OPERATOR'S MANUAL

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Disposable Electrode Vitrode N (N-03IS3)

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Some specifications of this product may differ depending on the destination country or region. Therefore descriptions in the Japanese manual and English and other language manuals may also differ.

Symbol	Description	Symbol	Description
\triangle	Caution	LOT	Lot number
40°)	Temperature limits	*	Keep away from sunlight
(2)	Non-reusable, single use	Σ	Expiration date
w	Manufacturer	(Background color: blue)	Follow instructions for use
EC REP	European representative		
CE	The CE mark is a protected conformity mark of the European Community. Products marked with this symbol comply with the requirements of the Medical Device Directive 93/42/EEC.		

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.

This disposable electrode can be connected with the following ECG connection cords.

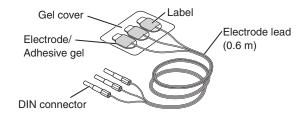
JC-906P (supply code: K922)JC-906PA (supply code: K922A)JC-916P (supply code: K925)

The electrode and electrode lead are made of carbon fiber to pass X-rays.

NOTE

Depending on the irradiated time and site, the electrode might make a slight shadow. The electrode does not perfectly pass X-rays.

Please read this manual thoroughly prior to operation to ensure optimum performance.



Model: N-03IS3 (supply code: G300A) Q'ty: 10 sets (3 electrodes/set)

Electrode size: 22 × 14 mm

Lead color: 3 colors (red, yellow, green)
Application: Neonate/low birth weight infant

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.
- lodine 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.

Composition

Electrode: Ag/AgCl applied carbon

Adhesive gel: Acrylic hydrophilic high polymer, glycerin, water,

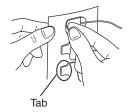
Electrode lead: Carbon, PVC

Attaching Electrodes

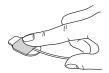
- Determine the electrode site. Do not place the electrode on a wound, inflamed, wrinkled or uneven skin surface.
- Clean the electrode site with a cotton pad moistened with alcohol.
- Thoroughly dry the skin with a clean cotton pad. Residual sweat or moisture may reduce the adhesive properties of the electrode.
- Open the package and pull out the electrodes from the package.
- Pinch the tab and remove the electrode from the gel cover.

NOTE

- · Avoid touching the adhesive surface.
- · Do not pull the lead when you remove the electrode from the gel cover. It may break the lead.



- Press one edge of the electrode down on the site, then continue to apply the rest of the electrode in the same manner.
- Press the label down firmly with a finger for secure contact as shown below.



Connect the electrode lead to the corresponding input.

When using a transmitter or a connection cord which has a red/yellow/black indication, connect the green electrode lead connector to the black connector of the transmitter or connection cord.

If necessary, fasten the electrode lead to the skin with surgical

NOTE

- · Make sure there is enough slack in the electrode lead. This prevents body movement from peeling the electrode off and breaking the electrode lead.
- · Do not connect the electrode connector directly to the transmitter. The signals are not transmitted properly and the monitor cannot receive the signals. Use the JC-933P ECG connection cord (supply code: K928).

Replacement

Replace the electrode about every 24 hours.

Storage

Store electrodes in a cool and dry place away from high temperatures or direct sunlight.

Specifications

Operating conditions

10 to 40°C (50 to 104°F) Temperature:

Humidity: 30 to 95 %

(When attaching to a place where the skin

surface is not wet)

Storage conditions

Temperature: $-10 \text{ to } +40^{\circ}\text{C} \text{ (14 to } 104^{\circ}\text{F)}$

Humidity: 15 to 95 %

Lifetime

The lifetime of the electrode is printed on the package. The lifetime is 24 months (including the month of manufacture) after manufacture. (tested by Nihon Kohden)

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