

# **TRIGNO™ Personal Monitor**

## **User's Guide**

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**PM-W02**

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**MAN-014-1-5**

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# Important Information

## Intended Use

The Trigno™ Wireless EMG Systems are battery-powered biofeedback devices that enable researchers and clinicians to acquire EMG and related signals from subjects for biofeedback purposes. They are intended for relaxation training and muscle reeducation. Interpretation of the EMG and supporting signals by a qualified individual is required.

Rx ONLY



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](http://www.delsys.com)

Contact us at:

telephone: (508) 545 8200

email: [support@delsys.com](mailto:support@delsys.com)

# 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 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.



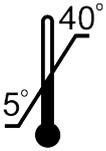
Please refer to Appendix I for important safety information regarding Mains Isolation.



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 40 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)



Authorized Representative



Manufacturer



FCC ID: W4P-SP-W03 (Trigno Body Worn Receiver)

FCC ID: W4P-SP-W01 (Trigno Sensor)

FCC ID: W4P-SP-W05 (Trigno Sensor)

IC: 8138A-DST02 (Trigno Personal Monitor System)

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



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.

## System Requirements

- EMGworks 4.0.11 or later
- Windows 8 or Windows 7, 32 or 64 bit x86-based operating systems. 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.

## Open Source License

The Trigno Personal Monitor is made possible by the following open source projects:

ALSA (LGPL version 2.1)  
ARMUBL (GPL version 2)  
FBSHOT (GPL version 2)  
Linux kernel 2.6.33 (GPL version 2)  
SDL (LGPL version 2.1)  
U-BOOT (GPL version 2)  
BusyBox (GPL version 2)

### Qt GUI Toolkit (GPL version 3)

The Qt GUI Toolkit is Copyright (C) 2010 Nokia Corporation and/or its subsidiary(-ies). Contact: Nokia Corporation (qt-info@nokia.com)

### GPSD

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### ZLIB

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2. Altered source versions must be plainly marked as such, and must not be misrepresented as being the original software.
3. This notice may not be removed or altered from any source distribution.

To access the GPL and LGPL source code used in the TPM, please contact support@delsys.com.

To access the GPL licenses used for these portions of the product, please visit:

GPL version 2: <http://www.gnu.org/licenses/gpl-2.0.html>

LGPL version 2.1: <http://www.gnu.org/licenses/lgpl-2.1.html>

GPL version 3: <http://www.gnu.org/licenses/gpl-3.0.html>

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# Trigno™ Personal Monitor Overview

The Trigno™ Personal Monitor is an EMG and physiological monitoring device intended for biofeedback and research applications. Each EMG sensor has a built-in triaxial accelerometer, a typical transmission range of 40 m and a rechargeable battery typically lasting 7 hours. The system is capable of either logging data internally or streaming it to EMGworks®. The unit communicates 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 ( $\pm 1.5g$ ,  $\pm 4g$ ,  $\pm 6g$ ,  $\pm 9g$ ). Full triggering features further expand the possibility for integration with additional measurement technologies. The Trigno Personal Monitor is part of the Trigno EMG System family.

The Personal Monitor can be used in either of two operational modes:

## 1) Mobile Monitoring and Datalogging

The device acts as a wearable, battery powered receiver for data from wireless sensors (as well as the optional GPS) and stores these data in on-board memory. The data may be later downloaded for post-collection analysis.



*Figure 1: The Trigno Personal Monitor used as an ambulatory physiological data logger.*

## 2) Desktop Signal Previewing

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, to preview how a datalogger session will proceed and evaluate signal quality.



*Figure 2: The Trigno Personal Monitor used as an ambulatory physiological data logger.*

# System Components



Figure 3: Trigno Personal Monitor System Components

- 1) Trigno Personal Monitor (TPM) Datalogger
- 2) Trigno Wireless Sensor
- 3) Trigno Desktop Base/Recharge Station
- 4) Trigno Personal Monitor Medical Grade Recharger
- 5) Trigno Base/Recharge Station Medical Grade Recharger
- 6) Computer (not included)

# Wireless EMG Sensor Features

Trigno Sensors are equipped with the following features:

- 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  $> 80$ dB
- 16-bit EMG signal resolution
- integrated 3DOF accelerometer ( $\pm 1.5, 4, 6$  &  $9g$ )
- 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

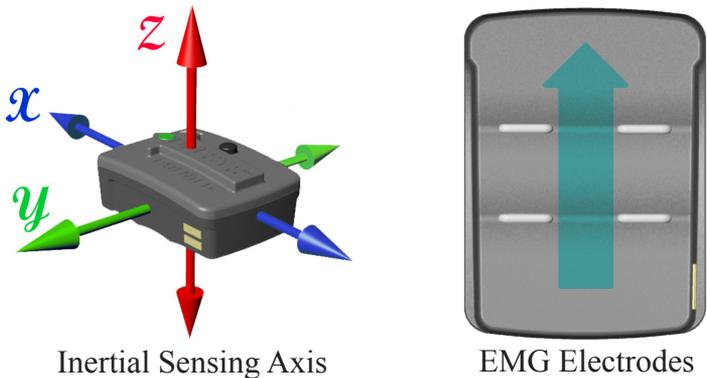


Figure 4: Personal Monitor Features.

