

OPAL



V2R Version 2 April, 2019

WELCOME TO MOTION STUDIO

Motion Studio provides an easy way to collect data with your Opal System. Features include advanced configuration, recording, data management, calibration, and real-time visualization.

Web: www.apdm.com

Support & FAQ: community.apdm.com

Sales: sales@apdm.com

CONTENTS

0	INFORMATION	4		TIPS	36
	PARTS	10	0	TROUBLESHOOTING	38
X	HARDWARE SETUP	16	Q	SPECIFICATIONS	40
0	MOTION STUDIO INSTALLATION	18		APPENDIX	42
0	USING YOUR SYSTEM	20			

INFORMATION



Information about Opal V2R System

Intended Use Statement

The Opal V2R is a small worn monitor designed for documenting physical movement associated with applications in research and engineering. The Opal V2R can be used in any instance where quantifiable analysis of physical motion is desirable. Intended uses include motion detection, quantification of motion. quantification of movement, and quantification of human movement. Application uses include motion research, biomechanics, sports, fitness, and animation.

Opal V2R System Description

The Opal V2R System ("Opal System") is a research-grade system comprised of one or more Opal V2R ("Opal") wearable sensors, a Docking Station to recharge the Opal's battery and transfer the raw sensor data logged to a computer, an Access Point to enable wireless streaming, adjustable straps for a variety of body locations, and Opal application software (Motion Studio, Mobility Lab, or Moveo Explorer) that provides functionality for 1) configuring the Opals, 2) collecting and storing Opal data, 3) analyzing and visualizing the collected data, and 4) exporting the data in various formats.

Contraindications

Do not apply Opals or the Opal straps to broken or otherwise non-intact skin. Opals and straps should not be used in conjunction with an MRI. Not a medical device. Medical uses require APDM's Opal V2C System (FDA Class II Medical Device, CE Class I Medical Device; Rx Only).

Warnings and Precautions

The Motion Studio system Opal is a Type B Applied Part, i.e., a part of the system which comes into contact with the patient. The Motion Studio system Docking Station, Access Point, USB cables, and Docking Station power supply are not applied parts, and are not intended to come into contact with the subject. Opals should be cleaned in between subjects. See Tips section on page 35 for cleaning directions.

Do not open any Motion Studio hardware enclosures; there are no user serviceable parts inside. The Opals contain a rechargeable lithium ion battery which is not intended to be replaced by the user.

The Motion Studio Docking Station should only be powered by the provided 12V 2A center positive power adapter. Do not use other power adapters with the Docking Station.

The Motion Studio Docking Station has a spare USB Type A port. Only attach USB peripherals and cables that comply with the USB 2.1 specification. The Motion Studio system can only be connected to a host computer via the USB Micro-B connector.



The Opal wearable sensor may become warm during use and rise as much as 5 °C (9 °F) above ambient temperature. At the Opal's maximum operational temperature of 50 °C (122 °F), the Opal could reach 55 °C (131 °F). Discontinue use if wearing the sensor becomes uncomfortable.

The Motion Studio system is designed to be stored and transported in a standard indoor environment: a temperature of +10° C (50 °F) without relative humidity control and +50° C (122 °F) at relative humidity up to 93% non-condensing.

The Opals are designed to be operated in either an indoor or outdoor environment, with an operating temperature of -10 to +50 °C (14 to 122 °F), O to 100% relative humidity, and an atmospheric pressure of 64.4 to 106.6 kPa. Opals are rated water resistant up to IP64, but are not waterproof. Do not submerge Opals in water.

The Access Point and Docking Station are designed to be stored, operated and transported in a standard indoor environment: a temperature of O to 30 °C (32 to 86°F), O to 100% relative humidity, and an atmospheric pressure of 80 to 106.6 kPa (at an altitude of less than 2000 m). The Access Point and Docking Station are not water resistant or waterproof.

Do not unplug the Access Point when in use during testing; this may result in lost data. If using a laptop, always make sure that your laptop is plugged into a power outlet when testing during test mode. A low battery during a test session may cause the test data to be lost. It is recommended that you backup your Motion Studio database before upgrading or uninstalling the software.

You must dispose of this product properly according to local laws and regulations. Because this product contains electronic components, it must be disposed of separately from household waste. When this product reaches its end of life, contact local authorities to learn about disposal and recycling options, or simply return it to APDM. For more information, please visit community.apdm.com.

This equipment has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2 standard. These limits are designed to provide reasonable protection against harmful interference in a typical medical 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 with other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, 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:

- Configure the system to use a different radio frequency.
- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.



