

WELCOME

TO MOBILITY Lab

Using the Opal V2R sensors, Mobility Lab makes it easy to collect, analyze, visualize and store precise movement data. Attach sensors to your research subject, and instruct them to perform a standardized test. A report is then automatically generated to compare against normative outcomes.

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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 ERT's Opal V2C System (FDA Class II Medical Device, CE Class I Medical Device; Rx Only).

Warnings and Precautions

The Mobility Lab system Opal is a Type B Applied Part, i.e., a part of the system which comes into contact with the patient. The Mobility Lab 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 Mobility Lab 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 Mobility Lab 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 Mobility Lab Docking Station has a spare USB Type A port. Only attach USB peripherals and cables that comply with the USB 2.1 specification. The Mobility Lab 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 Mobility Lab 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 0 to 30 °C (32 to 86°F), 0 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 Mobility Lab 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 ERT. For more information, please visit support.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 Mobility Lab

The Mobility Lab database may contain private or personal Protected Health Information (PHI). While Mobility Lab accommodates the need to protect PHI, the database itself is not secured or encrypted by Mobility Lab. 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 Mobility Lab 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 Mobility Lab 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 Mobility Lab system is online, use internet security software to prevent malware infections. Mobility Lab uses SSL to secure any communication with ERT servers that might contain personal information, and no PHI is collected without your consent. Any information on ERT 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 ERT could void the user's authority to operate the equipment. To access FCC and IC information on the ERT 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, ERT 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



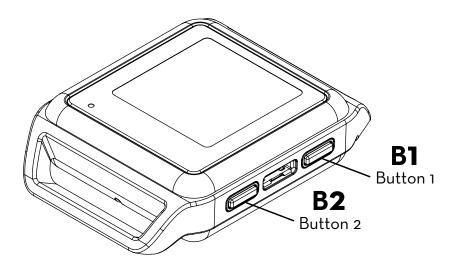
Symbols

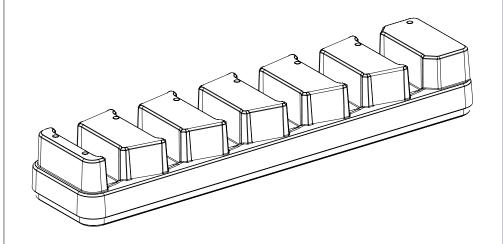
SN	Serial Number
X	Not for General Waste
€	FCC Compliance
†	Type B Applied Part
===	Direct Current
i	Refer to Instruction Manual/Booklet
IP64 I	Ingress Protection Rating
***	Manufacturer
C€	European Union (EU) Mark

PARTS









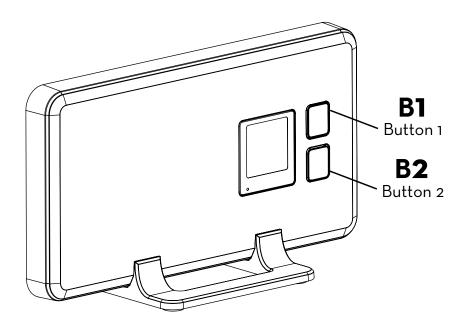
OPALS

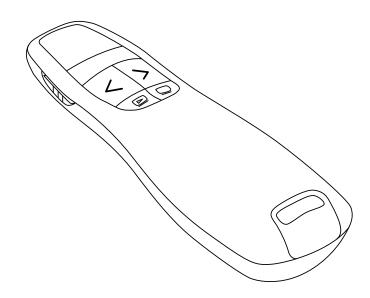
The Opal movement sensors precisely record movement with triaxial accelerometers, gyroscopes, and magnetometers.

