OPERATOR'S MANUAL

Finger Probe
TL-630T1, TL-630T3

NIHON KOHDEN

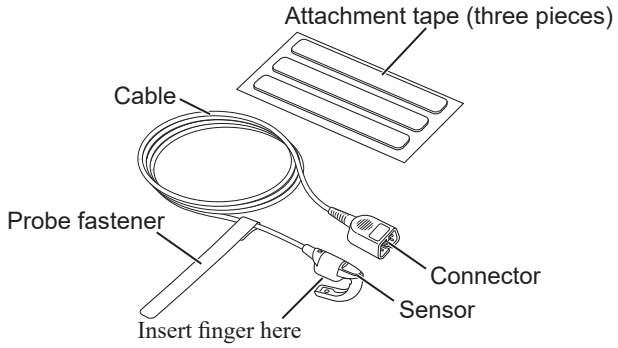
本品は、出荷される国や地域により仕様等が異なることがあります。
※日本向け製品については、日本語で記載しています。
英語などその他の言語で記載されている内容は、日本以外に出荷される製品の説明です。

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-630T1, TL-630T3 finger probe measures SpO_2 on the finger of an adult or child heavier than about 50 kg. This probe can be used with a Nihon Kohden product with SpO_2 measurement. Some products require a connection cable to connect this probe.

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



Composition

Model	Cable Length	Attachement Site	Suitable Weight
TL-630T1	60 cm	finger	50 kg [1] or more, adult or child
TL-630T3	160 cm		

[1] The weight is a reference only.

Options CE marking

Item	Qty	Supply Code
Probe fastener	30 pieces	P267
Attachment tape	3 pieces × 30 sets	P263
		P263A

0604-902719E

⚠ CAUTION

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.

Symbols

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

Symbol	Description	Symbol	Description
	Caution		Fragile
(Background color: blue)	Follow instructions for use		Keep away from rain
	Temperature limits		Humidity limits
EC REP	European representative		Atmospheric pressure limits
SN	Serial number		Finger mark
	Date of manufacture		Manufacturer
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.

⚠ WARNING

When performing an MR examination, remove this probe from the patient. Failure to follow this warning may cause skin burn on the patient. For details, refer to the MR equipment manual.

⚠ CAUTION

Only use Nihon Kohden specified attachment tape. Other tape 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.

⚠ CAUTION

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.

⚠ 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.

⚠ CAUTION

Use this probe fastener only with the specified probes.

⚠ CAUTION

Do not use a damaged, disassembled, modified or faulty probe. It causes incorrect measurement and may injure the patient.

⚠ CAUTION

Do not use a probe which is deteriorated by aging. Accurate measurement cannot be performed.

⚠ CAUTION

Do not use this probe on neonates, low birth weight infants, infants or children lighter than 50 kg because it may cause injury or incorrect measurement.

⚠ CAUTION

- Take extreme care to prevent a 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.

⚠ CAUTION

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

Selecting a Probe Attachment Site

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

Connected Instrument or Connection Cable	Recommended Thickness
Devices (BSM-6000 series bedside monitor or other) or connection cables other than below	6 to 18 mm
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 [1]
Pulse Oximeter: OLV-1100/1200 series	
Head Amplifier: AL-800PA	

[1] If the patient's finger is thin, a "Check probe" or "probe off" message may appear on the device and SpO_2 measurement may fail.

Attaching the Probe

⚠ WARNING

When using this finger probe, to avoid poor circulation, do not wrap the tape too tight. When using the probe fastener to attach the probe, do not wrap the probe fastener 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. Accurate measurement cannot be performed on a site with poor peripheral circulation.

⚠ CAUTION

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.

⚠ 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.

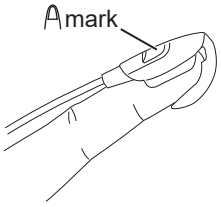
⚠ CAUTION

When removing the probe from the attachment tape, do not pull the sensor cable because this can damage the cable.

⚠ CAUTION

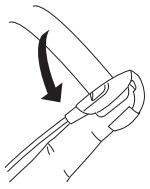
Make sure that the center of light emitter and the photo detector face each other with the measurement site between them. Otherwise the measured data is not correct.

1. Wipe the attachment site with a cotton moistened with alcohol.
2. Insert the finger into the probe. The side with the mark 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.

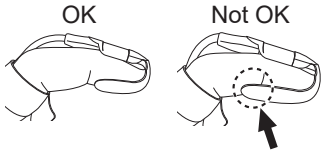


NOTE: If the patient's nail is too long and the tip of the nail touches the probe, cut the nail. The probe cannot be attached properly to a finger with a long nail.