Information Security for Computers running Motion Studio

The Motion Studio database may contain private or personal Protected Health Information (PHI). While Motion Studio accommodates the need to protect PHI, the database itself is not secured or encrypted by Motion Studio. Instead, you should secure access to the database using your operating system's built in security features. Always follow information security best practices on the Motion Studio computer, including:

- Use separate user and admin accounts
- Use strong passwords
- Lock the computer after a few minutes of inactivity
- · Control physical access to your computer
- Keep your operating system and Motion Studio software up-to-date
- Back up your computer regularly and store your backups securely
- Use your operating system's built-in strong disk-level encryption

If your Motion Studio system is online, use internet security software to prevent malware infections. Motion Studio uses SSL to secure any communication with APDM servers that might contain personal information, and no PHI is collected without your consent. Any information on APDM servers is securely maintained.



Compliance Information

FCC

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.
- 2. This device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by APDM could void the user's authority to operate the equipment. To access FCC and IC information on the APDM Opal and Access Point - Press Button 2 twice from the home screen.

Industry Canada (IC)

This device complies with Industry Canada license-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 Canadienne applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire d'interférence, et (2) l'utilisateur de l'appareil doit accepter toute interférence subie, même si l'interférence est susceptible d'en compromettre le fonctionnement.

WEEE Directive Statement for the European Union

In common with all Electronic and Electrical products, APDM equipment should not be disposed of in household waste.

Alternative arrangements may apply in other juristictions.

FCC ID: 2AHZD-OPAL IC: 21349-OPAL Model: Opal

FCC ID: 2AHZD-AP IC: 21349-AP Model: AP



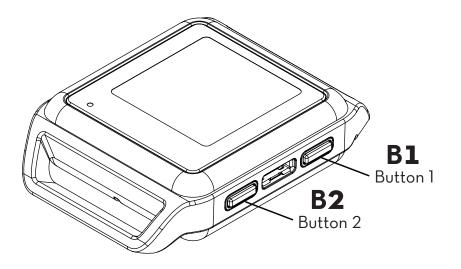
Symbols

SN	Serial Number
	Not for General Waste
FC	FCC Compliance
†	Type B Applied Part
===	Direct Current
i	Refer to Instruction Manual/Booklet
IP64 I	Ingress Protection Rating
	Manufacturer
CE	European Union (EU) Mark

PARTS



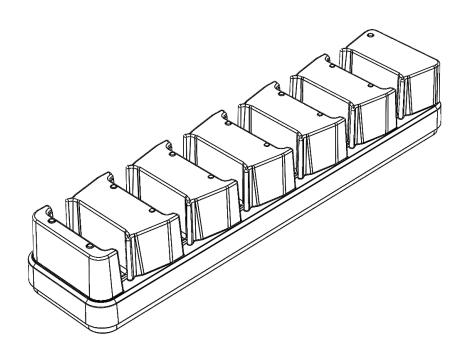


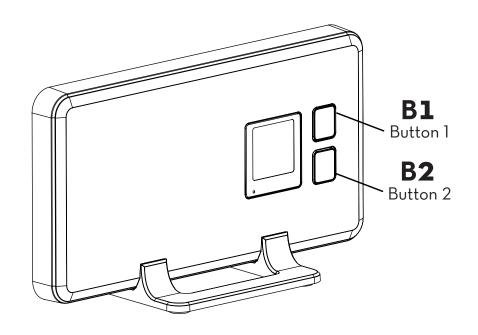


OPALS

The Opal movement sensors precisely record movement with triaxial accelerometers, gyroscopes, and magnetometers.







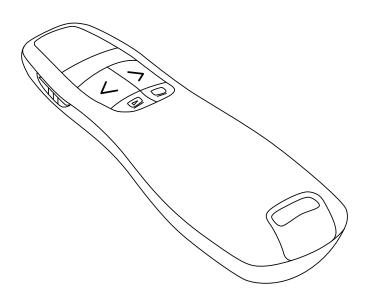
DOCKING STATION

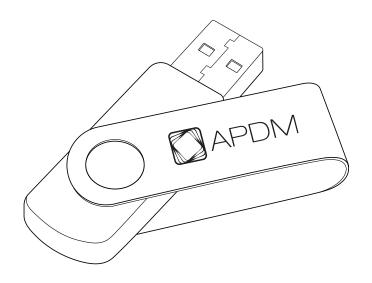
The Docking Station is used to charge and configure the Opal movement sensors.

ACCESS POINT

The wireless Access Point allows for wireless communication between the host computer and Opal movement sensors. A single Access Point can support up to 6 Opals at 128Hz sampling rate (maximum of 1,600 samples per second per access point).







