

OPERATOR'S MANUAL

Disposable SpO₂ Probe

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TL-535U

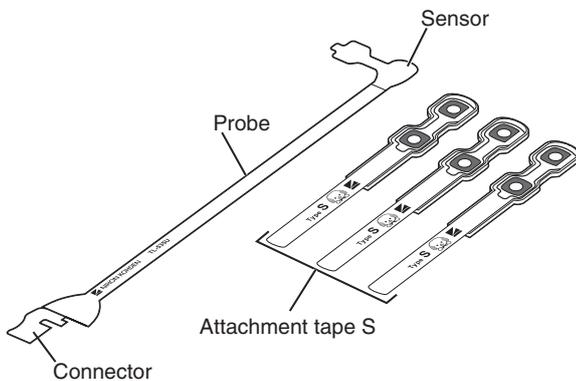
Symbol	Description	Symbol	Description
	Lot number		Fragile
	Date of manufacture		Keep away from rain
	Do not reuse, single patient use		Humidity limits
	Temperature limits		The CE mark is a protected conformity mark of the European Community. Products marked with this symbol comply with the requirements of the Medical Device Directive 93/42/EEC.
	Keep away from sunlight		
	Atmospheric pressure limits		Products marked with this symbol comply with the European WEEE directive 2002/96/EC and require separate waste collection. For Nihon Kohden products marked with this symbol, contact your Nihon Kohden representative for disposal.
	Latex free		
	Attention, consult operator's manual		

General

The TL-535U disposable SpO₂ probe is for neonates and preterm infants. The probe does not contain latex. The connector is card edge type. This probe can be connected to a Nihon Kohden monitor or other Nihon Kohden product with SpO₂ measurement excluding electroencephalographs. Some products require an SpO₂ connection cord to connect this probe.

WARNING

Do not use for electroencephalographs.



Composition

Description	Supply Code
Disposable SpO ₂ probe, 5 sets/box	P206
Attachment tape S, 3 pieces/set	

General Safety Information

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 the probe with the specified attachment tape and SpO₂ connection cord.

CAUTION

Use this probe only with the specified devices. Use of unspecified devices may cause skin burn on the patient.

CAUTION

Do not use a damaged, disassembled, altered or broken probe and SpO₂ connection cord.

CAUTION

The probe is non-sterilized and disposable. Use only for a single patient. Failure to follow this instruction may cause cross infection.

CAUTION

Handle the probe cable and SpO₂ connection cord so that the probe cable and SpO₂ connection cord are not damaged.

CAUTION

Do not immerse the probe and attachment tape in water or disinfectant.

CAUTION

Take extreme care to prevent the patient from swallowing or biting the probe.

Selecting a Probe Attachment Site

For proper light transmission and measurement, attach the probe to a site which is 6 to 18 mm thick (back of a hand and palm, or instep and sole).

Attaching the Probe

Take extreme care when attaching or removing the probe from the measurement site.

WARNING

To avoid poor circulation, do not wrap the tape too tight. Do not fasten the probe to the attachment site by wrapping with tape over the attachment tape especially by using high stretch tapes. If the tape is too tight, the probe cannot detect the pulse or the SpO₂ value may be incorrect. Even for short-term monitoring, there may be skin problems from poor blood circulation.

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.

CAUTION

In the following cases, the probe cannot detect the pulse or the SpO₂ value may be incorrect.

- The probe is attached to a moist site (such as sebum or exudate).
- The probe attachment site is not appropriate.
- The probe attachment site is too thick or thin.
- The probe is attached to a dirty site.
- The probe and attachment tape are dirty.
- The probe is loose.

CAUTION

Keep the patient away from the cable as much as possible.

