



INSTRUCTIONS FOR USE

NeoNatal ECG Electrodes

For Part Numbers:

A10055-SRT
A10077-SRT
A10058-SRT



CONSULT DFU FOR CAUTIONS AND WARNINGS



DO NOT REUSE



TEMPERATURE LIMITS



KEEP AWAY FROM SUNLIGHT



KEEP DRY



DO NOT USE IF DAMAGED OR OPENED



NOT MADE WITH NATURAL RUBBER LATEX



NOT MADE WITH PLASTICIZER DEHP



CONSULT DIRECTIONS FOR USE (DFU)

Rx ONLY PRESCRIPTION ONLY

EN ENGLISH

INDICATIONS FOR USE:

The Neonatal ECG Electrodes are intended for electrocardiogram (ECG) Monitoring. They are intended for use on pediatric (neonates, infants, and children) patients

DIRECTIONS FOR USE:

PREPARATION

Clean and dry skin per hospital protocol

NOTE: It is important for skin to be as clean and dry as possible. Electrodes will not adhere properly to moist skin or hair. Oils and lotions will also adversely affect adhesion. DO NOT USE ALCOHOL

APPLICATION

STEP 1: Before removing plastic liner, hydrocolloid adhesive must be actively warmed.

Warming techniques include:

- Hold between the palms of your hands for at least 60 seconds
- Hold near a radiant warmer for 10-15 seconds
- Hold against a chemical heel warmer for 10-15 seconds

STEP 2: One at a time, peel each lead from plastic liner, place the lead on the skin, and hold in place for 60 seconds to ensure proper adhesion

Discard the plastic liner.

REMOVAL

STEP 1: Replace lead every 5 days or per hospital protocol, whichever is sooner.

STEP 2: Saturate the lead with water or saline

STEP 3: Slowly peel the lead away from skin as you swab the area with water or saline.

CAUTIONS & WARNINGS:

- Federal law restricts this device to sale by or on the order of a physician.
- Leads should only be used while patient is under continuous direct supervision of healthcare professionals.
- Electrodes will not adhere properly to moist skin or hair. Oils and lotions will adversely affect adhesion
- Do not use alcohol to clean skin prior to application
- Do not use Radiolucent leads during MRI Procedures.
- Discontinue immediately if skin irritation occurs
- Disposable. Do not reuse.
- Single patient use only

Any Serious incident that has occurred in relation to this device should be reported to Nissha Medical Technologies.