Trigno® Wireless Biofeedback System

—

Maize EMG Sensor

User's Guide

MAN-044-1-2
6/16/2023
MP1355C

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Important Information

Intended Use

The Trigno Maize Sensor is a component of the Trigno Wireless Biofeedback System. It is a battery-powered biofeedback device that enables researchers and clinicians to acquire EMG (electromyographic) and related signals from subjects for biofeedback and research purposes. It 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 pacemakers 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 website at www.delsys.com or contact us via:

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.

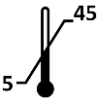
Immediately discontinue device use if skin irritation or discomfort occurs.

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-ion 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 the internal lithium-ion polymer battery. 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:
CS Life Sciences Europe Ltd.
The Black Church
St. Mary's Place
Dublin 7,
Dublin, D07P4AX, Ireland

Trigno Wireless Biofeedback System

Sensor Model: SP-W06-029
Base Station Model: SP-W02
System Model: DS-T03

FCCID: W4P-SP-W06 (Sensor)
FCCID: W4P-SP-W02 (Base Station)
IC: 8138A-DST03 (System)

IC: 8138A-DST03 (System)
211-190332 (DS-T03)
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.

Recommended PC Specifications

- Trigno Discover® Software
- Windows 10, x64
- USB 2.0 port
- 3.0 GHz processor clock speed, quad core
- 16 GB system memory
- 500 GB hard disk storage
- 1680 x 1050 resolution

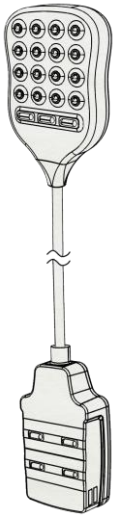
Trigno® System Overview

The Trigno® Maize Sensor is a component of the Trigno® Wireless Biofeedback System, which is a device designed to make EMG and biofeedback signal detection reliable and easy. The system transmits signals from Trigno sensors to a receiving base station unit using a time-synchronized wireless protocol that 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. The system is also capable of integrating with 3rd party lab equipment via an API software module and hardware triggering signal lines. **Refer to the Trigno System User Guide for System information and operational details.**

Trigno Maize Sensor Features

The Trigno Maize Sensor is a 16-channel surface EMG array that can detect EMG signals from different geometric positions. Each Maize Sensor is equipped with the following capabilities and design features:

- 16-contact EMG Sensing
- Multi-location referencing scheme
- Selectable AC dynamic range (max 20.8mV)
- Selectable DC dynamic range (83mv –1000 mV)
- Up to 17 bits of resolution
- Bandwidth: 20-450 Hz or 20-950 Hz
- Optional onboard RMS calculations
- On board IMU
- Inter-sensor latency < 1 sample period
- Wireless transmission range >20m[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.

16-contact EMG Sensing

Trigno Maize sensors are defined by a 16-channel, low noise, high signal fidelity architecture for detecting EMG biofeedback signals from the surface of the skin when muscles contract. The sensor bandwidth is optimized for surface signals at 20-450 Hz. The DC dynamic range and AC dynamic range are tunable for optimal signal-to-noise performance under a wide breadth of conditions spanning 83-1000 mV for DC offset management and 15.6-20.8 mV for AC (EMG) signals.

Multi-Location Referencing Scheme

The Trigno Maize sensor employs a unique reference differential architecture which detects signals with the low noise advantage of a differential measurement scheme, but effectively reports data as 16 monopolar signals with respect to a common electrode reference so that cross-signal analysis is simplified. This common electrode can be selected near the 16 detection contacts (proximal) of the sensor head, or further away in the sensor body (distal) which is the default and recommend mode of operation. Separately, the Maize sensor employs a global reference scheme to stabilize the detected signal under a variety of challenging environmental conditions.

Selectable Dynamic Range

The Trigno Maize sensor offers six gain settings which can be used to optimize detection conditions for a wide range of environmental conditions while accommodating DC skin offsets as high as 1V and EMG signals as large as 20.8mV.

High Resolution Bit Depth

The Trigno Maize sensor offers rich signal depth of 17 bits and accommodates full signal resolution for max dynamic range and low baseline noise.