## Personal Monitor Features

The Trigno Personal Monitor is equipped with the following features:

- support for 16 Trigno sensors (16 EMG, 48 Accelerometer)
- internal 3DOF accelerometer ( $\pm 1.5g$ ,  $\pm 4g$ ,  $\pm 6g$ ,  $\pm 9g$ )
- GPS capable
- 16 GB internal memory
- 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 recharge time

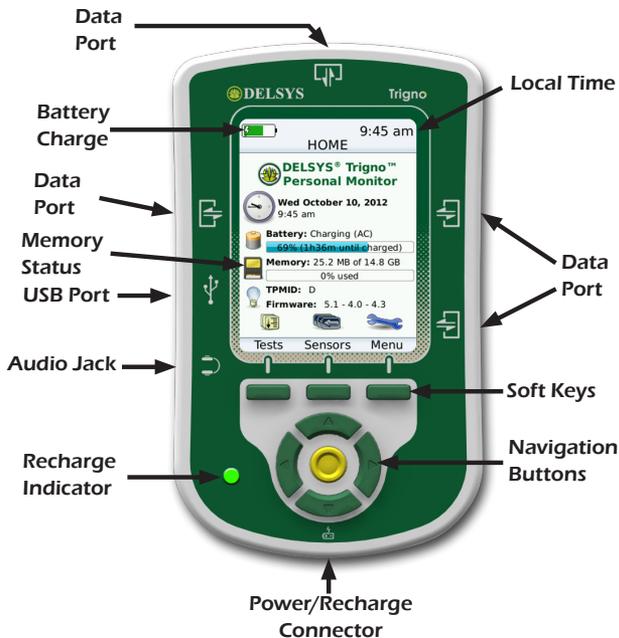


Figure 5: Personal Monitor Features.

# Basic Operations

## Charging the Trigno Sensors

Trigno™ SC-P05  
Power Supply  
DELSYS®



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 location. 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.



*Figure 6: Connecting the SC-P05 power supply to the Sensor Charge Station.*

# Charging the Personal Monitor



Connect the SC-P07 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 using an appropriate IEC320 power cord. Alternatively the Personal Monitor can be charged via the USB port by connecting it to a PC.

 5V



Figure 7: Connecting the SC-P07 power supply to the Personal Monitor for charging.

The TPM provides visual feedback to indicate the current battery level, charging status, and time until fully charged or discharged.



Figure 8: Charge/Discharge Status Indicators

The home screen indicator shows the charge level of the battery as a progress bar, a numeric charge percentage, as well as the charging source and the estimated time until a full charge (if charging) or

empty battery is expected (if discharging). As different functions are performed on the TPM, the rate of battery depletion will change so too will the charge level estimates. Battery time to empty estimates update approximately once every minute.

When connected to a PC, EMGworks will also show the charge state of the TPM.



Figure 9: TPM Charge Status reported by EMGworks when connected to the USB port (left) and the AC adaptor (right).

## Turning the Personal Monitor ON/OFF

To power on the device, hold the power button on the upper-left corner of the TPM for approximately 3s, until the screen illuminates.

There are three methods by which the device can be shut down:

1. Hold the power button on upper-left corner of the TPM for approximately 3 seconds or until the screen goes dark.
2. Allow the “Power down time” as set in the device settings to elapse. The device will only automatically shut down if it is not connected to a PC via the USB port.
3. In the hardware pane of the EMGworks protocol editor, set the TPM to power down when EMGworks closes. The device will be turned off when exiting EMGworks.



Figure 10: Setting the EMGworks options to automatically turn the TPM off when exiting the software.

Note that the device will automatically power off when a low-battery threshold is reached. In this case, the device must be connected to the AC adapter in order to operate.

## User Interface and Navigation Buttons

The Trigno Personal Monitor is equipped with 7 buttons for user interaction with the screen. The Navigation set consist of 5 buttons with up, down, left and right function arranged in a circle, and a select

button at the center. Use these to navigate between fields or through scrolling lists on the device.

An additional 3 softkey buttons are located at the base of the LCD screen. The function of these changes depending on the device's state, as indicated by the text at the bottom of the screen.



Figure 11: TPM Navigation keys (UP/DOWN/LEFT/RIGHT/SELECT) and the three Softkeys

## Connecting the Personal Monitor to a Computer

The TPM will charge when connected to any USB 2.0 compliant port. EMGworks will need to be installed in order to interact with the device.

The following screen is displayed when an active data transfer is in progress over the USB link. Do not unplug or power down the device when this screen is displayed, as data corruption may result.

