SAFETY AND PERFORMANCE INFORMATION | NIHON KOHDEN



Disposable Electrode NE-05 NE-05IS3

General

The NE-05 disposable electrode is for EEG measurement or EEG examination on neonates, low birth weight infants and children. The disposable electrode can be used with a Nihon Kohden EEG-1200A/J/K, EEG-1250 or EEG-9100A/G/J/K electroencephalograph, BM-120A shield junction cord or JE-905P or JE-906P EEG connection cord.

Safety Information

↑ WARNING

A warning alerts the user to the 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

- Do not use this electrode during MRI examination because it may cause skin burn on the electrode placement area.
- Do not reuse disposable electrodes.

⚠ CAUTION

- Do not use this electrode for ECG monitoring or electric stimulation.
- · Do not use electrodes which are past the expiration
- · Do not attach electrodes on a wound or inflamed skin.
- Do not alter the shape of electrodes. EEG may not be
- · 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.
- The NE-05 electrodes should not be used together with other types of electrodes because offset voltage becomes high and it may affect EEG recording.
- 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, neonate or low birth weight infant)
 - Delicate or weak skin
- · If the skin gets irritated or redness appears on the skin from the electrode, stop using the electrode or place a new electrode on a fresh site.
- If noise interferes with the EEG or the electrode starts to come off, replace the electrode with a new one.

- Take extreme care to prevent the patient from swallowing the electrode. The electrode is chemically harmless to people but the adhesive gel on the 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.
- When removing the electrode from a neonate or low birth weight infant, remove it carefully and slowly because neonatal skin is sensitive.
- When removing the electrode from the patient, remove it carefully and slowly from the edge. If you remove it forcefully, the skin may tear.
- · When using adhesive remover, wipe the adhesive remover completely before attaching the electrode. For usage of the adhesive remover, refer to the adhesive remover operator's manual.
- lodine may cause discoloration of the electrode. If the skin was disinfected with iodine, wipe the skin with ethanol before placing the electrode.
- · The electrode cannot be sterilized. Sterilizing the electrode may damage it.
- Do not bend the electrode leads with too much force. This may damage the leads.
- To prevent electrodes from being swallowed, make sure that the number of electrodes to be disposed of is the same as the number of electrodes that were taken out of the package.
- When separating the electrodes, separate them slowly to avoid twisting the leads. Otherwise the covering may peel off the wire and the electrodes may become unusable.
- Make sure not to drop the gel cover on the floor. It may cause injury if it touches the patient or the patient or operator may slip on the gel cover and fall.

⚠ 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.



NIHON KOHDEN CORPORATION
1-31-4 Nishiochiai, Shinjuku-ku,
Tokyo 161-8560, Japan
Phone +81 3-6996-8041
https://www.nihonkohden.com/

1st Edition: 23 Apr 2019 2nd Edition: 09 Aug 2023



EC REP European Representative

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

