



Trigno[®] Wireless Biofeedback System

User's Guide

**Download EMGworks[®] at
www.delsys.com/emgworks**

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MAN-031-1-4

MP1135E

February 2020



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Important Information

Intended Use

The Trigno[®] Wireless Biofeedback System is a battery-powered biofeedback device that enables researchers and clinicians to acquire EMG and related signals from subjects for biofeedback and research 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

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.



DO NOT USE in critical care applications.

Technical Service and Support

For information and assistance please visit our web site at:
www.delsys.com

Contact us at:

E-mail: support@delsys.com

Telephone: (508) 545 8200

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 ingress of liquids into the device 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.



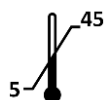
Delsys Inc. guarantees the safety, reliability, and performance of the equipment only if assembly, modifications and repairs are carried out by authorized technicians; the electrical installation complies with the appropriate requirements; and the equipment is used in accordance with the instructions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



Report any serious incidents with the device to Delsys at 508 545 8200 or support@delsys.com.



Trigno Systems should be stored and operated between 5 and 45 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)



Type BF Equipment.



Date of Manufacturing (appears on device)



Manufacturer:
Delsys Inc.
23 Strathmore Rd.
Natick, MA, 01760, USA



Serial Number (appears on device)



Dispose the device according to local rules for electronic waste.



Authorized Representative:
EMERGO EUROPE
Prinsessegracht 20, 2514 AP The Hague
The Netherlands

Trigno Wireless Biofeedback System

Sensor Model: SP-W06

Base Station Model: SP-W02

System Model: DS-T03

FCCID: W4P-SP-W06 (Sensor)

FCCID: W4P-SP-W02 (Base Station)

IC: 8138A-DST03 (System)

[R] 211-190332 (DS-T03)

[R] 211-190333 (SP-W06)



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 Class B digital apparatus complies with Canadian ICES-003.

Cet appareil est conforme à des règlements d'Industrie Canada exempts de licence standard RSS (s). Son fonctionnement est soumis aux deux conditions suivantes: (1) Ce dispositif ne doit pas causer d'interférences nuisibles, et (2) cet appareil doit accepter toute interférence reçue, y

compris les interférences pouvant entraîner un fonctionnement indésirable.

Cet appareil numéroté de la classe B est conforme à la norme NMB-003 du Canada

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

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.



Pursuant to FCC 15.21 of the FCC rules, changes not expressly approved by Delsys Inc. could void the User's authority to operate the equipment.

Windows PC Requirements

- EMGworks 4.7 or later
- Windows 7, 8.1, 10
- One USB 2.0 port
- At least 2.0 GHz processor clock speed
- At least 2 GB system memory
- 1280x1024 (SXGA) display resolution or better
- 50 GB hard disk storage (minimum)

Android Device Requirements

- Android V 7 (Nougat) operating system or later
- BLE 4.2 support
- RAM 1GB minimum
- Storage 8 GB minimum
- Screen Resolution 2048x1536 (recommended)
- Recommended Tablet:

Samsung Galaxy Tab S2
8" screen, 32 GB, WI-FI
(SM-T713NZKEXAR)

or

Samsung Galaxy Tab S5e
10.5" AMOLED screen, 64 GB Storage
Android 9.0 (Pie), WiFi & Bluetooth v.5.0

Trigno System Overview

The Trigno® Wireless Biofeedback System is a device designed to make EMG (electromyographic) and biofeedback signal detection reliable and easy. The system transmits signals from the Trigno Avanti™ sensors to a receiving base station using a time-synchronized wireless protocol which minimizes data latency across sensors. The core architecture of the Trigno System is designed to support high fidelity EMG signals, along with complementary biofeedback signals such as movement data, force signals, contact pressure events and timing and triggering information. For mobile biofeedback applications, Trigno Avanti™ Sensors can communicate with Bluetooth BLE 4.2 compliant host devices. The system is also capable of integrating with 3rd party lab equipment through a variety of interfaces which include analog signal generation, triggering scenarios and digital integration through the Trigno SDK (Software Development Kit) and the Trigno API (Application Program Interface). Refer to the specific component sensor User Guides for operational details of these system elements.

System Components

- 1) Trigno Avanti™ Wireless Sensors
- 2) Trigno Base Station
- 3) Power Supply
- 4) Adhesive Skin Interfaces
- 5) USB Cable
- 6) Windows PC
- 7) Android Mobile Device (optional)

Trigno Avanti™ Sensor Features

Each Trigno Avanti™ Sensor is equipped with the following capabilities:

- onboard configurable precision EMG sensor
- built-in 9-axis inertial measurement unit (IMU)
- dual-mode “BLE-Base” communication
- onboard RMS and Mean calculations
- onboard orientation calculation
- onboard median frequency calculation
- software selectable operational modes
- inter-sensor latency < 1 sample period
- wireless transmission range 20+m¹
- self-contained rechargeable battery
- battery charge monitoring and status indicator
- environmentally sealed enclosure
- low power mode
- auto shutoff
- internal magnetic switch
- LED User Feedback



1. Communication distance is dependent on the RF operating environment.

Onboard EMG Sensor

Trigno Avanti™ sensors support a low noise, high fidelity sensing circuit for detecting EMG (electromyographic) biofeedback signals from the surface of the skin when muscles contract. The sensor bandwidth can be selected between 10-850Hz or 20-450 Hz and the input range of the sensor can be selected between 22mV or 11mV depending on user needs.

Inertial Measurement Unit

Trigno Avanti™ Sensors have a built-in 9 DOF inertial measurement unit which can relay acceleration, rotation and earth magnetic field (compass) information. Users can use this information to discern movement activity time-synchronized with the EMG signals. One of 4 ranges can be selected for each sensor to span $\pm 2g$ to $\pm 16g$ for accelerometer outputs and $\pm 250^\circ/s$ to $\pm 2000^\circ/s$ for gyroscope outputs. The sensor is capable of estimating orientation in 3D space from the 9 channels of information.

Dual Mode “BLE-Base” Communication

Trigno Avanti™ sensors are capable of communication with a PC-connected Base station using the Trigno custom wireless communication protocol, or with Android devices using the Bluetooth Low Energy (BLE) industry standard protocol. Note that the information bandwidth when operating over Bluetooth is limited by the Bluetooth protocol and the host device capabilities.

Wireless Communication Distance

The Trigno wireless communication scheme offers robust data transmission for up to 16 sensors with a nominal distance of 20m. Under optimal environmental conditions (no RF path obstructions or interfering sources), this nominal distance can be notably superseded.

Data Synchronization

Data from each sensor and from each channel within a sensor are time synchronized over the Trigno wireless communication protocol so no time skew between data exists. A maximum of 16 sensors can stream data to a host base station at one time. These features are available only when communicating with the PC-connected Base Station; the Bluetooth/BLE protocol does not guarantee latency.

Rechargeable Battery

Sensors contain a sealed rechargeable lithium polymer battery for multiple hours of continuous use which can be extended when making use of low power modes. Actual duration will depend on usage conditions, which are expected to vary between 4 to 8 hours of performance. Charge status is conveniently reported through the wireless communication.

Sealed Enclosure

The environmentally sealed enclosure protects the electronics from the ingress of liquids and other environmental elements, and provides a high standard of user safety and durability.

Internal Magnetic Switch

The Trigno Avanti sensors are equipped with an internal magnetic switch which is used to turn the sensors “on” and to perform RF pairing operations. To activate the internal magnetic switch, the sensor must be placed on the magnet lock label located on the Base Station charging cradle. The internal magnetic switch will only react when the sensors are undocked from the charger or when the software is performing an RF pairing operation. Exposure to any magnetic fields outside of these 2 qualifying conditions will be ignored by the sensor. The internal magnetic switch is a feature which removes the need for a mechanical button and improves sensor durability and performance.