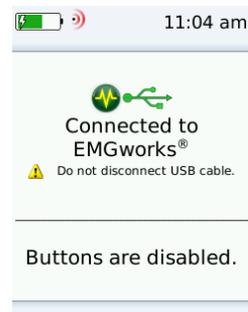


Figure 12: Data transfer over the USB port.

## Getting Started

To use the Trigno Personal Monitor, it must be first connected to a PC with EMGworks in order to create a data collection protocol, and load it onboard. Data can then be collected on the Personal Monitor which communicates with up to 16 wireless sensors (and the optional GPS module). The device can store up to 14 hours of recorded data from all 16 sensors. Once the data collection session is completed, the device is again connected to a PC running EMGworks in order to download the collected data.



*Figure 13: Using the Trigno Personal Monitor requires three basic steps: 1) setup the desired data acquisition protocols in EMGworks and download them onto the TPM; 2) Collect data on the TPM using the protocols; 3) Transfer the collected data from the TPM to EMGworks for analysis.*

## Loading Protocols on the Personal Monitor

To use the TPM as a mobile subject monitoring device, a protocol for data collection must first be created on a PC and loaded on the device.

Power on the TPM and connect it to a PC using the supplied USB cable. After device drivers are installed, the following dialog will appear:



Figure 14: Connecting the TPM to a USB port.

Choose “Start Recording” to automatically launch EMGworks. If this dialog does not appear, launch “EMGworks Acquisition” from the Start menu or desktop. As EMGworks is launching, the following dialog will be displayed:

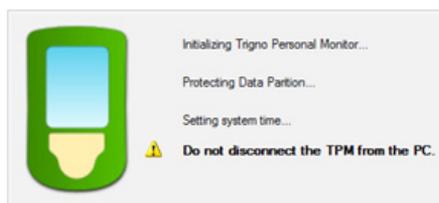


Figure 15: Initializing the TPM with EMGworks software.

Please wait a moment while the Trigno Personal Monitor is initialized. The prompt will disappear automatically when the initialization is complete.

If your system was shipped with sensors, these sensors are already paired to the Trigno Personal Monitor. Otherwise, it is necessary to first pair your existing sensors to the Trigno Personal Monitor. Refer to the section “Pairing Sensors” to perform this process.

Once sensors are paired, create a new configuration in EMGworks to be loaded onto the TPM. After the desired sensors, settings, and workflow steps have been configured, select “Synchronize with Trigno Personal Monitor” at the lower-right corner of the Test Configuration Manager. This will load the protocol and associated settings onto the device.

Changes to the PC settings may be synchronized with the Trigno Personal Monitor at any time by selecting the “Synchronize Now” option.



Figure 16: The TPM Synchronization options located at the lower right corner of the Test Configuration Manager.

## Data Collection

Data collection is initiated by selecting one of the loaded “Tests” (i.e. data collection protocols) on the Trigno Personal Monitor. Select “Tests” from the TPM home screen using softkey 1 to display a list of test protocols that have loaded onto the device. Scroll through the list of protocols using the directional arrows, and select the desired protocol using softkey 1 or the select button.

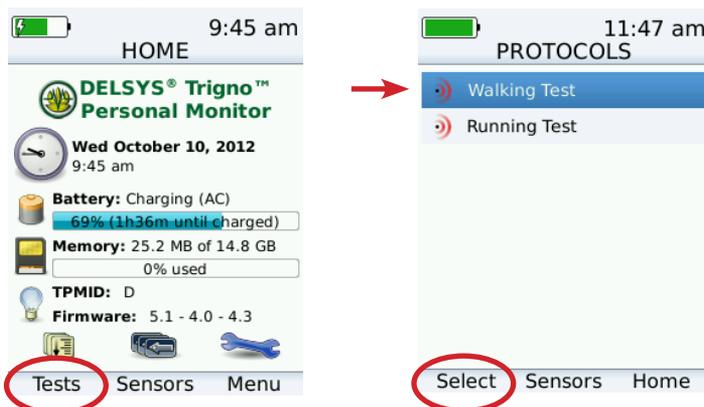


Figure 17: Using Sofkey 1 to select the “Tests” menu and then a specific test protocol.

Once a Test is selected, The Trigno Personal Monitor will show all the available resources for the test, and indicate if any are missing. It is possible to continue to data collection even if all resources needed for the protocol are not present, but the data collection may not run to completion if this is the case. Press softkey 1 to continue to data collection. Press softkey 1 again to begin collecting data.

