TRIGNO™ Wireless System

User's Guide

Feb. 2009 Edition

Specifications and procedures outlined in this document are subject to change without notice.

MAN-012-1-0

Table of Contents

Table of Contents **1**
Important Information **3**
Intended Use 3
Contraindications 3
Technical Service and Support 3
Warnings and Precautions 4
Device Information 5
Disclaimer 7
Limited Warranty 7
TrignoTM Wireless EMG System **8**
TrignoTM System Components **9**
Wireless EMG Sensor 9
Sensor LED Indicator Status 9
Base Station 10
Power Supply 10
Sensor Adhesive Skin Interfaces 11
Getting Started with the TrignoTM System **12**
Powering the Base Station 12
Charging the Sensors 12
Turing the Sensor ON 12
Using EMGworks with the TrignoTM System 13
Using the Wireless EMG Sensors 14
Orienting the EMG Sensors on the Skin 14
Using the Delsys Adhesive Sensor Interface 15
Maintenance and Care **16**
Trigno Sensors 16
Recharging Base Station 16
Specifications **18**
Trigno Sensors 18
Trigno Recharging Base Station 19

Important Information

Intended Use

The Trigno™ Wireless EMG Systems are designed for research, investigational and scholarship purposes only. Delsys® products are not intended for measurement purposes or for use in the treatment and diagnosis of humans.

Rx ONLY

Contraindications

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:

E-mail: support@delsys.com
tel: (617) 236 0599

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 presence of liquids may compromise the safety features of the device.

Handle with care.

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 or otherwise mishandle the device. Recharge only with the approved power supply and recharger.

Trigno Systems should be stored and operated between 5 and 50 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.

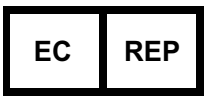
Type BF device (IEC 60601-1).

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)



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Manufacturer

FCC ID: W4P-SP-W02 (Trigno Base Station)
FCC ID: W4P-SP-W01 (Trigno Sensor)
IC: 8138A-DST01 (Trigno System)

This device complies with Part 15 of the FCC Rules. 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.

Changes not expressly approved by Delsys Inc.could void the User's authority to operate the equipment

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.

Limited Warranty

The Trigno™ Wireless EMG Systems are warranted against failure of materials and workmanship for a period of 1 year from the date of delivery, provided that the product is given proper care and has not been subject to abuse during this period. This warranty is in lieu of all other warranties expressed or implied. Operation of this device outside specifications determined by DELSYS INC. or use with any other input devices other than DELSYS INC. sensors constitute an invalidation of this limited warranty. This warranty is not transferable.

Trigno™ Wireless EMG System

The Trigno™ Wireless EMG System is a high-performing device unparalleled in its sophistication, its reliability and its ease-of-use. Each EMG sensor has a built-in triaxial accelerometer, a guaranteed transmission range of 20m and a rechargeable battery lasting 7 hours. The system is capable of streaming data to EMGworks Acquisition and Analysis software and of generating 16 EMG and 48 accelerometer analog channels for integration with motion capture and other 3rd party data acquisition systems. Full triggering features further expand the possibility for integration with additional measurement technologies.

1	Wireless Sensor	5	Analog Output Connectors
2	Base Station	6	Trigger Port
3	USB Port	7	Antenna
4	Power Jack/Power Supply	8	EMGworks Software (not shown)

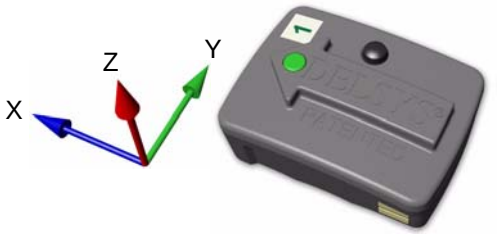
Figure 1. Complete Trigno Wireless System

Trigno™ System Components

Wireless EMG Sensor

Each Trigno Sensor is equipped with the following features:

- transmission range of 20m
- inter-sensor latency < 500us
- self-contained rechargeable battery
- EMG signal bandwidth 20- 450 Hz
- EMG signal sampling rate of 4000 samples/sec
- EMG baseline noise of 3uV pk-pk
- CMRR > 80dB
- 16-bit EMG signal resolution
- integrated triaxial accelerometer
- software selectable accelerometer sensitivity of ± 1.5g or ±6g
- LED User feedback
- battery charge monitoring and status indicator
- environmentally sealed device
- proven parallel bar technology
- contoured sensor-skin interface for maximum signal stability
- auto shutoff



