Trigno® Wireless Biofeedback System

—

Avanti Goniometer Adapter

User's Guide

Download EMGworks® at
www.delsys.com/emgworks

MAN-017-2-0
MP1308A
September 2019

Important Information

Intended Use

The Trigno Avanti Goniometer Adapters are components of the Trigno® Wireless Biofeedback System. This 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. The System is 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

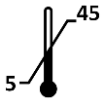
Immediately discontinue device use if skin irritation or discomfort occurs.

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-W06-023 (“Trigno Avanti Goniometer Adapter”)
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 numériqué de la classe B est conformé 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.

Please refer to the main Trigno System User Guide for additional information.

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

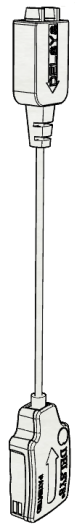
Trigno System Overview

The Trigno® Avanti Goniometer Adapter is a component of the Trigno Wireless Biofeedback System and is designed to provide relative angle information of joints, such as the elbow, the knee and the fingers. The sensor is compatible with Biometrics LTD. SG Series Goniometers which are available in multiple sizes to optimize performance in varieties of scenarios. Data can be related to angles (in degrees). These sensors are effective in measuring the biaxial angle data from different parts of the human body. The system transmits signals from the Trigno sensors to a receiving base station using a time-synchronized wireless protocol which minimizes data latency across sensors. For mobile biofeedback applications, Trigno 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 Trigno System User Guide for System information and operational details.**

Trigno Goniometer Adapter Features

The Trigno Goniometer Adapters are capable of detecting biaxial angle measurements using industry-standard goniometers. Each Sensor is equipped with the following capabilities and design features:

- 2 goniometer channels
- compatible with *Biometrics Ltd.* SG Series Goniometers
- bandwidth DC-50 Hz.
- built-in 3DOF IMU (accelerometer, gyroscope, magnetometer)
- onboard orientation calculation
- inter-sensor latency < 1 sample period
- wireless transmission range 20+m[1]
- 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.

Inertial Measurement Unit

Trigno 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 ±2g to ±16g for accelerometer outputs and ±250°/s to ±2000°/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 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

The Trigno wireless communication scheme offers robust data transmission for up to 16 Trigno sensors operating in full bandwidth mode, 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 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 protocol.

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 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. Common household magnets can be used to perform these functions as well.

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.

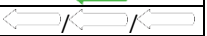
	State	Color	Pattern	Arrow Display
	Common States			
1	Power Off	Off	none	
2	Power On/Activate	White/Green	fade	
3	Charging	Amber	solid	
4	Charge Complete	Green	solid	
5	Identification Mode	White	rapid flash	
6	Scan (Startup)	Amber/Cyan	slow flash	
7	Power Up Error	Red	slow flash	
	Trigno RF Mode			
8	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.

Getting Started with the Goniometer Adapter

Please refer to the Trigno System User guide for key operational details regarding the base station, sensor charging, and initiating the sensor.

Configuring the Trigno Goniometer Adapter

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

Goniometer Channel Characteristics							
Input Range	1.5mV, 1.8mV, 2.3mV						
Bandwidth	DC-50 Hz						
Inertial Measurement Unit (IMU) Ranges							
Accelerometer[1]	±2 *g*	or	±4 *g*	or	±8 *g*	or	±16 *g*
Accelerometer Bandwidth[1]	24Hz - 470 Hz						
Gyroscope[1]	±250 *dps*	or	±500 *dps*	or	±1000 *dps*	or	±2000 *dps*
Gyroscope Bandwidth[1]	24 Hz - 360 Hz						
Orientation[2]	10 Hz						

[1]Accelerometer and gyroscope range, bandwidth and sampling rate are configured by the software.

[2]Note that the orientation is calculated on-board with a data fusion algorithm.

