SAFETY AND PERFORMANCE INFORMATION

NCS Electrode (NM-31) NM-317Y3, NM-319Y

General

This product is a disposable electrode for deriving evoked EMG signals in nerve conduction study. It has two types: two recording electrodes (red and black) with a grounding electrode (green), and four recording electrodes (red and black) without a grounding electrode. Paste is not necessary for attaching the electrodes.

Safety Information

	A warning alerts the user to possible injury or death associated with the use or misuse of the instrument.
	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.

- Never use this electrode in the presence of any flammable anesthetic gas or concentrated oxygen. Failure to follow this warning may result in explosion or fire.
- · When performing MRI test, remove all electrodes from the patient. Failure to follow this warning may cause skin burn on the patient. For details, refer to the MRI manual.
- · Do not reuse the disposable electrode.
- · Connect the DIN connector only to the specified instrument or connection cable. Failure to follow this warning may result in electrical shock to the patient.

- · For the following patients and skin sites, redness and skin erosion may occur and occasionally result in scar.
 - Patients with weak skin (patient with allergy)
 - Delicate or weak skin
- · Do not use this electrode for a neonate or low birth weight infant.
- · Do not attach the electrode on a wound or inflamed skin.
- This electrode should not be used in conjunction with other types of electrodes because offset voltage becomes high and it may affect EMG recording.

- · Do not get liquid on the electrode. If the electrode is wet, it may cause incorrect measurement.
- Take extreme care to prevent the patient from swallowing the electrode. The electrode is chemically harmless to people but the adhesive gel on the NCS electrode is highly expansive. If the electrode is swallowed, the adhesive gel absorbs gastric juice and swells several to several dozen times in size and stays in the stomach. Swelling adhesive gel in stomach will cause the patient to vomit and be unable to eat and drink. After removing the electrode, check there is no adhesive gel left on the patient.
- · If the gel is swallowed, immediately see a physician.
- · Use the electrodes as soon as possible after opening the package. Store the rest of the electrodes by folding the top of the package twice and sealing it with tape to prevent the electrodes from drying.
- · Do not use electrodes which are past the expiration date.
- · Do not use this electrode for ECG monitoring.
- Do not use this electrode for electric stimulation.
- · Do not sterilize this electrode.
- Do not alter the shape of electrodes. EMG may not be recorded.
- · If a noise appears, refer to the EP/EMG measuring systems operator's manual.
- Connect the DIN connector to the correct socket on the instrument, electrode junction box or extension cord. Otherwise, correct measurement cannot be performed.
- · Black spots may appear on the silver surface of the electrode. These are caused by variation in the Ag and AgCl coating thickness and have no effect on the quality or performance of the electrode. (NM-317Y3 only)
- When using remover to remove adhesive gel from the patient's skin, refer to the remover operator's manual.
- · When removing the electrode's from the patient, remove it carefully and slowly from the edge.

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.

Manufacturer

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