

Technical Documentation	ECG Electrodes Instruction for Use of ECG Electrodes	TD N 1-127
NISSHA MEDICAL TECHNOLOGIES		Issue: 003
		Page 1/2

Instruction for Use of ECG Electrodes

This document applies to all ECG electrodes of Nissha Medical Technologies Ltd. marketed under the brand names “swaromed”, “Lead Lok”, “VersaTrode” and “BluFlex”.

Manufacturer

Nissha Medical Technologies Ltd
Woodview Road, Paignton,
Devon, TQ4 7HP,
United Kingdom
Tel.: +44 (0) 1803 860100
HS.NisshaMedical.com

Authorised Representative

Nissha Medical Technologies SAS
23-25 Boulevard de la Paix,
95000 Cergy,
France
Tel.: +33 1 39 72 66 66

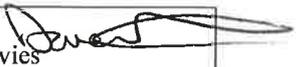
Intended Use

ECG-electrodes are intended to be applied to the intact skin of the patient’s chest and have to be connected to the respective ECG-monitor via a connection cable. They serve as passive sensors for the derivation of electrical signals from the heart, which are recorded by the ECG-monitor and evaluated by qualified medical personnel. The electrodes are self-adhesive pregelled single-use devices, which are intended for short-term application of up to 5 days on the patient’s skin. Depending on the application purpose (short-/long-term monitoring or stress test), there are different electrode types available. They differ in shape, support material, gel and cable connector.

General warning and safety precautions

ECG electrodes may be used by healthcare professionals only who must have undergone training on ECG applications.

- Follow handling instructions of the ECG-apparatus 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.
- Observe Instructions for Use on the electrode pouch (pictograms).
- The ECG electrodes are ready to be used. Do not use additional contact gel.
- Any modification of the electrode by the end user renders the Product Liability of Nissha Medical Technologies Ltd null and void.
- ECG electrodes are single-use products. They must not be re-used.
 - re-use may result in impeded performance
- If electrodes were misplaced, substitute them by fresh ones. Do not replace.
- 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.

File name: TDN 1-127_003 - Instructions for Use ECG Electrodes.docx	Editor: Marcel Salchner	Released:  Daren Davies
---	----------------------------	---

Technical Documentation	ECG Electrodes Instruction for Use of ECG Electrodes	TD N 1-127
		Issue: 003
		Page 2/2

Application and Safety Instructions

- 1.) Shave excessive hair carefully before application of the electrodes.
- 2.) Apply electrodes only to clean and dry skin (allow cleaning solvents to evaporate completely).
- 3.) Open pouch only immediately before use.
- 4.) Check if electrodes are undamaged.
- 5.) Connect connection cable with the electrode.
- 6.) Remove protective cover from the electrode.
- 7.) Place the electrode on the patient by pressing the carrier ring of the electrode in round movements firmly on the skin.
- 8.) Close pouch with unused electrodes by folding twice and fixing the fold with a clip.

Contraindications

- 1.) Do not apply ECG electrodes on injured skin.

Removal of ECG electrodes

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

Storage of ECG electrodes

- 1.) Store electrodes only in original packing in a dry and cool place.
- 2.) Avoid direct sun light or the immediate vicinity of light sources, heating, or other heat emitting devices.
- 3.) Keep storage temperature between 0°C and 40°C.

Disposal of ECG electrodes

- 1.) As ECG electrodes are single-use products they must be disposed after use.
- 2.) All ECG electrodes can be disposed without any damage to the environment. The materials used are non-toxic and can be either deposited or burnt expertly without forming toxic secondary products.
- 3.) Please note that disposal must be in line with the applicable laws and requirements of the respective country.

History:

Release Date	Issue	Description of Change
2020-02-28	001	Official Release based on Tyrolmed GmbH document TDN127 Rev. j
2020-06-19	002	Integration of EC-Rep and update to new webpage
2021-05-19	003	Update on EC-Rep address & to match MDR requirements