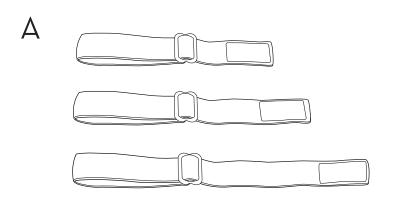
WIRELESS REMOTE

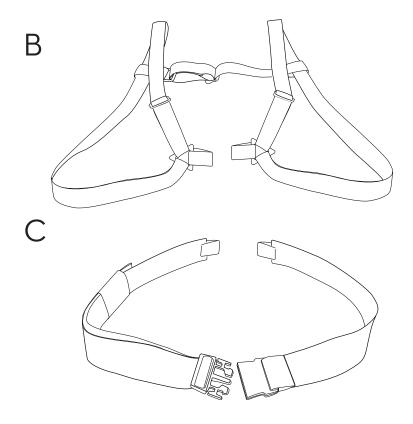
The Motion Studio software supports the use of a remote control to aid while collecting data.

USB DRIVE

The USB drive contains the Motion Studio software.







STRAPS

There are a number of options for securing the sensors on subjects using a selection of straps.*

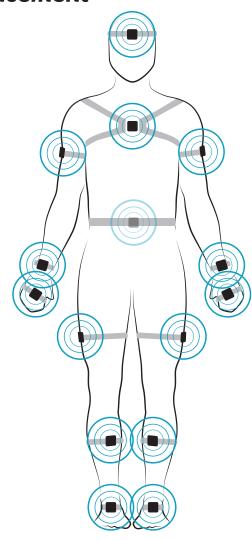
A. Multi-length straps are suitable for universal use including hand, wrist, upper arm, head, upper leg, lower leg, and foot.

B. Sternum strap

C. Lumbar strap



Suggested Sensor Placement



Foot

Centered on top of the foot

Lower Leg

Inside the front of the shin, on the flat surface of the bone, high enough for the strap to wrap just above the widest part of the calf muscle

Upper Leg

Side of thigh, midline, between muscular tissue, one hand's width above the knee

Lumbar

Centered on the low back, at the base of the spine

Sternum

Centered on the flat surface of the chest just below where the collar bones meet

Head

Centered on the front of the forehead

Upper Arm

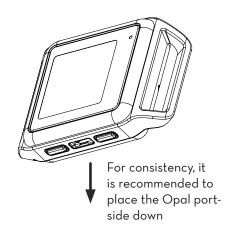
Centered on the outside of the arm, just below the shoulder muscle

Wrist

On the wrist worn like a watch

Hand

On the back of the hand

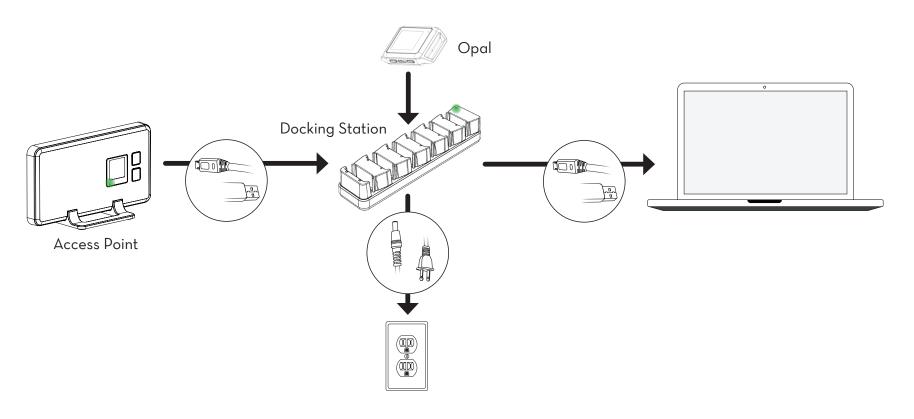


Your Opal System may come with a complete or partial set of the sensors shown. For high impact or long duration activities, we recommend reinforcing strap/sensor placement with double sided skin-safe adhesive or additional wraps.

HARDWARE SETUP







SETUP

- 1. Connect the Access Point to the Docking Station using a Micro USB cable.
- 2. Connect the external power adapter to the Docking Station, and plug it in to a power outlet.
- 3. Connect the Docking Station to your computer using a Micro USB cable.
- 4. Plug the Opals into the Docking Station in any order.

MOTION STUDIO INSTALLATION





Requirements

Operating System

Windows 7 (64-bit) or later.

(Make sure you have Internet Explorer 10 or later installed.)

OSX El Capitan or later.

RAM

4GB+

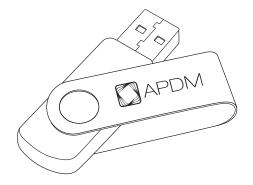
Processor

Intel Core i3 or better. Recommended Intel Core i5 or i7.

Drive Space

500MB for installation. Recommended 100GB+ for ample recording storage.

Installation



MacOS

Insert the provided USB drive into your computer.
 Double click the MotionStudio_Mac64.dmg file.
 Drag the Motion Studio icon into the Applications folder to install.