Sensor LED Feedback States

Trigno Avanti sensors indicate their status through various LED Arrow colors and blink patterns as indicated in the table below. Each of these states is described in subsequent sections of this User Guide.



































	State	Color	Pattern	Arrow Display
	Common States			
1	Power Off	Off	none	
2	Power On/Activate	White/Green	fade	 / 
3	Charging	Amber	solid	
4	Charge Complete	Green	solid	
5	Identification Mode	White	rapid flash	 /  / 
6	Scan (Startup)	Amber/Cyan	slow flash	 / 
7	Power Up Error	Red	slow flash	 / 
	Trigno RF Mode			
8	Scan (Base)	Amber/Green	Slow flash	 / 
9	Low Power Scan (Base)	Amber	Occasional Flash	 / 
10	Data Collection (Base)	Green	slow flash	 / 
11	Configuration Change (Base)	Green	rapid flash (3x)	 /  / 
12	Pairing (Base)	Amber	solid	
13	Pairing Success (Base)	Green	rapid flash (≥6x)	 /  / 
14	Pairing Fail (Base)	Red	double flash (≥3x)	 /  / 
	BLE Mode			
15	Advertise (BLE)	Cyan	Slow flash	 / 
16	Low Power Advertise (BLE)	Cyan	occasional flash	 / 
17	Data Collection (BLE)	Blue	slow flash	
18	Idle (BLE)	Magenta	slow flash	

Table 1: Sensor LED functions.

LED State Descriptions

- 1) **Power Off:** No LED arrow activity is present when the sensor is off.
- 2) **Power On:** When undocked, the sensor illuminates white and fades to black. A magnetic field will turn the sensor on within 6 seconds, otherwise the arrow fades to dark and sensor turns off.
- 3) **Charging:** Sensor Charging in the Trigno Base Station is denoted by continuous amber LED arrow illumination
- 4) **Charge Complete:** Once the internal sensor battery has been fully recharged, the LED arrow illuminates to continuous green.
- 5) **Identification Mode:** The arrows blink white upon this software command so that it can be easily identified and located.
- 6) **Startup Scan:** upon power up the sensor actively searches for a host to connect to (PC Base Station or BLE tablet).
- 7) **Power Up Error:** Sensor fails self-check on power up
- 8) **Scan (Base):** Sensor was previously paired and is scanning for the active base station.
- 9) **Low Power Scan (Base):** Sensor was previously paired and has been scanning for the active base station for more than 5 minutes.
- 10) **Data Collection (Base):** Data from sensor are streaming to a paired PC-connected base station.
- 11) **Configuration Change (Base):** Sensor acknowledges change in configuration sensor from host base station.
- 12) **Pairing (Base):** Sensor is performing a pair operation with the base host.
- 13) **Pairing Success (Base):** Sensor successfully completes a pair operation with the Base Station host.
- 14) **Pairing Fail (Base):** The pair operation did not complete successfully with the Base Station host.
- 15) **Advertise (BLE):** Sensor is broadcasting to connect with a BLE host.
- 16) **Low Power Advertise (BLE):** Sensor is broadcasting to connect with a BLE host for more than 5 minutes.
- 17) **Data Collection (BLE):** Sensor is sampling and streaming data to BLE host.
- 18) **Idle (BLE):** Sensor is waiting for a Bluetooth BLE command.

Base Station Features

Each Base Station is equipped with the following features:

- high speed USB communication with PC
- recharging cradle for 16 sensors
- 64-channel analog outputs
- $\pm 5V$ analog output range
- detachable antenna
- convenient carry case design
- communication & power feedback LEDs
- full trigger capability (Start/Stop, Input/Output)
- Medical Grade Universal Power Supply.

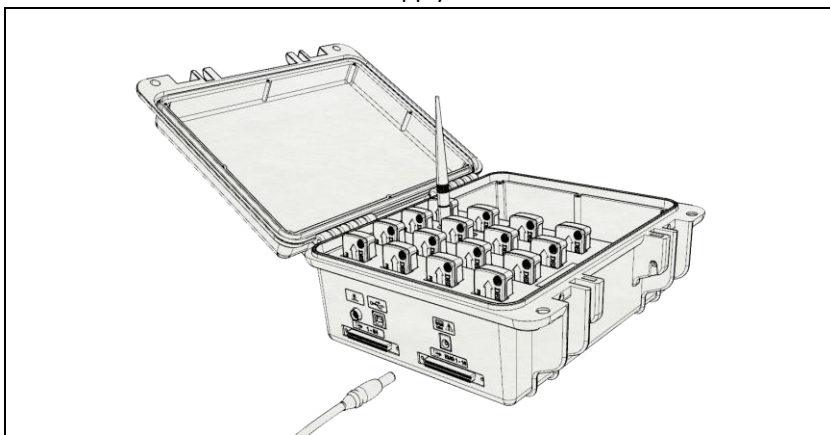


Figure 1: Trigno System Base Station for sensor recharging and communication.

Recharging Cradle: The Trigno Base Station is equipped with 16 charge pockets which can accommodate Trigno sensors for charging. The pockets are keyed so that sensors can only be inserted in one orientation.

Medical Power Supply: The system includes a universal 12V medical grade power supply for operating the base station. International plug adapters are included for connection to local mains power requirements.

USB Communication: The Base Station compiles data received from the active wireless sensors and transfers it over a USB 2.0 compliant connection to a Windows PC.

Analog Outputs (If Equipped): The Base Station is equipped with two 68-position analog output connectors that can be used to interface with analog data acquisition systems. Biofeedback signals acquired by the wireless sensors are made available as analog signals spanning a $\pm 5V$ range.

Trigger Capability: The Base Station is equipped with a trigger port that can be used to synchronize the starting and stopping data streams with 3rd party equipment. The Trigger Module is required for making device connections.

Base Station LED Feedback States

Trigno Base Stations are equipped with 2 LEDs, indicating power on/off and communication function (if equipped) as described in the table below:

	State	Color	Pattern	LED Display
1	Power Off	Off	none	● ●
2	Standby	Green	solid	● ●
3	Data Streaming	Green	flashing	● ● / ● ●
4	Communication Error	Green	double flash	● ● / ● ●

Charge-16 Station

A 16-sensor recharge station is available for the sole purpose of sensors recharging. This unit has the same physical appearance as the Base Station, but does not have any wireless or USB data capacities. Charge operation is otherwise identical to that of the Base Station.



Figure 2: Trigno System “Charge-16” Station for sensor recharging. No wireless or digital communication is available on the Charge-16 component of the system.

Charge-4 Station

A compact 4-sensor recharge station is available for the sole purpose of sensor recharging. Charge operation is identical to that of the Base Station, and uses the same power supply, but does not support any wireless or USB data capacities.

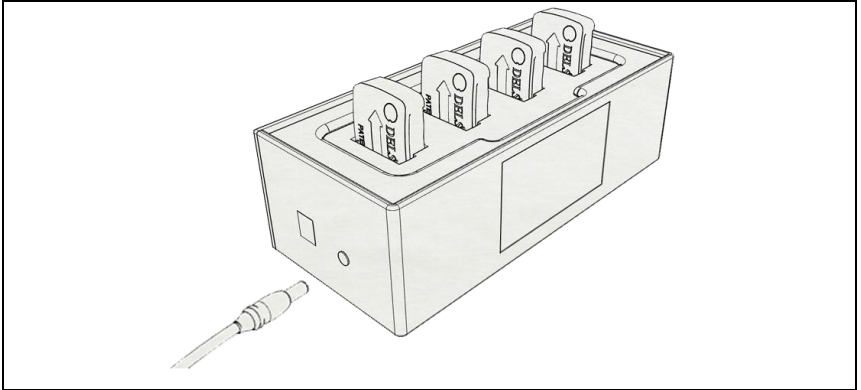


Figure 3: Trigno System "Charge-4" Station for sensor recharging. No wireless or digital communication is available on the Charge-4 component of the system.