DOCKING STATION

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







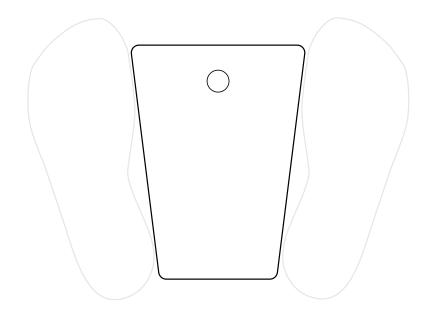
ACCESS POINT

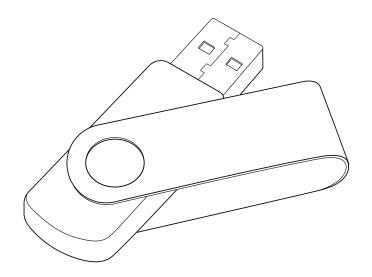
The wireless Access Point allows for wireless communication between the host computer and Opal movement sensors. A single Access Point can support up to 6 Opals at 128Hz sampling rate (maximum of 1,600 samples per second per access point).

WIRELESS REMOTE

The Mobility Lab software supports the use of a remote control to aid while collecting data.







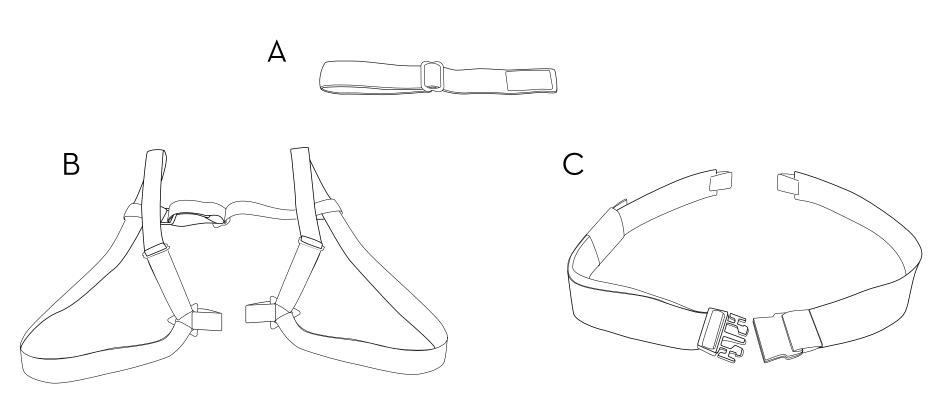
FOOTPLATE

The Mobility Lab Footplate is designed to standardize stance width in some of the Mobility Lab tests. Use as noted in test instructions.

USB DRIVE

The USB drive contains the Mobility Lab software.





STRAPS

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

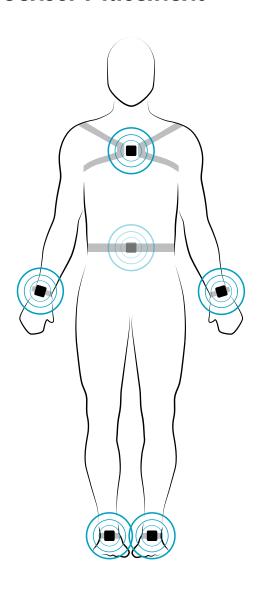
A. Wrist and Foot strap

B. Sternum strap

C. Lumbar strap



Sensor Placement



Foot

Centered on top of the foot

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

Wrist

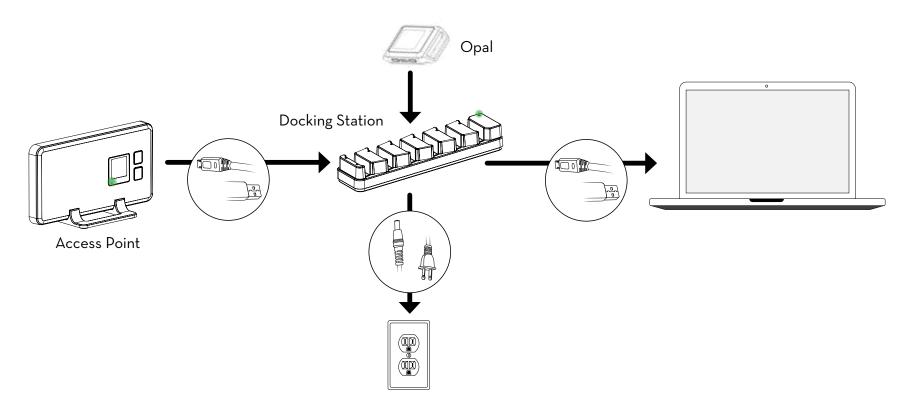
On the wrist worn like a watch



HARDWARE SETUP







SETUP

- 1. Connect the Access Point to the Docking Station using a Micro USB cable.
- 2. Connect the Docking Station power supply 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. Insert the Opals into the Docking Station, in any order, with the port facing down.

