

Disposable Electrode

Vitrode N (N-03IS3)

General

The Vitrode N disposable electrode is designed for monitoring ECG on neonates and low birth weight infants on a Nihon Kohden bedside monitor such as BSM-9101A/K, BSM-6000A/K series, BSM-3000 series or CSM-1000 series.

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

- Do not use this electrode during MRI examination because it may cause skin burn on the electrode placement area.
- When performing defibrillation, discharge as far as possible from electrodes on the chest of the patient. If there is a possibility that the defibrillator paddle could touch electrodes, remove the electrodes from the patient. If the defibrillator paddle directly contacts electrodes, the discharged energy may cause skin burn to the patient.

CAUTION

- Do not reuse disposable electrodes.
- Do not use this electrode for electric stimulation.
- Do not use electrodes which are past the expiration date.
- Do not attach electrodes on a wound or inflamed skin.
- Do not alter the shape of electrodes. ECG may not be recorded.
- After opening the package, use the contents soon to prevent the gel from drying. 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.

- Vitrode N electrodes should not be used together with other types of electrodes because offset voltage becomes high and it may affect ECG recording.
- For the following patients and skin sites, redness and skin erosion may occur and infrequently 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.
- Take extreme care to prevent a patient from swallowing the electrode. The adhesive gel on the Vitrode N is highly expansive. If the electrode is swallowed, the adhesive gel absorbs gastric juice and swells several times to several dozen times its size, and stays in the stomach. The electrode is chemically harmless to people. However, swelling adhesive gel in stomach will cause the patient to vomit and be unable to eat and drink.
- If noise interferes with the ECG or the electrode starts to come off, replace the electrode with a new one.
- Replace the electrode with a new one when the adhesive becomes weak from long term attachment.
- 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 remover for removing adhesive gel from the patient's skin, refer to the remover operator's manual.
- When using remover, wipe the remover completely before attaching a new electrode.
- The electrode cannot be sterilized. Sterilizing the electrode may damage it.
- Iodine may cause discoloration of the electrode. If the skin was disinfected with iodine, wipe the skin with ethanol before placing the electrode.

- 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
NIHON KOHDEN CORPORATION
1-31-4 Nishiochiai, Shinjuku-ku,
Tokyo 161-8560, Japan
Phone +81 3-5996-8041
<https://www.nihonkohden.com/>



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