Getting Started with the Trigno System

Powering the Base Station

Trigno Systems are equipped with a universal medical power supply and are provided with interchangeable country-specific plug adapters. 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. The power LED on the Base Station will illuminate anytime power is applied.



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

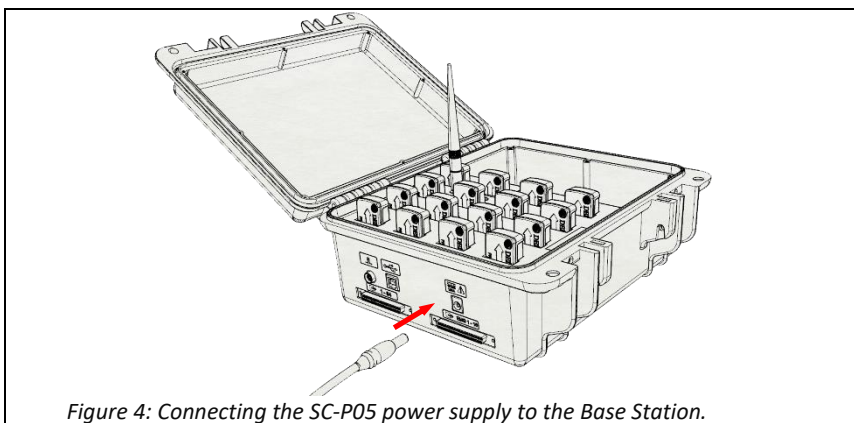


Figure 4: Connecting the SC-P05 power supply to the Base Station.

Charging the Sensors

All sensors are fitted with a sealed lithium polymer cell and are charged with the provided base station powered from a universal medical grade power supply. A full charge will generally require 3 hours or less to complete, depending on the battery age, usage history and particular charge conditions. The sensor arrow will glow amber during charging and illuminate green upon charge completion. It is recommended to keep sensors docked and charging even when not in use to maximize battery life, as sensor batteries will self-discharge with time and will degrade if left uncharged for extended periods of time.

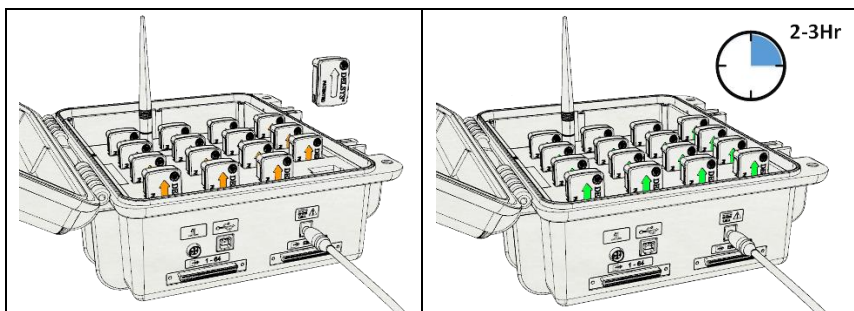


Figure 5: Docking a sensor in the charge cradle (left). When docked, sensors will turn off and begin battery charging indicated by an amber LED indicator. Once fully charged, the sensor LED indicator shows green (right).

Battery Performance

Battery performance and longevity is subject to a myriad of factors, which include charge/discharge conditions, usage scenarios, number of charge/discharge cycles, environmental temperature factors, and cell manufacturing parameters which are subject to statistical variations. Typical industry expectations assume an 80% charge capacity derating after 2-years or 300 charge/discharge cycles. Sensors are equipped with battery charge monitoring and automatic sensor turn off when charge is depleted to avoid deep discharge scenarios. Storage at temperature outside the 5-45°C may damage the battery.

Turning the Sensor ON

Trigno Avanti sensors are automatically turned on when they are removed from a powered charging dock. The sensors must be docked for a minimum of 3 seconds in the charge cradle, however, for the self-powering scheme to initiate upon undocking. Once undocked, the arrow illuminates to white and the sensor must be tapped on the cradle magnet to complete the power up sequence. The arrow will fade to black within 6 seconds and the sensor will turn off if not tapped on the cradle magnet. See Figure 6 for a pictorial representation of the power-on sequence.

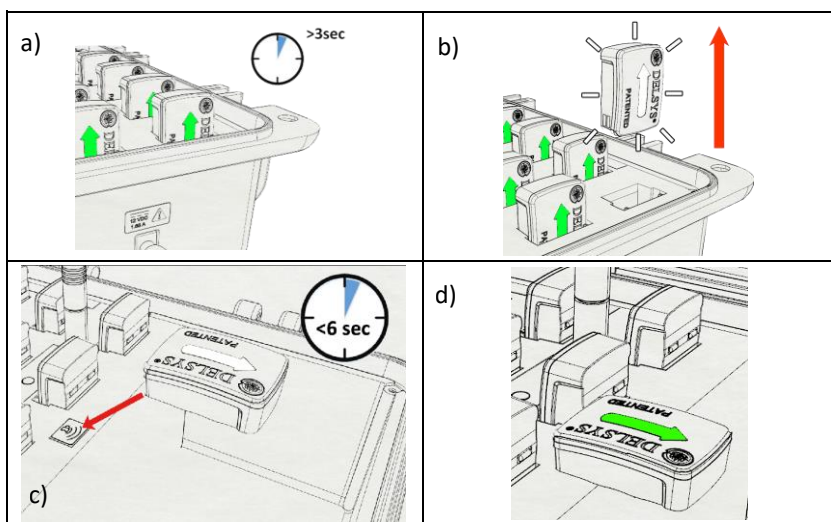


Figure 6: To turn sensors on: a) dock for 3 seconds or more, b) remove from cradle, c) tap sensor on magnet within 6 seconds to d) complete power-up sequence.

Turning the Sensors OFF

There are 3 mechanisms that will turn the sensors off:

a) Dock Sensors in Charger: docking the sensors in the charge cradle will automatically turn the wireless communication system of the sensor off and engage the battery charging circuit.

b) Undock Sensors, No Magnet: Undocking the sensors to initiate the power up sequence and allowing the 6-second magnetic activation window to lapse will turn off the sensors. Unplugging the base station will turn off all docked sensors.

c) Software Issued Command: Sensors that are paired with the base station and are communicating with the host software application can be turned off by way of an “off” command sent from the software application. Please refer to the software user guide for more information.

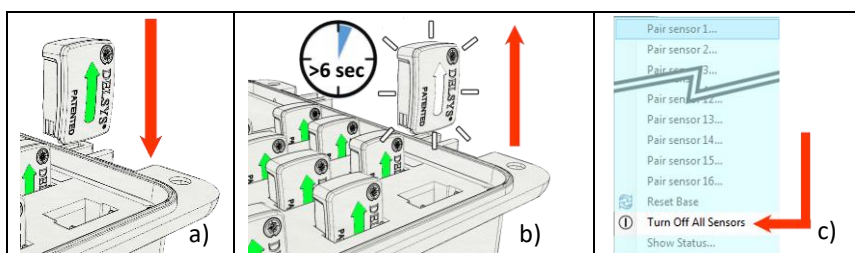


Figure 7: To turn sensors off: a) dock initiate charging, b) remove from cradle and let the 6-second magnetic activation window lapse, c) initiate a software off command.

Startup Scan Mode

Once the sensors turn on and complete the activation process, the LED will alternate between amber and cyan, indicating that the sensor is looking for a connection to the host. The host can either be a PC-connected base station or a Bluetooth enabled Android device. Once a connection to a host is made, the system will store this selection so that an immediate connection to this host is made on future power cycles as soon as the host is available. Refer to subsequent sections for information on how to pair a sensor to a Base Station or to Bluetooth device.

