

OPERATOR'S MANUAL

SpO₂ Probe

0604-900409C

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TL-271T/272T/273T/274T

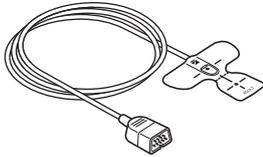
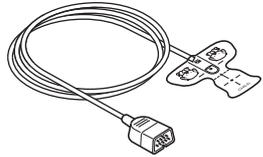
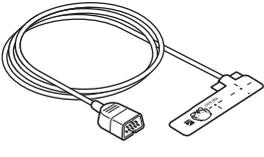
Symbol	Description
	Lot number
	The CE mark is a protected conformity mark of the European Community. The products herewith comply with the requirements of the Medical Device Directive 93/42/EEC.

CAUTION

United States law restricts this device to sale by or on the order of a physician.

Introduction

This probe is a disposable probe for a pulse oximeter or Nihon Kohden monitors with SpO₂ measurement for which the operator's manual specifies use of this probe. Some monitors require a connection cable to connect this probe.

Model	TL-271T		TL-272T		TL-273T		TL-274T	
								
Qty	5/package	24/package	5/package	24/package	5/package	24/package	5/package	24/package
Supply code	P204A	P203A	P204B	P203B	P204C	P203C	P204D	P203D
Suitable weight	30 kg or more, adult		10 to 50 kg, child		3 kg or less, neonate 40 kg or more, adult		3 to 20 kg, infant	
Attachment site	Finger or toe				Neonate: instep and sole Adult: finger or toe		Finger or toe	

The cable length of these probes is 80 cm.

General Safety Information

WARNING

Do not use this probe during MRI examination. Failure to follow this warning may cause skin burn on the probe attachment area due to local heating caused by dielectric electromotive force. For details, follow the MRI operator's manual.

CAUTION

Use this probe only with the specified instruments. Failure to follow this caution may cause skin burn on the patient.

CAUTION

When connecting the probe to the following instruments,

- If the patient's finger is thin, a "probe off" message may appear on the instrument and SpO₂ measurement may fail. Refer to "Selecting a Probe Attachment Site".

Applicable instruments:

BSM-2101/2102A/K Bedside Monitor, OLV-1100/1200 series Pulse Oximeters and AL-800PA SpO₂ Head Amplifier.

- When the probe is detached from the patient, a "pulse search" message instead of a "probe off" message may appear on the instrument.

Applicable instruments:

AL-801P SpO₂ Head Amplifier, BSM-2101/2102A/K Bedside Monitor, BSM-3101J/K Bedside Monitor, BSM-7100 series Bedside Monitors and OLV-1100/1200 series Pulse Oximeters.

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).

NOTE

Do not attach the probe to oily skin site. Otherwise, the probe may lose adhesion and peel off.

Connected Instrument or Connection cable	Recommended thickness
Connection cord: JL-900P, JL-302T, JL-201T	6 to 18 mm
Transmitter: ZB series, ZS series	
Bedside Monitor: BSM-7100 series, BSM-3101J/K	6 to 14 mm
Head Amplifier: AL-801P	
Bedside Monitor: BSM-2101/2102A/K	9 to 14 mm
Pulse Oximeter: OLV-1100/1200 series	
Head Amplifier: AL-800PA	

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 or pressure necrosis 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

This probe is disposable and is not sterilized. Use this probe only for one patient. Do not reuse this probe for another patient because it causes cross infection.

CAUTION

Do not use a damaged or disassembled probe. It causes incorrect measurement and may hurt the patient.

CAUTION

Keep the patient away from the cable as much as possible. If the cable coils around the patient by their body movement, the patient may get injured. If this happens, remove the cable promptly.

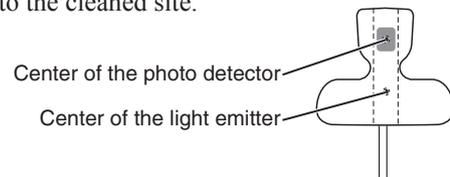
CAUTION

If the attachment site is dirty with blood, 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.

CAUTION

Do not attach the probe to a finger, toe or instep of the same arm or foot that is used for NIBP measurement or an IBP catheter. It affects the blood circulation of the probe attachment site prevents proper measurement.

1. Wipe the attachment site with a cotton moistened with alcohol.
2. Remove the backing paper from the probe and attach the probe to the cleaned site.

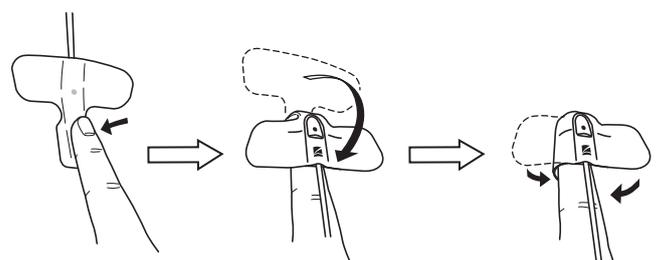


NOTE

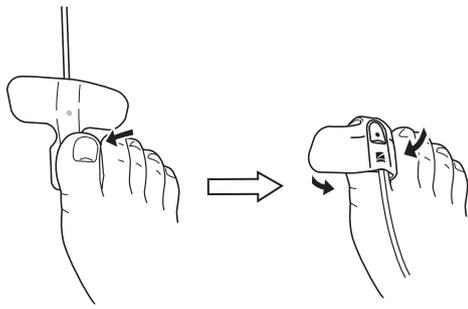
Make sure that the light emitter and the photo detector face each other with the measurement site between them. Otherwise measured data is not correct.

