TRIGNO™ Personal Monitor

User's Guide

October 2011 Edition (DRAFT)
PM-W02

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

MAN-014-1-0 (DRAFT)

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Important Information

Intended Use

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

Rx ONLY

Contraindications

DO NOT USE on Patients with implanted electronic devices of any kind, including cardiac pace-makers or similar assistive devices, electronic infusion pumps, and implanted stimulators.

DO NOT USE on irritated skin or open wounds.

DO NOT USE on Patients with allergies to Silver.

Technical Service and Support

For information and assistance visit our web site at:

www.delsys.com

Contact us at:

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

Warning and Precautions

Consult all accompanying documents for precautionary statements and other important information.

Consult accompanying user's guide for detailed instructions.

Keep the device dry. The presence of liquids may compromise the safety features of the device.

Handle with care.

Sensitive electronic device. Avoid static discharges. Do not operate or store near strong electrostatic, electromagnetic, magnetic or radioactive fields. Interference from external sources may decrease the signal-to-noise ratio or result in corrupted data.

Connect only to Delsys-approved devices.

Connecting a patient to high-frequency surgical equipment while using Delsys EMG systems may result in burns at the site of the EMG sensor contacts.

Immediately discontinue device use if skin irritation or discomfort occurs.

Immediately discontinue device use if a change in the device's performance is noted. Contact Delsys technical support for assistance.

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

Device contains a Lithium-Polymer battery. Do not damage, crush, burn, freeze or otherwise mishandle the device. Recharge only with the approved power supply and recharger.

Trigno Systems should be stored and operated between 5 and 50 degrees Celsius due to the presence of an internal Lithium Polymer rechargeable cell. Storing or operating the device, and consequently the cell, outside of this temperature range may compromise the integrity and the safety features of the cell.

Device Information

Complies with Requirements put forth by the Medical Device Directive 93/42/EEC. Class I device, Annex VII.

Type BF device (IEC 60601-1).

Isolated device, (Class II, IEC 60601-1)

Do not dispose this product with house waste. Contact Delsys Inc. for instructions on responsibly disposing this device. This product should not be mixed with other commercial wastes.

Date of Manufacturing (appears on device)

Serial Number (appears on device)

EMERGO EUROPE
Molenstraat 15
2513 BH, The Hague
The Netherlands

Authorized Representative

DELSYS INC.
650 Beacon St.
Boston MA 02215
USA

Manufacturer

FCC ID: W4P-SP-W03 (Trigno Body Worn Receiver)
FCC ID: W4P-SP-W01 (Trigno Sensor)
IC: 8138A-DST02 (Trigno Personal Monitor System)

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference. and (2) this device must accept any interference received, including interference that may cause undesired operation.

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

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.

Pursuant to Part 15.21 of the FCC Rules, any changes or modifications to this product not expressly approved by Delsys Inc. might cause harmful interference and void the FCC authorization to operate this product.

To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (EIRP) is not more than that required for successful communication.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. There is no guarantee that interference,will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into outlet on a separate circuit.

Disclaimer

DELSYS INC. makes no warranties, express or implied, as to the quality and performance of this product including but not limited to, any implied warranty of applicability for other than research uses by qualified individuals. DELSYS INC. shall not be liable to any person for any medical expenses or any direct or consequential damages resulting from any defect, failure or malfunction, whether a claim for such damages is based upon theory of warranty, contract, tort or otherwise. No representative, agent, or licensed practitioner is authorized to waive this disclaimer. DELSYS INC. makes no diagnosis or prescription by virtue of anything about this product.

Limited Warranty

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

System Requirements

- EMGworks 4.0.2 or later
- Windows 7, 32 bit operating systems only. Alternate OS: Windows Vista or Windows XP with service pack 3.
- 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
- 1 GB hard disk storage
- Users of Windows 7 and Vista can simply ensure that they have a Windows Experience Index of 4.0 or greater.

Trigno™ Personal Monitor Overview

The Trigno™ Personal Monitor is a high-performing EMG and physiological monitoring device unparalleled in its sophistication, its reliability and its ease-of-use. Each EMG sensor has a built-in triaxial accelerometer, a guaranteed transmission range of 40 m and a re-chargeable battery lasting a minimum of 7 hours. The system is capable of either logging data internally or streaming it to EMGworks®. The unit is capable of communicating with 16 Trigno sensors (resulting in 64 data channels), as well as logging GPS information and internal 3 DOF accelerometer data which has 4 selectable ranges (±1.5g, ±4g, ±6g, ±12g). Full triggering features further expand the possibility for integration with additional measurement technologies.

