NISSHA
MEDICAL TECHNOLOGIES

Graphic Controls Acquisition Corp.
d.b.a. Nissha Medical Technologies
400 Exchange Street
Buffalo, NY 14204 USA
HS.NisshaMedical.com

ECG DIAGNOSTIC PREWIRED ELECTRODE

INSTRUCTIONS FOR USE FOR PREWIRED ECG ELECTRODES

This document applies to **Prewired ECG Electrodes** of Nissha Medical Technologies manufactured in the US with REF numbers **A10010-S**, **A10057-S**, **A10060-SRT** and **A10061-SRT**. Please reference the appropriate documents for **Standard ECG Electrodes** and **Tab ECG Electrodes**.

INTENDED USE

ECG Electrodes are an accessory for ECG monitoring and diagnosis. They are intended to be applied to the intact skin of the patient's chest and have to be connected to the respective ECG machine or patient monitoring system. ECG Electrodes serve as passive sensors for the derivation of electrical signals from the heart, which are recorded by the ECG machine or patient monitoring system and evaluated by qualified medical personnel. Depending on the application purpose, there are different electrode types available. They differ in shape, support material, gel, and cable connector. ECG Electrodes are single-use, non-sterile, and non-invasive medical devices

INDICATIONS

Any medical condition that is monitored and diagnosed by an ECG machine or a patient monitoring system.

CONTRAINDICATIONS

Do not apply ECG Electrodes on injured skin.

INTENDED USER GROUP

ECG Electrodes may be used by medical professionals only who must have undergone training regarding the use of ECG machine or patient monitoring system equipment.

INTENDED PATIENT POPULATION

Patient population are neonates.

CAUTIONS, WARNINGS & SAFETY PRECAUTIONS

- CAUTION: Federal law restricts this device to sale by or on the order of a physician.
- ECG electrodes should only be used by or in consultation with a health care provider familiar with their proper placement and use.
- Follow handling instructions of the ECG machine or a patient monitoring system in use.
- Choose an electrode that is suited for the application (e.g. stress test). Information is available in the brochure and on the home page.
- Observe expiry date on the electrode pouch.
- The ECG electrodes are ready to be used. Do not use additional contact gel.
- Products are categorized as Type CF and Defibrillation-Proof applied parts according to IEC 60601-1.
- Any modification of the electrode by the end user renders the Product Liability of Nissha Medical

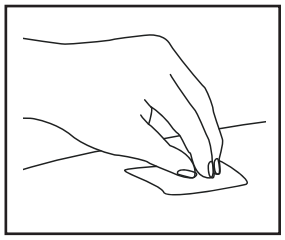
Technologies null and void.

- ECG electrodes should be applied only to intact, clean skin (e.g., not over open wounds, lesions, infected, or inflamed areas).
- During surgical procedures, electrodes should be placed as far as possible from any electro-surgical area to minimize unwanted RF current flow.
- If electrodes were misplaced, substitute them by fresh ones. Do not relocate electrodes.
- Electrodes should be replaced if they no longer stick firmly to the skin.
- ECG electrodes may damage the skin if removed carelessly.
- Minor skin irritation can occur with electrode use. If skin irritation occurs, please contact your prescribing physician or health care professional.
- ECG electrodes should be properly disposed of after use.
- ECG electrodes are single-use products. They must not be re-used. Re-use may result in impeded performance
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the state in which the user and/or patient is established.

STORAGE INSTRUCTIONS

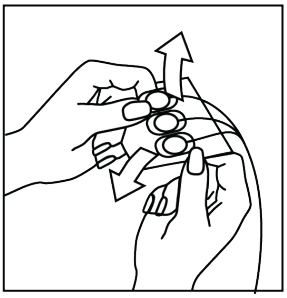
- Store electrodes only in original packing in a dry and cool place.
- Avoid direct sun light or the immediate vicinity of light sources, heating, or other heat emitting devices
- Keep storage temperature between 10°C and 32°C / 50°F and 90°F.

APPLICATION INSTRUCTIONS



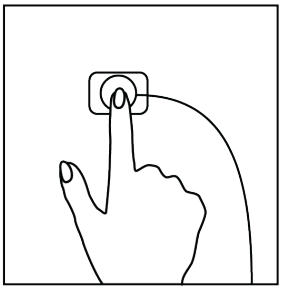
- **Prep**

1. Prep
Clean the skin to remove dirt, oils, and lotions, then dry completely.



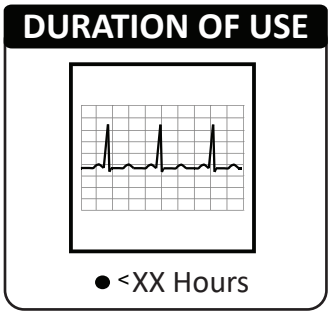
- **Peel**

2. Peel
Check that electrode is free from any damage. Then, peel off the ECG Electrode from the protective foil. Do not use damaged electrodes.



3. Apply
Place the electrodes on the patient. Do not apply the Electrode on injured skin.

- **Apply**



DURATION OF USE
Maximum duration of use for each Electrode variant is indicated with the pictogram shown on the pouch label.

REMOVAL INSTRUCTIONS

- Remove ECG electrodes with care from one point.
- Uncareful removal of electrodes can cause skin irritations (reddening).

DISPOSAL INSTRUCTIONS

- As ECG electrodes are single-use products they must be disposed after use.
- Please note that disposal must be in line with the applicable laws and requirements of the respective country.

EXPLANATION OF PACKAGING SYMBOLS

	Consult electronic instructions for use		Do not re-use
	Not made with natural rubber latex	Rx ONLY	Prescription only
	Temperature limitations		Keep away from sunlight
	Keep dry	QTY	Quantity
	Use by date	REF	Catalog Number
	Manufacturer	LOT	Lot Number