Acquiring Data with the System

PC Software Installation

Trigno software for Microsoft Windows Operating Systems can be downloaded from the Delsys website (www.delsys.com) or installed from media included with the system. Acquiring data with a PC requires the Trigno Base Station to be connected via the USB port. The Trigno Base Station uses a custom RF protocol to guarantee high data bandwidth across 16 sensors with no inter-sensor latency. Refer to the software user guide and help information for detailed explanation of software functions. Data collection and sensors configuration is initiated through the software.

Pairing the Sensors with the Base Station

Data acquisition functions of the sensor, wireless transmission to the base station and data transfer from the base station to the software require the sensors to be paired to the base station. The pairing process links the unique ID of the sensor to the unique ID of the base station to establish a wireless data link. Pairing information is retained after the base station and sensors are powered off. Pairing is initiated through the software pairing command and completed by activating the internal magnetic switch in the sensor. The magnetic switch in the sensor is activated by placing the sensor over the built-in magnet of the base station, indicated the lock decal.

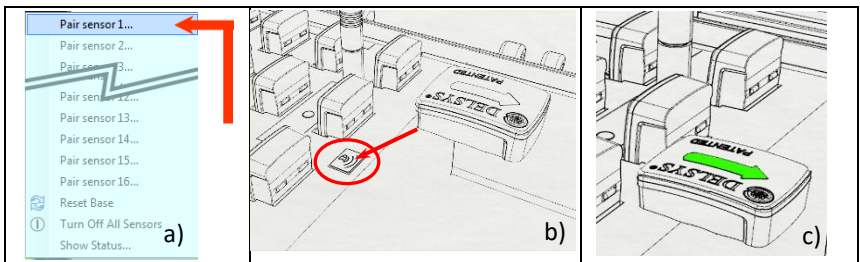


Figure 8: To pair the sensors with the base station: a) initiate a pair command from software, b) place the sensor on the base station magnet, c) confirm green blinks for successful pair.

Configuring the Trigno Sensors

Once paired to the system, EMG data and IMU data from sensor can be configured through software in the following ways:

Electromyographic (EMG) Sensing Ranges							
Input Range ¹	11 mV	or	22 mV				
Bandwidth ¹	20-450 Hz	or	10-850 Hz				
RMS Window (optional) ⁴		100ms					
Inertial Measurement Unit (IMU) Ranges							
Accelerometer ²	±2 <i>g</i>	or	±4 <i>g</i>	or	±8 <i>g</i>	or	±16 <i>g</i>
Accelerometer Bandwidth ²		24 Hz – 470 Hz					
Gyroscope ²	±250 <i>dps</i>	or	±500 <i>dps</i>	or	±1000 <i>dps</i>	or	±2000 <i>dps</i>
Gyroscope Bandwidth ²		24 Hz – 360 Hz					
Orientation ³		10Hz					

¹EMG range, bandwidth selection and sampling rate are configured by the software. Please refer to specifications section for additional details.

²Accelerometer and gyroscope range, bandwidth and sampling rate are configured by the software. Please refer to specifications section for additional details

³Note that the orientation is calculated on-board with a data fusion algorithm.

⁴An onboard RMS calculation can be invoked to reduce data transmission rates and maximize bandwidth resources

Sensor Data Throughput

The Trigno RF protocol is structured with 16 data “slots” capable of supporting 35556 bits/sec each. Sensors can occupy one or more slots depending on the required data rates and channel counts determined by their configured mode (see data mode tables in appendix). For configurations supporting 1 slot, a total of 16 synchronized sensors can be operated at the same time. Configurations requiring more than 1 slot will decrease the total permissible sensor count. See diagram for example showing 16 sensors occupying 1 data slot each, vs 4 sensors occupying 4 slots each. Variations and permutations are allowed.

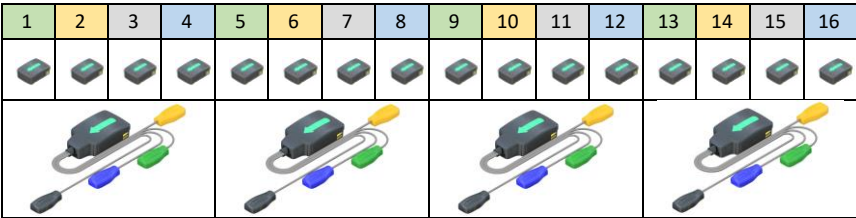


Figure 9: The Trigno System is capable of transmitting data on 16 individual slots. These slot can be used to transmit data from 16 single sensors or aggregated (into groups of 2 or 4) to transmit higher data rates.

Android Device Operation

Trigno Avanti™ Sensors can communicate using the Bluetooth Low Energy (BLE) communication protocol as an alternative to the PC-connected Base Station. This feature is available when operating the Trigno Android Apps for Android mobile devices which can be downloaded from the Delsys website (www.delsys.com). Upon power up, the sensors will scan for BLE devices and PC connected Base Stations. Sensors are paired on a “first come, first serve” basis. Previously-paired sensor will automatically connect to their corresponding host. Sensors can only communicate with one host at time. The BLE performance will depend on individual sensor configuration and the host capabilities. Users are encouraged to test the performance of specific configurations prior to performing biofeedback research activities.

Using the Wireless EMG 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 maximum signal amplitude, 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 and the edge of the muscle. The sensor is easily attached to the skin using the Delsys Adhesive Sensor Interface.

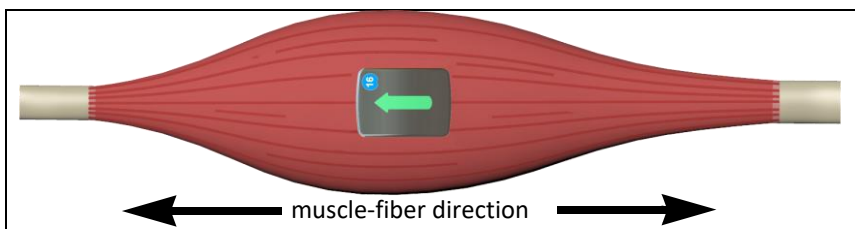


Figure 10: EMG Sensors must be properly oriented with the muscle fibers. Align the sensor's arrow with the direction of the underlying muscle fibers

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 high-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 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 and 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. Discard after using. Reseal storage bag to maintain freshness.



Immediately discontinue use if skin irritation or discomfort occurs. Patients with sensitive skin may experience temporary redness and irritation.



Do not use on Patients with allergies to silver.



Do not apply over open wounds or irritated skin.

Inertial Measurement Unit (IMU)

Trigno Sensors are fitted with an internal Inertial Measurement Unit (IMU) that will output 3 degree-of-freedom (DOF) acceleration data as well as 3 DOF rotational data as oriented in the figure. These data can be used to provide movement biofeedback of the sensor in physical space. Additionally, an on-board magnetometer provides compass heading information to the IMU. When engaged in orientation mode, the magnetometer data are fused with the accelerometer and gyroscope data to estimate the orientation of the sensor in space. This output is expressed as Euler angles or Quaternions.

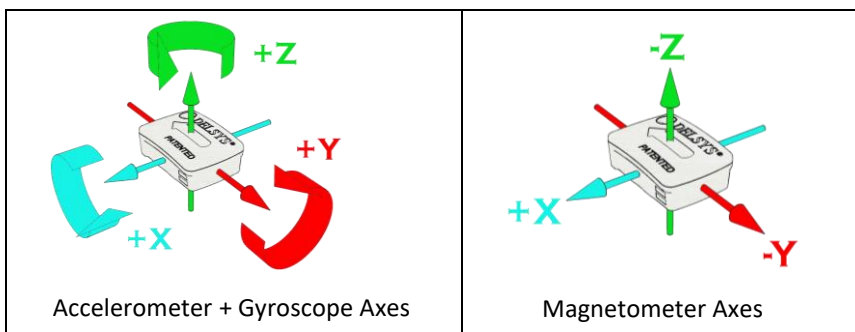


Figure 11: Trigno Sensors are fitted with an internal Inertial Measurement Unit (IMU) that will output 3 DOF acceleration data as well as 3 DOF rotational data as oriented in the figure (left). An onboard magnetometer measures compass heading and can be used to calculate orientation along with the accelerometer and gyroscope data.