Optimal Bandwidth 20-450 Hz or 20-950Hz

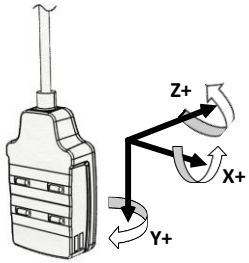
The Trigno Maize sensor is designed to detect the full range of biopotential signals on the skin and processes these signals to extract the full bandwidth of the EMG content. Onboard filtering employs a 4-pole Hi-pass Butterworth filter at 20 Hz and an 8-pole low pass Butterworth filter at 450 Hz or 950Hz as selected in the software. Additionally, the system employs a sinc filter with amplitude correction to maintain a maximally flat passband region and absolute anti-aliasing assurance from out-of-band noise sources.

RMS Mode

The sensor can report raw EMG data or RMS amplitudes calculated with 50 ms, 100ms and 200 ms windows.

Onboard IMU

The sensor has a built-in IMU which can report back triaxial accelerometer data with a ±2g, ±4g, ±8g, or ±16g range, as well as triaxial rotational data from a ±250, ±500, ±1000 and ±2000 dps gyroscope. EMG data can only be reported in RMS mode when operating the onboard IMU.



Rechargeable Battery

Sensors contain a sealed rechargeable lithium polymer battery for continuous use whose life can be extended when making use of low power modes. Actual duration will depend on usage conditions, which are expected to vary between 1 to 2 hours of performance. Charge status is conveniently reported through wireless communication.

Sensor LED Feedback States

The Trigno Maize sensor indicates its status through various LED Arrow colors and blink patterns as indicated in the table below. Each of these states is described on Page 10 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)	
	FW Update Mode			
15	Connecting (BLE)	Magenta	slow flash	
16	Bootloader (Dis)/ Connect	Green/Green Magenta	double flash (1x) rapid flash	
17	Bootloader/Firmware update	Blue/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) **Connecting (BLE):** Sensor is broadcasting to connect with a BLE host for firmware update activity.
16) **Bootloader Connect / Disconnect:** Sensor is placed into bootloader mode awaiting firmware update process.
17) **Bootloader / Firmware update**: Sensor is updating firmware.

Data Synchronization

Data from each *Trigno sensor* and from each *channel within a sensor* are time synchronized over the Trigno wireless communication protocol such that no time skew between data exists. Triggering functionality, as described in the main system user guide, is available with the Maize sensor.

Wireless Communication

The Trigno wireless communication scheme offers robust data transmission for up to four Maize sensors operating in full bandwidth mode, with a range of 20m. Under optimal environmental conditions (no RF path obstructions or interfering sources), this nominal distance can be notably superseded. When operating the sensors in RMS mode, up to 16 can be used simultaneously.

Sealed Enclosure

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

Internal Magnetic Switch

The Trigno Maize sensor is equipped with an internal magnetic switch that is used to turn the sensor “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.

Getting Started with the Trigno Maize Sensor

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 Maize Sensors

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

Electromyographic (EMG) Sensing Ranges							
Gain Selection[1] (V/V)	1	2	3	4	6	8	12
DC Input Range[2] (mv)	1000	500	333	250	167	125	83
AC Input Range[2] (mv)	15.6	15.6	20.8	15.6	20.8	15.6	20.8
Baseline Noise[2,3] (uV_{rms})	1.125	0.835	0.757	0.728	0.684	0.678	0.668
RMS Windows[4] (ms)	50 100 200	N/A	50 100 200	N/A	50 100 200	50 100 200	50 100 200
Accelerometer Range[5] (g)	±2 ±4 ±8 ±16	N/A	N/A	N/A	±2 ±4 ±8 ±16	N/A	±2 ±4 ±8 ±16
Gyroscope Range[5] (dps)	±250 ±500 ±1000 ±2000	N/A	N/A	N/A	±250 ±500 ±1000 ±2000	N/A	±250 ±500 ±1000 ±2000
Frequency Ranges							
Sampling Rate[1] (sa/sec)	1000			2000			
Bandwidth[6] (Hz)	20 – 450			20 – 450 or 20 - 950			
Number of Channels[7]	16			9 or 8			

[1]EMG range, bandwidth selection and sampling rate are configured by the software.
[2]Selection of EMG input range is optimized by selecting the lowest noise setting for the required DC signal elements dictated by measurement conditions.
[3]Baseline Noise is a typical measurement with all inputs shorted to ref.
[4]Representation of EMG data as an RMS signal is optional.
[5]Reporting of IMU data requires EMG data to be represented as an RMS signal.
[6]Filter response is a maximally flat Butterworth topology.
[7]in order to maintain wireless transmission robustness, the higher sampling rate of 2000 sa/sec necessitates a reduction in channel count from 16 to 9 or 8.