The Personal Monitor can be used in either of two operational modes:
1) Mobile Monitoring (Figure 1A): The device acts as a wearable communicator, receiving data from wireless sensors and storing these in on-board memory to be downloaded for future analysis.

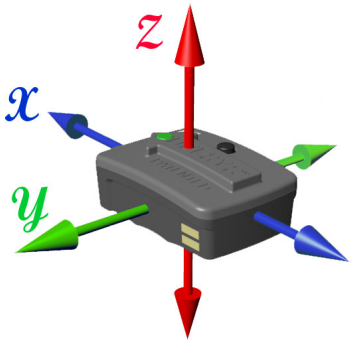
2) Destktop Data Acquisition (Figure 1B): In this mode the device is connected with a USB port to a host computer and sensor data are streamed into EMGworks®for real-time viewing and analysis. This mode also allows the Personal Monitor to be configured by EMG-works® and permits stored data to be downloaded from memory.

Figure 1. A) Mobile Monitoring, B) Desktop Transmission

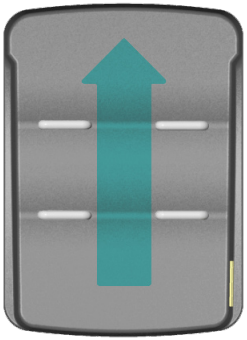
Wireless EMG Sensor Features

Trigno Sensors are equipped with the following features:

- transmission range of 40m
- no inter-sensor latency (< 1 sample period)
- self-contained rechargeable battery
- EMG signal bandwidth 20- 450 Hz
- EMG signal sampling rate of 2000 samples/sec
- EMG baseline noise of 750 nV RMS
- CMRR > 80dB
- 16-bit EMG signal resolution
- integrated 3DOF accelerometer (± 1.5g or ±6g)
- LED User feedback
- battery charge monitoring and status indicator
- environmentally sealed device
- proven parallel bar electrode technology
- contoured sensor-skin interface for maximum signal stability
- auto shutoff



Inertial Sensing Axis


EMG Electrodes

Status	LED Behavior	LED
Data Streaming	Green flash, 1Hz	
Scanning	Amber/green, 1Hz	
Pairing Successful	Green flash 3X, button pressed	
Pairing Unsuccessful	Red flash, 3X, button pressed	
Battery Charging	Amber solid, in cradle	
Charging Complete	Green solid, in cradle	
Charging Error	LED off, in cradle with power	
Sensor Off	LED off	

Figure 2. Trigno 4-channel wireless sensor features.

Personal Monitor Features

The Trigno Personal Monitor is equipped with the following features:

- support for 16 Trigno sensors (16 EMG, 48 Accelerometer)
- internal 3DOF acceerometer (±1.5g, ±4g, ±6g, ±12g)
- GPS capable
- 16 GB memory for data storage
- 8-14 hr battery life (usage dependent)
- QVGA LCD display screen
- Automatic DAQ protocols
- Audio/Visual prompts
- USB support for real-time data viewing and memory download.
- sensor status feedback
- charge status feedback
- auto shutoff
- 2-hr reacharge time

Figure 3. Personal Monitor Features.

Getting Started with the Personal Monitor

Charging the Trigno Sensors

Connect the Trigno power supply to the circular DC jack located on the side of the Recharge Station. Energize the power supply by connecting it to a Mains outlet. Be sure to use the appropriate plug adapter for your locations (Figure XX). Ensure that the Trigno sensors are properly fitted in the recharge pockets. The sensor LEDs will illuminate to amber during charging and green when charge is complete. The recharge unit will periodically check sensors and apply a top-off charge to ensure that the battery kept at full capacity during extended periods of storage, as long as power is connected.

Charging the Personal Monitor

Connect the Personal Monitor power supply to the DC jack located on the bottom side of the device. Energize the power supply by connecting it to a Mains outlet. Be sure to use the appropriate plug adapter for your locations (Figure XX). Alternatively the Personal Monitor can be charged via the USB port, by connecting it to a host device.

Checking Sensor Status

From the home screen, select the "Sensors" button to display the status of all active sensors. The status shows sensor charge status, channel number, sensor type, network status and wireless signal strength. Sensors can be paired from this screen, or turned off. Use the scroll arrows to navigate the display as needed.

