Trigno® Wireless Biofeedback System

—

Avanti FSR Adapter

User's Guide

MAN-019-2-2
MP1278C

Important Information

Intended Use

The Trigno Avanti FSR 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

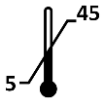
Immediately discontinue device use if skin irritation or discomfort occurs.

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 Regulation MDR 2017/745. 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:
CS Lifesciences Europe Ltd
The Black Church
St. Mary's Place, Dublin 7
Dublin D07P4AX Ireland

Trigno Wireless Biofeedback System

Sensor Model: SP-W06-020 ("Trigno Avanti FSR 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

- 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)

Trigno System Overview

The Trigno® Avanti FSR Adapter is a component of the Trigno Wireless Biofeedback System and is designed to provide relative pressure information of body-contact surfaces, such as the heel, the toe, and the fingers. Three FSR membrane sizes are available for optimizing performance in a variety of scenarios. Data are expressed as a percentage of the sensor's full-scale limits. These devices are useful for identifying the timing of significant events and for making relative amplitude comparisons of pressure but are not suitable for making *absolute* measurements of force or pressure. 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 FSR Adapter Features

The Trigno FSR Adapters are capable of detecting pressure disturbances using industry-standard force sensitive resistors (FSRs). Each Sensor is equipped with the following capabilities and design features:

- 4 FSR channels
- Compatible with Interlink Electronics 0.2", 0.5" & 1.5" FSR sensors
- 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.

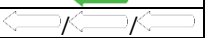
	State	Color	Pattern	Arrow Display
	Common States			
1	Power Off	Off	none	
2	Power On/Activate	White/Green	fade	
3	Charging	Amber	solid	
4	Charge Complete	Green	solid	
5	Identification Mode	White	rapid flash	
6	Scan (Startup)	Amber/Cyan	slow flash	
7	Power Up Error	Red	slow flash	
	Trigno RF Mode			
8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

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

Configuring the Trigno FSR Adapter

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

FSR Channel Characteristics							
Input Range	0 ohms to open circuit						
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 covers 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	FSR A	20-450 Hz
Ch. x.2	148 sa/sec	FSR B	DC-50 Hz
Ch. x.3	148 sa/sec	FSR C	DC-50 Hz
Ch. x.4	148 sa/sec	FSR D	DC-50 Hz

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

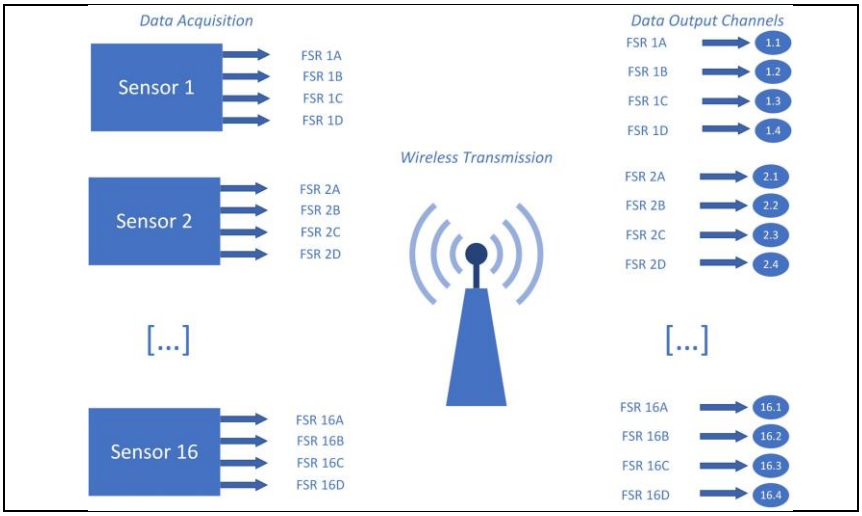


Figure 1: Analog Output Data Flowchart

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

Working with FSR Membranes

Handling FSR Membranes

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

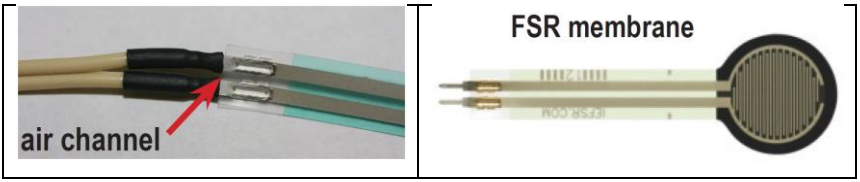


Figure 2: Ensure that the air channel at the joint of the membrane and the cable remains clear so that air can flow during membrane compressions.

Connecting the FSR Membranes to the Adapter

The Trigno FSR Adapter has a connector head hosting four receptacles for the membrane transducers. Connect the FSR membranes to the four receptacles, taking care to fully mate the plug. The connectors are labeled “1” through “4” on the sensor and portrayed in this order within the Delsys software. All FSR membranes are interchangeable.

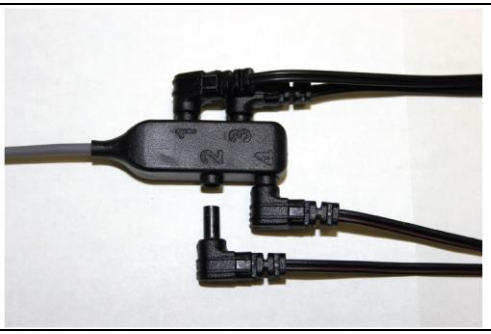


Figure 3: Mating the FSR membrane connectors to the sensor connector head. Ensure that the barrels are fully inserted.