Using the Analog Outputs (if Equipped)

The Trigno System provides simultaneous analog signal reconstruction of data being detected by all active sensors. These signals are made available on the 68-pin connectors located on the Base Station and range cover the the +/-5V range. Analog outputs are engaged through software and are only available for specific sensor sampling configurations as stated below for the Standard Avanti Sensor:

	Sampling Rate	Data Type	Bandwidth
Ch. x.1	1926 sa/sec	EMG	20-450 Hz
Ch. x.2	148 sa/sec	ACC or Gyro X	DC-50 Hz
Ch. x.3	148 sa/sec	ACC or Gyro Y	DC-50 Hz
Ch. x.4	148 sa/sec	ACC or Gyro Z	DC-50 Hz

Table 2: Analog Output signal details. Note that sampling rates are approximate; please refer to specification table for precise sampling periods.

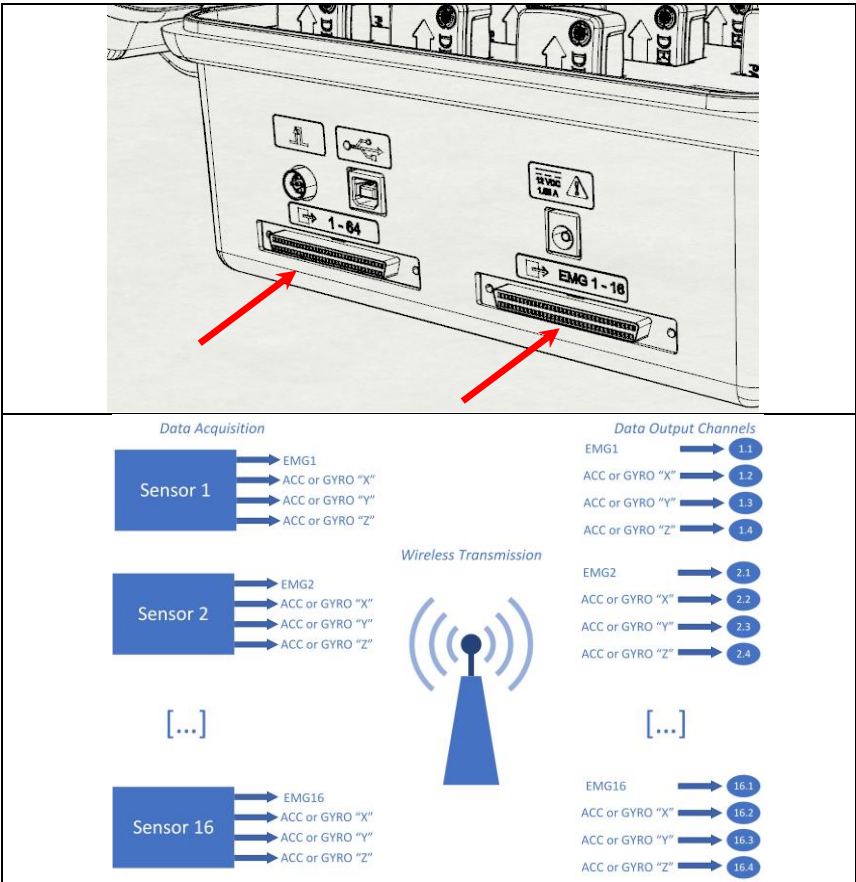


Figure 12: Analog Output Connectors on Base Station (top), Analog Output Data Flowchart (bottom).

Analog Output Delay

Data collection, wireless transmission, and reconstruction that occurs within the Trigno System incurs time-delays associated with the analog output channels. The delay is a combination of the delay associated with the individual sensor settings (dependent on sensor type) as well as the specific analog output channel on the base station connector. The total delay for a specific channel can be calculated by adding the delay associated with the sensor setting and the DAC output delay for the affected channel as depicted in the figure below.

Sensor Setting	Setting Delay
2 - 30 Hz	19.6 ms
DC - 50 Hz	15.6 ms
DC - 100 Hz	4.5 ms
20 - 450 Hz	1.5 ms
10 - 850 Hz	0.9 ms
DC - 1000 Hz	0.5 ms
10 - 2000 Hz	0.2 ms

+

DAC Output Delay	Affected Channels							
59.6 ms	CH 1.1	CH 2.1	CH 3.1	CH 4.1	CH 5.1	CH 6.1	CH 7.1	CH 8.1
	CH 9.1	CH 10.1	CH 11.1	CH 12.1	CH 13.1	CH 14.1	CH 15.1	CH 16.1
109.3 ms	CH 1.2	CH 2.2	CH 3.2	CH 4.2	CH 5.2	CH 6.2	CH 7.2	CH 8.2
	CH 1.3	CH 2.3	CH 3.3	CH 4.3	CH 5.3	CH 6.3	CH 7.3	CH 8.3
	CH 1.4	CH 2.4	CH 3.4	CH 4.4	CH 5.4	CH 6.4	CH 7.4	CH 8.4
	CH 9.2	CH 10.2	CH 11.2	CH 12.2	CH 13.2	CH 14.2	CH 15.2	CH 16.2
	CH 9.3	CH 10.3	CH 11.3	CH 12.3	CH 13.3	CH 14.3	CH 15.3	CH 16.3
	CH 9.4	CH 10.4	CH 11.4	CH 12.4	CH 13.4	CH 14.4	CH 15.4	CH 16.4

Total delay = Sensor setting delay + DAC channel delay

Table 3: Trigno Avanti Analog Output Delay Architecture.

Analog Output Connectors

Channels 1-64

64 analog output channels of the system are available through a 68-pin, 1.27 mm pitch, PCS series connector compatible with National Instruments data acquisition modules. There are 16 clusters of 4 channels, with each cluster representing up to 4 signals from 1 sensor, denoted as x.1, x.2, x.3 and x.4.

Channels 1-16, EMG Signals

The pinout of this connector replicates the pinout of the Bagnoli desktop EMG systems to facilitate connectivity between shared equipment for the Channels 1-16. This connector is a 1.27mm, PCS series connector and is compatible National Instruments data acquisition modules.