MOBILITY LAB INSTALLATION





Requirements

Operating System

Windows 7 (64-bit) or later.

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

OS X El Capitan (10.11) or later.

RAM

4GB+

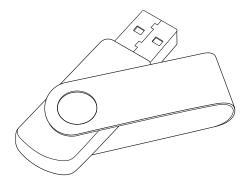
Processor

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. Drag the Mobility Lab icon into the Applications folder to install. Right click the Mobility Lab Icon in your Applications folder and select "Open." If you receive a security warning, right click and select "Open" a second time to launch the application. This behavior is dependent on the version of MacOS you are running and your specified security preferences.

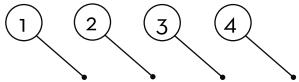
Windows

• 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. Subjects

The Subjects tab shows all of the subjects in your Mobility Lab system for a selected subject group.

2. Options

The Options tab shows all of the display options in your Mobility Lab system for a selected subject group.

3. Hardware Configuration

The Hardware Configuration tab shows assigned sensor locations on the body.

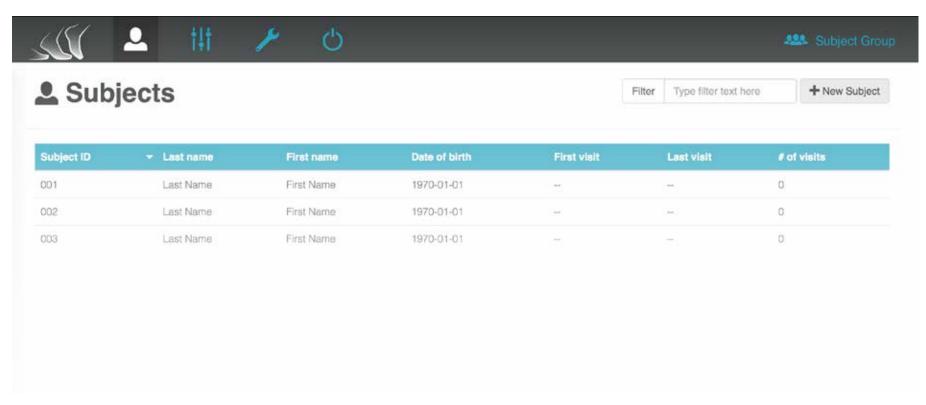
4. Power Off Sensors

The Power Off Sensors tab turns off any docked sensors. Sensors will power off once undocked.

5. Subject Group Selection

The Subject Group Selection dropdown allows you to select, add, edit, delete, and export data for a specific subject group.





SUBJECTS

The Subjects tab shows all of the test subjects in your Mobility Lab system for a selected subject group.

Adding a Subject

Click on the "+New Subject" button on the top right of your screen. Fill in the required fields and click Save.

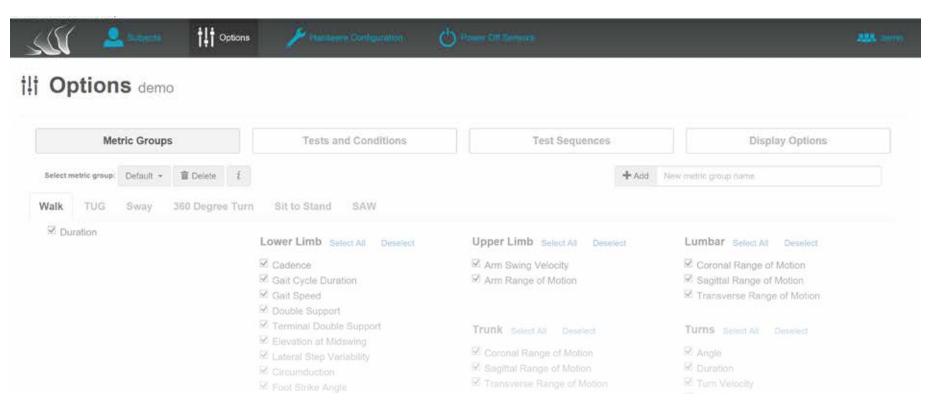
Running a Test

Click on the subject you wish to test. Click on the "New Test" button on the top right of your screen.