Windows

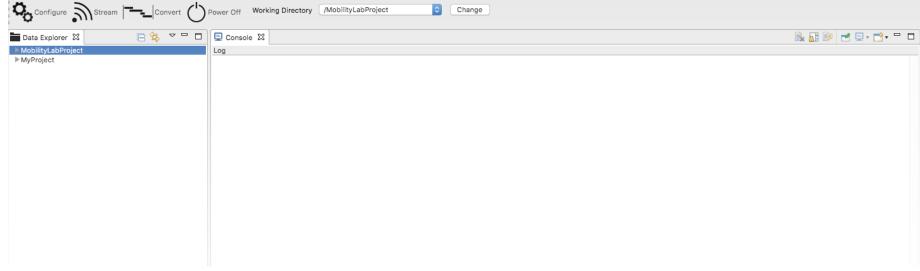
• Insert the provided USB drive into your computer. Double click on the setup file. This will guide you through the installation process.

USING YOUR SYSTEM









MENU

1. Configure

The Configuration panel allows you to select your recording mode for logging or streaming data. You can also select your wireless channel, sample rate, and customize sensor labels and button events.

2. Stream

The Stream button allows you to stream data wirelessly from your sensors.

3. Convert

The Convert button allows you to convert and merge logged recordings into an HDF format.

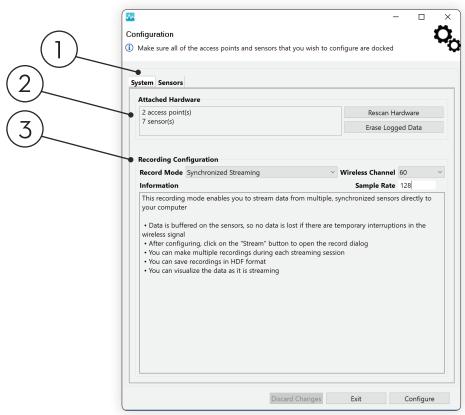
4. Power Off Sensors

The Power Off Sensors tab turns off any docked sensors for storage.

5. Working Directory

The Working Directory shows the project and folder that recorded data will be saved to.





HARDWARE CONFIGURATION

1. System Tab

The system tab provides an overview of the major configuration details.

2. Attached Hardware

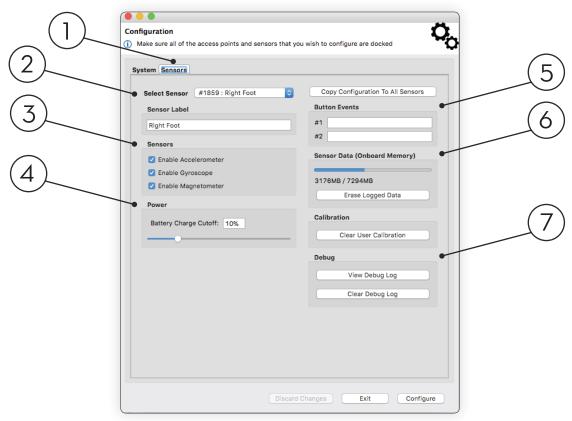
The Attached Hardware section lists all of the detected hardware. To connect or disconnect hardware, add or remove hardware and click the "Rescan Hardware" button. To clear the current memory used on the sensors, click "Erase Logged Data." To clear sensor debug logs, click "Clear Sensor Debug Logs."

3. Recording Configuration

The "Recording Configuration" section allows you to choose the type of recording that occurs on the sensors, adjust the wireless channel, and add sample rate. Sample rate can range from 20-800Hz. *Note default rate for APDM products is 128Hz. Up to 1600 samples per second can be streamed on one Access Point.

The "Record Mode" drop down list contains options for choosing the recording mode. These options rely on what hardware is currently attached. The "Information" box below contains details pertaining to the current selected mode.





HARDWARE CONFIGURATION

1. Sensors Tab

The Sensors Tab provides specific configuration details for a particular sensor.

2. Select Sensor

The Select Sensor dropdown allows you to customized configuration details for the selected sensor.

3. Sensors

The Sensors section allows you to enable and disable attributes of the currently selected sensor.

4. Power

The Power section allows you to select at what battery level the sensors will go into standby mode. In standby mode, the clock on the Opal will continue to keep time.

5. Button Events

The Button Events section allows you to specify the text for events that will be saved to your Opal when in logging mode. See the "Opal Screen Interface" page for details on putting an Opal into the Event Logging mode.