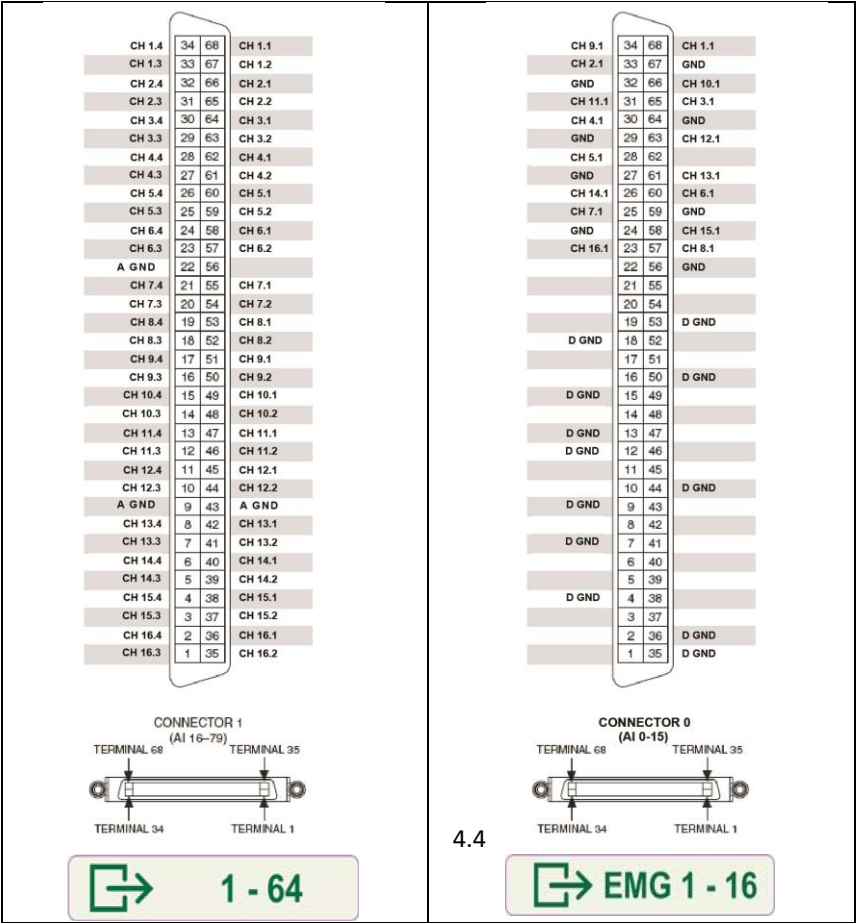


Figure 13: Pinouts of the analog output connectors

Screw Terminal Connections

Many data acquisition systems are equipped with screw-type wire terminations. In these cases, Delsys can supply the DC-A22 cable assembly that mates with the analog output connectors and breaks out the individual channels onto single conductors. This cable connects to the “channel 1-64 connector” and breaks out the 64 channels to individual conductors alongside 3 ground conductors as indicated in the table below. Each conductor employs a unique color scheme to identify its signal using a primary and secondary color.



 <u>White / Black</u>	 <u>Black / White</u>
--	---

Table 4: Color scheme example



All output signals are low voltage and low current and thus pose no electrical risk to the operator while handling these during installation. None-the-less, only qualified personel should make these connections. Care should be taken to ensure that these are properly secured and covered once the installation is complete. ..



Ensure the Base Station is unplugged while completing screw-terminal connections.



Connect the GND wires to the data acquisition system ground for analog inputs. It is recommended to twist all three wires together and connect these to a common ground point on the measurement system to avoide the risk of creating ground loops.



Ensure that any unused conductors are not exposed and will not come into contact with each other or any other signal or voltage potential. This can be done by clipping the bare ends of the conductors or using heat shrink tubing or electrical tape to enclose the bare ends.

Trigno Output	Trigno Pin	Conductor Color Primary / Secondary
CH. 1.1	68	Violet / Orange
CH. 1.2	67	Blue / Orange
CH. 1.3	33	Orange / Blue
CH. 1.4	34	Orange / Violet
CH. 2.1	66	Green / Orange
CH. 2.2	65	Yellow / Orange
CH. 2.3	31	Orange / Yellow
CH. 2.4	32	Orange / Green
CH. 3.1	64	Gray / Pink
CH. 3.2	63	Violet / Pink
CH. 3.3	29	Pink / Violet
CH. 3.4	30	Pink / Gray
CH. 4.1	62	Blue / Pink
CH. 4.2	61	Green / Pink
CH. 4.3	27	Pink / Green
CH. 4.4	28	Pink / Blue
CH. 5.1	60	Yellow / Pink
CH. 5.2	59	Orange / Pink
CH. 5.3	25	Pink / Orange
CH. 5.4	26	Pink / Yellow
CH. 6.1	58	Gray / Brown
CH. 6.2	57	Violet / Brown
CH. 6.3	23	Brown / Violet
CH. 6.4	24	Brown / Gray
CH. 7.1	55	Green / Brown
CH. 7.2	54	Yellow / Brown
CH. 7.3	20	Brown / Yellow
CH. 7.4	21	Brown / Green
CH. 8.1	53	Orange / Brown
CH. 8.2	52	Pink / Brown
CH. 8.3	18	Brown / Pink
CH. 8.4	19	Brown / Orange
CH. 9.1	51	Gray / Tan
CH. 9.2	50	Violet / Tan

Trigno Output	Trigno Pin	Conductor Color Primary / Secondary
CH. 9.3	16	Tan / Violet
CH. 9.4	17	Tan / Gray
CH. 10.1	49	Blue / Tan
CH. 10.2	48	Green / Tan
CH. 10.3	14	Tan / Green
CH. 10.4	15	Tan / Blue
CH. 11.1	47	Yellow / Tan
CH. 11.2	46	Orange / Tan
CH. 11.3	12	Tan / Orange
CH. 11.4	13	Tan / Yellow
CH. 12.1	45	Pink / Tan
CH. 12.2	44	Brown / Tan
CH. 12.3	10	Tan / Brown
CH. 12.4	11	Tan / Pink
CH. 13.1	42	Violet / White
CH. 13.2	41	Blue / White
CH. 13.3	7	White / Blue
CH. 13.4	8	White / Violet
CH. 14.1	40	Green / White
CH. 14.2	39	Yellow / White
CH. 14.3	5	White / Yellow
CH. 14.4	6	White / Green
CH. 15.1	38	Orange / White
CH. 15.2	37	Pink / White
CH. 15.3	3	White / Pink
CH. 15.4	4	White / Orange
CH. 16.1	36	Brown / White
CH. 16.2	35	Tan / White
CH. 16.3	1	White / Tan
CH. 16.4	2	White / Brown
GND	9	White / Gray
GND	22	Brown / Blue
GND	43	Gray / White
NC	56	Blue / Brown

Table 5: DC-A22 Output cable Conductor Assignments

Configuration Options for Trigno System

Trigno System Information

The Information tab in Trigno PC software presents information pertaining to the system and its settings.

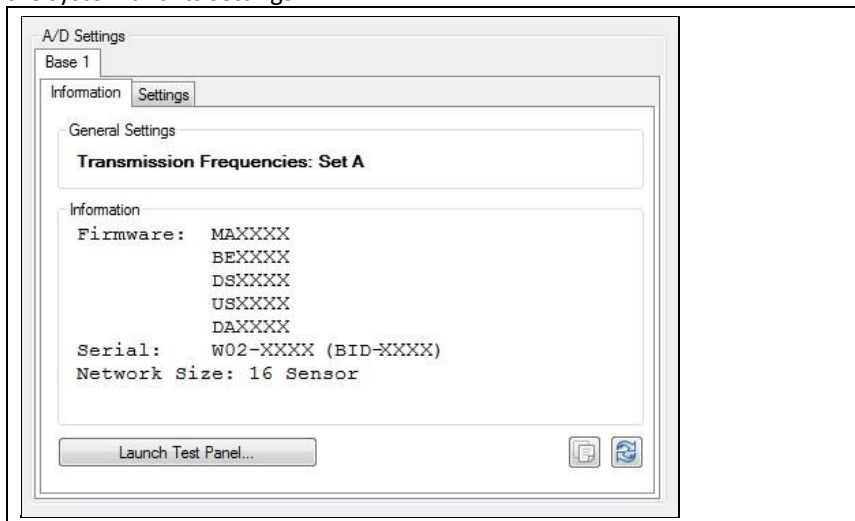


Figure 14: Trigno System panel.

Transmission Frequencies

Wireless communication occurs on varieties of frequencies throughout the acceptable 2.4 GHz spectrum. Four frequency sets are available ("A", "B", "C" and "D") and are displayed in this field.

Firmware Version

The current firmware version is shown in this field.

Serial Number

Each Trigno Base Station has a unique serial number and identifier address which is shown in this field.

Network Size

This field indicates the number of sensors supported by this base.