Sensor LED Indicator Status

Status	LED Behavior
Data Streaming	flashing green, 1 second cycle
Scanning	alternating green/amber flash, 1 second cycle
Pairing	Solid Amber, button depressed
Pairing Successful	Rapid green flashing, button depressed
Pairing Unsuccessful	Rapid red flashing, 5x, button depressed
Mode Switch	Rapid green flashing, 3x
Firmware Update	Rapid green flashing, 3x
Battery Charging	Solid amber, in cradle
Charging Complete	Solid green, in cradle
Charging Error	LED off, sensor in cradle, cradle powered up
Sensor Off	LED off

Base Station

Each Base Station is equipped with the following features:

- recharging cradle for 16 sensors
- high speed USB communication with PC
- 64-channel analog output connector (16 EMG, 48 ACC)
- ± 5V analog output range
- detachable Antenna
- full trigger capability (Start/Stop, Input/Output)
- communication feedback LED
- power LED

Figure 2. Trigno Base Station

Power Supply

Trigno Systems are equipped with an isolated medical grade power supply. The green power LED on the base station will illuminate when power is connected to the Base Station. The power supply is provided with interchangeable country-specific plug adapters. Please contact Delsys if specialized adapters are required. The power supply can be conveniently stored in the Base Station storage space when the system is not in use.

Figure 3. Trigno Power Supply

Trigno System are specifically designed and approved to function only with the provided Power Supply. Power Supply substitutions constitute a violation of the medical safety approvals and will void the warranty.

If using a mains-powered PC then an additional isolation transformer is required for medical compliance to IEC60601-1. Refer to Appendix I for further details. No PC isolation is required for operation on a battery-powered laptop.

Sensor Adhesive Skin Interfaces

Trigno sensors can be affixed to the body with convenient double-sided adhesive interfaces. Ensure that the sensor site is cleaned with isopropyl alcohol immediately prior to application. It is recommender to affixed the interface first to the sensor, taking care to properly align the sensor contacts with the slots, and then to the skin site.

Figure 4. EMG Sensor Adhesive Skin 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.

Getting Started with the Trigno™ System

Powering the Base Station

Connect the Trigno power supply to the circular DC jack located on the side of the Base Station. Energize the power supply by connecting it to a Mains outlet or to an isolation transformer. Ensure that the PC to be used with the Base Station is connected to the same isolation transformer. Please refer to Appendix I for clarification on using an Isolation Transformer. The power LED on the Base Station will illuminate anytime power is applied. Ensure that the Base Station antenna is securely attached to the antenna connector.

Charging the Sensors

Before using the system, the sensors should be fully charged by placing them in the Base Station cradle slots. Ensure the Base Station is powered and that the green power LED is illuminated. When charging, the sensor LEDs will illuminate to an amber color. Once the sensor battery is fully charged the sensor LED will turn off. A blinking LED indicates an incomplete charge. Remove the sensor from the device and let stand for 5 minutes. Cycle power on the Base Station and re-dock the sensor to restart the charge cycle. A complete charge cycle form a fully depleted sensor takes approximately 2.5 hours.

Recharge only with the approved power supply originally included with the system. Charging with any other power supply may damage the device and will void the warranty.

Turing the Sensor 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 within its range. If no Base Station is found, the LED will alternate between amber and green, indicating that it does not have an established communication link. As soon a link is established with the Base Station, the sensor LED will flash green approximately once per second, indicating that data is streaming.

Using EMGworks with the Trigno™ System

Install EMGworks according to the instructions provided with the software. Define a Hardware Configuration and an appropriate Test as described in the EMGworks User's Guide. Note that the sampling rate for Trigno Sensors is fixed 4000 samples/sec for EMG data and 296 samples/sec for accelerometer data.

When the Trigno Test is initiated, the Trigno System Console will appear in a separate window. This console monitors the status of the Base Station and Sensors in real time to give the User appropriate feedback on battery voltage, number of dropped frames and makes available sensor settings such as accelerometer range and transmission channel selection.

Note that the sensor must be turned on and linked to the Base prior to initiating data acquisition in EMGworks.

Using the Wireless EMG Sensors

Orienting the EMG Sensors on the Skin

The Trigno EMG Sensor is fitted with 4 silver bar contacts for detecting the EMG signal at the skin surface. It is crucial that the orientation of these bars be perpendicular to the muscle fibers for maximum signal detection. 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 and the edge of the muscle. The sensor is easily attached to the skin using the Delsys Adhesive Sensor Interface.

