NIHON KOHDEN

OPERATOR'S MANUAL

Finger Probe
TL-201T

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。

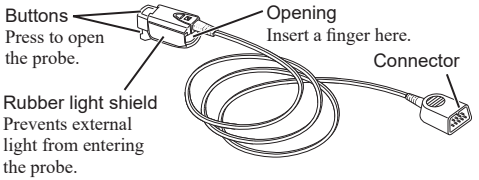
Some specifications of this product may differ depending on the destination country or region. Therefore descriptions in the Japanese manual and English and other language manuals may also differ.

General

The TL-201T finger probe is a reusable probe for a Nihon Kohden pulse oximeter, monitor or transmitter with SpO_2 measurement. Some devices require a connection cable to connect the probe.

The probe is not sterilized and is not made with natural rubber latex.

Model	TL-201T	
Qty	1 piece/box	
Supply Code	P225F	P225H
Suitable Weight (reference)	Adult or child heavier than 20 kg	
Attachment Site	Finger	
Cable Length	1.6 m	0.6 m
Recommended maximum attachment time at one measurement site is **4 hours**. Refer to the "Safety Information – Measurement" section for details.		



Symbols

The following symbols are used with the finger probe. The descriptions of each symbol are given in the table below.

Symbol	Description	Symbol	Description
⚠	Caution	SN	Serial number
	Date of manufacture	EC REP	European representative
Background color: blue	Follow instructions for use		Finger nail
			Fragile
	Keep away from rain		Temperature limits
	Manufacturer		Humidity limits
IPX4	Protected against splashing water		Atmospheric pressure limits
Rx Only	CAUTION: United States law restricts this product to sale by or on the order of a physician.		
CE XXXX	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 all electrodes and transducers from the patient which are connected to this instrument. Failure to follow this warning may cause skin burn on the patient. For details, refer to the MRI manual.

⚠ CAUTION

- Use the probe only with the specified instruments. If the 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, modified or disassembled probe. It causes incorrect measurement and may injure the patient or give the patient electrical shock.
- Do not use a probe which is deteriorated by aging. Accurate measurement cannot be performed.
- Do not use this probe on neonates, low birth weight infants, infants or children lighter than 20 kg because it may cause injury or incorrect measurement.

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- 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.
- 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.
- The clip adapter is a clip type and change in body position may cause the probe to move or become detached even if the probe is attached properly. Use a disposable SpO_2 probe such as TL-271T, TL-272T, TL-273T or TL-274T if necessary.
- United States law restricts this product to sale by or on the order of a physician.

Measurement

⚠ WARNING

- SpO_2 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).
- When monitoring SpO_2 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 SpO_2 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.
- Change the measurement site every 4 hours for the probe and check the skin condition of the attachment site. When using the probe on the following patients, change the measurement site more frequently according to symptoms and degree by checking the patient condition and skin condition of the attachment site. Otherwise, skin problems may occur at the measurement site. The skin temperature may increase at the attached site by 2 or 3°C (4 or 5°F) and cause a burn.
  - Elderly patients
  - Unconscious patients
  - Patients with insufficient peripheral circulation
  - Patients 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.
- 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.
- Do not use this probe for long term measurement. Use a disposable probe such as TL-271T, TL-272T, TL-273T or TL-274T SpO_2 probe for long term measurement.
- Do not use the probe on a patient with significant body movement. Measurement may be inaccurate or impossible to perform.

Selecting a Probe Attachment Site

For proper light transmission and measurement, attach the probe to a site with the recommended thickness.

NOTE: If the patient's finger is thin, a "Check Probe" message may appear on the device and SpO_2 measurement may fail.

Connected Device or Connection Cable	Recommended Thickness (reference)
Devices such as BSM-6000 series bedside monitor and connection cables other than those listed below.	6 to 18 mm
JC-024P, JC-025P connection cable (blue)	6 to 14 mm

Attaching the Probe

⚠ WARNING

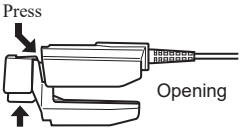
Do not fasten the probe and cable to the finger by wrapping with tape over the probe and cable. This may cause burn, congestion or pressure necrosis from poor blood circulation.

⚠ 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 with alcohol.
2. Press the button to open the probe.

   NOTE: Do not expand the opening of the probe because it may damage the probe.