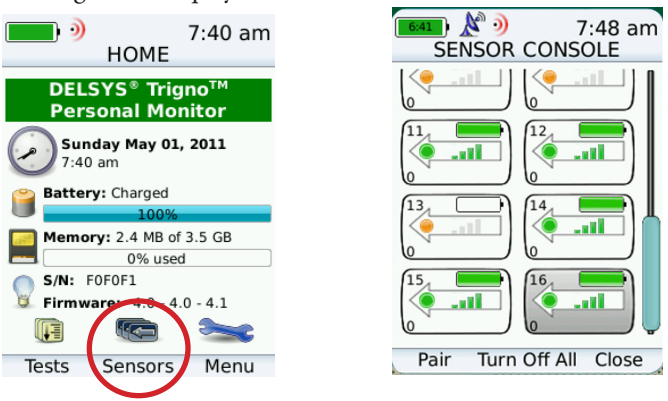


Figure 4. Checking the sensor status on the TPM.

Running a Test

From the home screen, select the "Tests" button to display a list of available data acquisition test protocols. Use the navigation keys to choose the desired Test and press the "Select" button to run it.

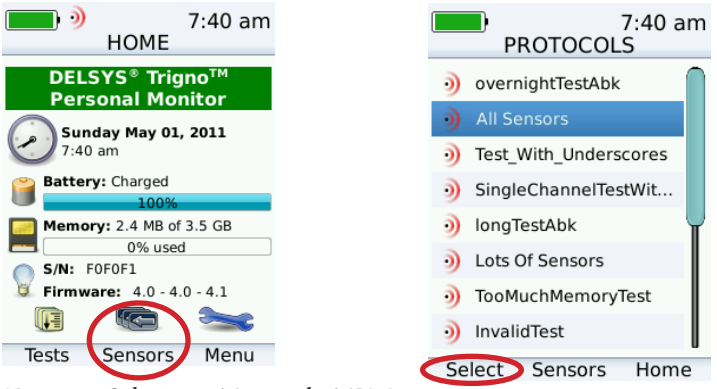


Figure 5. Selecting a Test on the TPM.

Managing Data Files

Data files can be listed by selecing the "Menu" button on the home screen and then selecting "View Data Files". A listing of the all the-stored data files on the device will be available. These files are generated by a corresponding Test file and synchronized in EMGworks. Files can be deleted to free memory on the Personal Monitor either through EMGworks or by selecting the "Delete" command on the device itself. The amount of free memory is displayed at the top of the screenFile deletions on the TPM are permanent.

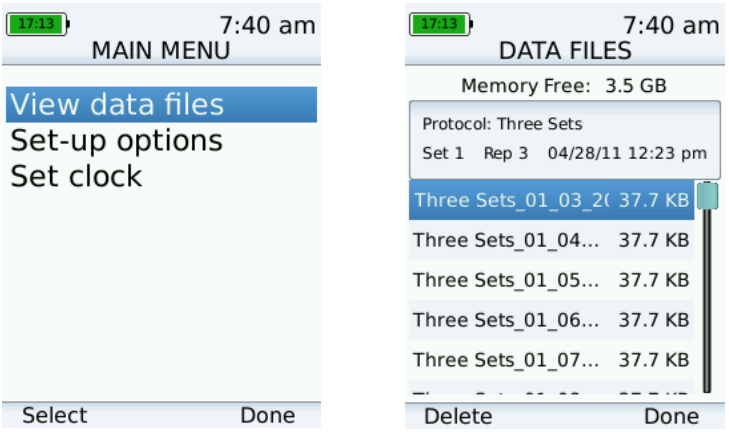


Figure 6. Selecting a Test on the TPM.

Setting the TPM Options

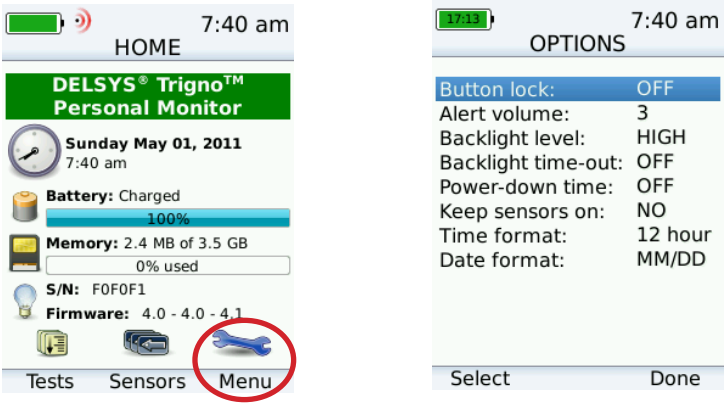


Figure 7. Setting the TPM Options.

