

English

TETRASENS
Pediatric

Rx Only

TETRAGRAPH Electrode
Instructions for Use

Ref. Nr.: 1 x SEN 1011
15 x SEN 2013



senzime.com/ifu



Rx Only



MD

 **SENZIME**

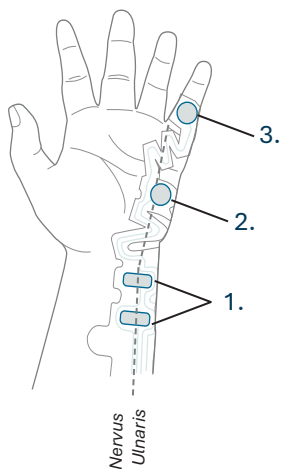
1. Warnings and Cautions

- TetraSens Pediatric (SEN 1011) is only to be used by appropriately trained and experienced clinicians.
- Read all instructions before use.
- The TetraSens Pediatric is not sterile.
- TetraSens Pediatric is single use only. Reuse of TetraSens Pediatric electrode is prohibited and may lead to inaccurate measurement, cross-contamination, infection and superficial burns.
- TetraSens Pediatric is of a specific size, shape, and type for use with TetraGraph and may therefore only be used with TetraGraph monitor and TetraCord cable.
- Do not use the product on neonates.
- The electrical performance and characteristics of electrodes may affect the safety and effectiveness of electrical stimulation and recording, therefore only TetraSens Pediatric shall be used with the TetraGraph monitor.
- Using stimulation electrodes that are too large or 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 Pediatric 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.

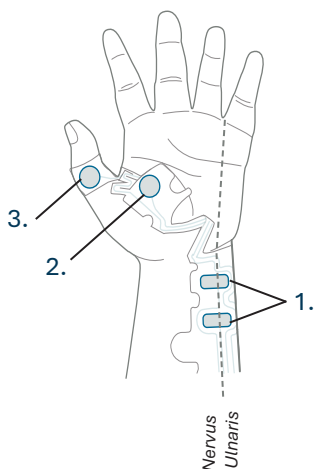
2. Application

- The TetraSens Pediatric is intended to be used together with a TetraGraph monitor. For intended use, see instructions for use for TetraGraph monitor.
 - The TetraSens Pediatric SEN 1011 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 Pediatric can be used for ages from 1 month or older.
 - TetraSens Pediatric 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.
 - If it is necessary to remove hair, clip instead of shaving.
 - 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. Open the pouch by peeling apart the seams starting from the arrow-shaped seal. remove the TetraSens Pediatric from the pouch.
 2. Tear the perforation in the liner between the stimulation electrodes (proximal, oval) and the recording electrodes (distal round).
 3. 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)
 4. Tear the perforation in the liner between the recording and the reference electrode (distal, round).
 5. 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)
 6. Remove reference electrode from the liner and apply over a joint or bone. (3)
 7. Apply electrodes by firmly pressing down on the center of the electrode first and then smoothing down the electrode edge.

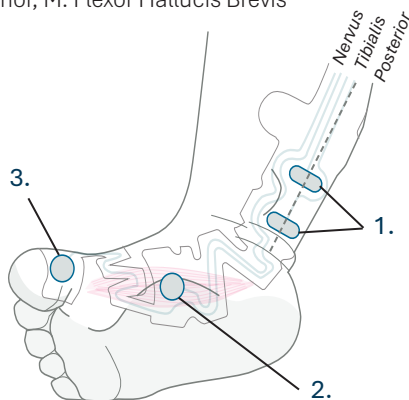
N. Ulnaris, M. Abductor Digiti Minimi



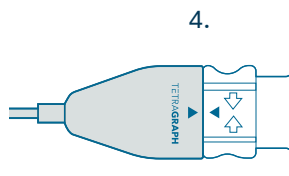
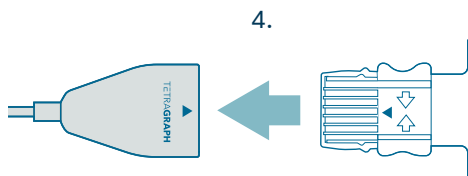
N. Ulnaris, M. Adductor Pollicis



N. Tibialis Posterior, M. Flexor Hallucis Brevis



8. 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.



Manufacturer:
Senzime AB
Verkstadsgatan 8
753 23 Uppsala
Sweden

UK Responsible Person:
QAdvis UK Ltd
56-66 Frederick Street
Edinburgh, EH2 1LS, GB



senzime.com/ifu

www.senzime.com
info@senzime.com

Copyright © Senzime AB all rights reserved – updated 2026
The information in this document is the property and copyright of Senzime AB. This document is only intended for users of the device and shall not be copied, circulated, or transmitted electronically to other parties.