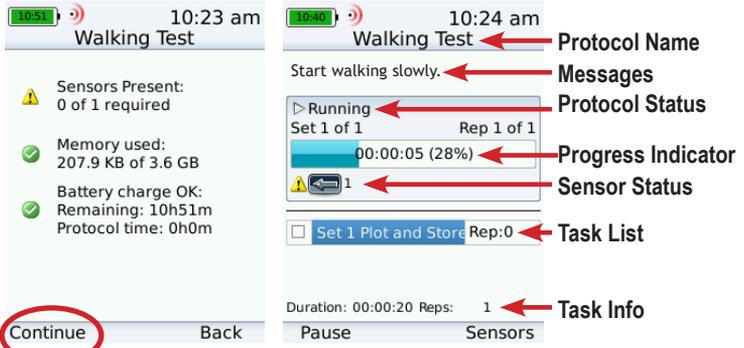


Figure 18: Running a Test protocol. Left) checking available resources. Right) Test status feedback.

During data collection, press softkey 3 (“Sensors”) to view the sensor status, including signal strength, battery lifetime, and an indication of which sensors are being logged. Pressing softkey 3 again (“Return”) will bring back the test status screen.

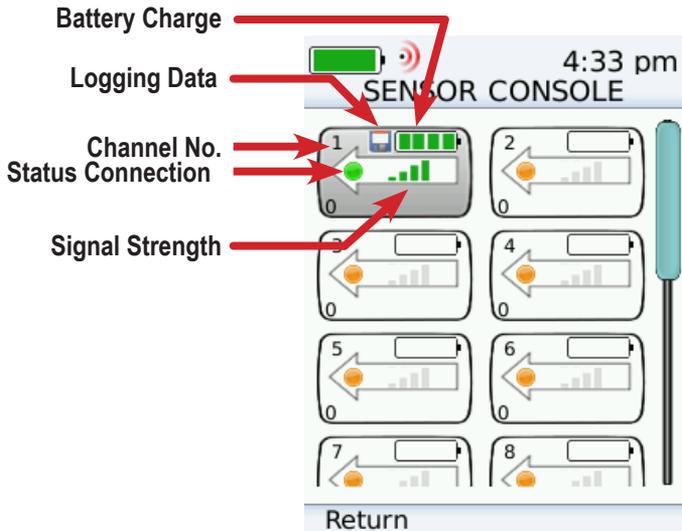


Figure 19: Checking the individual sensor status using the console.

When all tasks are finished, a “Test Complete” message will display. Pressing Softkey 3 (“Exit”) will bring back the Test protocol list. Refer to the section “Downloading Data from the Mobile Monitor” to retrieve the data that has been stored on the device during the recording session.



Figure 20: The Test Complete screen.

## Downloading Data from the Personal Monitor

When a TPM is connected to the PC, EMGworks will display a menu option in the Test Configuration Manager which allows the download of data collected on the device.

To download data, select “Manage Protocols and Data on TPM”. This will display all configurations loaded on the device, and data files (if they exist) that have been collected for each configuration.

Using the check boxes, select those data files which you would like to download, and select “Close and Download Selected Data”. On a computer meeting the minimum system requirements, the download time of data is approximately 1 second for each minute of collected data. Data will be automatically removed from the device once it has been synchronized with a PC.

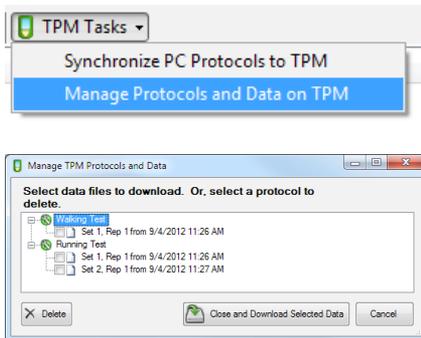


Figure 21: Downloading data from the TPM to the PC. Select the “Manage Protocols and Data” option (Top), and then “Close and Download Selected Data” (Bottom) after the desired selections have been made..

To remove a protocol from the device, select a protocol and choose

“Delete”. A protocol cannot be removed if data files exist on the device for that protocol.

## Previewing Data Collection Protocols

In addition to logging data, the Trigno Personal Monitor can be used to view the signals from the wireless sensors in real-time, when connected to a PC. Power up the device, connect it to a PC, and allow the device drivers to install. Select “Start recording” from the dialog that appears, or launch “EMGworks Acquisition” from the Start menu or desktop if this window does not present itself.



Figure 22: Connecting the TPM to a USB port.

Please wait a moment while the Trigno Personal Monitor is initialized. The dialog will disappear automatically when initialization is complete.

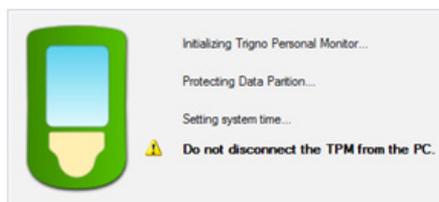


Figure 23: Initializing the TPM with EMGworks software.

Once sensors are paired, create a new configuration in EMGworks using the Trigno Personal Monitor as the hardware device. Refer to the EMGworks User’s Guide for more details on collecting and viewing real time data in the software.

