TRIGNO™ EMG System

Snap Lead Sensor User's Guide

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Important Information

Intended Use

The Trigno™ Wireless EMG Systems are battery-powered biofeedback devices that enable researchers and clinicians to acquire EMG and related signals from subjects for biofeedback purposes. They are intended for relaxation training and muscle reeducation. Interpretation of the EMG and supporting signals by a qualified individual is required.

Rx ONLY

DO NOT USE on Patients with implanted electronic devices of any kind, including cardiac pace-makers or similar assistive devices, electronic infusion pumps, and implanted stimulators.

DO NOT USE on irritated skin or open wounds.

DO NOT USE on Patients with allergies to Silver.

DO NOT USE in critical care applications.

Technical Service and Support

For information and assistance visit our web site at:

www.delsys.com

Contact us at:

telephone: (508)-545-8200

email: support@delsys.com

Warnings and Precautions

Consult all accompanying documents for precautionary statements and other important information.

Consult accompanying user's guide for detailed instructions.

Keep the device dry. The device is not waterproof and should not be submerged under any circumstance. The ingress of liquids may compromise the safety features of the device. The device is not intended for use under high sweat conditions. Situations which may result in the entrapment of sweat around the sensors must be avoided.

Handle with care. Trigno™ sensors and instruments are precision devices and not designed for excessively rugged use. Carefully inspect devices prior to each use to ensure that no mechanical deterioration has occurred.

Sensitive electronic device. Avoid static discharges. Do not operate or store near strong electrostatic, electromagnetic, magnetic or radioactive fields. Interference from external sources may decrease the signal-to-noise ratio or result in corrupted data.

Connect only to Delsys-approved devices.

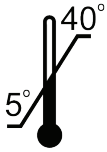
Connecting a patient to high-frequency surgical equipment while using Delsys EMG systems may result in burns at the site of the EMG sensor contacts.

Immediately discontinue device use if skin irritation or discomfort occurs.

Immediately discontinue device use if a change in the device's performance is noted. Contact Delsys technical support for assistance.

Delsys Inc. guarantees the safety, reliability, and performance of the equipment only if assembly, modifications and repairs are carried out by authorized technicians; the electrical installation complies with the appropriate requirements; and the equipment is used in accordance with the instructions for use.

Device contains a Lithium-Polymer battery. Do not damage, crush, burn, freeze, heat or otherwise mishandle the device. Recharge only with the approved power supply and recharger. Sensors should be charged at least once every 3 months to prevent battery damage from excessive self discharge. Extended periods in the discharged state may damage the internal lithium polymer cell.



Trigno™ Systems should be stored and operated between 5 and 40 degrees Celsius due to the presence of an internal Lithium Polymer rechargeable cell. Storing or operating the device, and consequently the cell, outside of this temperature range may compromise the integrity and the safety features of the cell.

Device Information

Complies with Requirements put forth by the Medical Device Directive 93/42/EEC. Class I device, Annex VII.

Type BF device (IEC 60601-1).

Isolated device, (Class II, IEC 60601-1)

Do not dispose this product with house waste. Contact Delsys Inc. for instructions on responsibly disposing this device. This product should not be mixed with other commercial wastes.

Date of Manufacturing (appears on device)

SN

Serial Number (appears on device)

EC REP

EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Authorized Representative

DELSYS INC.
23 Strathmore Rd.
Natick, MA 01760
USA

Manufacturer

FCC ID: W4P-SP-W01 (Trigno™ Sensor)
FCC ID: W4P-SP-W05 (Trigno™ Sensor)

This device complies with Part 15 of the FCC Rules and Industry Canada's RSS-210 License Exempt Standards. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This product complies with FCC OET Bulletin 65 radiation exposure limits set forth for an uncontrolled environment.

Pursuant to Part 15.21 of the FCC Rules, any changes or modifications to this product not expressly approved by Delsys Inc. might cause harmful interference and void the FCC authorization to operate this product.

To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (EIRP) is not more than that required for successful communication.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. There is no guarantee that interference,will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into outlet on a separate circuit.

Disclaimer

DELSYS INC. makes no warranties, express or implied, as to the quality and performance of this product including but not limited to, any implied warranty of applicability for other than research uses by qualified individuals. DELSYS INC. shall not be liable to any person for any medical expenses or any direct or consequential damages resulting from any defect, failure or malfunction, whether a claim for such damages is based upon theory of warranty, contract, tort or otherwise. No representative, agent, or licensed practitioner is authorized to waive this disclaimer. DELSYS INC. makes no diagnosis or prescription by virtue of anything about this product.