Skin conditions and EMG signal characteristics can vary greatly between sensor applications, usage conditions, and environmental considerations. Range settings for the Trigno Maize sensor are designed to accommodate this high degree of variation by employing a unique signal conditioning and sampling scheme that can be tuned for optimal performance. A recommended nominal operating point is gain 6V/V, which provides a wide DC offset operating range, a full AC (EMG) signal operating range, and low baseline noise. Once the sensor is affixed to the skin, and skin offsets have settled after a few minutes, noise baseline can be further improved by using higher gain settings. Note that high skin impedance conditions from improper skin prep can contribute to large DC offsets, which may cause the signal to clip to 0V, particularly during dynamic

activities. In these situations, reducing the gain will increase the dynamic range of the sensor and restore the signal amplitudes. Conditions of high skin impedance can be mitigated by following proper skin preparation as described in the Trigno Wireless Biofeedback System User Guide.

Electrode Contact Configuration

Maize sensors employ a unique differential electrode geometry which provides optimal signal detection with respect to a single common electrode contact. The default location of the common contact is selected in software to be *distal* to the 16 EMG sensor contacts, which minimizes inter-electrode distance variations to yield uniform amplitude measurements across all the contacts. The sensor can also be operated with the common electrode in a *proximal* configuration which can be used under specific conditions to accentuate local

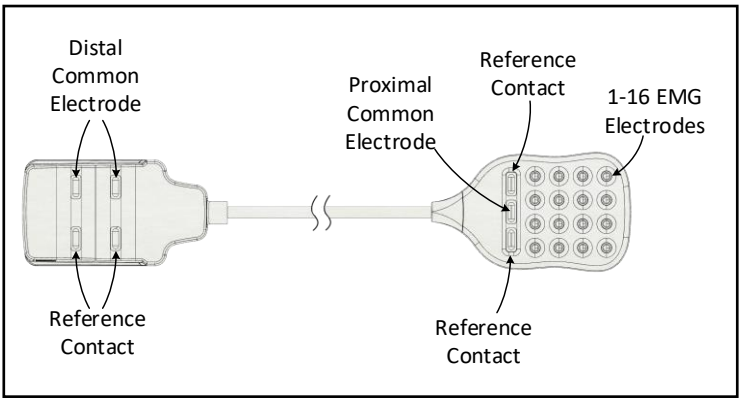


Figure 1:Identification of the Common electrodes, the reference electrodes and the 16 EMG signal electrodes.

signal variations. The distal configuration is recommended for almost all measurement scenarios. The sensor is designed with several reference contacts to ensure stable, noise-free signal recordings.

Channel Assignments

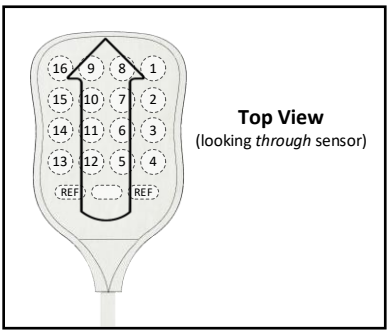


Figure 2: 16-Channel Assignments

The EMG signal channel arrangements are presented in the Figure 2, and are defined by the hardware. The full complement of 16 EMG channels are sampled at 1000 samples/sec and captured with a 17-bit resolution depth.

9-Channel Subset Assignment

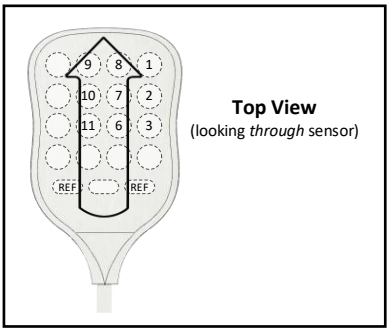


Figure 3: 9-channel mode.