# Advanced Features

## Sensor Console

The sensor status can be viewed anytime, even if a protocol is not currently running. From the home screen, select the “Sensors” button to display the Sensor Console. The screen shows sensor charge status, channel number, sensor type, network status and wireless signal strength. Sensors can be turned off from this screen. Use the scroll arrows to navigate the display as needed.



Figure 24: Displaying the Sensor Console.

## Managing Data Files (Main Menu)

### Viewing Data Files

Data files can be listed by selecting 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(softkey 1) on the device itself. The amount of free memory is displayed at the top of the screen.

When first launching the data files screen, the files on the device must be indexed. This process takes a few minutes (proportional to the number of data files on the device). To abort the indexing process and return to the main menu, press softkey 3.

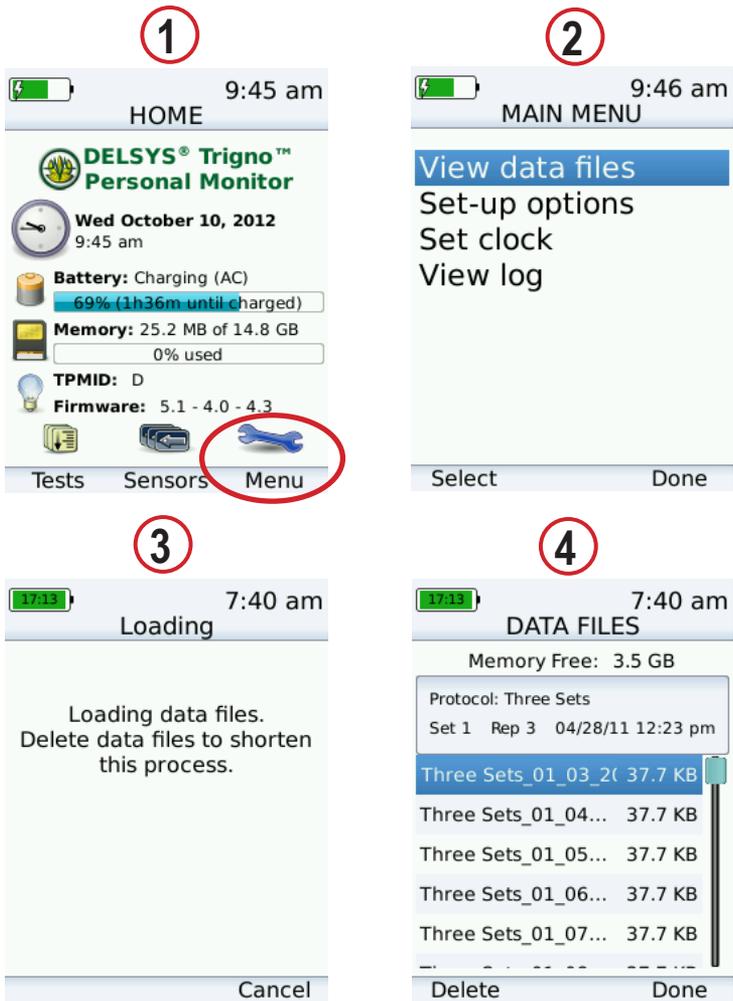


Figure 25: Viewing Data Files. 1) Select the menu button from the home screen (Softkey 3). 2) Select the “View Data Files” option. 3) Device will index data files. 4) Navigate through list of files.

## Deleting Data Files

Data files can be deleted from the device by using the navigation keys and selecting the “Delete” option (softkey 1) from the Data Files View. After selecting a file to delete, the deletion confirmation screen is displayed. Press softkey 1 to confirm the deletion, and softkey 2 to cancel the deletion and return to the data files list. Deleted files are usually not recoverable. After file deletion is complete, the files are

re-indexed and the data files screen is displayed. The time to delete a file is proportional to the size of the file. Buttons on the device are disabled while a file is being deleted.

It is not recommended to power down the device as data changes are in progress. Doing so may result in data corruption. Wait for the progress bar to complete before attempting to power down the device

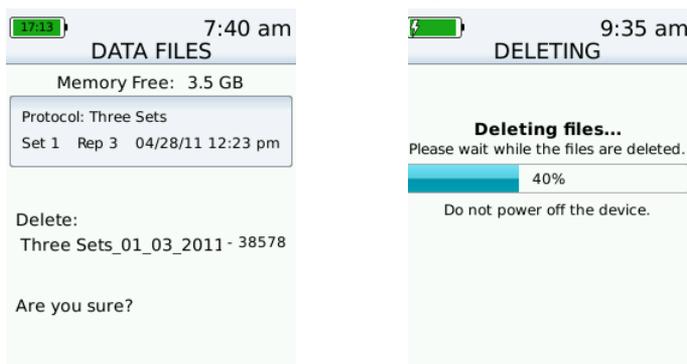


Figure 26: The file deletion process.

## Setup Options (Main Menu)

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 during a test, so that inadvertent button presses will have no effect on the device behavior. The lock is released by simultaneously pressing the left and right arrow keys, as stated on the screen.

