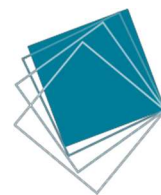


PAMSys™ User's Manual



© 2017 BioSensics LLC
January 1st, 2017
Version 2.0



BioSensics

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Welcome to PAMSys

Introduction

Thank you for purchasing PAMSys. PAMSys uses advance signal processing algorithms and novel biomechanical models of human motion to identify a complete physical activity map of the user from data measured by a single, lightweight, wearable motion sensor. This User's Manual will help you familiarize yourself with PAMSys and get you up and running in no time. Should you have any questions, help and support are available from 9am to 5pm Monday through Friday (Eastern Standard Time).

E-mail: support@biosensics.com

Telephone: 1-888-589-6213

Intended Use

PAMSys is intended for long-term monitoring of posture (sitting, standing, walking or lying down), postural transitions (duration and time of occurrence), gait (duration, number of steps, cadence and step time variability) and falls (number of falls and time of occurrence). PAMSys is neither offered, marketed nor intended for use as a medical device, as defined by the Food and Drug Administration. PAMSys is intended and marketed solely for use in research settings.

Components of Your System

PAMSys consists of a wearable motion sensor with strap, software, and a charging unit for the sensor. The included Windows-compatible software, PAMWare, is used to visualize data collected with your sensor.



Pamware



Sensor



Charging Unit



Chest Strap

PAMSys Options

BioSensics offers the following variations of PAMSys:

PAMSys-X™: Synchronized monitoring of multiple body segment movements.

PAMSys-ECG™: Synchronized long-term co-monitoring of physical activity, heart rate and heart rate variability using a 3-lead electrocardiogram.

PAMSys with GPS: Synchronized monitoring of physical activity and GPS signal.

PAMSys with Gyroscope: Synchronized monitoring of physical activity and continuous tri-axial accelerometer and tri-axial gyroscope data.

Additional Accessories

PAMShirt™: A customized cotton t-shirt with a pocket for the PAMSys sensor.

Multi-Unit Charger: Charge up to 7 PAMSys sensors simultaneously. Included free with orders of 5 or more PAMSys sensors.

Contact us at 1-888-589-6213 or sales@biosensics.com (M-F 9am to 5pm EST) for more information about PAMSys Options or additional accessories.

Safety Instructions

Make sure you have read and understood all the information listed in this document prior to using PAMSys. If you require additional information and/or training, please contact customer service.

- If motion sensors are used among numerous individuals and placed directly onto the patient (instead of over clothing) they should be cleaned and disinfected in an appropriate manner prior to use. PAMSys sensors can be cleaned using an alcohol swab.
- Ensure that motion sensor straps are not cutting off blood flow.
- BioSensics motion sensors should be charged only using the charger provided with your purchase.

Warning: The PAMSys sensor contains a lithium polymer battery. Please follow local regulations regarding disposal or recycling of lithium-containing electronics. Do not throw the device away in the trash.

FCC Compliance Information

Changes or modifications not expressly approved by BioSensics, LLC could void the user's authority to operate the equipment.

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 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. However, 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 of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

WARNING!

FCC and IC Exposure Statement

This portable equipment with its antenna complies with FCC's RF radiation exposure limits set forth for an uncontrolled environment. To maintain compliance follow the instructions below:

1. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.
2. Avoid direct contact to the antenna, or keep contact to a minimum while using this equipment.

Industry Canada

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

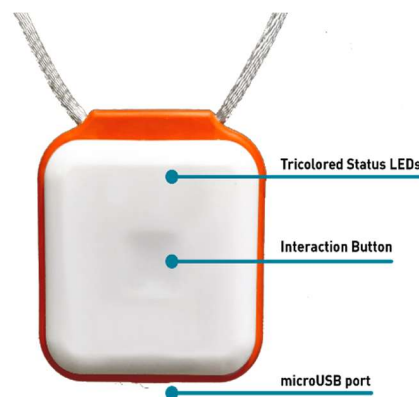
Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Getting Started

Software Installation

At this time, PAMWare is only available for Windows.