Finishing a Test Sequence

Click on the subject you wish to test. Click on the red "bell" icon to the right of an unfinished test sequence. This option will be active for 24 hours after the sequence is started.





OPTIONS

The Options tab shows all of the display options in your Mobility Lab system for a selected subject group.

Metric Groups

The "Metric Groups" page allows you to change which metrics are displayed in the test results window, and add custom metric groups for each test.

Tests and Conditions

The "Tests and Conditions" page allows you to add, edit, and delete custom tests and test conditions.

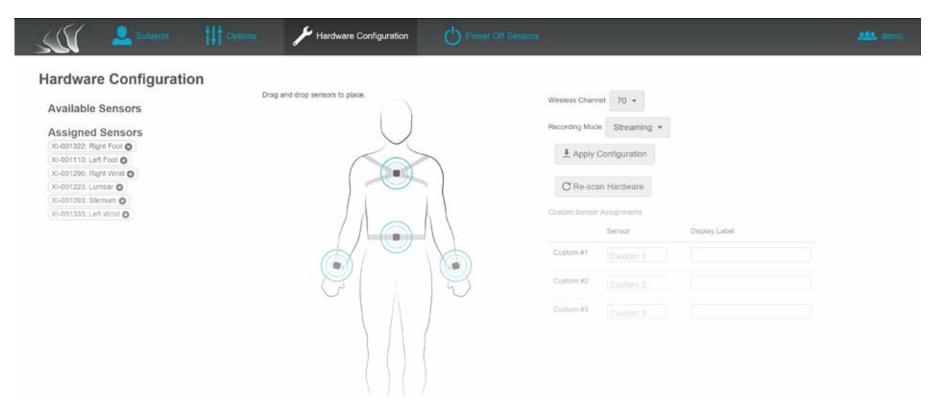
Test Sequences

The "Test Sequences" page allows you to add, edit, and delete custom test sequences.

Display Options

The Display Options page allows you to set editable subject fields, enable recording annotations, and enable configuration for logging mode.





HARDWARE CONFIGURATION

The Hardware Configuration tab shows assigned sensor locations on the body.

Sensor Assignment

Assign Opals to a body site location by dragging from the Available Sensors list and dropping on the human model. The sensors will now show in the Assigned Sensors list.

Custom Sensor Assignments

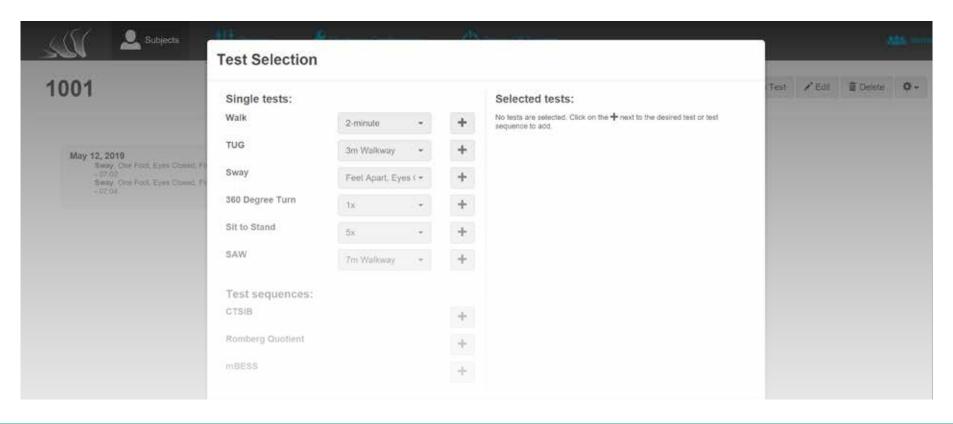
You can also assign custom sensor locations by typing in the Custom Sensor Assignments fields.

Apply Configuration

Click here when you are done choosing your configuration options.

External Synchronization settings can be accessed in the Tools dropdown of the menu bar. Sync Box required.