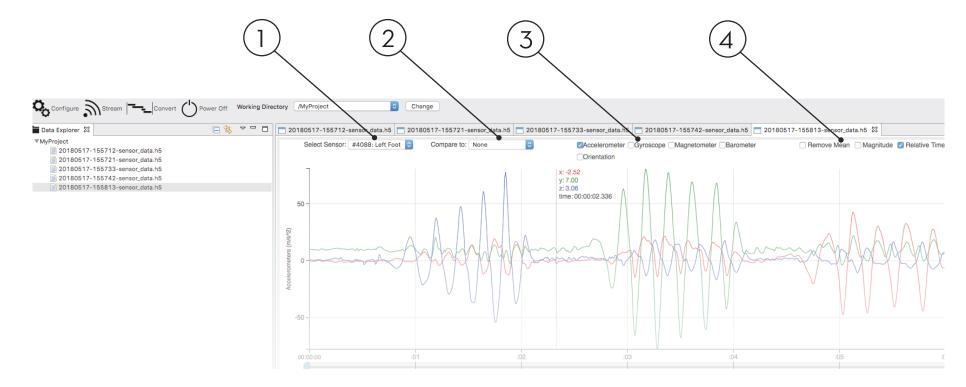
6. Sensor Data

The Sensor Data section allows you to view and clear the current memory used on the selected sensor.

7. Debug

The Debug section allows you to view and clear the debug log on the selected sensor.





VIEWING YOUR DATA

1. Select Sensor

The Select Sensor dropdown allows you to see data from each sensor.

2. Compare To

The Compare To dropdown allows you to see data from one sensor compared to another sensor.

3. Component Selections

The Component Selections allow you to select which sensor components to display below.

4. Other Selections

Use the Other Selections to Remove Mean, show Magnitude, and Reset Zoom. Click and drag with your mouse or use the time scrubbing bar below to select a zoom region on the x-axis. Use the scroll wheel in your mouse to zoom the y-axis.



Synchronized Streaming Modes

If the synchronized streaming mode is selected in the configuration dialogue, you can stream data from multiple synchronized sensors directly to a computer.

Starting a Streaming session

After configuring for streaming and undocking your Opals, wait for the Access Point to start blinking green to indicate that it is ready to stream. Once the Access Point is ready, press the "Stream" button in the menu.

Record Duration

Fixed Duration - Specify the number of hours, minutes, and seconds for each recording. Press the "Stop" button to stop your recording before the specified duration has lapsed.

Indeterminate - The recording will continue until the "Stop" button is pressed.



Statistics

Latency - The current latency between the time data is recorded to the time it is received by the computer. This may increase with poor wireless reception or sensors that are occluded from the Access Point (e.g. against a metal chair, around a corner). Additional latency will be incurred by the plotting of the data to the screen.

Dropped Samples - The number of samples dropped since the current streaming session was started. In the event that data is dropped, all of the recorded data will be present on the sensor's on-board memory and can be recovered manually using the Import Manager after the sensor is docked. The Opal's robust streaming mode is designed to not drop data - dropping samples should be very rare.

Annotations

Use the Annotation buttons to add annotations to an ongoing recording. When the button is clicked, a timestamped marker will be added to the recorded file. Add custom text about the marker in the text box. The remote may also be used to annotate data from a distance.

Real Time Chart

Use the "Select Sensor" combo box to view the real-time data from different sensors (subject to wireless and plotting latency). The real-time chart allows you to view the data streaming from your sensors. There are a number of visualizations:

Strip chart - Shows the calibrated data from all activated sensors.

Orientation - Shows the estimated orientation of the sensor as a rendered 3D model. To initialize the visualization, hold the sensor so the port is facing you and press the "Center" button.

2D - Shows one of the axes of an individual accelerometer or gyroscope versus one of the other axes. For example, "Y vs. Z Accelerometer" or "X vs. Y Gyroscope."



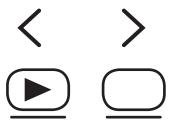
Remote Control

Motion Studio supports the use of a remote control to aid while recording in the Synchronized Streaming mode. This functionality makes it possible to start and stop recording away from the computer.

Supported Remotes - Motion Studio has been designed to use a standard presentation remote. Other presentation remotes will most likely assume the same functionality.

Enabling the Remote - Enabling and disabling the remote can be performed in the streaming dialogue by clicking on the "Enable Remote" checkbox. When the remote is enabled, on-screen buttons that are mapped to remote functionality will have their standard icons either overlayed or replaced by special remote icons.

The "Start" and "Stop" buttons are mapped to the "Next" and "Previous" slide buttons on the remote. The "Annotation" buttons are mapped to the "Start" and "Stop" presentation buttons on the remote.





Synchronized Logging Mode

In the synchronized logging mode, multiple sensors can be wirelessly synchronized with each other. Each sensor's data will be recorded to the on-board flash memory.

To Start Recording

Undock the sensors after configuration. After a few seconds, they will start recording to their flash memory. When within wireless contact with each other, they will synchronize their clocks. To start an additional recording in a separate file, connect and disconnect the sensors from their cables or Docking Stations. No re-configuration is necessary.

To Import Recorded Data

Dock the sensor(s). Click on the "Convert" button in the toolbar. You can specify regions of the logged data to convert to HDF format (identical to the streamed data format) based on time ranges or button events.