1. Download the installation files from the link or CD provided to you.
2. If you have a 32-bit version of Windows, double click PAMWareInstaller v1.x.x 32Bit.exe to run the PAMWare Installer. If you have a 64-bit version of Windows, double click PAMWareInstaller v1.x.x 64Bit.exe to run the PAMWare Installer.



To determine your system type (in Windows 10), search for 'System and Security' in your computer's Control Panel and click 'System' to view detailed system information. For earlier versions of Windows please consult your computer's user manual.

Getting to Know Your Motion Sensors

BioSensics Motion Sensors should be attached to the body with the top surface (with the BioSensics logo) facing away from the body. The Reset/Power button is used to power-on, power-off or start a new measurement and is recessed from the surface by design.

- If the sensor is off, pressing the button turns on the sensor and starts a new measurement.
- If the unit is on, pressing the button briefly will start a new measurement and will create a new folder on the embedded MicroSD card.
- If the unit is on, pressing the button for 5 seconds or longer will power off the sensor.

The tri-colored status LED (Green, Orange and Red) shows the condition of the PAMSys motion sensor. A steady green light indicates the start of a new measurement. The LED will blink green every 3 seconds during a measurement. A solid orange light indicates low battery power and will turn red when battery power is too low to record data any further. When the sensor is charging, the LED will be solid orange. When the sensor is fully charged, the LED will be solid green.

Charging

Each PAMSys motion sensor is equipped with a rechargeable lithium battery. The sensor's battery life is approximately 7 days. When recharging, please use only the supplied charging unit.

If the sensor unit is powered off the units will still be charging. If the sensor unit is powered on, the charger indicator will light up, indicating that the sensor unit has been correctly plugged in. During recharging, the charger indicator is steady orange. When the battery is fully charged, the charger indicator turns steady green.

The normal charge time is about 2.5 hours. For a highly-depleted battery, a longer recharge and battery conditioning period might be needed.

Storage and Maintenance

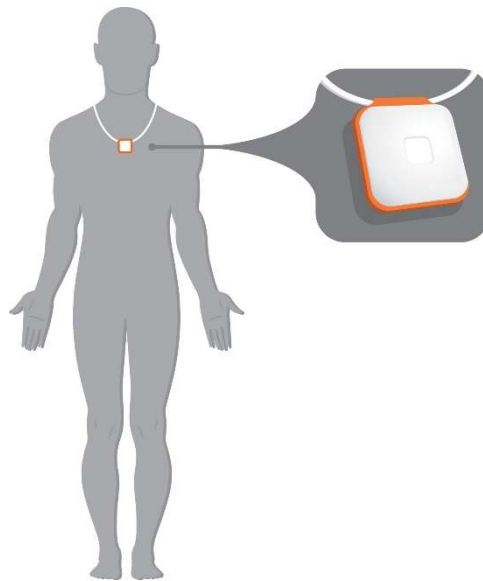
BioSensics Motion Sensors should be stored in a cool dry place. Motion sensors should be fully charged prior to storage to maximize battery lifetime. If BioSensics motion sensors become dirty they can be cleaned using an alcohol swab. During cleaning be careful not to allow moisture into the external docking port.

Data Collection

Sensor Placement (on the body)

Single sensor configuration

The PAMSys motion sensor can be affixed to the body with either the provided chest strap or a PAMSys shirt (sold separately). BioSensics recommends placing the motion sensor in the chest strap or PAMSys shirt the same way each time it is worn; preferably with the PAMSys logo facing forward and the arrow pointing to the person's left (see picture below).



