SAFETY AND PERFORMANCE INFORMATION NIHON KOHDEN



TL-260T Clip Adapter YS-087P9

General

This reusable clip adapter is an optional accessory for the TL-260T multi-site Y probe. SpO₂ measurement on an earlobe is available with the TL-260T multi-site Y 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

Position the clip and probe so that the cable cannot wind around the face or the neck of the patient.

WARNING

SpO₂ measurement may be incorrect in the following

- When fluctuations or pulsations in the patient's venous blood affect the measurement.
- · When the measurement site is lower than the heart (supine position).
- · When the patient has congestion.
- · When the patient is chewing, swallowing, yawning, or coughing.
- When the pulse wave is small (insufficient peripheral circulation).

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.

WARNING

Change the measurement site every 4 hours for clip and probe and check the skin condition of the attachment site. When using the clip and 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

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.

CAUTION

Use the clip adapter only with the specified products. If this clip adapter 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 damaged, disassembled, modified or faulty clip and probe. It causes incorrect measurement and may injure the patient or give the patient electrical shock.

CAUTION

Do not use the clip and probe which are deteriorated by aging. Accurate measurement cannot be performed.

CAUTION

Do not use this clip and probe on neonates, low birth weight infants or children because it may cause incorrect measurement and injure the patient.

CAUTION

- Take extreme care to prevent the patient from swallowing or biting the clip and probe. Clip and probe pieces may cause inability to eat or drink, stomach ache or diarrhea.
- Always check the clip and probe appearance (such as a change in appearance or a loss of part) and make sure that the patient does not swallow the clip and probe or pieces.

CAUTION

Do not fasten the clip and probe to the earlobe by wrapping with tape over the probe. 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

If the attachment site is dirty with blood or bodily fluids, clean the attachment site before attaching the clip and probe. Otherwise, the amount of transmitted light decreases, and measured value may be incorrect or measurement cannot be performed.

CAUTION

Make sure that the windows of the clip adapter are clean before inserting the probe. Dirt on the windows may reduce the light transmission and causes incorrect results or prevents measurement.

CAUTION

Make sure that the emitter and detector are properly inserted in the clip adapter without sticking out of the edge of the clip adapter. If the sensors are not inserted properly, it may degrade the light transmission, and cause incorrect results or prevent measurement.

CAUTION

Do not use the clip and probe for long term measurement. Use a disposable SpO_2 probe such as TL-271T/272T/273T/274T for long term measurement.

CAUTION

Do not use the clip and probe on a patient with significant body movement. Measurement may be inaccurate or impossible to perform.

CAUTION

If the patient is wearing pierced earrings or other accessories on the measurement area, remove them before measurement. They may cause incorrect measurement or injury around the attached area.

CAUTION

- Avoid areas with pierce holes. Light shining directly through a hole onto the photo detector may cause incorrect measurement.
- Position the clip and probe on the skin so that light does not shine directly on the photo detector.
 Otherwise it may cause incorrect measurement.

CAUTION

Position the clip and probe so that nothing is pressing on the clip and probe. Pressure on the clip and probe may cause incorrect measurement and injury.

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

If the skin gets irritated or redness appears on the skin from the clip and probe, change the attachment site or stop using the clip and probe. Take extreme care for patients with delicate skin.

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

When removing the clip and probe from the patient, open the clip adapter before removing the clip and probe. Pulling the cable to remove the clip adapter may injure the skin at the attachment site.

CAUTION

Do not pull the cable when detaching the light emitter and the photo detector. This may damage the cable.

CAUTION

Do not use a tool with a sharp edge to detach the light emitter and the photo detector. A sharp edge may break the outer cover of the sensor.

CAUTION

Do not sterilize the clip adapter. This may damage or deteriorate the clip adapter.

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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