Low Power Logging Mode

In the low power logging mode, each sensor's radio is turned off to save power. The sensors will be synchronized at the start of recording, but they will not be actively synchronized while logging and some level of clock drift will occur during long recordings.

To Start Recording

Undock the sensors after configuration. The sensors will stop recording once they are docked again.

To Import Recorded Data

Dock the sensor(s). Click on the "Convert" button in the toolbar.



Logged Data Conversion Manager

The Logged Data and Conversion Manager enables you to import the data saved on the sensors and convert it to a format that can be read by a number of software analysis packages. Click the "Convert" button in the toolbar to open the Logged Data and Conversion Manager. Raw data files are displayed in the Logged Recordings Available for Conversion table.

Selecting Data for Import

In the Recordings Ready for Conversion table, you can select data for conversion by using the checkboxes. When you click on a file in the table, any other files that have overlapping recording times will be highlighted. This functionality aids in the finding and merging of data that was recorded on multiple monitors synchronously.

Conversion Options

Convert Each Recording to its own File - When chosen, instead of merging the selected logged recordings into a single HDF file, each logged recording will be converted into its own HDF file. When this is option is chosen, the selected recordings do not have to overlap in time. This can be useful for batch processing multiple files at the same time, if it is not required that they are merged. An example use case would be if you are using a single Opal in your recordings and you wish to convert a month's worth of data all at once.



Save Selections

To save logged recordings to your local hard drive, select the recordings you wish to save and click on the "Save Selections" button. Recordings that are saved on your hard drive will have "Yes" indicated in the "Saved" column.

File Naming Options

Base File Name - The name of the file the data is being converted into.

Include Sensor ID - The case ID of the sensor being converted will be embedded in the file name.

Include Sensor Label - The label of the sensor being converted will be embedded in the file name.

Add Date - Add the date of the start of the recording to the file name. You can choose to leave it out, or to prepend append the date to the file name.

After Import

Converted data will show in your current working directory. Double click on the file or right click and select "Plot" to plot the data to the screen.



Managing Data

The Data Explorer shows a hierarchical view of your projects and folders. Projects are the top level containers in the Data Explorer, and can hold any number of folders. Folders hold other folders or data files. The projects and folders that are visible in the Data Explorer are called your Workspace.

Working Directory

The Working Directory Tool is displayed in the application's toolbar. You can change your Working Directory by clicking on the "Change" button and selecting a different project or folder. Whenever data is recorded through the streaming interface or imported from your sensors, it will appear in the current Working Directory.

Creating New Projects

- 1. Right-click in the Data Explorer and select "New > Project"
- 2. Select the "Project" option from the New Project Wizard
- 3. Specify the project name
- 4. By default, the project and all contained files will be placed in Motion Studio's workspace directory, which is indicated in the console when Motion Studio is launched. If you wish to specify a different location on your hard drive to create the project, uncheck the "Use default location" box and choose the location of the new directory.
- 5. Click "Finish"
- 6. To make this your current working directory, click on the "Change" button in the Working Directory Tool and choose the new project.



Creating New Folders in Projects

- 1. Right-click in the Data Explorer and select "New > Folder"
- 2. Select the parent project or folder for the folder you wish to create
- 3. Specify the folder name
- 4. By default, the folder will be created in the project's directory structure on your hard drive. It is possible, however, to associate the folder with a project but to store the data in a different location. If you wish to specify a different location on your hard drive to create the folder, click the "Advanced" button, select the "Link to alternate location (Linked Folder)" option, and specify the folder on your hard drive that you wish to store this folder's data in.
- 5. Click "Finish"
- 6. To make this your current working directory, click on the "Change" button in the Working Directory Tool and choose the new folder.

Plotting

To plot a recorded file, either double-click on the file in the Data Explorer, or right-click on the file and select the "Plot" option. The plot dialogue enables you to specify the monitor to plot.

Workspaces

Your workspace contains all of your recorded data and application settings. You can create and use multiple workspaces to organize and partition your data at a high level. One use case is to have different users on a shared computer each use a workspace in their own user directory to prevent other users from accessing their data. To create a new workspace or switch to a different, existing one, click on "File" and select "Switch Workspace" from the menu bar.



On, Off, and Standby Modes

Docking Sensors

In most situations, it is sufficient to simply dock the sensors when not in use. When docked, the sensors stop recording, stop broadcasting, and start charging their batteries. Once fully charged, the batteries will enter a trickle charge mode to keep them topped off.

Power Off

For transport or storage, it is often desirable to power off all system components. This can be done by docking the sensors and clicking on the "Power Off" button in the toolbar. When this option is chosen, the sensors will power down the next time they are undocked. To power off the Access Point, simply shut down your computer or unplug the access point from your computer.

Power On

From a standby or off state, the sensors can be powered on by docking them. If the Access Point was also powered down, simply plug it back into your computer. Your previous configuration will be remembered.