Launch Test Panel

Places the Trigno Base Station in a test mode to assist with verification of analog output signal connections. Each of the 64 analog output channels is configured to produce a unique sinusoid which can be verified by properly sampling these channels with secondary acquisition system.

Trigno System Settings

The Settings tab allows several system parameters to be modified as needed.

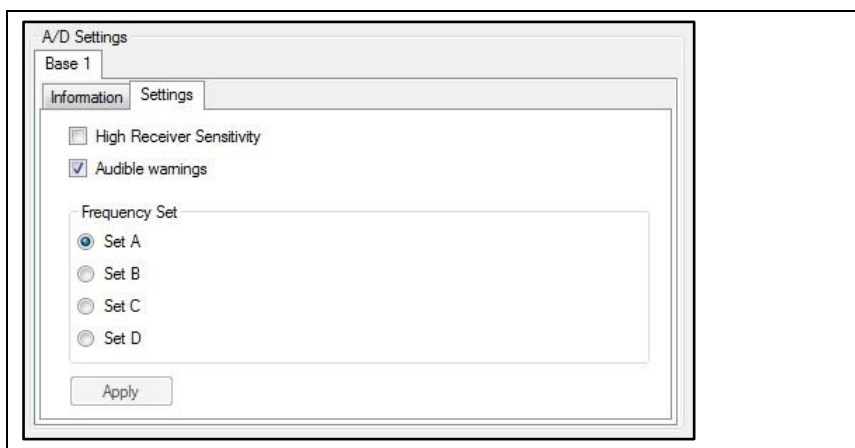


Figure 15: Trigno System Settings panel.

Frequency Set

Use this setting to change the frequencies being used for wireless communication. The default set is “A”. The frequency set should only be changed if nearby sources are interfering with Trigno communications or the particular operating environment is causing significant path loss on the current frequency set. Note that changing the communication frequency set will require sensor re-pairing. Frequencies within the sets are defined by the system and cannot be changed by the User.

Audible Warnings

This option will generate an audible “ping” along with a small message, whenever a sensor falls out of range or its battery is excessively low.

Using the Base Station Trigger Functions

The Base Station supports 4 key triggering functions through the Trigno Trigger Module (SP-U02) which is connected to the base station via the Trigger Port indicated in the figure below. The supported trigger functions for data acquisition are:

- | | |
|------------------------------|--|
| Trigger Start Input: | Data collection starts when an external digital input is received. |
| Trigger Stop Input: | Data collection stops when an external digital input is received. |
| Trigger Start Output: | A digital pulse for external devices toggles when data acquisition starts. |
| Trigger Stop Output: | A digital pulse for external devices toggles when data acquisition stops. |

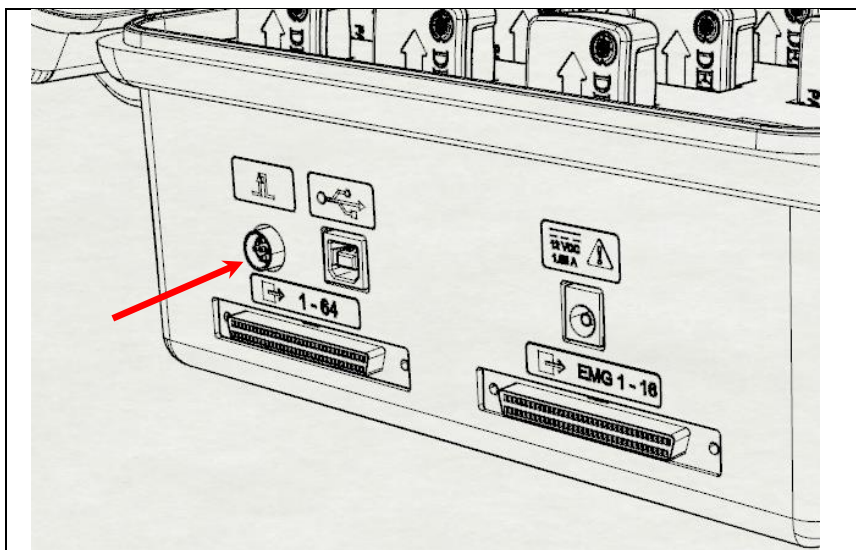


Figure 16: Trigger Module Connector on Base Station.

Triggers must be armed through software options as indicated in the example screenshot below.

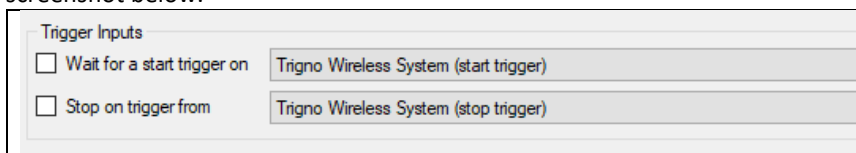


Figure 17: Arming the start and stop triggers in software for external start/stop control of data acquisition.

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 with isopropyl alcohol swabs. Ensure that the sensor contacts remain clean at all times for proper operation.
- While the sensors are sealed and are water-resistant, these 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 electro-magnetic fields should be avoided to prevent the risk of irreparable damage to the sensors.

Trigno 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 during its use and handling:

- 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 isopropyl alcohol swabs if necessary. Do not expose the base station to any liquid. It is not a sealed device.
- The units not be dropped or be subjected to excessive forces of impact 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.

Reference Specifications

RF Frequency Band	2400-2483 MHz (ISM band)
Dimension	27 x 37 x 13 mm
Mass	14 g
Temperature Range ⁽¹⁾	5 - 45 degrees Celsius
EMG Signal Input Range	11mV / 22mV r.t.i.
EMG Signal Bandwidth	20-450 Hz / 10-850 Hz
EMG Contact Dimensions	5x1 mm
Contact Material ⁽²⁾	99.9% silver
Accelerometer Range	±2g, ±4g, ±8g, ±16g
Accelerometer Bandwidth	24 Hz – 473Hz (configurable in software)
Gyroscope Range	±250 dps, ±500 dps. ±1000dps, ±2000dps
Gyroscope Bandwidth	24Hz – 360 Hz (configurable in software)
Magnetometer Range	±4900 uT
Magnetometer Bandwidth	50 Hz
Inter-Sensor Delay	< 1 sample period (Base Station only)
Intra-Channel Delay	< 1-2 sample period
Analog Output Range	± 5 V (Base Station only)
Analog Output Bandwidth ⁽³⁾ (Ch. X.1)	DC-500 Hz (Base Station Only)
Analog Output Bandwidth ⁽³⁾ (Ch. X.2, X.3, X.4)	DC-50 Hz (Base Station Only)

1) Exposure beyond these temperature limits may damage the rechargeable battery.
2) Sensor skin contacts are made from pure silver and should not be used if allergic reactions to silver are expected or found to occur.
3) Refer to table 3 for the time-delays associated with analog outputs

EMG Measurement Data Modes

		Configuration ID	# Data Slots ¹	EMG Sampling Period ² (ms)	EMG Sampling Rate ² (sa/sec)	RMS Window ³ (ms)	RMS Sampling Period ² (ms)	RMS Update Rate ⁴ (sa/sec)	EMG Bandwidth ⁵ (Hz)	EMG Input Range ⁶ (mV)	EMG Resolution Depth ⁷ (bits)	ACC Sampling Period ² (ms)	ACC Sampling Rate ² (sa/sec)	ACC Bandwidth ⁸ (Hz)	ACC Range ⁹ (g)	ACC Resolution ⁷ (bits)	Gyro Sampling Period ² (ms)	GYRO Sampling Rate ² (sa/sec)	GYRO Bandwidth ⁸ (Hz)	Gyro Range ¹⁰ (dps)	Gyro Resolution ⁷ (bits)
EMG	1	1	1	0.465	2148	--	--	--	20-450 10-850	11 22	16	--	--	--	--	--	--	--	--	--	--
EMG	2	2	2	0.23	4370	--	--	--	20-450 10-850	11 22	16	--	--	--	--	--	--	--	--	--	--

- 1) The Trigno System is designed with 16 data slots for wireless transmission. Sensors can occupy up to 4 slots depending on the sampling rate settings.
- 2) Sampling period is the precise time elapse between samples in milliseconds. The sampling rate is a rounded expression of 1/"sampling period" expressed as samples/second (sa/sec).
- 3) Analog EMG Sensor Butterworth filter bandwidth: 2 pole high pass corner, 4 pole low pass corner in Hz.
- 4) EMG signal input range of sensor in millivolts.
- 5) sensor resolution depth across input range.