Multi-sensor configuration (PAMSys-X)

The PAMSys-X system consists of 5 sensors to be used with 5 Velcro straps (one chest strap, two small straps for each wrist and two large straps for each leg). Each sensor is labeled with a body assignment. BioSensics recommends placing the motion sensor in the chest strap the same way each time it is worn; preferably with the PAMSys logo facing forward and the arrow pointing to the person's left (see picture above). To attach the wrist and leg sensors, Move the thin band to the side and out of the way of the opening. Slide the appropriately marked sensor (logo side facing up) into the sleeve then move the thin band over the sensor to secure it in place. Fasten the Velcro strap to the body so that the sensor's charging port is facing away from the hands and feet. Repeat these steps for each WRIST and LEG sensor.

For PAMSys-X, the multi-sensor configuration must first be synchronized before beginning to record data. Press the Reset/Power button on the front face to power each of the five sensors, with the CHEST sensor being turned on last. The LED will quickly blink orange when the sensor is on. Once all the sensors are on, the CHEST sensor briefly shows a red light, then they will attempt to sync amongst each other. The sensors are successfully synced when the CHEST sensor blinks orange independently, and slightly before, the WRIST and LEG sensors, which will blink orange simultaneously. This sequence will occur every three seconds.

Recording Data with PAMSys

To begin recording data, turn the sensor on by pressing the reset/power button. Next, the user should stand up and place the sensor on the body using the chest strap or PAMSys shirt as directed above. If using the PAMSys-X system please synchronize the sensors before beginning to record data. The user must stand in place for at least 10 seconds. After this period of time, the sensor is now ready to collect and record physical activity data. **The time when a new measurement is started and when the subject is standing still and upright should be noted. These times will be used in PAMWare to properly analyze the data (see 'Data Analysis').**

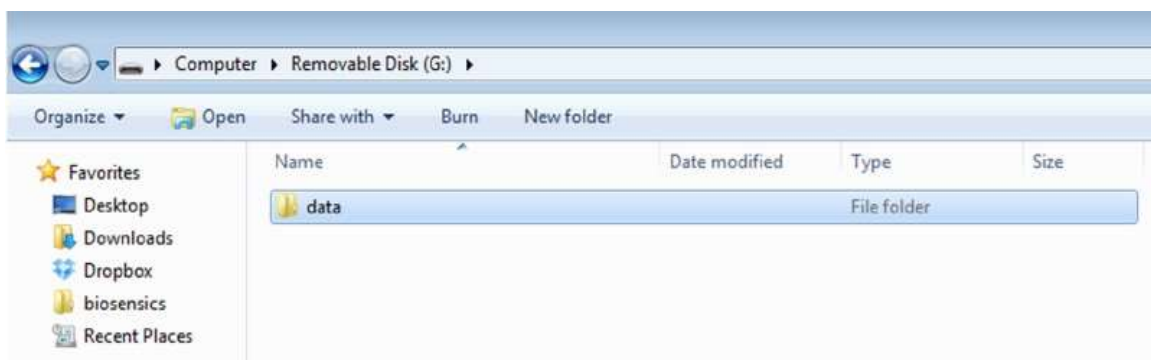
Data Transfer

Recorded data is transferred to a computer using the USB cable provided with each purchase of PAMWare. First, connect the sensor to the computer using the USB cable. After plugging in the sensor for the first time, the appropriate software drivers will be automatically installed.