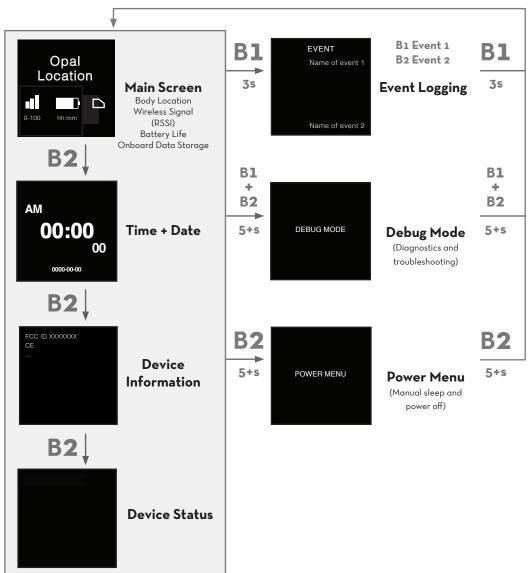
Standby

When you put the sensors into standby mode, all components are turned off except for the clock. This is particularly important if you are recording in logged mode and need to know the time of the recordings. In the configuration dialog, you can specify the battery percentage at which your Opals will automatically go into standby mode. The default is 10%, which is sufficient to keep the clock running for up to 2 days.



Opal Screen Interface

The screen interface on the Opal Sensors provides important information about the registration and operating state of the hardware. The table below shows the navigation to different screens on the interface. Navigation of these screens is not required to complete a test.





Access Point Screen Interface

The screen interface on the Access Point provides important information about the registration and operating state of the hardware. The table below shows the navigation to different screens on the interface.



The Status screen on the AP indicates if the Opal sensors are ready to record data. Symbols on the left-hand side of the screen identify the following:

- Opal is ready to stream data
- Communicating with the Opal wirelessly, but not yet ready to stream data.
- Not receiving data from the Opal.

 The Opal may be docked or out of range.

TIPS





Charging

Opals charge any time they are connected to a Docking Station or are plugged into a USB cable. It is recommended that sensors be charged for 1 to 3 hours to provide a peak charge to the battery. The sensor uses a Lithium battery that charges best in 5-35°C or 40-95°F.

Storage

In daily use situations, it is sufficient to simply dock your sensors when not in use. When docked, sensors stop recording, stop broadcasting, and charge batteries.

For periodic users, it is best to power off all system components for storage and transport. This can be done by docking the sensors and clicking the "Power Off" button in the Motion Studio menu. The sensors will power down the next time they are undocked.

Cleaning

As the Opal wearable sensors come in direct contact with subjects, they should be cleaned after every use. To clean the Opal use a low-level disinfectant on a soft, lint-free cloth. Examples of low-level disinfectants include 70% or greater isopropyl alcohol, 10% bleach solution, or various commercial disinfectant wipes. Do not immerse in or spray the Opals with a liquid. Do not use abrasive cleaners.

The Access Point, Docking Station, and all associated cabling do not require cleaning. If you wish to clean these, please use a mild cleaning solution on a soft, lint-free cloth. Do not immerse in or spray the Access Point or Docking Station with a liquid. Do not use abrasive cleaners. The sensor straps can be removed and washed separately using mild soap and water.

TROUBLESHOOTING

APDM is pleased to assist you with any questions you may have about your hardware, software, or the use of the technology in your study.

Please contact us at:

web: support.apdm.com



LED Patterns and Error Messages

The LED on the system hardware provides important information about the operating state of the hardware. The table below lists the LED flashing patterns associated with these states, which can be useful in troubleshooting issues encountered with the hardware.

	Pattern	State			
	0	Solid white - Startup			
Docked Opal		Solid blue - charge is >90%			
		Blue, green every 2s - charge is >30% and <90%			
	• •	Blue, green every 1s - charge is <30%			
Undocked Opal	brief	Green every 2s - Opal is transmitting data, <5s of latency			
	long	Green every 2s - Opal is transmitting data, >5s of latency			
		Solid green - Opal has not transmitted any data in >5s			
		Battery is <10%			
		Error			
Access Point	brief	Green every 2s - latency is <5s			
	long	Green every 2s - latency is >5s			
		Solid green - AP has not received data from at least 1 Opal in >5s			
		Error			
Docking Station		Solid Green (Dock body front) - Power on			
		Green (Opal slot) - Opal has been detected by computer			
S		Solid Green (Dock body back) - USB port device detected by computer			