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 +/-5V range. Analog outputs are engaged through software and are only available for specific sensor sampling configurations as stated below:

	Sampling Rate	**Data Type**	**Bandwidth**
Ch. x.1	1926 sa/sec	Goni A	DC-50 Hz
Ch. x.2	148 sa/sec	N/A	DC-50 Hz
Ch. x.3	148 sa/sec	N/A	DC-50 Hz
Ch. x.4	148 sa/sec	Goni B	DC-50 Hz

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

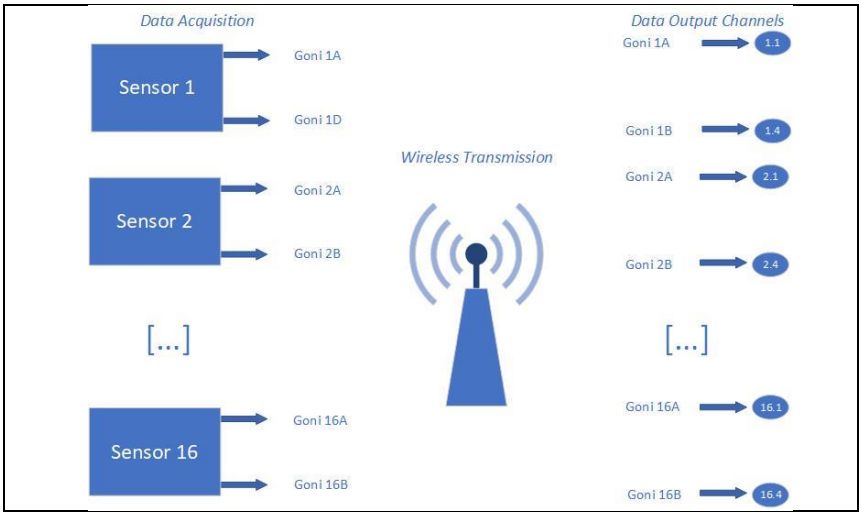


Figure 1: Analog Output Data Flowchart

Refer to the Trigno System User Guide for more information on Analog Output Operation.

Working with Goniometers

Connecting the Goniometer to the Adapter

The Trigno Goniometer Adapter has a connector head hosting 2 receptacles for the membrane transducers. Connect the 2 goniometer connectors to the 2 receptacles taking care to fully mate the plug.

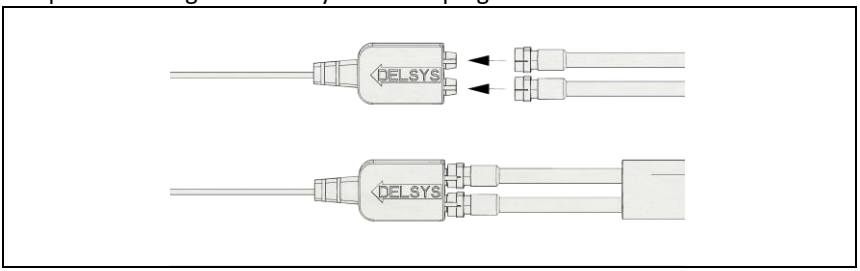


Figure 2: Mating the Goniometer connectors to the sensor connector head. Ensure that the connectors are fully inserted.

Applying the Goniometer

Goniometers can be used in a wide variety of circumstances and applications: thus, each case must be evaluated for any particular challenge it may pose. One common application is to measure the angle of joints while performing dynamic movements. Considering the knee while walking, the sensor can be affixed in the figure below. Goniometers should be used according to their manufacturer-supplied instructions for use.

Figure 3: Affixing the Goniometer to the knee joint.

The example above serves to illustrate common techniques that researchers employ when using goniometer type devices. Each situation and use-case is unique, however, so the User is encouraged to explore other strategies as needed.

Figure 4: Biometrics SG Series goniometer offerings.

Since each Goniometer sensor can support up to 2 channels, it is possible to observe biaxial measurement with 1 sensor.

Placing the Goniometer Adapter

The Trigno Goniometer Adapter and the associated connection head can be easily affixed to the surface of the body using the Delsys Adhesive interfaces. Additional self-adhesive wraps or tapes can be used to further secure the sensor on the body.