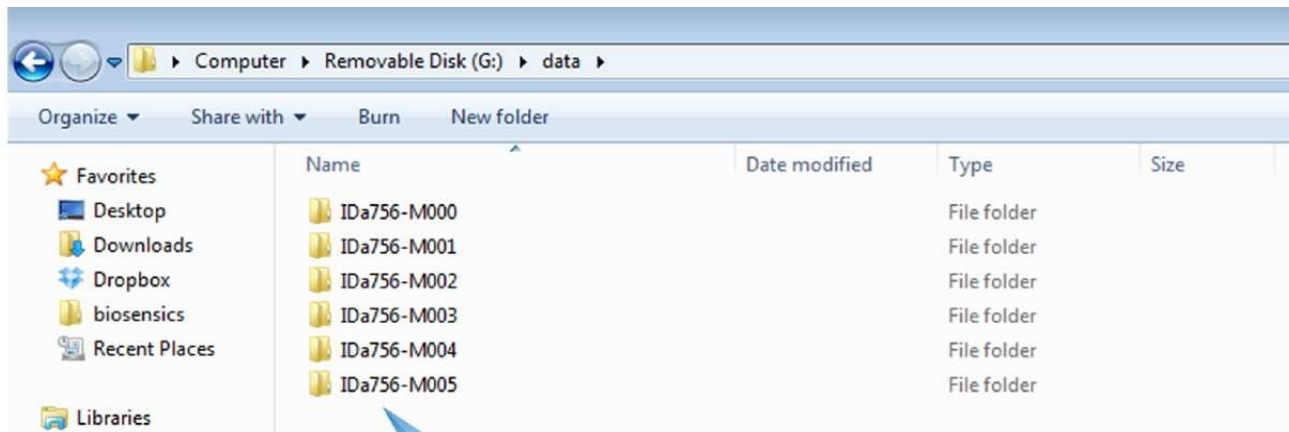
After the sensor is connected, the measured data can be accessed by clicking on the drive letter associated with the USB (G: in the example shown here) under the 'My Computer' folder, and the contents of the embedded flash memory card may be browsed. Note that the PAMSys motion sensor must be powered on to access the stored data.



All data measured by the PAMSys motion sensor is stored in the folder named 'data,' as shown below.

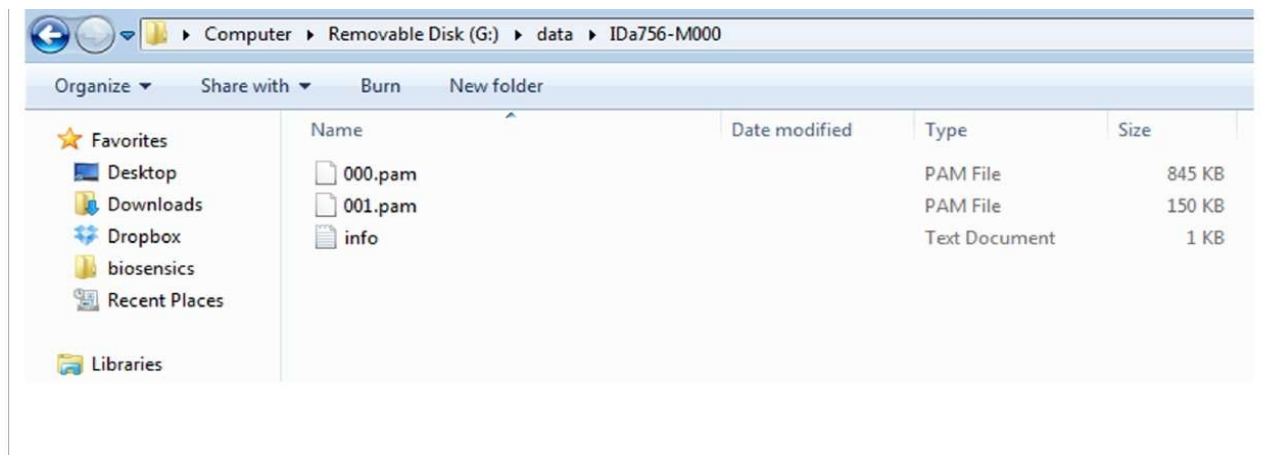


After clicking on this folder, each subfolder corresponds to one measurement. The subfolders are named automatically according to the following convention: 'IDxxxx-Myyy', where 'xxxx' is the unique ID of the PAMSys motion sensor and 'yyy' is the measurement number.



IDa756 indicates the unique sensor ID is "a756"

Within each subfolder, each file contains an hour-long segment of the recorded data.