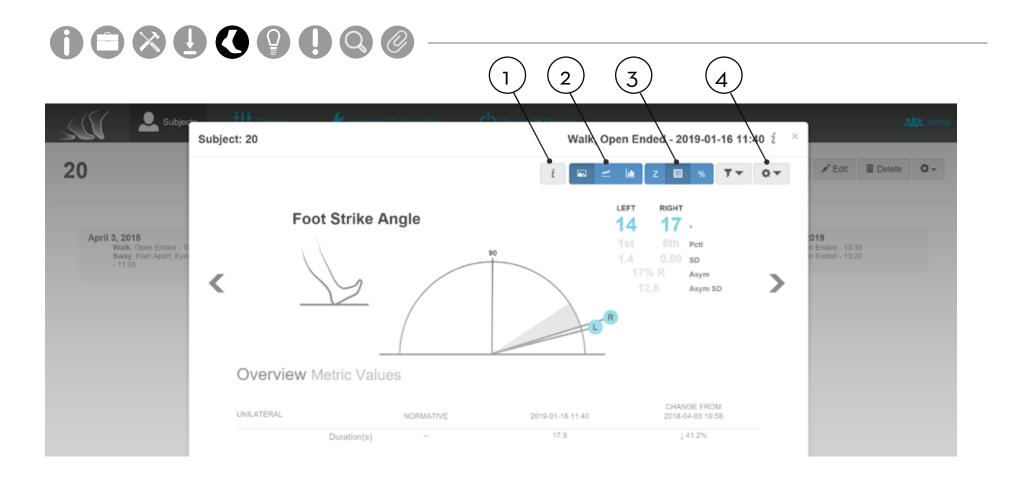


RUNNING A TEST

- 1. Click on the subject you wish to test. Click on the "New Test" button on the top right of your screen.
- 2. Select the test(s) and condition(s) you would like to run. You may select multiple tests or one predefined test sequence. Click Next to continue.
- Follow the instructions on each dialog box to complete each test. Click on blue text for more instructions, including how to place sensors. Click Next.

- 4. Subject instructions should be read out loud, and Administrator instructions should be referred to for more information.
- 5. If annotations were enabled under Display Options enter label(s) for the annotation buttons.
- 6. If using the wireless remote, press the forward button to start and stop each test.

Tip: Your subject should remain still during the 3 second countdown at the beginning of the tests for proper calibration.



TEST RESULTS WINDOW

1. Information Key

The Information Key shows definitions for each metric, and information on how to read each graph.

2. Visualization Options

The Visualization Options show the data graph in different formats for a selected test, including detail view, drill-down, and longitudinal views with option to Filter by condition, sequence or day.

3. Report Table Options

The Report Table Options include Z-Score, Metric Values and Percentiles.

4. Tools Dropdown

The Tools Dropdown allows you to edit displayed metrics, access print view, export trial data, delete a test, and more.

For more information on normative data, search "normative" on support.apdm.com.



Tests



The Mobility Lab system comes equipped with multiple tests from published scientific studies. The table below indicates what each test can measure, and how many Opal sensors are necessary to run each test.

	Published Outcome Measures	Opals
W	Gait, Asymmetry, Variability and Turning	3+
	Postural transitions (sit, stand, and turning)	2+
S	Postural sway	1+
C	Postural sway, Visual dependence, Proprioceptive dependence, and Vestibular loss	1+
mB	Postural stability in varying conditions	1+
360	Turn velocity, Turn time	1+
sS	Trunk excursion, Stand time, Total time	2+
Sw	Gait, Asymmetry, Variability, Turning, and Postural Stability	3+



