

English

# TETRA**SENS**

Rx Only

## TETRA**GRAPH** Electrode Instructions for Use

Ref. Nr.: 1 x SEN 1010  
20 x SEN 2012



[senzime.com/ifu](http://senzime.com/ifu)



Rx Only



MD

# 1. Warnings and Cautions

- TetraSens (SEN 1010) is only to be used by appropriately trained and experienced clinicians.
- Read all instructions before use.
- The TetraSens is not sterile.
- TetraSens is single use only. Reuse of TetraSens electrode is prohibited and may lead to inaccurate measurement, cross-contamination, infection and superficial burns.
- TetraSens is of a specific size, shape, and type for use with TetraGraph and may therefore only be used with TetraGraph monitor and TetraCord cable.
- The electrical performance and characteristics of electrodes may affect the safety and effectiveness of electrical stimulation and recording, therefore only TetraSens shall be used with the TetraGraph monitor.
- Using stimulation electrodes that are too small or applied incorrectly may result in poor performance, patient discomfort or burns to the skin.
- Apply electrodes to the patient before connecting to the TetraCord cable.
- Do not use electrodes which are past their expiry date or electrodes not specifically manufactured for use with TetraGraph.
- If irritation develops discontinue use on the patient.
- On patients with fragile skin, electrode use may cause skin damage (if removed rapidly), rash (allergic reaction), or redness. Ensure slow and gentle removal.
- Tattoo pigments can cause skin burns when subject to electrical stimulation.
- Only apply electrodes to normal, clean, and dry skin with normal sensation.
- Store in a dry, cool place away from heat sources.
- In the USA, Federal law restricts this device to use by prescription only.
- The TetraGraph system shall not be taken into an MRI environment.
- TetraSens shall be removed before x-ray imaging the area of its application.
- Symbols used in the labelling for this product are further described in the instructions for use of TetraGraph.

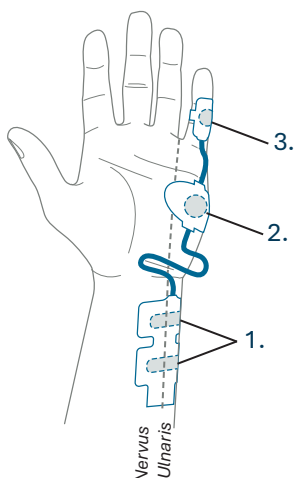
## 2. Application

- The TetraSens is intended to be used together with a TetraGraph™ monitor. For intended use, see instructions for use for TetraGraph™ monitor.
- The TetraSens SEN 1010 is used to electrically stimulate a superficial peripheral nerve and record the muscular response (muscle action potentials) from the innervated muscle. The stimulating electrodes are placed over the nerve and the recording electrode

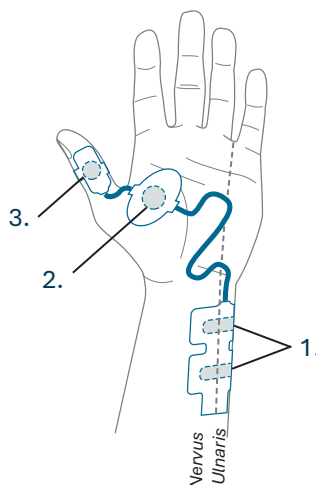
is placed over the innervated muscle. Examples are shown in the illustrations for placement on M. Adductor Pollicis and M. Abductor Digiti Minimi, both innervated by the ulnar nerve, and M. flexor hallucis brevis innervated by the posterior tibial nerve.

- TetraSens is intended for positioning on different sized hands/feet and can be applied on either hand/foot.
  - Apply only to intact, dry, and clean skin.
  - Thoroughly cleanse and completely dry the skin sites prior to application.
  - Clip to remove hair if necessary. Do not shave the skin application area.
  - Electrodes must be replaced if they no longer stick firmly to the skin.
  - One electrode array can be used for up to 24 hours.
1. Tear the pouch open along the dotted line (Do not use scissors) and remove the TetraSens from the pouch.
  2. Remove stimulation (proximal, oval) electrodes from the liner by lifting the edge of the electrodes and apply it over the peripheral nerve, see examples in the illustrations. (1)
  3. Remove recording (distal, round) electrode from the liner by lifting the edge of the electrodes and apply to the muscle as illustrated in the examples. (2)
  4. Remove reference electrode from the liner and apply over a joint or bone. (3)
  5. Apply electrodes by firmly pressing down on the center of the electrode first and then smoothing down the electrode edge.

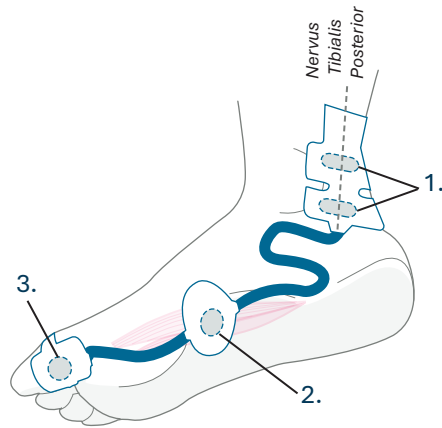
N. Ulnaris, M. Adductor Pollicis



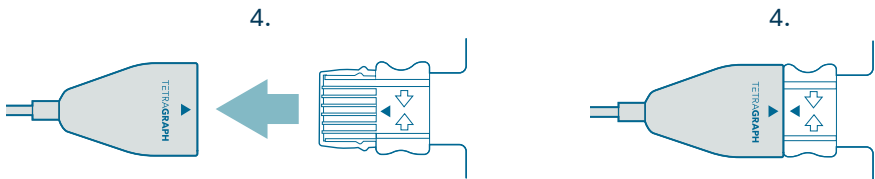
N. Ulnaris, M. Abductor Digiti Minimi



## N. Tibialis Posterior, M. Flexor Hallucis Brevis



6. Connect the TetraCord cable to the electrode by inserting the electrode connector into the cable connector, ensuring correct orientation as illustrated. (4) A click sound confirms correct pairing.



### 3. Removal

1. Turn the TetraGraph™ monitor off or select “New Patient”.
2. Disconnect the TetraCord cable from the electrode by squeezing the tabs on the side of the electrode connector while pulling it out of the cable connector.
3. Remove the electrode from the skin by gently peeling from the edge.
4. Remove possible gel residue from the skin.
5. Dispose of used electrodes as clinical waste.

**Note** Any serious incident that has occurred to the user and/or the patient in relation to TetraSens should be reported to Senzime and the competent authority of the Member State in which the user and/or patient is established.





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