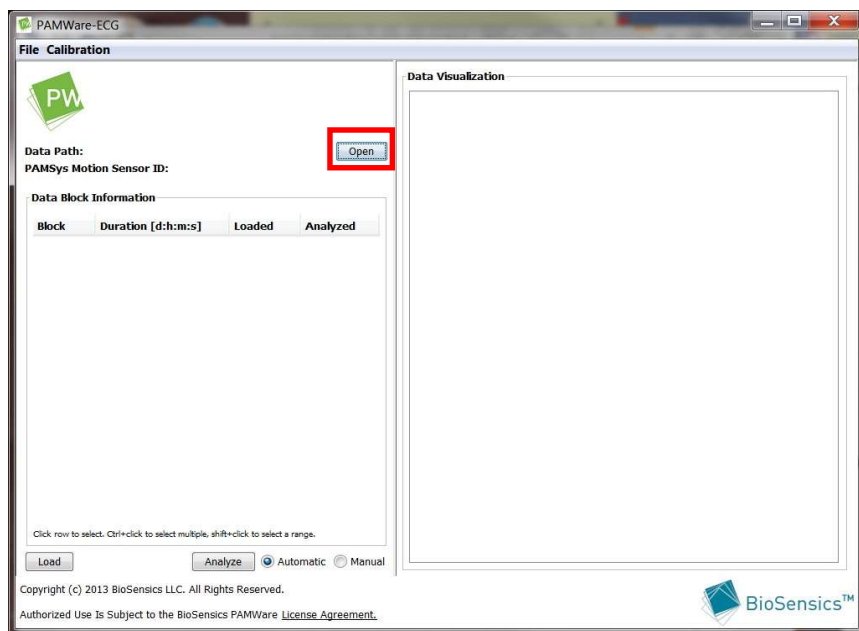


The measured data can be analyzed and plotted using the PAMWare. For easy access, copy the entire subfolder ('IDxxxx-Myyy') to your PC; **do not just copy the .pam files**.

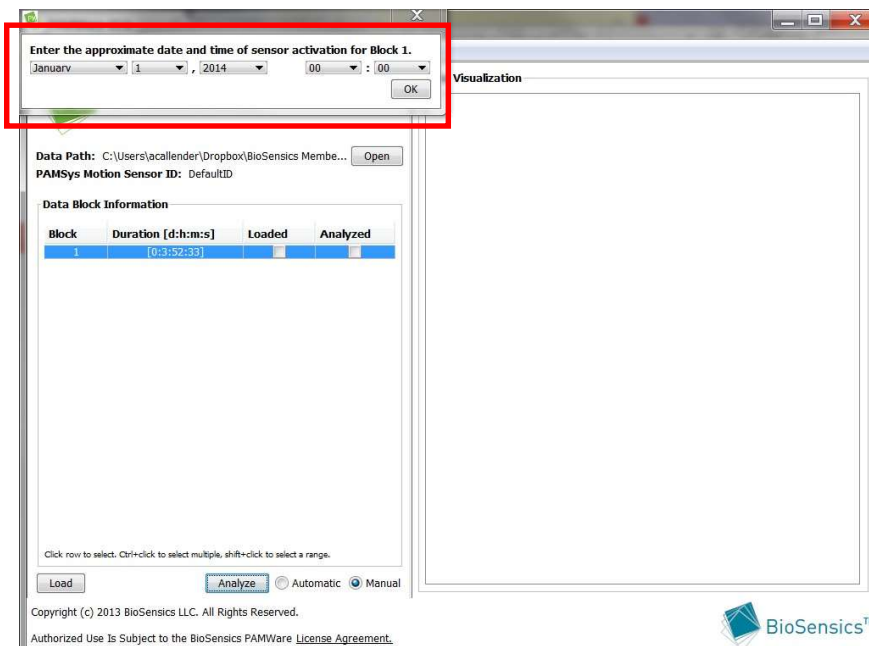
Data Analysis

Loading Data

Run PAMWare to open and visualize data collected with your PAMSys motion sensor. Click the open button to locate the subfolder for the data you want to load (e.g., 'IDxxxx-Myyy').



Next press the 'Load' button to load the raw data. A small window will appear to input the approximate date and time when the measurement was started. The PAMSys sensor does not have a clock; it only knows time elapsed from the start of each new measurement.