- When attaching TL-271T/TL-272T
 - (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 to a nail 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 wing 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 wing.

Attaching to a finger



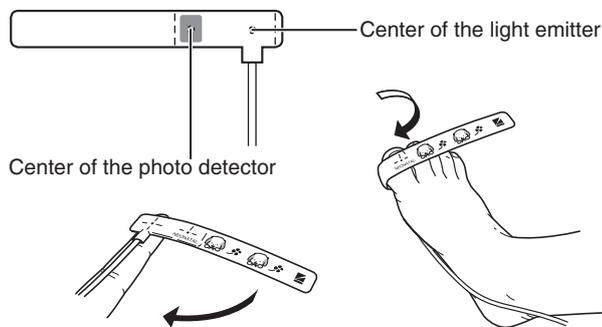
Attaching to a toe



- When attaching TL-273T/TL-274T to a finger or toe
 - (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 left.
 - (2) Wrap the probe around the finger or toe so that the light emitter and the photo detector face each other.

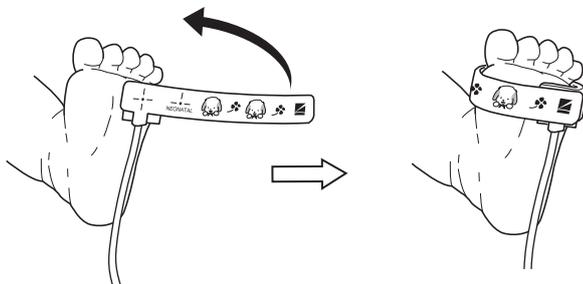
Attaching TL-273T/TL-274T to a finger or toe

(The figure is TL-273T)



- When attaching TL-273T to an instep
 - (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 so that the light emitter and the photo detector face each other.

Attaching TL-273T to an instep



3. For stable SpO₂ measurement, secure the cable to the back of the hand, instep or sole with surgical tape to minimize the effect of body movement and prevent excess force on the probe.

Monitoring

WARNING

SpO₂ measurement may be incorrect in the following cases.

- 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).

WARNING

Check the circulation condition by observing the skin color of the measuring site and the pulse waveform. Change the measuring site every 8 hours. The skin temperature may increase at the attached site by 2 or 3°C 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.

- A patient with a fever
- A patient with a peripheral circulation insufficiency
- Neonate or low birth weight infant with delicate skin

CAUTION

When the probe is attached on a site of recommended thickness and an error message about attachment site repeatedly appears, the probe may be deteriorated. Replace it with a new one.

CAUTION

Under normal conditions, this probe is almost unaffected by light. However, when measuring under strong light (surgical light, sunlight, etc.), cover the probe with a blanket or cloth. Otherwise, measurement accuracy is affected.

CAUTION

Do not pull or bend the probe cable, and do not let caster feet run over the probe cable. Failure to follow these cautions may cause cable discontinuity, short circuit, skin burn on the patient and incorrect measurement data. Replace any broken probe with a new one.

CAUTION

Redness or skin irritation may appear on the attachment site. Take extreme care of patients with weak skin. In case of redness or skin irritation, change the attachment site or stop using the probe.

NOTE

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.

Removing the Probe

When removing the probe, hold the cable where it joins the probe and remove the probe slowly from the edge of it.

CAUTION

Do not pull the cable. Otherwise the cable may break.

CAUTION

Take extreme care when removing the probe from a neonate.

Sterilization

CAUTION

Do not immerse the probe in chemical solutions or water. If the probe adhesive gets wet, adhesiveness becomes weak and may cause incorrect data and skin burn on the patient.

NOTE

Do not autoclave the probe. High temperature and high pressure damage the probe.

This probe is not sterilized. Before use, sterilize the probe if necessary. This probe can be sterilized only once and before use. When sterilizing with ethylene oxide gas, refer to the example below. The sterilizing conditions depend on the contamination of the probe. Refer to the manual of the sterilizing equipment.

Gas:	EO 30% + CO ₂ 70%
Relative humidity:	50%
EO concentration:	710 mg/L
Pressure:	-93.3 kPa to 49.5 kPa
Temperature:	45°C, 113°F
Period:	4 to 10 hours

To remove the remaining gas from the probe after sterilization, first decrease the internal pressure of the sterilization equipment to -760 mmHg with a vacuum pump, then add carbon dioxide or antiseptic gas in the equipment. Repeat this procedure (aeration) at least 5 times. Take the probe out of the sterilization equipment and do not use it for at least 3 days.

Disposal of Probe

Dispose of the probe as medical waste.

Specification

Operating temperature:	18 to 40°C (64.4 to 104°F)
Measuring accuracy:	±2 (80 ≤ SpO ₂ ≤ 100%) ±3 (70 ≤ SpO ₂ < 80%)

- The Japanese manual is published according to guidelines of the Health, Labor and Welfare Ministry in Japan. Content of the English and Japanese manuals may differ.
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