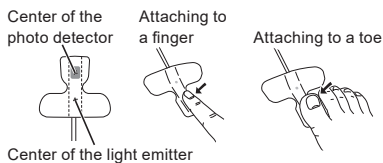
NOTE: Do not attach the probe to oily skin site. The probe may lose adhesion and peel off.

2. Remove the backing paper from the probe and attach the probe to the cleaned site.

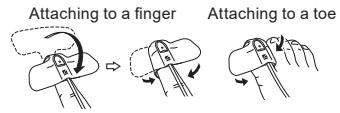
- NOTE**
- Make sure that the center of light emitter and the photo detector face each other with the measurement site between them. Otherwise the measured data is not correct.
 - Do not place the center of the light emitter over the joint.
 - In order to maintain sufficient blood circulation, keep the measurement site warm by covering with a blanket or something similar. Warming the site is effective, especially for a patient with a small pulse amplitude.
 - To avoid too much wrapping pressure, do not stretch or pull the tape when wrapping it. Wrap lightly.

When Attaching TL-271T, TL-271T3, TL-272T or TL-272T3

- 1) Attach the center of the photo detector to the opposite side of the finger or toe from the nail.

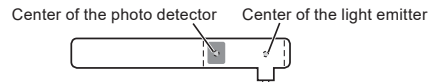


- 2) Fold back the probe over the fingernail so that the light emitter and the photo detector face each other. Position the adhesive face of the light emitter on the nail.
- 3) Wrap the left and right wings of the probe adhesive face one at a time to the finger or toe to attach the whole probe. Be careful not to wrinkle the wings.

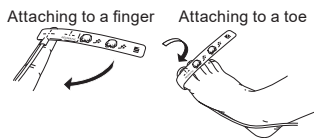


When Attaching TL-273T, TL-273T3, TL-274T or TL-274T3 to a Finger or Toe (the example is TL-273T)

- 1) Attach the center of the light emitter or the photo detector to the base of the nail for a finger or to the opposite side of the nail for a toe as shown below.

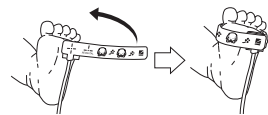


- 2) Wrap the probe around the finger or toe so that the centers of the light emitter and the photo detector face each other.

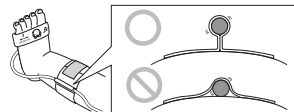


When Attaching TL-273T or TL-273T3 to an Instep and Sole

- 1) Attach the center of the light emitter to the little toe at the bottom of the foot where the toe joins the foot.
- 2) Wrap the probe around the instep and sole so that the centers of the light emitter and the photo detector face each other.



3. For stable SpO₂ measurement, secure the cable to the site such as the back of the hand or instep with surgical tape to minimize the effect of body movement and prevent excess force on the probe. Take care when using surgical tape on neonates, elderly or patients with delicate skin. It may cause dermatopathy.



4. Connect the probe to the instrument by using SpO₂ connection cable. When using the transmitter, connect the probe to the transmitter directly. Check the pulse waveform and SpO₂ value on the connected device.

Removing the Probe

CAUTION

- When removing a probe that is taped to the skin, do not pull the probe cable because this can damage the cable.
- Remove the probe carefully and slowly from the skin. The adhesion may damage the skin. Especially when removing it from a neonate, pay attention to the neonatal skin because it is delicate.

NOTE: When removing the probe from the skin, hold the base of the cable on the probe and slowly remove the probe from the edge of it.

Reattaching the Probe

If you need to reattach the probe on the skin, check that there is no damage on the light emitter and photo detector. Use a new probe when the adhesiveness is weak.

Sterilization

This probe is non-sterilized.

CAUTION

Do not sterilize the probe. This may damage or deteriorate the probe.

Disposal of Probe

Dispose of the probe as medical waste. For detailed information about disposal, contact your Nihon Kohden representative.

Specifications

For details about configurations which comply with standards, refer to the operator's manual of the connected device.

Temperature range of guaranteed SpO₂ accuracy:

18 to 40°C (64.4 to 104°F)

SpO₂ accuracy (rms)^{1, 2}:

80%SpO₂ ≤ %SpO₂ ≤ 100%SpO₂: ±2%SpO₂

70%SpO₂ ≤ %SpO₂ < 80%SpO₂: ±3%SpO₂

Less than 70%SpO₂ is not specified.

¹ "rms":

The SpO₂ accuracy was tested on an OLV-3100 pulse oximeter using the TL-201T, TL-260T, TL-271T and TL-631T SpO₂ probes and JL-302T SpO₂ connection cord. The testing was performed during induced hypoxia on healthy volunteers (Ethnicity: 7 Caucasians, 2 Africans, 1 Asian, 1 Hispanic/Caucasian, 3 Indians), (Skin: 6 Very light, 5 Olive hue, 3 Dark olive), (Age: 21 to 30), (10 men and 4 women) under the condition of no motion. Arterial blood was sampled and measured by a CO-oximeter. The difference between SpO₂ measured by the SpO₂ probe and functional SaO₂ measured by a CO-oximeter was calculated using the root-mean-square (rms) according to ISO 80601-2-61: 2011. This measurement accuracy figure represents 2/3 of all test measurements.

NOTE: A pulse oximeter tester that generates simulated signals can be used to check the difference from the design specification, but it cannot be used as a replacement for human signals for testing accuracy.

² TL-273/274 neonate:

Clinical functionality has been demonstrated on a population of hospitalized neonate patients. The observed SpO₂ accuracy was 2.6% in a study of 42 patients with weight from 447 to 2,458 grams, and 368 observations made spanning a range of 70 to 100% SaO₂.

Transport and storage environment:

Temperature: -20 to +65°C (-4 to +149°F)

Humidity: 10 to 95%RH

Atmospheric pressure: 700 to 1060 hPa

Operating environment:

Temperature: 0 to 45°C (32 to 113°F)

(SpO₂ accuracy is guaranteed at surrounding temperature of 18 to 40°C (64.4 to 104°F).)

Humidity: 30 to 95%RH

Atmospheric pressure: 700 to 1060 hPa

Degree of protection against harmful ingress of water:

Depends on the connected device. When the probe is not connected to any device, the probe is rated IPX0 (non-protected).

Type of protection against electrical shock:

Depends on the connected device.

Degree of protection against electrical shock:

Type BF applied part

Degree of safety of application in the presence of a flammable anaesthetic mixture with air, or with oxygen or nitrous oxide:

Not suitable for use

Mode of operation:

Depends on the connected device.

Condition of installation:

Depends on the connected device.

Note for users in the territory of the EEA and Switzerland:

Any serious incident that has occurred in relation to the device should be reported to the European Representative designated by the manufacturer and the Competent Authority of the Member State of the EEA and Switzerland in which the user and/or patient is established.

Copyright Notice

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