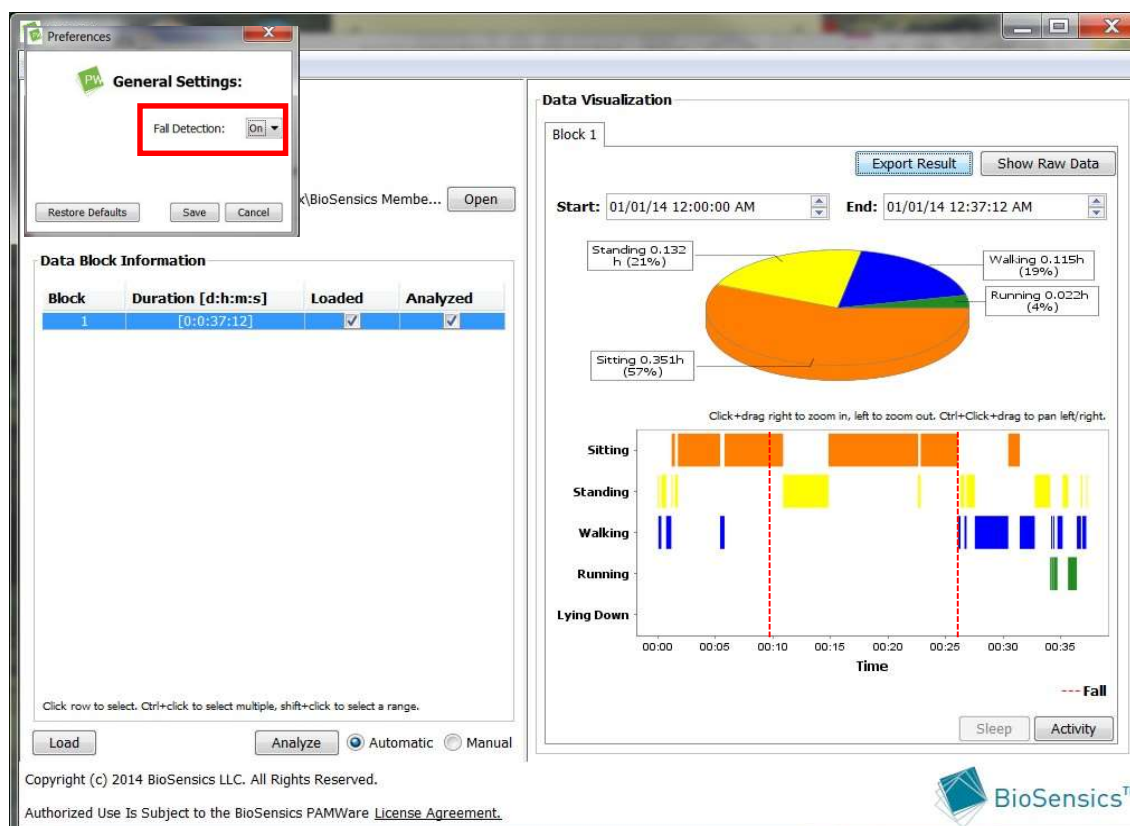
Analyzing Data

To analyze the data properly PAMWare must know the orientation of the sensor and a start time when the user was standing still and upright. PAMWare can detect sensor orientation and start time automatically or you can input this information manually; select 'Automatic' or 'Manual' before clicking the 'Analyze' button.

If 'Manual' is selected, a new window will appear where you can select the sensor orientation and start time. The 'Detect Orientation' and 'Detect Start Time' buttons will perform these operation automatically. Click the 'Start Analysis' button to begin analyzing your data.

