TRIGNO™ EMG System

4-Channel FSR Adapter User's Guide

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Important Information

Intended Use

The TrignoTM Wireless EMG Systems are battery-powered biofeed-back 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 regularly to extend the battery life. 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





FCC ID: W4P-SP-W03 (Trigno Body Worn Receiver)

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

IC: 8138A-DST02 (Trigno Personal Monitor System)

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 4-channel FSR Sensor is designed to be used with the Trigno Wireless EMG System.

FSR Sensor Overview

The Trigno 4-channel FSR (Force Sensitive Resistor) Sensor is an accessory to the Trigno EMG System designed to provide relative pressure information of body-contact surfaces, such as the heel, the toe and the fingers. Each sensor transmits 4 independent analog signals, each servicing an individual FSR membrane. Three FSR membrane sizes are available for optimizing performance in varieties of scenarios. One 4-channel FSR Sensor occupies one position of the 16 possible sensors in a Trigno network. Data are expressed as a percentage of the sensor's full scale limits. These devices are useful for identifying the timing of significant events and for making relative amplitude comparisons, but are not suitable for making absolute measurements of force or pressure.



Figure 1. 4-Channel FSR Sensor for Trigno EMG Systems.

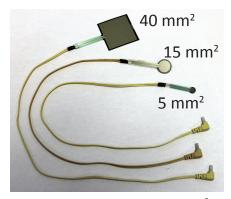


Figure 2. FSR membrane options at 5 mm², 15 mm² and 40 mm² surface area.

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 3. 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. 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.

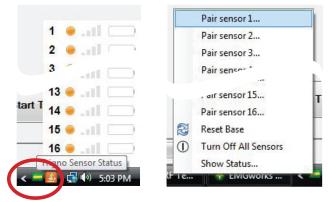


Figure 4. Invoking the Pair command. Right click on the Trigno icon in the system tray (left) and select the desired channel to pair to (right).

2. 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.

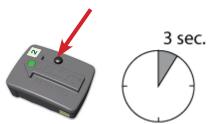


Figure 5. Pushing the sensor button to complete the pairing task.

Trigno systems are shipped with all sensors appropriately paired. Sen-

sor 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).



Figure 6: The calibration can be auto-detected, or entered manually if the sensor is being paired for the first time.

Smart Sensors

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 4-channel FSR Sensors will appear with a unique icon shown below in EMGworks once it has been properly paired and identified.

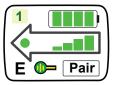


Figure 7. Trigno FSR Sensor icon appearing EMGworks, identified as a type "E" device. (Note that the icon may appear different than shown.



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

Working with the FSR Membranes

Handling FSR Membranes

The FSR membranes are delicate transducers constructed in multiple layers that have an ability to change resistance as pressure is applied. Delsys supplies these membranes with a 30 cm cable extension, terminated with a shrouded barrel connector for mating with the wireless sensor. Care must be exercised when using these membranes as excessive forces will damage them. These are particularly vulnerable to shear forces, such as those encountered during walking or running, which may cause the membrane to delaminate. It is recommended to place the membrane in a protected location where its exposure to these forces is limited. Alternatively, the FSR membrane can be protected by layering it between two pieces of clear vinyl packaging tape. In this case, care must be taken to ensure that the air channel at the membrane edge is not occluded and remains clear.

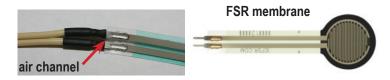


Figure 8. The FSR membrane. Ensure that the air channel at the joint of the membrane and the cable remains clear so that air can flow during membrane compressions.

Connecting the FSR Membranes to the Sensor

The Trigno FSR Sensor has a connector head hosting 4 receptacles for the membrane transducers. Connect the FSR membranes by to the 4 barrel receptacles taking care to fully mate the plug. The connectors are labeled numbers 1-4 on the sensor, and portrayed in this order in the EMGworks software. All FSR membranes are interchangeable.



Figure 9. Mating the FSR membrane connectors to the sensor connector head. Ensure that the barrels are fully inserted.

Applying the FSR Membrane

The FSR membranes can be used in a wide variety of circumstances and applications; thus each case must be evaluated for any particular challenges it may pose. One common application of this device is to use it as footswitch during walking or running. With this example, one can consider several options for affixing the sensor to the heel, as shown in the figures below.

Taping the sensor directly to the heel will produce a very sensitive and responsive signal. However this approach subjects the FSR membrane to high load and shear forces, which may cause signal saturation accelerated wear. Protecting the FSR membrane with vinyl tape or similar material is recommended to extend usage life.