**Alert Volume:** Audio prompts and alerts are accessible on the headphone port. The volume for these can be set between 0 (muted) to 6 (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. Any button press will turn it back on.

**Power-Down Time:** when engaged, this feature will power down

the device 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 (an ISO 8601 or a US-standard date format).

**Battery Level Reset:** The battery level reset is used to re-calibrate the battery level estimation. Use the option only when directed to do so by Delsys Support.

**Device Charging:** When set to OFF, the device will not charge from the USB port. This is useful when the device is connected to a battery-powered laptop, and it is preferred to preserve the laptop battery power.

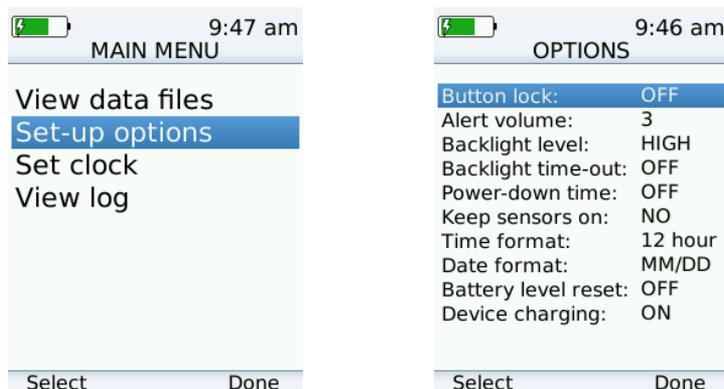


Figure 27: Selecting the Setup Options from the main menu.

## Set Clock (Main Menu)

The TPM contains a real-time clock which is synchronized with EMGworks to reflect the local date and time. The local date and time can also be adjusted on the device by selecting the “Set clock” option in the Main Menu. Use the left and right navigation buttons to move between fields, and the up and down navigation buttons to adjust a field. Use softkey 3 to save and exit.

Only a limited range of adjustment is allowed, to accommodate time zone differences from coordinated universal time. Since the local time is updated by EMGworks, daylight savings time can be automatically corrected by connecting to a PC and launching EMGworks. In the absence of a PC, daylight savings time may be manually adjusted directly on the device.

Note: It is recommended to set the PC where EMGworks is installed to use NTP (network time protocol) for clock synchronization to ensure an accurate device time. Windows 7 and Windows Vista automatically use NTP. Configure this manually for Windows XP.

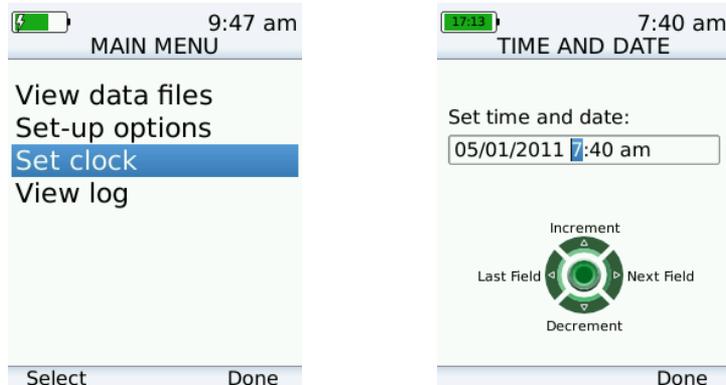


Figure 28: Setting the Date and Time.

## Log File (Main Menu)

### View Log

The device contains an event log which is used during manufacturing and when providing technical support. This file can be viewed by selecting the “View Log” option from the Main Menu.

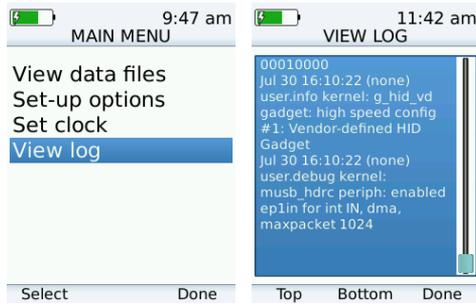


Figure 29: Viewing the Log File from the Main Menu.

## Retrieving Log File

The log file can be retrieved through EMGworks. To do this, launch EMGworks and open or create a protocol that uses the TPM. Click “Retrieve Device Log” from the A/D Settings pane under the Hardware node in the configuration tree. You will be prompted to select a location to save the file, and then wait a few moments while the log is transmitted to the PC.