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.
- Sensor leads are delicate and should be handled gently. Do not pull, kink or twist leads as damage may occur.

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.

Do not pull the cable as this will result in damage.

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.

Specifications

Physical Specifications

Dimension (Body)	27 x 46 x 13 mm
Cable Length	102mm
Mass	25g
Temperature Range[1]	5 - 45 degrees Celsius

1) *Exposure beyond these temperature limits may damage the rechargeable battery.*

Electrical Specifications

RF Frequency Band	2400-2483 MHz (ISM band)
Dynamic Range	1.5mV, 1.8mV, 2.3mV
Bandwidth	DC-50 Hz
Accelerometer Range	±2g, ±4g, ±8g, ±16g
Accelerometer Bandwidth	50 Hz – 246Hz (configurable in software)
Gyroscope Range	±250 dps, ±500 dps. ±1000dps, ±2000dps
Gyroscope Bandwidth	50 Hz – 361 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

Inertial Measurement Data Modes

	Configuration ID	# Data Slots[1]	# Goni Channels	Goni Sampling Period[2] (ms)	Goni Sampling Rate[2] (sa/sec)	Goni Channel Bandwidth[3] (Hz)	Goni Input Range (mV)	Goni Resolution Depth[4] (bits)	ACC Sampling Period[2] (ms)	ACC Sampling Rate[2](sa/sec)	ACC Bandwidth[5] (Hz)	ACC Range[6] (g)	ACC Resolution[4] (bits)	Gyro Sampling Period[2] (ms)	GYRO Sampling Rate[2] (sa/sec)	GYRO Bandwidth[5] (Hz)	Gyro Range[7](dps)	Gyro Resolution[4](bits)
DEG ACC GYRO	1	1	2	3.375	296	DC-50	1.5 1.8 2.3	16	6.75	148	50	±2 ±4 ±8 ±16	16	6.75	148	50	±250 ±500 ±1000 ±2000	16
DEG AO	2	1	1 1	27 / 52 6.75	1926 148	DC-50	1.5 1.8 2.3	16 10	--	--	--	--	--	--	--	--	--	--
ACC GYRO	3	1	0	--	--	--	--	--	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 elapse between samples in milliseconds. The sampling rate is a rounded expression of 1/"sampling period" expressed as samples/second (sa/sec).
3) Analog Butterworth filter bandwidth:2 pole low pass corner in Hz.
4) sensor resolution depth across input range.
5) IMU bandwidth determined by onboard digital low pass filter
6) Accelerometer signal input range in "g" (i.e. 9.8 m/s^2)
7) Gyroscope angular rate input range in degrees per second (dps).

DEG — Denotes raw Goniometer signal acquisition.

ACC — Denotes onboard 3 DOF accelerometer data.

GYRO — Denotes onboard 3 DOF gyroscope data.

AO — Denotes analog output supported mode.

Orientation Measurement Data Modes

	Configuration ID	# Data Slots[1]	Goni Sampling Period[2] (ms)	Goni Sampling Rate[2] (sa/sec)	Goni Bandwidth[3] (Hz)	Goni Input Range (mV)	Goni Resolution Depth[4] (bits)	Orientation Sampling Period[2] (ms)	Orientation Sampling Rate[2] (sa/sec)	Orientation Resolution [8] (bits)
DEG Φ	4	1	2.7	370	DC-50	1.5 1.8 2.3	16	13.5	74	32

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 Sensor Butterworth filter bandwidth: 2 pole low pass corner in Hz.

4) Goniometer sensor resolution depth across input range.

5) Orientation vector output resolution in bits. Orientation is expressed in quaternions and is performed on the sensor using a fusion algorithm that combines the accelerometer, gyroscope and magnetometer data.

DEG Denotes raw Goniometer signal acquisition.

Φ Denotes onboard calculation of orientation fused from 3 DOF accelerometer, 3 DOF gyroscope and 3 DOF magnetometer data.

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