Gait Definitions

п	Owor		
	OWOR	Im	h

Lower Limb	
Cadence	The number of steps per minute, counting steps made by both feet
Gait Cycle Duration	The duration of a full gait cycle, measured from the left foot's initial contact to the next initial contact of the left foot
Gait Speed	The forward speed of the subject, measured as the forward distance traveled during the gait cycle divided by the gait cycle duration
Foot Clearance	The height of the foot sensor measured at midswing, relative to its start position while standing
Double Support	The percentage of the gait cycle in which both feet are on the ground
Lateral Step Variability	In a series of 3 consecutive foot placements of the same foot, the variability of perpendicular deviations of the middle foot placement from the line connecting the first and third
Circumduction	The amount that the foot travels perpendicular to forward movement while swinging forward during an individual stride
Foot Strike Angle	The angle of the foot at the point of initial contact. The pitch of the foot when flat is zero and positive when the heel contacts first.
Toe Off Angle	The angle of the foot as it leaves the floor at push-off. The pitch of the foot when flat is zero.
Stance	The percentage of the gait cycle in which the foot is on the ground
Step Duration	The duration of a step, measured as the period from initial contact of one foot to the next initial contact of the opposite foot
Stride Length	The forward distance travelled by a foot during a gait cycle
Swing	The percentage of the gait cycle in which the foot is not on the ground
Toe Out Angle	The lateral angle of the foot during the stance phase, relative to the forward motion of the gait cycle. Positive angle is outward rotation.
Upper Limb	
Arm Swing Velocity	The maximum rotational velocity of the arm swing
Arm Swing Range of Motion	The angular range of the arm swing
Trunk Range of Motion	
Coronal	The angular range of the thoracic spine in the coronal plane (roll)
Sagittal	The angular range of the thoracic spine in the sagittal plane (pitch)
Transverse	The angular range of the thoracic spine in the transverse plane (yaw)
Lumbar Range of Motion	
Coronal	The angular range of the lumbar spine in the coronal plane (roll)
Sagittal	The angular range of the lumbar spine in the sagittal plane (pitch)
Transverse	The angular range of the lumbar spine in the transverse plane (yaw)
Sit To Stand	
Duration	The duration of the sit to stand transition
Lean Angle	The angular range of motion of the trunk during the sit to stand transition
Turning	
Angle	The rotational angle of the turn
Duration	The duration of the turn
Velocity	The peak angular velocity of the turn



Each test within the Mobility Lab system is designed to capture data for certain outcome measures. The table below indicates the outcome measures that each test captures, and how many Opal sensors are necessary to gather data for each measure.

ower Limb	1 Opal sensor	3 Opal sensors	6 Opal sensors
Cadence		✓	✓
Gait Cycle Duration		✓	✓
Gait Speed		✓	✓
Elevation at Midswing		✓	✓
Double Support		✓	✓
Lateral Step Variability		✓	✓
Circumduction		✓	✓
Foot Strike Angle		✓	✓
Toe Off Angle		✓	✓
Stance		✓	✓
Step Duration		✓	✓
Stride Length		✓	✓
Swing		✓	✓
Toe Out Angle		✓	✓



Upper Limb	1 Opal sensor	3* Opal sensors	6 Opal sensors
Maximum Velocity			✓
Range of Motion			✓
Trunk Range of Motion			
Coronal			✓
Sagittal			
Transverse			✓
Lumbar Range of Motion			
Coronal		✓	✓
Sagittal		✓ ✓	✓
Transverse		✓	✓
Sit To Stand			
Duration	✓	✓	✓
Lean Angle		√ *	
Stand To Sit			
Duration	✓	✓	✓
Lean Angle		/ *	

^{*} Lean angle minimum Opal sensor requirement = 2.



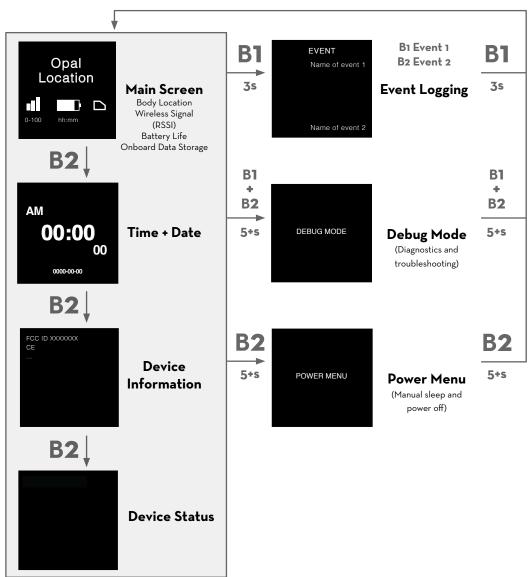
Turning	1 Opal sensor	3 Opal sensors	6 Opal sensors
Angle	✓	✓	✓
Duration	✓	✓	✓
Velocity	✓	✓	✓
Steps in Turn		✓	✓
Postural Sway			
95% Ellipse Sway Area	✓	✓	✓
RMS Sway	✓	✓	✓
Coronal RMS Sway	✓	✓	✓
Sagittal RMS Sway	✓	✓	✓
Anticipatory Postural Adjustment			
Duration		✓	✓
First Step Duration		✓	✓
First Step Range of Motion		✓	✓
Sagittal Max Acceleration		✓	✓
Coronal Max Acceleration		✓	✓