Applying the FSR Membrane

The FSR membranes can be used in a wide variety of circumstances and applications; thus, each case must be evaluated for any particular challenges it may pose. One common application of this device is to use it as a footswitch while walking or running. With this example, one can consider several options for affixing the sensor to the heel, as shown in the following figures. Taping the sensor directly to the heel will produce a very sensitive and responsive signal. However, this approach subjects the FSR membrane to high load and shear forces, which may cause signal saturation and accelerated wear. Protecting the FSR membrane with tape or similar material can be done to extend its usage and life.

An alternative approach to affixing the FSR membrane to the heel is to instrument the shoe by taping it to the sole. This will produce a similar response to the previous example but may offer some added convenience for repetitive data trials. Applying tape to the FSR membrane may extend its usage and life.

Figure 4: Affixing the FSR membrane to the top of the inner sole.

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

Figure 5: Affixing the FSR membrane to the bottom of the inner sole.

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

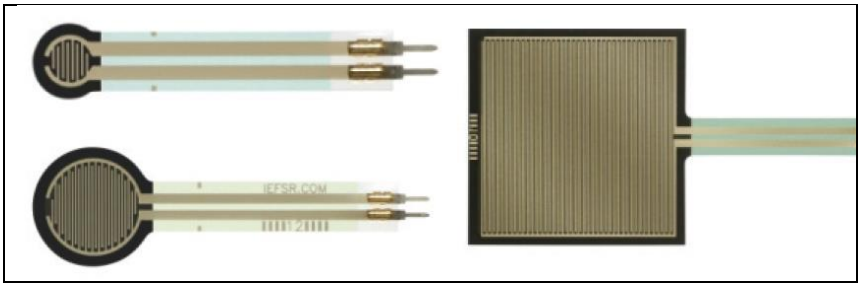


Figure 6: FSR membrane options for a variety of applications servicing 5 mm², 15 mm², and 40 mm² areas.

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

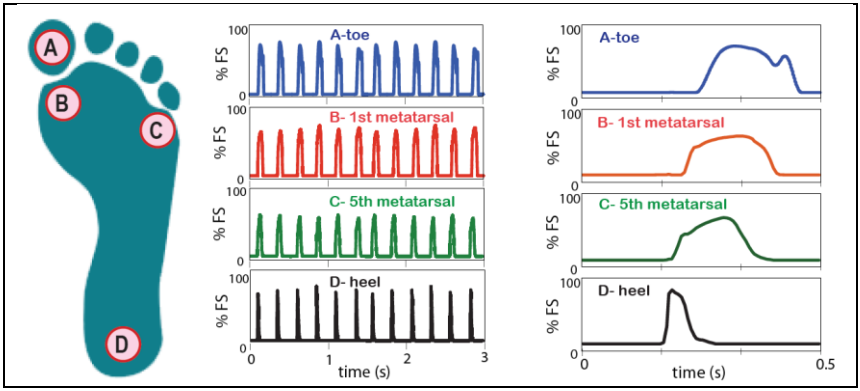


Figure 7: Mapping four pressure points of the foot. Left: Shows the location of the four pressure points being monitored. Middle: Shows data from the four points during low intensity running on a treadmill as acquired by EMGworks. Right: Expands the time scale for one foot strike, showing the time-course and relative intensity of each pressure point.

Placing the FSR Adapter

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

Maintenance and Care

Trigno Sensors

Trigno sensors are encased in a sealed polycarbonate enclosure. The following points should be kept in mind when handling the sensors.

- All sensors should be visually inspected before each use to ensure that no mechanical deterioration has occurred.
- 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)
FSR Resistance Range	180 – 300000 ohms
Dynamic Range	0 ohms – open circuit
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]	# FSR Channels	FSR Sampling Period[2] (ms)	FSR Sampling Rate[2] (sa/sec)	FSR Channel Bandwidth[3] (Hz)	FSR 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)
FSR ACC GYRO	1	1	4	3.375	296	DC-50	16	6.75	148	50	±2 ±4 ±8 ±16	16	6.75	148	50	±250 ±500 ±1000 ±2000	16
FSR	2	1	4	27 / 14	519	DC-50	16	--	--	--	--	--	--	--	--	--	--
FSR ACC GYRO	3	4	4	0.90	1111	DC-50	16	1.35	741	246	±2 ±4 ±8 ±16	16	1.35	741	361	±250 ±500 ±1000 ±2000	16
FSR AO	4	1	1 3	27 / 52 6.75	1926 148	DC-50	16 10	--	--	--	--	--	--	--	--	--	--
ACC GYRO	5	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).

FSR Denotes raw FSR 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]	FSR Sampling Period[2] (ms)	FSR Sampling Rate[2] (sa/sec)	FSR Bandwidth[3] (Hz)	FSR Resolution Depth[4] (bits)	Orientation Sampling Period[2] (ms)	Orientation Sampling Rate[2] (sa/sec)	Orientation Resolution [8] (bits)
	5	1	2.7	370	DC-50	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) FSR 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.

Denotes raw FSR signal acquisition.

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