SAFETY AND PERFORMANCE INFORMATION

NIHON KOHDEN

Finger Probe
TL-631T1, TL-631T3

General

The TL-631T1 and TL-631T3 finger probes are reusable probes for Nihon Kohden products with SpO_2 measurement. Some products require a connection cable to connect this probe.

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 the Operator's Manual or Installation Guide.

⚠ 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.

⚠ 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 probe sensor may cause a burn where the probe is attached. Photodynamic therapy uses a photosensitizing agent that may cause photosensitive side effects.

⚠ 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

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 skin problems from poor blood circulation. Accurate measurement cannot be performed on a site with poor peripheral 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

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

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 20 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

When measuring SpO_2 under strong light such as surgical light or sunlight, cover the measuring site with a blanket to block the light. Otherwise measurement accuracy may be affected.

⚠ 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

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

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

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

⚠ 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.

⚠ CAUTION

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

⚠ CAUTION

When removing a probe from the skin, do not pull the probe cable because this can damage the cable.

⚠ CAUTION

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

This Safety and Performance Information is an extract from the general and safety information sections of the most recent edition of Operator's Manual or Installation Guide. Therefore, the contents of your Operator's Manual or Installation Guide may differ from those of this Safety and Performance Information. For detailed operating procedures, follow the instructions of your Operator's Manual or Installation Guide.

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