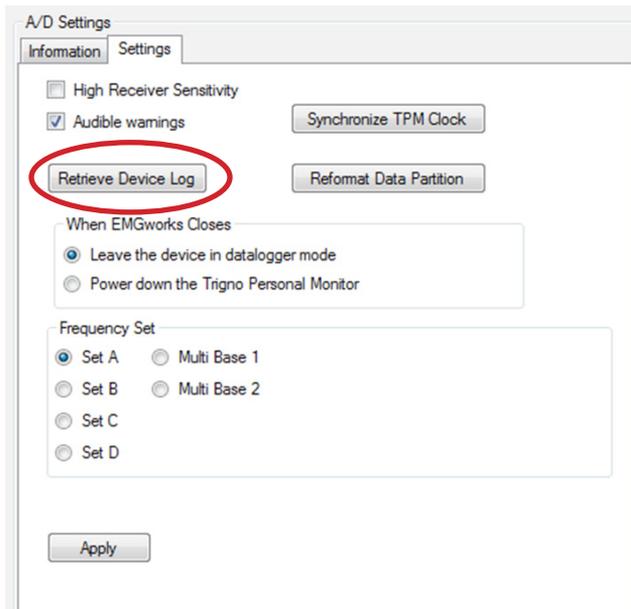


Figure 30: Retrieving the TPM Log File from EMGworks.

# Resetting the Device

## Initialization

If the battery is fully depleted, initial configuration is needed to re-store device settings. To perform this configuration, plug the USB cable into any PC with EMGworks installed and launch EMGworks. When EMGworks is closed, the device will be fully configured.

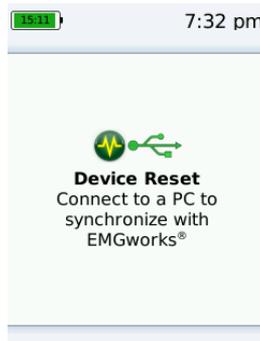


Figure 31: Initializing the TPM with EMGworks.

## System Clock Reset

The TPM will automatically synchronize its clock to the system clock of any PC to which it is connected whenever EMGworks is launched. The clocks can also be manually synchronized via a button click in EMGworks.

## Hard Reset



**Note:** A hard-reset of the device may cause internal memory corruption. Consultation with Delsys technical support prior to initiating a hard reset is recommended.

If the device becomes non-responsive, it may be powered off with a hardware reset sequence. Depending on the state of the TPM when the hard-reset is initiated, the hardware reset may cause unintended corruption to the device's persistent memory. Use care when initiating a hard-reset.

The hard reset is performed by pressing softkey 1, softkey 3, and select/enter simultaneously. When these three buttons are depressed, power is immediately cut to all portions of the device.

After the hard reset, the device may be powered on normally.

# Reformatting the Data Partition

In general, it is not necessary to reformat the data memory (partition) on the device, however, under particular circumstances this partition may become corrupt (for example if the device is disconnected while a data file is being read), and reformatting will be necessary.

EMGworks offers an option to reformat the data partition, and it will make a best effort to restore the files stored on the data partition to the device after the reformat is completed. The PC hard drive is used as a temporary storage for data files and protocols from the device while the reformat is proceeding.

The reformat command can be accessed on the A/D settings tab of a protocol opened in EMGworks. A confirmation window will appear once the command is invoked.



**Caution:** Ensure the PC's boot drive have sufficient free space for temporary storage of the data files and protocols from the device. Loss of data or irrecoverable damage to the data partition is likely if the USB connection is lost while a reformat is in progress.

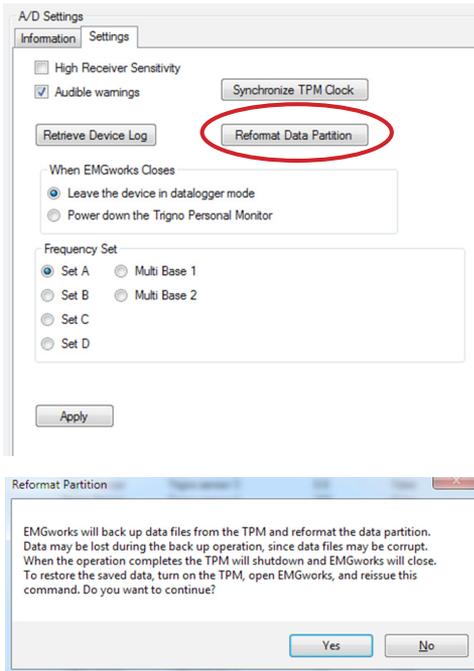
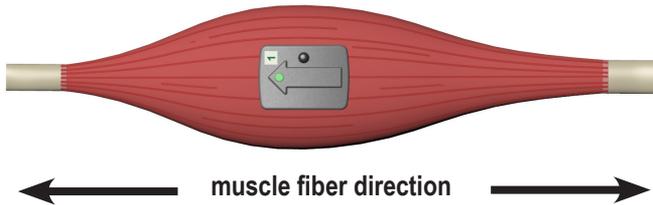


Figure 32: Invoking the Reformat Data Partition command in EMGworks.