To upgrade your ERT sensor system, contact us at 888-988-APDM (2736) orsales@apdm.com.



Opal Screen Interface

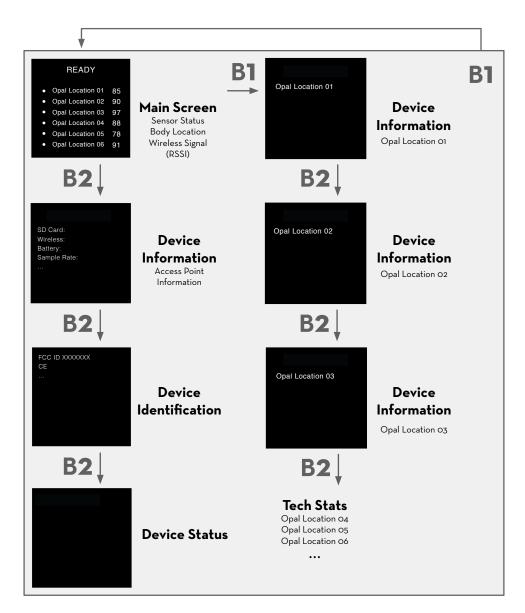
The screen interface on the Opal sensors provides important information about the registration and operating state of the hardware. The table below shows the navigation to different screens on the interface. Navigation of these screens is not required to complete a test.





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





Storage

In daily use situations, it is sufficient to simply dock your Opal sensors when not in use. When docked, Opal 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 Opal sensors and clicking the "Power Off" button in the Mobility Lab menu. The Opal 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.

Subject Attire

The subject should wear clothing that does not bind their movement in any significant way. Walking shoes should be worn (i.e. no heels or flip-flops). If walking shoes are unavailable, it is preferable that the subject walk barefoot.

TROUBLESHOOTING

ERT 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.

State Pattern 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% Green every 2s - Opal is transmitting data, <5s of latency brief **Undocked Opal** 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 brief Green every 2s - latency is <5s **Access Point** long Green every 2s - latency is >5s Solid green - AP has not received data from at least 1 Opal in >5s Error Solid Green (Dock body front) - Power on Docking Station Green (Opal slot) - Opal has been detected by computer Solid Green (Dock body back) - USB port device detected by computer

LED Colors

() White

Red

Yellow

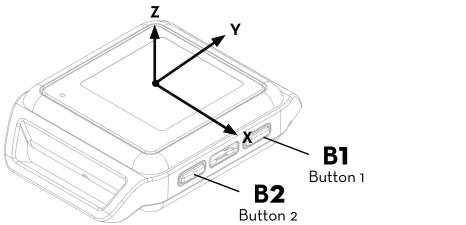
Green

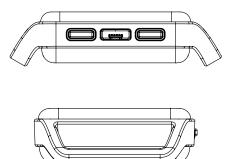
Blue

SPECIFICATIONS









Dimensions	55mm x 40.2mm x 12.5mm	
Material Polycarbonate, glass		
Weight	<26 grams (with battery)	
Battery Life	Wireless Streaming (8h), Synchronous Logging (12h), Asynchronous Logging (16h)	
Wireless Radio Nordic Semiconductor nRF51822		
Frequency Band	zy 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) Nominal		
Synchronization ≤1ms 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 ERT 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	± 8 kV contact ± 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	<u>+</u> 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 differential mode ± 2 kV common mode	± 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 (below)."	
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 frequency range ^b .	
			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	0.23		
O.1	0.38	0.38	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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