CAUTION

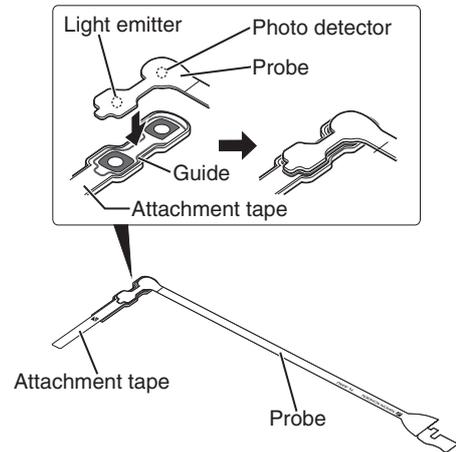
Attach the probe where there is no pigmentation. If the attachment site is dirty with blood or bodily fluids, clean the attachment site before attaching the probe. If there is nail polish on the attachment site, remove the polish. Otherwise, the amount of transmitted light decreases and the probe cannot detect the pulse or the SpO₂ value may be incorrect.

1. Remove the release film of the attachment tape.

NOTE

Do not remove the transparent protection film on the probe.

2. Attach the probe sensor along the guide on the attachment tape.



3. Check if there is dirt on the attachment site and remove any dirt.

NOTE

Vernix, sebum or moisture on the attachment site may cause the probe to detach from the skin. Attach the probe at a dry site.

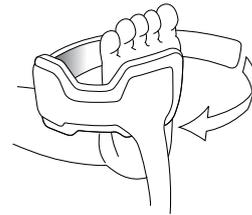
4. Attach the probe to the measurement site so that the light emitter and the photo detector face each other with the measurement site between them.

NOTE

To prevent too much wrapping pressure, do not hold the edge of the tape and pull the tape tightly when wrapping it. Wrap lightly along the measurement site.

Attaching the probe to the instep and sole

- i) Position the center of the photo detector at the bottom of the foot where the little toe joins the foot. The probe cable comes to the bottom of the foot.
- ii) Wrap the attachment tape lightly around the instep and sole so that the centers of the light emitter and the photo detector face each other.



- iii) Fasten the entire probe with the hook and loop fasteners of the attachment tape.

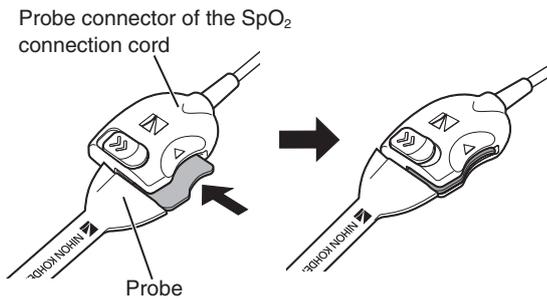


Attaching the probe to the lower leg

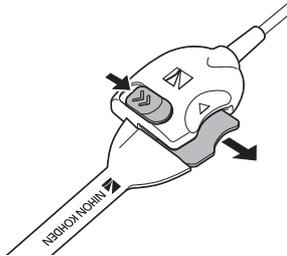
For a patient with significant body movement, you can attach the probe to the lower leg. This prevents excess force on the probe and minimizes the effect of body movement.

Take care if you use a bandage or surgical tape to attach the probe to a patient with immature skin such as a preterm infant in acute stage because it may cause skin problems.

5. Insert the probe straight into the probe connector of the SpO₂ connection cord and slide it down until it clicks.



6. Connect the probe to the monitoring device with an SpO₂ connection cord.
7. Check the pulse waveform on the connected device.
8. After measurement, disconnect the probe from the SpO₂ connection cord by sliding the button on the probe connector as shown below.



Monitoring

WARNING

In the following cases, the probe cannot detect the pulse or the SpO₂ value may be incorrect.

- 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

- When using the probe on the following patients, change the measurement site frequently. Otherwise, skin problems may occur at the measurement site.
 - Unconscious patients
 - Patients with insufficient peripheral circulation
 - Patients with a fever
- Change the measurement site every 8 hours for the probe and check the skin condition of the attachment site. Change the measurement site more frequently according to the symptoms and degree. Otherwise, skin problems may occur at the measurement site.

WARNING

When monitoring SpO₂ of a patient who is receiving photodynamic therapy, the light from the 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.

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 the incorrect measurement value may be displayed.

CAUTION

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.

CAUTION

The probe uses hook and loop fasteners to attach the probe. Change in body position may cause the probe to move or become detached even if the probe is attached properly. If this is a problem, use a probe such as TL-273T or TL-274T.

CAUTION

If the skin gets irritated or redness appears on the skin from the probe, change the attachment site or stop using the probe.