## Using the Wireless EMG Sensors

### Orienting the Sensors on the Skin

Trigno EMG Sensors are fitted with 4 silver bar contacts for detecting 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 33: 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 Sensors 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 may 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 to 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 motion artifacts and the ill-effects of line interference. To ensure a strong bond with the skin, it is advised to remove excessive hair and wipe the skin area and the EMG Sensor with isopropyl alcohol to remove oils and surface residues. Allow the skin to dry completely before applying the interfaces.



Adhesive Sensor Interfaces are for single use only.



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

Do not use on Patients with allergies to silver.

Do not use on open wounds or injured or irritated skin.

## Sensor Pairing

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

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.

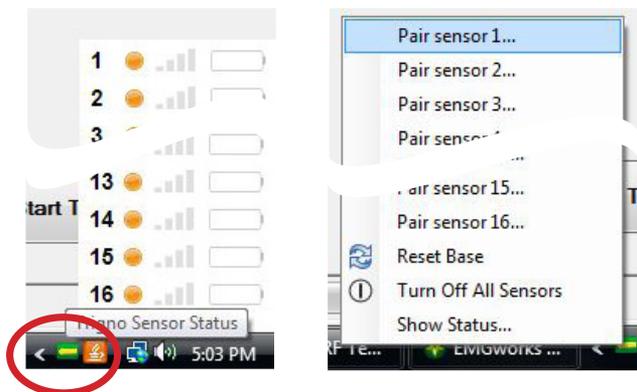


Figure 34: Invoking the Pair command. Right click on the Trigno icon in the system tray (left) and select the desired channel to pair to (right).

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.

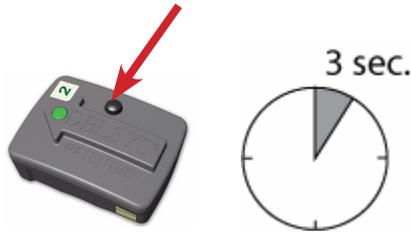


Figure 35: Pushing the sensor button to complete the

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 of 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.

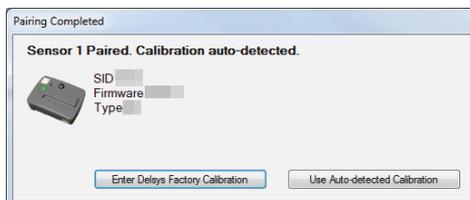


Figure 36: The calibration can be autodetected, or entered manually if the sensor is being paired for the first time.

# 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 chosen on the sensor settings pane. Note that the number of modes available is determined by the Trigno sensor type.

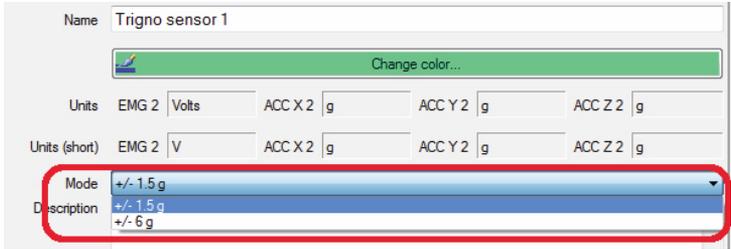


Figure 37: Setting Sensor Modes in EMGworks.

## Sensor States

There are 8 sensor states which are easily discernible by the behavior of the sensor’s on-board LED.

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

## **1) Data Streaming**

This is the typical data transmission state, where a sensor is communicating with the TPM receiver and all data packets are being properly received. This state is indicated by a constant green blink every second.

## **2) Receiver Scanning**

This state indicates that the sensor is not transmitting data to the receiving unit, and more specifically not receiving any information from the base. This can happen if the sensor is out of range or if the base station has become inactive (powered off or entered a sleep mode), and is denoted by an alternating green then amber flash once per second.

## **3) Sensor Pair Complete**

Three successive green LED flashes indicate that the pairing operation between the sensor and the receiving unit has successfully been completed.

## **4) Sensor Pair Incomplete**

Three successive red LED flashes indicate that the initiated pair command did not complete correctly, most likely because the sensor is too far from the base station.

## **5) Battery Charging**

When docked in the recharge station, sensors will show an amber LED during recharging.

## **6) Charge Complete**

When docked in the recharge station, sensors will show a green LED when their charge cycle is complete.

## **7) Charge Error**

When docked in the recharge station, an LED that is off indicates a charge error. Re-seat the sensor to ensure a proper connection with the charge contacts and to restart the charge cycle. Contact Delsys technical support if the problem persists after re-seating the sensor.

## **8) Sensor Off**

When out of the recharge station, a sensor with no LED illumination is powered off.

# Appendix I

## Mains Isolation

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



Delsys does not supply isolation transformers for Personal Computers and their peripherals.

Delsys recommends model IS1000HG manufactured by Tripp Lite ([www.tripplite.com](http://www.tripplite.com)) for this task. This device is a medical grade isolation transformer capable of delivering up to 1000 W. A smaller similar version for 500W is also available (IS500HG).

Similar products compliant with IEC60601-1 are acceptable.