The device options can be set by selecting the Menu function from the home page, followed by the "Set-up options" function. Following options are available:

Button Lock: when engaged this feature will lock all buttons on the TPM so that inadvertent button presses will have not effect on the device behaviore. The lock is released by selecting the designated 3 keys simulataneously.

Alert Volume: audio prompts and alerts are accessable on the headphone port. The volume for these can be set bewteen 0 (low) to 10 (highest).

Backlight Level: the screen can be set to 3 levels of brightness. Power consumption increases with screen brightness.

Backlight Time-Out: when engaged, this feature will turn the screen backlight off to save battery power, after the number of selected minutes expires.

Power-Down Time: when engaged, this fill will power down the device only if it remains idle for the duration specified.

Keep Sensors On: This feature will ensure that the wireless sensors remain turned on even when idle. When this feature is disengaged, the wireless sensors will turn off after 5 minutes of inactivity.

Time Format: This option specifies whether to display the time in 12h or 24h format.

Date Format: This options specifies the date format presentation.

Setting the Time

In order to guarantee data integrity and proper file synchronization with EMGworks, it is fundamentallly important that the Personal Monitor retain accurate time settings during operation. The internal clock is automallicatly synchronized by EMGworks when the device is connected to a PC. In cases where access to a PC is restricted, it is possible to manually set the time by selecting the "Set Clock" option from the Menu options.

Figure 8. Setting the Date & Time

Using the Wireless EMG Sensors

Orienting the Sensors on the Skin

Trigno EMG Sensors are fitted with 4 silver bar contacts for detectinUg the EMG signal at the skin surface. It is crucial that the orientation of these bars be perpendicular to the muscle fibers for maximum signal detection. The top of the sensor is shaped with an arrow to aid in the determination of this orientation. The arrow should be placed parallel to the muscle fibers underneath the sensor. The sensor should also be placed in the center of the muscle belly away from tendons and the edge of the muscle. The sensor is easily attached to the skin using the Delsys Adhesive Sensor Interface

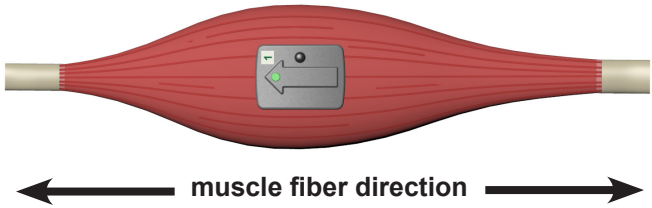


Figure 9. EMG Sensors must be properly oriented with the muscle fibers. Align the sensor's arrow with the direction of the underlying muscle fibers.

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 is critical. 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 Sensor Interface

Trigno System are supplied with specially-designed adhesive interfaces to simplify sensor attachment. These interfaces are cut from double-sided 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 mo-

tion 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.

Immediately discontinue use if skin irritation or discomfort occurs. All Adhesive Sensor Interfaces and Reference Electrodes are for single use only. Discard after using. Reseal storage bag to maintain freshnes

Sensor Pairing

Trigno sensors communicate with a custom wireless protocol that links each sensor to a Personal Monitor. This linking process is known as sensor "pairing", and is initiated through the "Pair" command.

1. Initiate sensor pairing in software.
When using EMGworks, initiate pairing by right-clicking the Trigno hardware icon in the system notification area, and selecting the appropriate menu item.

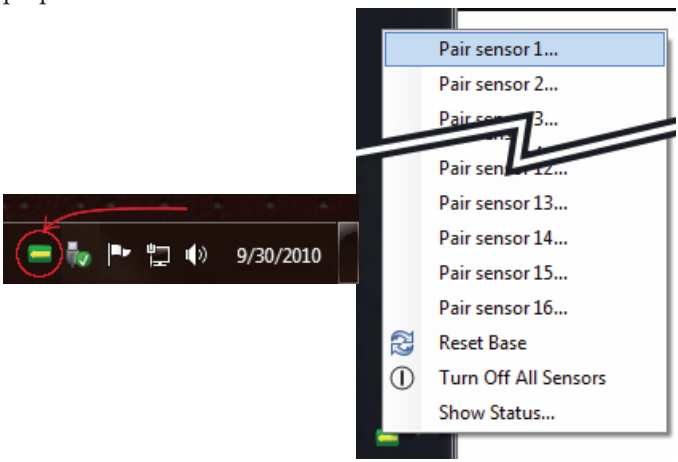


Figure 10. Selecting the Pair command form the Windows Tray Icon. Right click to access menu options.