CAUTION

Connect the probe connector to the monitoring device after attaching the probe to the patient. Otherwise, noise may cause an incorrect value on the monitoring device when attaching the probe.

Replacing the Attachment Tape

When the attachment tape is dirty or the sponge is deteriorated, replace the attachment tape with a new one even if the time of use is short.

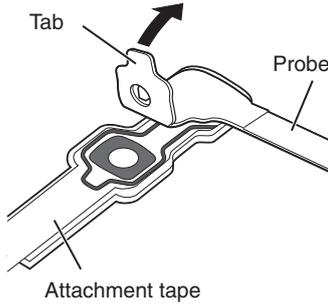
CAUTION

If the adhesiveness of the hook and loop fasteners becomes weak, replace the attachment tape with a new one.

1. Remove the probe from the attachment tape.

NOTE

When removing the attachment tape, hold the tab of the probe and remove the attachment tape carefully and slowly from the edge of adhesive side.



2. Remove the release film of the new attachment tape and then attach the probe sensor along the guide on the attachment tape.

Sterilization

This probe is non-sterilized and cannot be sterilized.

CAUTION

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

Disposal

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

SpO₂ Accuracy

Temperature range of guaranteed SpO₂ accuracy:
 18 to 40°C (64 to 104°F)
 SpO₂ accuracy (rms)*:
 80%SpO₂ ≤ %SpO₂ ≤ 100%SpO₂: ±2%SpO₂
 70%SpO₂ ≤ %SpO₂ < 80%SpO₂: ±3%SpO₂
 Less than 70%SpO₂ is not specified.

***NOTE**

The SpO₂ accuracy was tested on an OLV-3100 pulse oximeter using the TL-535U SpO₂ probe and JL-302T and JL-030U1 SpO₂ connection cords. The testing was performed during induced hypoxia on healthy volunteers; age 23 to 29, men and women with various skin pigmentation, 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) method according to ISO 9919: 2005. This SpO₂ accuracy figure represents 2/3 of all test measurements.

Environment

Operating environment:

Temperature: 0 to 45°C (32 to 113°F)**

** SpO₂ accuracy is guaranteed at surrounding temperature of 18 to 40°C (64 to 104°F).

Humidity: 30 to 95% RH

Atmospheric pressure: 700 to 1060 hPa

Transport and storage environment:

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

Humidity: 10 to 95% RH

Atmospheric pressure: 700 to 1060 hPa

IP Classification

IPX0 (non-protected)

Vertically falling drops have harmful effect on this product as specified in IEC 60529.

Options

Attachment Tape

Description	Suitable Weight (Reference)	Attachment Site	Supply Code
Attachment tape S, 6 pieces/bag × 4 bags	Less than 1 kg, preterm infants	Back of the hand and palm, or instep and sole	P264A
Attachment tape L, 6 pieces/bag × 4 bags	Less than 2.5 kg, preterm infants		P264B

SpO₂ Connection Cord

Description	Application	Model	Supply Code
SpO ₂ connection cord	for monitor	JL-930P	K930
		JL-330U	L315
	for 9 pin rectangular	JL-030U1	K929A
		JL-030U2	K929B

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Manufacturer

NIHON KOHDEN CORPORATION
 1-31-4 Nishiochiai, Shinjuku-ku, Tokyo 161-8560, Japan
 Phone +81 3-5996-8036 Fax +81 3-5996-8100
<http://www.nihonkohden.com/>

NIHON KOHDEN AMERICA, INC.
 15353 Barranca Parkway, Irvine, CA 92618, U.S.A.
 Phone +1 949-580-1555 Fax +1 949-580-1550

EC REP European Representative

NIHON KOHDEN EUROPE GmbH
 Raiffeisenstrasse 10, D-61191 Rosbach, Germany
 Phone +49 6003-827-0 Fax +49 6003-827-599

SHANGHAI KOHDEN
 MEDICAL ELECTRONIC INSTRUMENT CORP.
 7th Floor, Dawing Center Tower A, No.500, Hongbaoshi Road
 Changning District, Shanghai 201103, China
 Phone +86 21-6270-0909 Fax +86 21-6270-9700