EMG

Denotes raw EMG signal acquisition.

Inertial Measurement Data Modes

			Configuration ID	# Data Slots ¹	EMG Sampling Period ² (ms)	EMG Sampling Rate ² (sa/sec)	RMS Window ³ (ms)	RMS Sampling Period ² (ms)	RMS Update Rate ⁴ (sa/sec)	EMG Bandwidth ⁵ (Hz)	EMG Input Range ⁶ (mV)	EMG Resolution Depth ⁷ (bits)	ACC Sampling Period ² (ms)	ACC Sampling Rate ² (sa/sec)	ACC Bandwidth ⁸ (Hz)	ACC Range ⁹ (g)	ACC Resolution ⁷ (bits)	Gyro Sampling Period ² (ms)	GYRO Sampling Rate ² (sa/sec)	GYRO Bandwidth ⁸ (Hz)	Gyro Range ¹⁰ (dps)	Gyro Resolution ⁷ (bits)
<div><div>RMS</div><div>ACC</div><div>GYRO</div></div>	3	1		0.5	2000	100	6.75	148	20-450	11 22	16	3.375	296	111	±2 ±4 ±8 ±16	16	3.375	296	111	±250 ±500 ±1000 ±2000	16	
<div><div>EMG</div><div>ACC</div><div>GYRO</div></div>	4	1		0.8	1259	--	--	--	20-450	11 22	16	6.75	148	50	±2 ±4 ±8 ±16	10	6.75	148	50	±250 ±500 ±1000 ±2000	10	
<div><div>EMG</div><div>ACC</div><div>AO</div></div>	5	1		$\frac{27}{52}$	1926	--	--	--	20-450 10-850	11 22	16	6.75	148	50	±2 ±4 ±8 ±16	16	--	--	--	--	--	
<div><div>EMG</div><div>GYRO</div><div>AO</div></div>	6	1		$\frac{27}{52}$	1926	--	--	--	20-450 10-850	11 22	16	--	--	--	--	--	6.75	148	50	±250 ±500 ±1000 ±2000	16	
<div><div>EMG</div><div>ACC</div><div>GYRO</div></div>	7	2		$\frac{135}{17}$	1259	--	--	--	20-450	11 22	16	$\frac{27}{14}$	519	197	±2 ±4 ±8 ±16	16	$\frac{27}{14}$	519	246	±250 ±500 ±1000 ±2000	16	
<div><div>EMG</div><div>ACC</div><div>GYRO</div></div>	8	2		$\frac{135}{17}$	1259	--	--	--	20-450	11 22	16	$\frac{27}{26}$	963	473	±2 ±4 ±8 ±16	16	13.5	74	24	±250 ±500 ±1000 ±2000	16	
<div><div>EMG</div><div>ACC</div><div>GYRO</div></div>	9	2		$\frac{135}{17}$	1259	--	--	--	20-450	11 22	16	3.375	296	111	±2 ±4 ±8 ±16	16	1.35	741	361	±250 ±500 ±1000 ±2000	16	
<div><div>EMG</div><div>ACC</div><div>GYRO</div></div>	10	2		.25	4000	--	--	--	20-450 10-850	11 22	16	13.5	74	24	±2 ±4 ±8 ±16	16	13.5	74	24	±250 ±500 ±1000 ±2000	16	
<div><div>ACC</div><div>GYRO</div></div>	11	1		--	--	--	--	--	--	--	--	2.7	370	111	±2 ±4 ±8 ±16	16	2.7	370	152	±250 ±500 ±1000 ±2000	16	

- 1) The Trigno System is designed with 16 data slots for wireless transmission. Sensors can occupy up to 4 slots depending on the sampling rate settings.
- 2) Sampling period is the precise time elapsed between samples in milliseconds. The sampling rate is a rounded expression of 1/"sampling period" expressed as samples/second (sa/sec).
- 3) RMS window is the period of raw signal that is captured and process to produce singular RMS value.
- 4) RMS update rate is the rate at which the RMS calculation is updated, expressed as samples/sec (sa/sec).
- 5) Analog EMG Sensor Butterworth filter bandwidth: 2 pole high pass corner, 4 pole low pass corner in Hz.
- 6) EMG signal input range of sensor in millivolts.
- 7) sensor resolution depth across input range.
- 8) IMU bandwidth determined by onboard digital low pass filter
- 9) Accelerometer signal input range in "g" (i.e. 9.8 m/s²)
- 10) Gyroscope angular rate input range in degrees per second (dps).








Denotes raw EMG signal acquisition.



- Denotes onboard RMS calculation of the EMG signal.
- Denotes onboard 3 DOF accelerometer data.
- Denotes onboard 3 DOF gyroscope data.
- Denotes analog output supported mode.

Orientation Measurement Data Modes

	Configuration ID	# Data Slots ¹	EMG Sampling Period ² (ms)	EMG Sampling Rate ² (sa/sec)	EMG Bandwidth ³ (Hz)	EMG Input Range ⁴ (mV)	EMG Resolution Depth ⁵ (bits)	Orientation Sampling Period ² (ms)	Orientation Sampling Rate ² (sa/sec)	Orientation Resolution ⁶ (bits)
	12	1	0.675	1481	20-450	11 22	16	13.5	74	32
	13	1	0.5625	1778	20-450 10-850	11 22	16	13.5	74	16
	14	2	0.42	2370	20-450 10-850	11 22	16	4.5	222	32
	15	2	0.27	3704	20-450 10-850	11 22	16	13.5	74	32
	16	2	0.25	4000	20-450 10-850	11 22	16	13.5	74	16

- The Trigno System is designed with 16 data slots for wireless transmission. Sensors can occupy up to 4 slots depending on the sampling rate settings.
- Sampling period is the precise time elapse between samples in milliseconds. The sampling rate is a rounded expression of 1/"sampling period" expressed as samples/second (sa/sec).
- Analog EMG Sensor Butterworth filter bandwidth: 2 pole high pass corner, 4 pole low pass corner in Hz.
- EMG signal input range of sensor in millivolts.
- sensor resolution depth across input range.
- Orientation vector output resolution in bits. Orientation is expressed in quaternions and is performed on the sensor.





- Denotes raw EMG signal acquisition.
- Denotes onboard calculation of orientation fused from 3 DOF accelerometer, 3 DOF gyroscope and 3 DOF magnetometer data.

Appendix I

Mains Isolation

The Trigno Base Station is provided with Medical Grade isolated power supply which is compliant with IEC60601 series of harmonized standards for Medical Devices. However, full compliance with IEC60601-1 Basic Safety for Medical Devices requires that the PC operating the software be isolated as well. This stems from the basic requirement to have all patients electrically isolated from equipment within their reach, and since the PC running the Trigno Software is conceivably within their reach, it too must be isolated.

	Delsys does not supply isolation transformers for Personal Computers and their peripherals.
	Delsys recommends model IS1000HG manufactured by Tripp Lite (www.tripplite.com) for this task. This device is a medical grade isolation transformer capable of delivering up to 1000 W. A smaller similar version for 500W is also available (IS500HG). Similar products compliant with IEC60601-1 are acceptable.