Figure 10. Affixing the FSR membrane directly on the heel.

An alternative approach to affixing the FSR membrane to the heel, is to instrument the shoe by taping it to the sole. This will produce a similar response as the previous example, but may offer some added

convenience for repetitive data trails. It is also advisable in this case to protect the FSR membrane with vinyl tape in order to extend its usage life.



Figure 11. Affixing the FSR membrane to the top of the inner sole.

Placing the FSR membrane on the bottom of the inner shoe sole, provides some added protection to the device, as load and shear forces are diffused between the show base and the sole. This location may also be convenient to avoid signal saturation in cases of high loads.



Figure 12. Affixing the FSR membrane to the bottom of the inner sole.

The examples above serve to illustrate common techniques that Researchers employ when using FSR type devices. Each situation and use-case is unique, however, so the User is encouraged to explore other strategies as needed. The 3 supported FSR membrane size can be used in a wide range of applications which can include activities such as sitting, walking, lying down, jumping, fingertip contact and many others.



Figure 13. FSR membrane options for varieties of applications servicing 5 mm², 15 mm² and 40 mm² areas.

Since each FSR sensor can support up to 4 channels, it is possible to observe 4 pressure points with 1 sensor. Continuing with the previous example of monitoring footstrike at the heel, one could add 3 additional monitoring points to the 1st metatarsal, the 5th metatarsal and the toe, resulting in well-characterized contact point map of the foot.

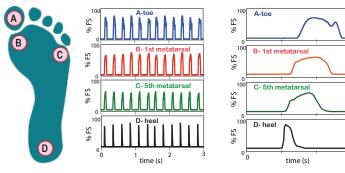


Figure 14. Mapping 4 pressure points of the foot. Left panel shows the location of the 4 pressure points being monitored. Middle panel shows data from these during low intensity running on a treadmill as acquired by EMGworks. Right panel expands the time scale for 1 footstrike, showing the time-course and relative intensity of each pressure point.

Placing the FSR Sensor

The Trigno FSR Sensor and the associated connection head can be easily affixed to the surface of the body using the Delsys Adhesive interfaces. The connector head is easily serviced by cutting a full-size interface in half. Additional self-adhesive wraps or tapes can be used to further secure the sensor on the body.



Figure 15. Placing the FSR Sensor on the body.

Connecting the FSR Sensor Analog Outputs

When paired to a Trigno EMG System, the 4-channel FSR Sensor effectively replaces the EMG channel and 3 accelerometer channels (X, Y and Z) of the standard EMG sensor originally associated with those positions. As such, analog outputs of these channels will output the FSR analog signals. Note that FSR 1 takes the position of the EMG signals and thus sampled at 1926 samples/sec with a resolution depth of 16 bits. Remaining connectors FSR 2, 3 and 4 occupy the accelerometer channel positions of X, Y and Z respectively and are thus sampled at 148 samples/sec to a resolution depth of 10 bits. Please refer the Trigno EMG System Manual for further details on the analog output connections.

Specifications

Typical Operating Range ⁽¹⁾	20 m	
RF Frequency Band	2400-2483 MHz (ISM band)	
Power Consumption	<65 mW	
Effective Radiated Power	9 mW	
RF Protocol	Proprietary	
Case Dimension (main sensor)	27 x 37 x 15 mm	
Full-charge Operation Time(2)	8 hours (typical)	
Recharge Time ⁽³⁾	<2.5 hours	
Auto Shut-down timer	300 seconds	
Temperature Range ⁽⁴⁾	5 - 50 degrees Celsius	
FSR resistance range ⁽⁵⁾	180 - 30000 ohms	
Bandwidth	DC-50 Hz ± 5 Hz, 20 dB/dec	
Channel 1 Sampling Rate	1926 samples/sec	
Channels 2-4 Sampling Rate	148 samples/sec	
Channel 1 Resolution Depth	16 bits	
Channels 2-4 Resolution Depth	10 bits	
Analog Output Range (6)	-4.85 V to 5.00 V	

- (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) The resistance range is characterized by the full scale ability of the sensor output the minimum signal above 50 mV and the maximum at 3.30V. FSR membranes operated within these bounds, but not necessarily at the full range limits.
- (6) The analog output signal is scaled to full range of the FSR sensor, where an output of 0% in EMGworks corresponds to the most negative output of -4.85V and a full scale output of 100% corresponds to +5.00V. Refer to the Trigno EMG System User's Guide for additional details on the analog output specifications.