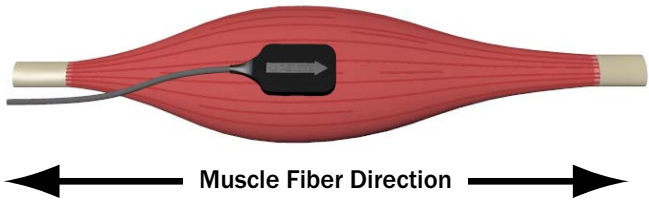


Figure 5. EMG Sensor orientation with respect to the muscle fibers. It is important that the orientation of the arrow on the sensor be parallel to the underlying muscle fibers.

Using the Delsys Adhesive Sensor Interface

The Adhesive Sensor Interfaces use medical-grade adhesive specifically designed 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 and the EMG Sensor with isopropyl alcohol to remove oils and surface residues. Allow the skin to dry completely before applying the interfaces.

1) *Remove the interface from its strip and apply to the sensor.*

2) *Remove liner to expose the adhesive.*

3) *Apply to the skin site. Do not reposition once skin contact is made.*

Figure 6. Application of the Adhesive Sensor Interface.

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.

Maintenance and Care

Trigno Sensors

Trigno sensor 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 and sterilized with a damp cloth and mild detergent, with isopropyl alcohol swabs, or with a 70% isopropyl alcohol solution. Ensure that the sensor contacts remain clean at all times for proper operation.
- The sensors are completely sealed and are water-resistant. These can be used on damp skin surfaces and in the presence of sweat without compromise to safety, sensor integrity or operation. The sensors should never be completely submerged in any liquid.
- 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.

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 possible irreparable damage to the sensors.

Recharging Base Station

The Trigno System is designed to provide years of reliable service when proper care is followed. While the Base Station enclosure is made of durable plastic, the following points should be kept in mind when using and handling it:

- The device and its accessories should be visually inspected before every use to ensure that no mechanical deterioration has occurred.

- The Base Station can be easily cleaned with a damp cloth and mild detergent or with a 70% solution of isopropyl alcohol. DO NOT IMMERSE THE BASE IN LIQUID.
- The units are not shockproof and should not be dropped or be subjected to excessive forces or accelerations.

The recharging Base Station is not water-resistant. Under no circumstance should this unit be exposed to water or any other type of liquids.

Specifications

Trigno Sensors

GENERAL SPECIFICATIONS	
Typical Operating Range	10 m
Transmission Source	2.4 GHz, 1 mW
Power Consumption	<66 mW
Case Dimension	41 x 20 x 5 mm
Case Material	polycarbonate
Operation Time/charge	>8 hours
Recharge Time	<2.5 hours
Mass	< 10g
Auto Shut-down timer	5 minutes
Temperature Range[1]	5 - 50 degrees Celsius

EMG SENSOR SPECIFICATIONS	
Resolution (EMG Signal)	168 nV/bit, 16 bits
Range	11 mV (r.t.i.)
Bandwidth (EMG Signal)	20±5 Hz, >40 db/dec 450±50 Hz, >80 dB/dec
Passband Ripple	<2%
Overall Channel Noise	<0.75uV (RMS, RTI)
CMRR	>80 dB
Sampling Rate[2]	2000/4000 samples/sec
Number of Contacts	4
Contact Dimension	5 x 1 mm.
Contact Material	99.9% Ag

ACCELEROMETER SPECIFICATIONS	
Number of Axis	3
Range[2]	±1.5g ±6g
Resolution[2]	0.012g/bit, 8 bits 0.047g/bit, 8 bits
Bandwidth	DC - 50±5 Hz, >20dB/dec
Sampling Rate[2]	148 / 296 samples sec

Trigno Recharging Base Station

GENERAL SPECIFICATIONS	
Typical Operating Range	10 m
Transmission Source	2.4 GHz, 1 mW
Power Consumption	<10W
Sensor Recharge Time	< 2.5 hours
USB type	USB 2.0 compliant, high speed
Temperature Range[1]	5 - 50 degrees Celsius
Maximum number of Sensors	16
Inter-sensor delay	<500 us

ANALOG OUTPUT SPECIFICATIONS	
Number of outputs	16 EMG, 48 Accelerometer
Signal group delay[3]	<50 ms
EMG Signal Range	±5 V
Accelerometer Signal Range	±1.5 V
Connector Type	SCSI-68, Type II

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

(2) Software selectable

(3) Delay from sensor event to analog output is fixed.