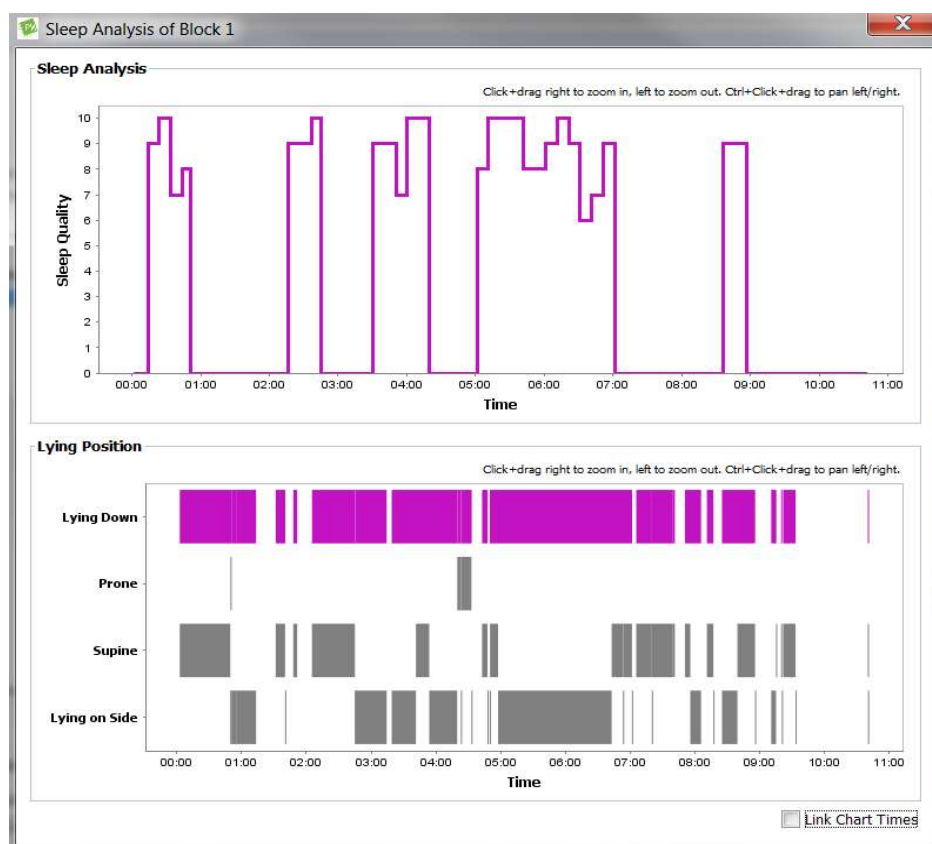
Interpreting Analyzed Data

In the 'Data Visualization' pane, the raw data will now be categorized based on physical activity (sitting, standing, walking, running or lying). Fall incidents can also be visualized by going to File -> Preferences and choosing between 'On' and 'Off' from the dropdown menu. Fall events will appear on the graph as dashed red lines.



Sleep

To view the analysis of lying data, including sleep quality and lying posture, click the 'Sleep' button at the bottom of the 'Data Visualization' pane. A new 'Sleep Analysis' pane will appear with two sections: (1) Sleep Analysis and (2) Lying Position. Sleep quality is determined by the amount of movement, or restlessness, collected by the sensor during periods of sleep. The greater the number reported, the better the quality of sleep. The 'Link Chart Times' box at the bottom right hand corner can be checked to link the times in the two graphs so that zooming one graph will change the time axis on both graphs.