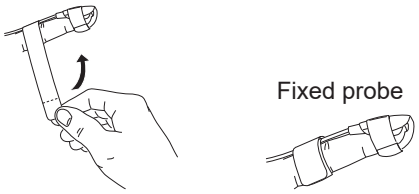
3. Wrap the attachment tape lightly around the finger to fasten the probe.



NOTE
- To avoid too much wrapping pressure, do not stretch or pull the tape when wrapping it. Wrap lightly.
- If the tip of the finger cover reaches beyond the DIP joint when bending the finger, stop using the TL-630T finger probe and use the TL-631T finger probe instead.



4. Wrap the probe fastener between the second joint and third joint. This minimizes the influence from body movement, prevents excess force on the probe and allows stable SpO_2 measurement.



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 patients with a small pulse amplitude.

5. Connect the probe to the monitor with the SpO_2 connection cable or connect the probe directly to the other divice. Check the pulse waveform on the connected device.

Monitoring

⚠ 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).

⚠ WARNING

Change the measurement site every 8 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.
- Unconscious patient
- Patients with insufficient peripheral circulation
- Patients with a fever
- Elderly patients

⚠ WARNING

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.

⚠ CAUTION

Normal external light does not affect measuring accuracy but strong light such as a surgical light or sunlight may affect meausuring accuracy. If affected, cover the measuring site with a blanket.

⚠ 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.

⚠ CAUTION

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.

⚠ CAUTION

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.

⚠ CAUTION

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.

⚠ CAUTION

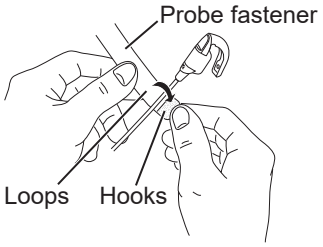
The probe may move or become detached from body movement even if it is attached properly. The adhesive becomes weak from sebum or sweat.

Replacing the Probe Fastener

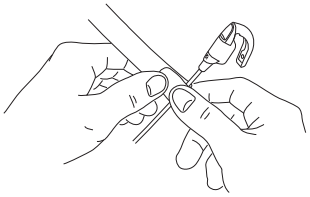
Replace the probe fastener with a new one when the probe fastener is damaged or the probe fastener is dirty even if it has been cleaned.

1. Remove the probe fastener from the probe.

   NOTE: Remove the probe fastener from the probe carefully. Do not put excessive force on the sensor cable.



2. Wrap the new probe fastener around the sensor cable and attach the loops and hooks.



Replacing the Attachment Tape

Replace the attachment tape with a new one when changing the attachment site, the attachment tape is damaged or the tape is dirty.

⚠ CAUTION

When removing the probe from the attachment tape, do not pull the sensor cable because this can damage the cable.

⚠ CAUTION

Take extreme care when removing the probe and attachment tape from the patient. The adhesive of the tape may injure the skin.

Cleaning and Disinfecting the Probe and Cleaning the Probe Fastener

Be sure to clean and disinfect the probe and clean the probe fastener after 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.) referring to the disinfectant manual.

Cleaning

Wipe the probe and probe fastener with a cotton or a soft cloth moistened with ethanol (15°C (59°F), 76.9 to 81.4% by vol). Dry the probe and probe fastener completely after cleaning.

Disinfection (Probe only)

Soak the probe in one of the disinfectants below. Refer to the instructions of the disinfectant for how to disinfect.

Disinfectant	Concentration (%)
Glutaraldehyde solution	2.0%
Alkyldiaminoethylglycine hydrochloride	0.5%
Benzalkonium chloride	0.2%
Benzethonium chloride solution	0.2%

Rinse the probe with running water and dry completely after disinfection.

NOTE
- Do not let the probe 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

Follow your local laws for disposing of medical waste.

⚠ 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]:
$80\%SpO_2 \leq \%SpO_2 \leq 100\%SpO_2$: ±2%$SpO_2$
$70\%SpO_2 \leq \%SpO_2 < 80\%SpO_2$: ±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.

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).

Storage environment
Temperature: –20 to +65°C (–4 to +149°F)
Humidity: 10 to 95% RH
Atmospheric pressure: 700 to 1060 hPa

Degree of protection against harmful ingress of water:
Depends on a connected device. Only the sensor parts are rated IPX4 (protected against splashing water as specified in IEC 60529).

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

Condition of installation:
Depends on a 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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