2. Complete the pairing process by depressing the desired sensor button for a minimum of 3 seconds. Successful pairing will result in 3 green LED flashes on the sensor, and a confirmational message in the software.

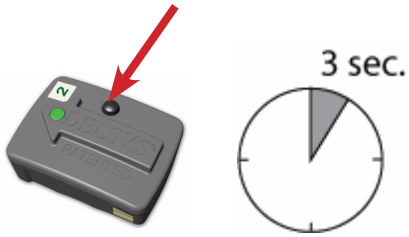


Figure 11. Pushing the sensor button to complete the pairing process..

Trigno systems are shipped with all sensors appropriately paired. Sensor pairing is typically needed if sensors are being replaced within the network group, when the communication frequency sets are changed, and after a firmware upgrade is performed.

Sensor Factory Calibration

The system stores calibration information for sensors which have been paired with it. When collecting data with EMGworks, this calibration information is used to accurately display measured values, in many cases without the need for a user-initiated manual calibration. After a pairing operation is completed, the system automatically searches for pre-existing factory calibration data on the particular sensor. If the sensor has never been paired with the system (for example, in the case of a new additional sensor), the software will prompt the user to enter factory calibration data, which can be obtained from Delsys. Factory calibration data are a string a numbers and letters which encode the calibration values for a specific sensor. Factory calibrations are specific to a single sensor and will not be accepted by the software for use on another sensor. At any time a nominal, "default" calibration may be selected for a sensor, or the specific factory calibration may be re-entered. This feature is accessed by re-pairing the sensor.

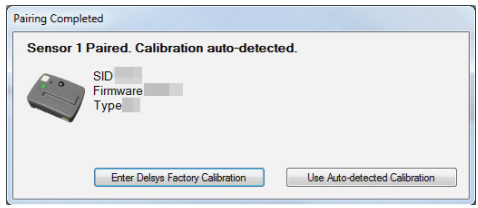


Figure 12. Factory Calibration Prompt. The calibration can be either autodetected,or entered manually if the sensor is being paired for the first time.

Smart Sensors

After pairing, the association of sensors to the TPM is retained for all future uses. Any configuration in EMGworks can be made to reflect the last paired set of sensors by clicking the "Refresh Smart Sensors" button in the "Add Sensors" pane in EMGworks. When data collection starts, the software will verify that the sensors currently communicating match those used in the configuration. If there is a mismatch, cancel the recording and repair the sensors.

Sensor Modes

Each Trigno sensor can operate in one of 4 possible data collection modes, which determines the type of data being collected. When using EMGworks, the sensor mode can be set on the sensor settings pane for each sensor. Note that the number of modes available is determined by the Trigno sensor type.

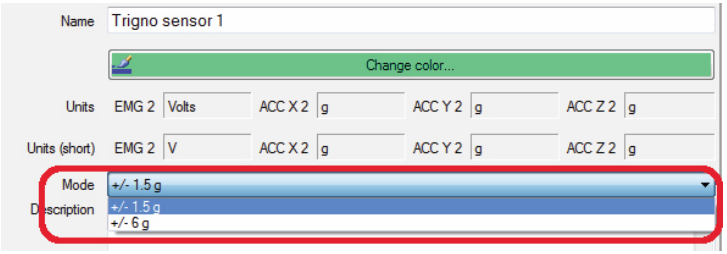


Figure 13. Setting Senosr Modes in EMGwork.

Maintenace and Care

Smart Sensors

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

- All sensors should be visually inspected before each use to ensure that no mechanical deterioration has occurred.
- The sensors can be cleaned and sterilized with a damp cloth and mild detergent, or with 70% 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. They are design to be used on damp skin surfaces and in the presence of sweat without compromise to safety, sensor integrity or operation.
- 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 groun or step on them.

Do not submerge the sensors in any liquid under any circumstance.

The sensors contain sensitive electronic circuitry. Static discharges and intense magnetic fields should be avoided to prevent the risk of irreparable damage to the sensors.