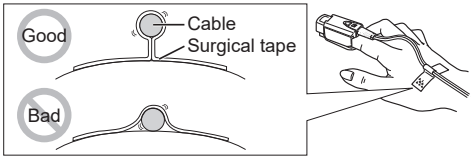


3. Insert the finger to the probe. The ⍓ marked side must be on the nail side (the cable must be on the nail side) and there should be slight contact between the tip of the finger and the probe.

   NOTE
   - Make sure that the cable is on the nail side. Otherwise, measured data will be incorrect.
   - If the patient's nail is too long to attach the finger probe to the optimum position, cut the nail.

4. For stable SpO_2 measurement, secure the cable to the back of the hand with surgical tape to minimize the effect of body movement and prevent excess force on the probe.

   Take care when using surgical tape on elderly or patients with delicate skin. It may cause skin problems.



   NOTE: In order to maintain sufficient blood circulation, keep the attachment site warm by covering with a blanket or something similar. Warming the site is effective, especially for patients with a small pulse amplitude.

5. When using a monitoring device such as a bedside monitor with the probe, connect the probe to the device using the specified connection cord. When using a transmitter with the probe, connect the probe to the transmitter directly. Check the pulse waveform and SpO_2 value on the connected device.

Cleaning and Disinfection

Clean and disinfect the probe after every use.

NOTE
- Use the Nihon Kohden specified disinfectant. Otherwise the probe may be deformed or damaged.
- Before and after cleaning or disinfection, confirm that the probe is not deteriorated or damaged. If it is deteriorated or damaged, stop using it.
- Use the disinfectant correctly (concentration, immersion time, ventilation etc.) by referring to the disinfectant manual.

Cleaning

Clean the probe and cable with a soft cloth or cotton swab moistened with ethanol (15°C (59°F), 76.9 to 81.4% by vol) and dry it thoroughly.

Disinfection

Rinse the probe thoroughly with water before disinfection to remove the surface dirt. To disinfect the probe, soak it in either of the disinfectants below.

Glutaraldehyde solution:	2.0%
Alkyldiaminoethylglycine hydrochloride:	0.5%

After disinfection, rinse the probe with sterilized or distilled water. Push the rubber part of the probe to completely remove liquid inside it. Dry the probe thoroughly.

After disinfection, the light emitter and the window of light receiver may be colored. It does not affect the measurement.

NOTE
- Do not let the connector get wet with disinfectants or water. If it gets wet, thoroughly wipe it. Do not use the probe with the connector wet.
- Do not use chlorhexidine gluconate such as Hibitane and ethanol mixture for disinfection. It may deteriorate the resin.

Sterilization

This probe is non-sterilized and cannot be sterilized.

⚠ CAUTION

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

Disposal of Probe

⚠ CAUTION

Dispose of Nihon Kohden products according to your local laws and your facility's guidelines for waste disposal. Otherwise, it may affect the environment. If there is a possibility that the product may have been contaminated with infection, dispose of it as medical waste according to your local laws and your facility's guidelines for medical waste. Otherwise, it may cause infection.

Specifications

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

Temperature range of guaranteed SpO_2 accuracy:
18 to 40°C (64 to 104°F)

SpO_2 accuracy (rms) [1]:
$80\%SpO_2 \leq \%SpO_2 \leq 100\%SpO_2$: $\pm 2\%SpO_2$
$70\%SpO_2 \leq \%SpO_2 < 80\%SpO_2$: $\pm 3\%SpO_2$
Less than $70\%SpO_2$ is not specified.

[1] "rms":
The SpO_2 accuracy was tested on an OLV-3100 pulse oximeter using the TL-201T, TL-260T, TL-271T and TL-631T SpO_2 probes and JL-302T SpO_2 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 SpO_2 measured by the SpO_2 probe and functional SaO_2 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.

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) [2]
Humidity: 30 to 95% RH
Atmospheric pressure: 700 to 1060 hPa

[2] SpO_2 accuracy is guaranteed at surrounding temperature of 18 to 40°C (64 to 104°F).

Degree of protection against harmful ingress of water:
Depends on the connected device (only the sensor part complies with IPX4 (protected against splashing water as specified in IEC 60529))

Type of protection against electric shock:
Depends on the connected device

Degree of protection against electric shock:
Type BF applied parts

Degree of safety of application in the presence of a flammable anaesthetic mixture with air, 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.

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