System Requirements

The Trigno™ Snap Lead Sensor is designed to be used with Trigno™ Wireless EMG Systems.

Snap Lead Sensor Overview

Delsys recommends to use Snap Lead sensors with care as motion artifact and cross-talk issues are commonly associated with these types of wire-lead electrode sensors. Also, please be aware that large inter-electrode distances may increase the EMG signal cross-talk from adjacent and underlying muscles and could possible obscure the surface EMG signal of inerest.

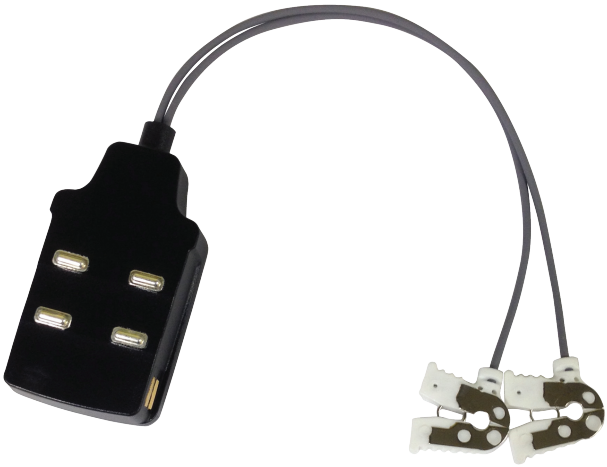


Figure 1. Snap Lead Sensor- The main body host 4 contacts for establishing a local reference, and includes an on-board ±1.5g/±6g accelerometer.

Using the Sensors

Charging the Sensors

Connect the Trigno™ power supply to the circular DC jack located on the side of the Trigno™ Base/Recharge Station. Energize the power supply by connecting it to a Mains outlet. Be sure to use the appropriate plug adapter for your location. Ensure that the Trigno™ sensors are properly fitted in the recharge pockets. The sensor LEDs will illuminate to amber during charging and green when charge is complete. The recharge unit will periodically check sensors and apply a top-off charge to ensure that the battery is kept at full capacity during extended periods of storage, as long as power is connected.

Figure 2. Connecting the SC-P05 power supply to the Sensor Charge Station.

Sensor Pairing

Trigno™ sensors communicate with a custom wireless protocol that links each sensor to the active Trigno™ network This linking process is known as sensor "pairing", and is initiated through the "Pair" command in EMGworks®.

1. Turn sensor on by depressing the sensor button.

2. Initiate sensor pairing in software.

When using EMGworks®, initiate pairing by right-clicking the Trigno™ hardware icon in the system notification area, and selecting the appropriate menu item.

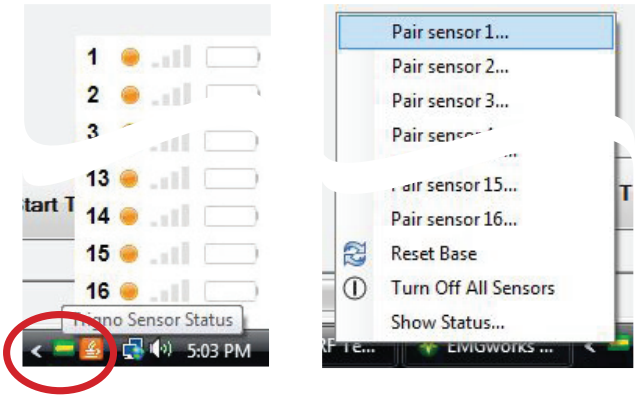


Figure 3. Invoking the Pair command. Right click on the Trigno™ icon in the system tray (left) and select the desired channel to pair to (right).

3. Complete the pairing process by depressing the desired sensor button for a minimum of 3 seconds. Successful pairing will result in 3 green LED flashes on the sensor, and a confirmation message in the software.

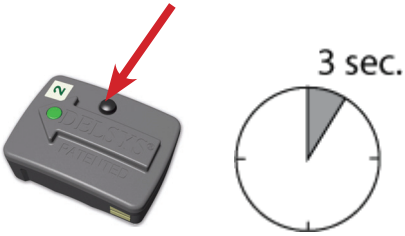


Figure 4. Pushing the sensor button to complete the pairing task.

Trigno™ systems are shipped with all sensors appropriately paired. Sensor pairing is typically needed in the following situations: a) if sensors are being replaced within the network group, b) when the communication frequency sets are changed, and c) after a firmware upgrade is performed.