The Maize sensor can be operated in a fast sampling mode of 2000 samples/sec across 9 channels, to a resolution depth of 15 bits. In this mode a choice of signal bandwidth between 20 – 450 Hz or 20 – 950 Hz is available. Figure 3 identifies the channel allocations when operating in this mode.

8-Channel Subset Assignment

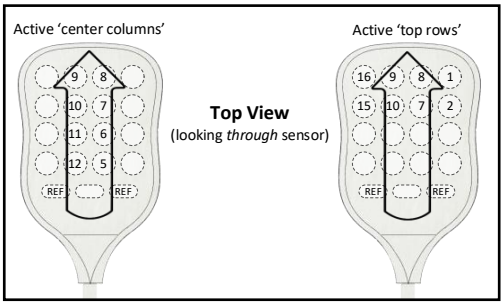


Figure 4: 8-channel modes, with center column engaged electrodes (left) or top row engaged electrodes (right).

The Maize sensor can be operated in a fast sampling mode of 2000 samples/sec across 8 channels, to a resolution depth of 17 bits. In this mode a choice of signal bandwidth of 20 – 450 Hz or 20 – 950 Hz is available. Additionally, the electrode arrangement can be selected between the sensor's center columns or top rows as shown in Figure 3.

Cleaning the Sensor Site

Prior to affixing the Maize sensor on the surface of the skin, the sensor site for the reference contacts and the EMG detection contacts must be properly cleaned to remove dry dermis and 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 intended 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 strong adhesion 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.

Placing the Maize Sensor on the Skin

Trigno Maize Sensors host 16 detection contacts which should be located near the centroid of the muscle to detect the maximum amount of EMG activity. The sensor body should be affixed in a convenient nearby location to provide a stable detection reference point. The sensor body and sensor head are easily attached to the skin using the Delsys Adhesive Sensor Interfaces. The arrow features on the sensor head and sensor body can be used to align the detection contacts with the propagation direction of the EMG signals along the muscle fibers.

Maintenance and Care

Trigno Maize Sensors

Trigno Maize 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. Using other cleaning agents may weaken and compromise the integrity of the plastic enclosure.
- 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.

Do not pull, excessively bend, or excessively rotate 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
Dimension (Head)	50 x 30 x 9 mm
Cable length	150 mm
Mass	20 g
Temperature Range [1]	5 - 45 degrees Celsius
EMG Contact Dimensions	2 mm diameter
Reference / Common Contact Dimension	5 x 1 mm
EMG Contact Grid spacing	6 mm
Contact Material [2]	99.99% silver

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.*

Electrical Specifications

RF Frequency Band	2400-2483 MHz (ISM band)
EMG Signal Input Range[1]	15.6 – 20.8 mV r.t.i.
DC Signal Input Range[1]	83 – 1000 mV r.t.i.
EMG Signal Bandwidth[2]	20 - 450 Hz 20 - 950 Hz
High Pass Filter Characteristics	2-pole Butterworth
Low Pass Filter Characteristics	8-pole Butterworth
PassBand Flattening	SinX/X correction
Sensor Gain	1, 2, 3, 4, 6, 8, 12 V/V
Signal Sampling Rate[3]	1000 samples / sec / ch. 2000 samples / sec / ch.
RMS Mode EMG Sampling Rate	2000 samples /sec / ch.
RMS update rate	74 samples/sec/ch
RMS Window Sizes	50 ms, 100 ms, 200 ms
Resolution[4]	17 bits 15 bits 29 bits
Inter-Sensor Delay	< 1 sample period
Intra-Channel Delay	< 1 sample period

1) AC and DC signal range is dependent on gain selection.
2) Bandwidth setting of 20-950 Hz is only available when a sampling rate of 2000 samples/sec/ch is selected.
3) Sampling rate of 2000 sa/sec/ch. is only supported in 9 or 8-channel modes.
4) 9-channel modes can only support a resolution depth of 15 bits. RMS modes support resolution depths of 29 bits.

IMU Specifications

Accelerometer Range	±2g, ±4g, ±8g, ±16g
Accelerometer Bandwidth	111 Hz
Gyroscope Range	±250 dps, ±500 dps. ±1000dps, ±2000dps
Gyroscope Bandwidth	151 Hz

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