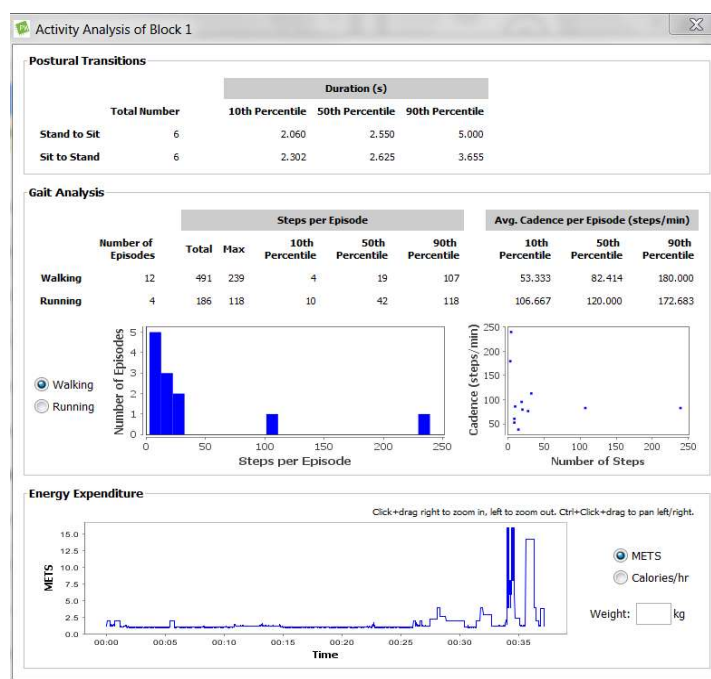


Activity

To view the analysis of postural transitions, walking and running, and energy expenditure click the 'Activity' button at the bottom of the 'Data Visualization' pane. A new 'Activity Analysis' window will appear with three main sections: (1) Postural Transitions, (2) Gait Analysis, and (3) Energy Expenditure, which can be viewed as METS or Calories/hr.

The Postural Transition section presents the total number of transition events and the duration, in seconds, of the 10th, 50th and 90th percentiles over the total number of postural transitions. The Gait

Analysis section shows the number of walking and running episodes, the total number of steps taken across all episodes and the maximum number of steps taken in an episode of walking and running. Additionally 10th, 50th and 90th percentiles for steps taken and average cadence are reported over all the episodes. You can switch between walking and running by clicking on the 'Walking' or 'Running' radio buttons. Energy Expenditure is displayed over the duration of the monitoring period and can be visualized as METS or Calories/hr. A MET, or metabolic equivalent, is a measure of the energy expended during physical activity expressed as a ratio of metabolic rate for a given task to a reference metabolic rate during quiet sitting. One MET is equivalent to one Calorie per kg body weight per hour. Note: 1 kcal = 1 Calorie = 1000 calories. Energy expenditure calculations in PAMWare are based on movement intensities measured by the sensor and task specific metabolic equivalents as reported in Compendium of Physical Activities: an update of activity codes and MET intensities (Medicine and Science in Sports and Exercise, 2000; 32 (Suppl):S498-S516).



Exporting Data

Both analyzed and raw data can be exported. To export analyzed data to an excel file, click the 'Export Result' button at the top of the 'Data Visualization' pane. You can view the raw data at any time by clicking the 'Show Raw Data' button at the top right-hand corner of this pane. To export the raw data as DAT or CSV files, click the 'Export Data' button at the top of the 'Data Visualization' pane when viewing Raw Data.

Specifications

Condition	Specification
Waterproof rating	IPX7
Sampling Frequency	50 Hz
Accelerometer	± 2g
Motion Sensor Size	3.5 cm x 3.5 cm x 1.5 cm
Motion Sensor Weight	24 grams (0.85 oz)
Storage Temperature	-30 to 50 degrees C
Operating Temperature	10 to 40 degrees C
Battery Life	200 hours (upgradeable to 340 hours)
Bluetooth Radio	Bluetooth v4.1, Class II, FCC ID: 2AA5HPM002

Certifications

ISO 13485:2016

FCC ID: 2AA5HPM002

IC ID: 22184-PM002

Additional Resources and Support

Help and support are available from 9am to 5pm Monday through Friday (Eastern Standard Time).

Please contact us at:

E-mail: support@biosensics.com

Telephone: 1-888-589-6213



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Watertown, MA 02472

DISCLAIMER:

The PAMSys platform and algorithms for physical activity measurement are protected by U.S. Patent No. 8,206,325, and other patents pending. PAMSys is neither offered, marketed nor intended for use as a medical device, as defined by the Food and Drug Administration. PAMSys is intended and marketed solely for use in research settings. Developed and designed by BioSensics in Massachusetts.

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