Upon pairing sensors, EMGworks® will present the option to enter a "Delsys Factory Calibration" sequence or to use the "Auto-Detected Calibration". Select the "Auto-Detected Calibration" option unless the sensor is specifically supplied with a calibration key (this is not common). Note that if the sensor is being paired for the first time with the base station, the choice will read "Use Default Calibration" rather than "Use Auto-detected Calibration".

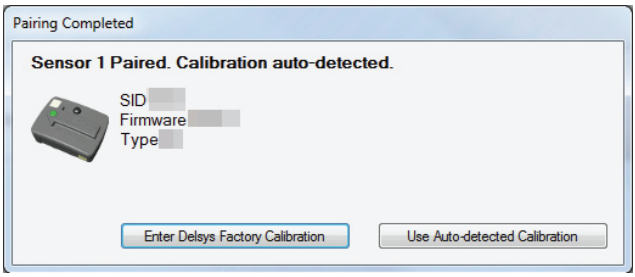


Figure 5: The calibration can be auto-detected, or manually retrieve..

Smart Sensor Features

After pairing, the association of sensors to the Trigno™ System is retained for all future uses. Any configuration in EMGworks® can be made to reflect the last paired set of sensors by clicking the "Refresh Smart Sensors" button in the "Add Sensors" pane in EMGworks®. When data collection starts, the software will verify that the sensors currently communicating match those used in the configuration. If there is a mismatch, cancel the recording and repair the sensors.

The Snap Lead EMG Sensor will appear with a unique icon shown below in EMGworks once it has been properly paired and identified.

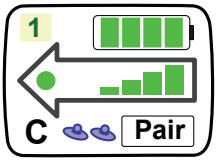


Figure 6. Trigno™ Snap Lead Sensor icon appearing EMGworks, identified as a type "J" device. (Note that the icon may appear different than shown.

Please refer the Trigno™ EMG System User Guide for further details on system and sensor operation.

Working with the Snap Lead Sensors

As with all EMG sensor technolgoy, the Trigno Snap Lead sensors must be propoerly position above the muscle to to obtain a qualtiy EMG signal. The snap electrodes must be placed to parallael to the muscle fiber direction for maximmal signal detection. Rotational skew from this optimal orientation will diminish signal amplitude

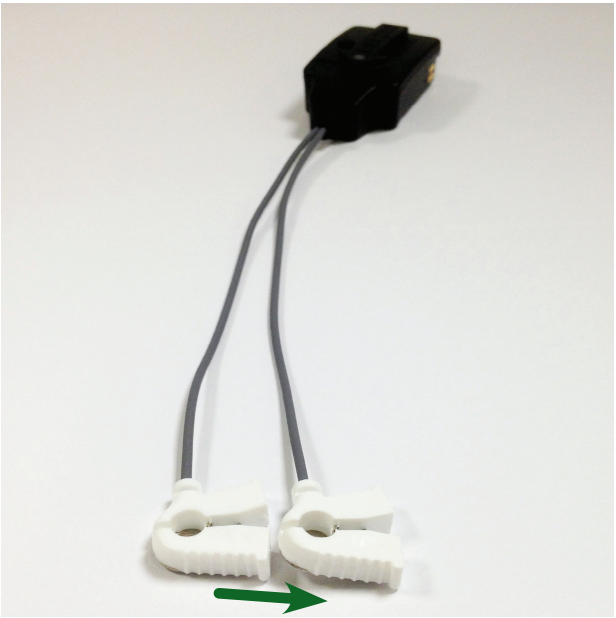


Figure 7. The Snap Lead sensor top is marked with an arrow which must be placed parallel to the muscle fiber direction in order to properly detect an EMG Signal.

and increase the potential for signal crosstalk.

The sensor body and its 4 silver contacts must be well-affixed to the skin to provide a quality signal reference point for the Snap Lead EMG contacts. Use the Delsys SC-F03 four-slot adhesive skin interface to adhere the sensor to the skin. These interfaces are manufactured from medical grade adhesive approved for dermatological ap-

plications. Usage of the interface promotes a high quality connection between the sensor bars and the skin, minimizing motion artifacts and the potential disturbances from line interference. Other methods of skin attachment are not recommended.

Adhesive Sensor Interfaces are for single use only.

Immediately discontinue use if skin irritation or discomfort occurs. All Adhesive Sensor Interfaces are for single use only. Discard after using. Reseal storage bag to maintain freshness.