LED Colors

White

Red

Yellow

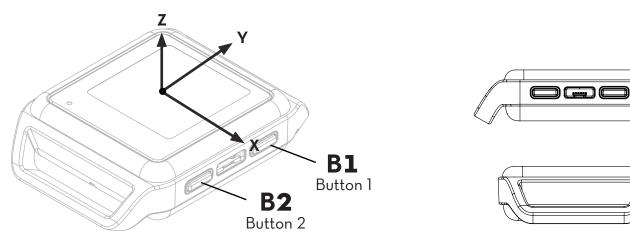
Green

Blue

SPECIFICATIONS







Dimensions	54.9 x 40.0 x 14.3 mm		
Material	Polycarbonate, glass		
Weight	<25 grams (with battery)		
Battery Life	Wireless Streaming (8h), Synchronous Logging (12h), Asynchronous Logging (16h)		
Wireless Radio	Nordic Semiconductor nRF51822		
Frequency Band	2.40-2.48GHz ISM band, adjustable		
Data Rate	2Mbps on-air data-rate		
Latency	300ms (typical) with data buffer, 30ms (typical) without data buffer		
Transmission Range	30m line of sight, 10m indoors		
Data Buffer	8Gb (~450 hours)		
Synchronization	≤lms difference, up to 24 Opals		
Screen Resolution	128px x 128px		

APPENDIX





EMC Declarations

The Opal Wearable Sensor, Docking Station, and Access Point ("Opal System hardware") must be installed and put into service according to the electromagnetic compliance (EMC) guidelines and declarations provided here.

EMC Declarations and Guidance

Table A-1	Electromagnetic emissions
Table A-2	Electromagnetic immunity
Table A-3	Electromagnetic immunity for non-life-supporting equipment
Table A-4	Recommended separation distances between radio-frequency (RF) communications equipment for non-life-supporting equipment

Note: Portable and mobile RF communications equipment can affect the operation of the Opal System hardware.

Warning: The use of accessories and cables other than those provided by APDM may result in increased emissions or decreased immunity of the Opal System hardware.



Table A-1: Guidance and Manufacturer's Declarations - Electromagnetic Emissions

The Opal System is intended for use in the electromagnetic environment specified below. The customer or user of the Opal System should ensure that they are used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions	CISPR 11	Group 1 The Opal System uses very low level RF energy and are not likely to cause any interference in nearby electronic equipment.
RF Emissions	CISPR 11	Class B The Opal System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Current Emissions IEC 61000-3-2	Class B	
Voltage Fluctuations and Flicker IEC 61000-3-3	Complies	



Table A-2: Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The Opal System is intended for use in the electromagnetic environment specified below. The customer or user of the Opal System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	<u>+</u> 8 kV contact <u>+</u> 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transients and Bursts (EFT) IEC 61000-4-4	<u>+</u> 2kV for power supply lines	± 2kV for power supply lines	The mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 2kV differentialmode± 2 kV commonmode	± 2kV differential mode ± 2 kV common mode	The mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips and Interruptions IEC 61000-4-11	100% dip in 0.5 cycles 60% dip in 5 cycles 30% dip in 25/30 cycles 100% dip in 250/300 cycles	100% dip in 0.5 cycles 60% dip in 5 cycles 30% dip in 25/30 cycles 100% dip in 250/300 cycles	The mains power quality should be that of a typical commercial or hospital environment. If the user of the Opal System requires continued operation during a power mains interruption, it is recommended that the Opal System be powered from an uninterruptible power supply or battery.
Magnetic Field Immunity (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location a typical commercial or hospital environment.



Table A-3: Guidance and Manufacturer's Declarations - Electromagnetic Immunity for Non-life-supporting Equipment

The Opal System is intended for use in the electromagnetic environment specified below. The customer or user of the Opal System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Opal System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted Immunity IEC 61000-4-6	>= 6 VRMS 150 kHz to 80 MHz	3 VRMS	d = 1.2√P
Radiated Immunity IEC 61000-4-3:2010	>= 10 V/m 80 MHz to 2700 MHz	10 V/m	d = 1.2√P 80 MHz to 800 MHz d = 1.2√P 880 MHz to 2.5 GHz
			Where P is the maximum output power rating of the transmitter in Watts according to the transmitter manufacturer and d is the recommended separation distance in meters. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each
			Interference may occur in the vicinity of equipment marked with the following symbol: (((*)))



- **Note 1** At 80 MHz and 800 MHz, the higher frequency range applies.
- **Note 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
- Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Opal System is used exceeds the applicable RF compliance level above, the Opal System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Opal System.
- **b** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.



Table A-4: Recommended separation distances between portable and mobile RF communications equipment and the Opal System.

The Opal System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Opal System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Opal System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output	Separation distance (meters) according to frequency of transmitter					
power (Watts) of transmitter	150 kHz to 80 MHz d = 1.2√P	80 MHz to 800 MHz d = 1.2√P	800 MHz to 2.5 GHz d = 1.2√P			
0.01	O.12	O.12	O.23			
O.1	0.38	O.38	0.73			
1	1.2	1.2	2.3			
10	3.8	3.8	7.3			
100	12	12	23			

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.

- **Note 1** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- **Note 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structure, objects, and people.

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