

TRIGNO™ EMG Biofeedback System

Trigno Flex 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.

The Trigno Flex Sensor (also known as Trigno DR Sensor) is a component of the Trigno System and is used to detect electromyographic signals from the surface of the skin. It is designed to function exclusively with the Trigno System. .

Rx ONLY



Refer the Trigno EMG System User Guide for important information regarding the Trigno System

DO NOT USE for diagnostic or critical care applications.

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.

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.



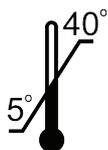
Immediately discontinue device use if a change in the device's performance is noted. Contact Delsys technical support for assistance.



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)



Serial Number (appears on device)



EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Authorized Representative



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

Manufacturer



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™ Flex Sensor is designed to be used with Trigno™ Wireless EMG Systems.

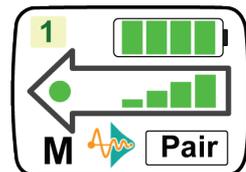
Trigno Flex Sensor Overview

The Trigno Flex sensor is an EMG biofeedback sensor designed to be used exclusively as a component of the Trigno EMG System. The sensor is designed to accommodate research needs requiring an expanded bandwidth range (10-850 Hz) or an expanded amplitude input range (0-22mV). The original recommended parameters of the standard sensor are available as well, so that the expanded parameter settings need only be engaged if the researcher specifically requires this level of performance. The table below identifies the choices available.

Parameter Setting	Description
Standard Amplitude 11 mV (r.t.i.)	This is the standard input amplitude range recommended for typical EMG signals from skeletal muscles.
Expanded Amplitude 22 mV (r.t.i.)	The extended input amplitude accommodates larger amplitude input signals but decreases the resolution of the baseline by a factor of 2. This setting should be used in cases where signal clipping is occurring due to large amplitude signals at the skin site.
Standard Bandwidth 20-450 Hz	This is the recommended bandwidth for maximizing the signal-to-noise ratio of the raw EMG signal without compromising the fidelity of the signal.
Expanded Bandwidth 10-850 Hz	The expanded bandwidth maximizes the frequency capture content of the Trigno sensor and will necessarily detect higher noise levels. This setting can be used to explore the EMG signal characteristics at the high and low frequency extremes and to more accurately capture noise disturbances should the quantification of these signals be of interest.

Smart Sensor Features

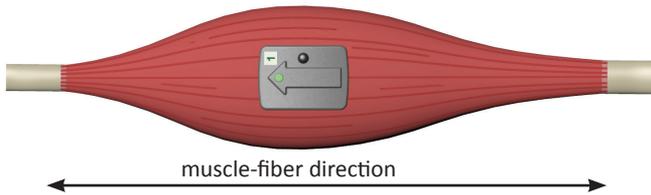
The Trigno Flex Sensor will appear with a unique icon in EMGworks for easy identification once it has been properly paired. Battery charge status, wireless signal strength and pairing status are reported from the the s Please refer to the EMGworks User Guide for software operation and details.



Using Trigno Flex Sensors

Orienting the EMG Sensors on the Skin

Trigno EMG Sensors employ 4 silver bar contacts for detecting the EMG signal at the skin surface. For optimal performance, it is important to orient these bars perpendicular to the muscle fiber direction. The top of the sensor is shaped with an arrow to aid in the determination of this orientation. The arrow should be placed parallel to the muscle fibers underneath the sensor. The sensor should also be placed in the center of the muscle belly away from tendons or the edge of the muscle. The sensor is easily attached to the skin using the Delsys Adhesive Sensor Interface



Cleaning the Sensor Site

Prior to affixing the EMG sensor on the surface of the skin, the sensor site must be properly cleaned to remove dry dermis and any skin oils. Wiping the skin prior to sensor application helps ensure a quality signal. If excessive hair is present, it will 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 to the tape's adhesive when it is removed. Be sure to wipe with isopropyl alcohol to remove any adhesive residue that may remain.

Applying the Trigno Adhesive Skin Interfaces

Trigno Systems are supplied with specially-designed adhesive interfaces to simplify sensor attachment. These hypo-allergenic interfaces are manufactured from medical grade adhesive approved for dermatological applications. Usage of the interface promotes a high quality electrical connection between the sensor bars and the skin, minimizing motion artifacts and the ill-effects of line interference. To ensure a strong bond with the skin, it is advised to remove excessive hair and

wipe the skin area along with the EMG Sensor with isopropyl alcohol to remove oils and surface residues. Allow the skin to dry completely before applying the interfaces.



Adhesive Sensor Interfaces are for single use only.



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



Do not use on Patients with allergies to silver.



Do not apply over open wounds or irritated skin.

Turning the Sensors ON

Trigno Sensors are turned on by depressing the rubber button for approximately one second. The green LED on the sensor will immediately begin to flash, and begin searching for a Base Station that has been properly paired and is within its range. As soon a link is established with the Base Station, the sensor LED will flash green approximately once per second, indicating that data are streaming.

If no Base Station is found, the LED will alternate between amber and green, indicating that it does not have an established communication link. In this case the sensor must be paired with the base station which is easily done by initiating a pair command from the software and depressing the sensor button for approximately 3 seconds. Refer to the Trigno EMG system User Guide for information on sensor pairing and additional system details.

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. Do not use if any deterioration of the enclosure integrity is noted.
- The sensors can be cleaned with 70% isopropyl alcohol swabs. Ensure that the sensor contacts remain clean at all times for proper operation. No other cleaning agents are recommended.
- 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.
- Handle the sensors with care: do not drop them on the ground or step on them.
- 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 its 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 to maintain optimal battery performance.



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⁾	20 m
RF Frequency Band	2400-2483 MHz (ISM band)
Power Consumption	<0.130 W
Effective Radiated Power	9 mW
RF Protocol	Proprietary
Full-charge Operation Time ^(2,3)	>6 hours (typical)
Recharge Time ⁽³⁾	2.5 hours
Auto Shut-down timer	300 seconds
Temperature Range ⁽⁴⁾	5 - 40 degrees Celsius
Sensor Input Range ⁽⁵⁾	11 mV (r.t.i.) 22 mV (r.t.i.)
EMG Signal HPF Corner ⁽⁶⁾	20 ± 5 Hz, ≥40 dB/dec 10 ± 5 Hz, ≥40 dB/dec
EMG Signal LPF Corner ⁽⁶⁾	450 ± 50 Hz, ≥80 dB/dec 850 ± 100 Hz, ≥80 dB/dec
Filter Design	Butterworth
Sampling Period ⁽⁷⁾	27/52 ms
Resolution Depth	16 bits
Baseline Noise	≤ 2.5 uV(r.m.s., r.t.i.) ⁽⁸⁾ ≤ 3.0 uV(r.m.s., r.t.i.) ⁽⁹⁾
CMRR ⁽¹⁰⁾	≤ -80 dB
Enclosure Dimension (sensor)	26 x 37 x 15 mm
Electrode Material	Silver

- (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. Range is also expressed as a typical area coverage, which would circumscribe a circle with diameter 40m.
- (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) Signal input range is software selectable.
- (6) High-pass filter (HPF) and Low-pass filter (LPF) corners are software selectable.
- (7) Guaranteed by firmware and cannot be changed.
- (8) Maximum root mean-square (r.m.s.) noise referred to input (r.t.i.) with bandwidth setting of 20-450 Hz, and input range of 11 mV.
- (9) Maximum root mean-square (r.m.s.) noise referred to input (r.t.i.) with bandwidth setting of 10-850 Hz, and input range of 11 mV.
- (10) Common Mode Rejection Ratio measured at 60Hz, 200 mVpp input.

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