Prior to affixing the EMG sensor on the surface of the skin, it is recommended to clean the area to remove dry dermis and skin oils. If excessive hair is present, it may also be necessary to shave the site. In cases where the skin is excessively dry, it may be useful to dislodge dry skin cells by dabbing the site with medical tape. The dry cells will attach the tape's adhesive when it is removed. Be sure to wipe with isopropyl alcohol to remove any adhesive residue that may remain.

Maintenance and Care

Trigno™ sensors are encased in a sealed polycarbonate enclosure. The following points should be kept in mind when handling the sensors.

- All sensors should be visually inspected before each use to ensure that no mechanical deterioration has occurred.
- The sensors can be cleaned with 70% isopropyl alcohol swabs. Ensure that the sensor contacts remain clean at all times for proper operation.
- The sensors are not waterproof and should not be submerged in any liquids under any circumstance. The ingress of liquids may compromise the safety features of the device. These devices are not intended for use under high-sweat conditions, where the accumulation or the entrapment of sweat can expose the sensor to sustained levels of dampness.
- The sensor contacts are made of pure silver and are quite soft. Care should be taken to preserve the integrity of these contacts. Do not scrape or dent these contacts.
- Handle the sensors with care: do not drop them on the ground or step on them.
- The cables connecting the Snap Lead sensing element to the sensor body is designed to be supple and unobtrusive while being worn. Take care to never pull device by the cable, or excessively stress this cable as this may result in cable damage. Inspect the device prior to each use to ensure that not deterioration has occurred.
- Battery duration is a function of battery age and charge/discharge conditions. Optimal battery performance is obtained when the device is operated at room temperature. Excessive heating (above 40 deg. C) or excessive cooling (below 5 deg. C) may damage the internal battery. Contact Delsys Technical support if the device is exposed to temperatures outside of these limits.
- The device battery capacity is typically expected to decrease to 80% of it's original capacity after 300 charge/discharge cycles. Batteries will self-discharge with time if unused. Excessive self-discharging may damage the battery. Periodically charge the sensors at least once every 3 months, to extend battery life.

Do not submerge the sensors in any liquid under any circumstance.

The sensors contain sensitive electronic circuitry. Static discharges and intense magnetic fields should be avoided to prevent the risk of irreparable damage to the sensors.

Specifications

Typical Operating Range(1)	40 m
RF Frequency Band	2400-2483 MHz (ISM band)
Power Consumption	<65 mW
Effective Radiated Power	9 mW
RF Protocol	Proprietary
Enclosure Dimension (main sensor)	27 x 37 x 15 mm
Full-charge Operation Time(2)	8 hours (typical)
Recharge Time(3)	<2.5 hours
Temperature Range(4)	5 - 40 degrees Celsius
Signal Range	11 mV (r.t.i)
EMG Channel Bandwidth	20 ± 5 Hz, >40 dB/dec 450 ± 50 Hz, >80 dB/dec
ACC Channels Bandwidths	DC - 50 Hz ± 5 Hz, 20 dB/dec
EMG Channel Sampling Rate	1925.93 samples/sec
Accelerometer Sampling Rate	148.1 samples/sec/axis
EMG Channel Resolution Depth	20 ± 5 Hz > 40 dB/dec 450 ± 50 Hz > 80 dB/dec
Accelerometer Resolution Depth	0.016 ± 0.001 g/bit (at ± 1.5 g) 0.063 ± 0.005 g/bit (at ± 6 g)
EMG Channel Noise(5)	<500 nV (rms), r.t.i.
Accelerometer Noise	0.004g (rms, ± 1.5g) 0.016g (rms, ± 6g)

(1) Range is characterized in open office environments. Interfering RF sources in the 2.4 GHz spectrum, as well as absorptive objects occluding the RF communication path may degrade transmission distance. Stated range can be exceeded under favorable RF conditions.

(2) Battery duration is a function of charge and discharge conditions. Optimal battery performance is obtained when the device is operated at room temperature. Note that the stated Operation Time reflects the expected performance of a fully charged new battery used in a sensor that is transmitting data. Operation Time is expected to decrease as a function of charge cycles, and when the sensor is searching for a network.

(3) 80% of original battery capacity is maintained after 300 discharge/recharge cycles or after 2 years if recharge cycles are less than 300. These values represent typical expectations under normal conditions. Actual performance will vary depending on usage conditions.

(4) Operation beyond these temperature limits may damage the rechargeable battery.

(5) Input-referred noise is calculated as a root mean square over a 3 second window sampled at 1926 kHz.

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