

**PERFORMANCE-BASED MEASUREMENTS  
POSTURAL SWAY, 20-METER WALK AND 6-MINUTE WALK**

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## **1. Background and rationale**

Direct assessments of physical performance have become standard measurements in epidemiological studies in the elderly. These assessments generally tap multiple domains of physiological performance, including lower extremity strength, balance, coordination, and flexibility. The assessment techniques used in MOST have been derived from several previous studies, are reliable when performed in a standardized fashion, and are well tolerated by elderly participants.

Performance-based measurements are discussed in this chapter.

Postural sway is a test of quiet standing with arms at the side and feet shoulder width apart for 30 seconds with eyes open and 30 seconds with eyes closed while wearing a motion sensor on a belt to determine center of gravity movement and other measures of postural sway.

The 20-meter walk is a modification of the short walk test used in many epidemiological and clinical studies. The 6-Minute Walk Test (6MWT) is a commonly used test of functional status and endurance.

During these measurements, the participants will be wearing the Opal activity sensors (accelerometers). See Appendix 3 for instructions.

The Postural sway exam should be performed first. Then the two walks should be performed back to back, starting with the 20-meter walk.

## **2. Equipment and supplies**

1. Digital stopwatch with lap counter
2. Bright cloth tape
3. Tape measure
4. Two small cones to mark the turnaround points
5. Examiner Cards with Borg Scale
6. A chair that can be easily moved along the walking course
7. A source of oxygen
8. Aspirin
9. Sphygmomanometer for taking blood pressure
10. Telephone or other means to call for help
11. Automated electronic defibrillator

## 2.1 Use of the stopwatch



**Figure 1**

UAB Procedures. Examiners at the University of Alabama at Birmingham will use the stopwatch in Figure 1 to time the walk tests. Press and hold the right or left hand button (labeled START\*SPLIT) for two seconds to clear the memory. The display should read 00:00.00 in both rows and there should be a 0 in the lap counter column.

To time the task, just press the right OR left-hand button (labeled START\*SPLIT) at the top of the stopwatch to begin. Once you begin the timer will start, and the lap count will move to “1”.

Once the participant has completed the first lap, press the right or left-hand button (labeled START\*SPLIT) to record the first lap time. The timer on the screen will stop and you will see a “1” in the top left corner for the lap count (the cumulative time will still be running in the background but will not appear on the screen at this point).

To continue timing and display lap two on the screen, press the middle button (RELEASE MEMORY). The display will show the cumulative time of the walk in the top row and the current lap time in the bottom row. Continue timing the walk (and counting laps in the way described above until the time reaches 6 minutes for the 6-minute walk). To stop the test at any time press the START\*SPLIT button.

U-Iowa Procedures. Examiners at the University of Iowa will use the built-in clock application on the iPad to time the walk tests. With an internet browser (e.g., Safari) open to the appropriate REDCap form, examiners can place their index finger on the vertical center, right-hand edge, of the screen and swipe left. This opens a multi-tasking mode in the right-hand side of the screen, in which the iPad can display both REDCap forms and stopwatch simultaneously. This mode should default to opening the Clock application in the right-hand portion of the screen. If this does not happen and a list of applications appears instead, scroll through it and select the “Clock” application from the list.

Ensure “Stopwatch” is selected from the icons that appear at the bottom of the screen. To begin timing, touch the “Start” icon that appears below the timer. To record a lap, touch the “Lap” icon while timing. The application will automatically count laps each time the examiner touches the “lap” icon. The timer is displayed in minutes:seconds:hundredths of a second. When finished timing, touch the “Stop” icon. Touch REDCap form and record the time (and number of laps when applicable) data in the REDCap form. This will automatically exit the multitask mode.

### **3. Safety issues and exclusions**

The postural sway measurement should NOT be performed if the participant is using usual walking aids (e.g., cane).

The postural sway measurement AND the walks should NOT be performed by a participant who:

1. Needs the assistance of another person to transfer or walk, OR
2. Is using a walker or crutches.

Usual walking aids (e.g., cane) may be used for both the 20-meter and the 6MWT if believed to be necessary for safety.

Do NOT perform the 6MWT if the participant:

1. Reports chest pain, pressure or tightness during the previous 30 days.
2. Reports a myocardial infarction/heart attack during the previous 30 days.
3. Has a systolic blood pressure greater than 199 mm Hg systolic.

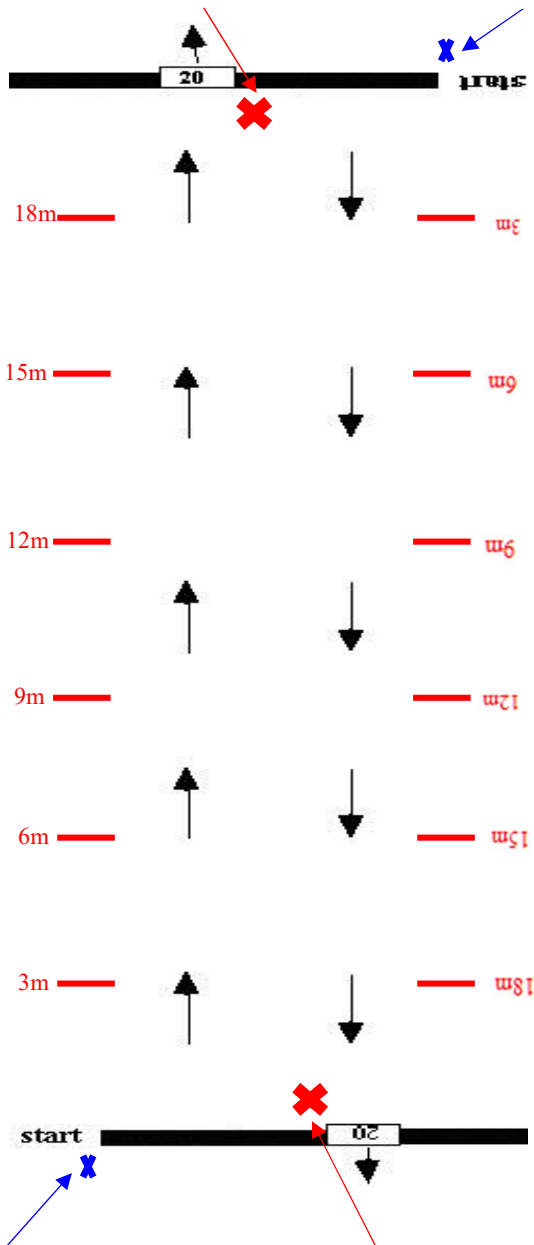
Other exclusions should be based on an individualized assessment of impairments and safety concerns for each test. The examiner should ask questions, describe the tests, and as is necessary, discuss with the participant whether they should attempt that test given any physical problems or disabilities present. The participant should not perform the test if they exhibit signs of vision, gait, balance impairment, or severe joint pain that may pose a possible safety risk *and*, when questioned, expresses uncertainty in the ability to safely walk short distances.

Although the risk of falling during quiet standing is extremely low in the ambulatory participants who will be asked to perform the “sway” test, during this test the examiner should stand close enough to the participant to help them steady themselves if they begin to lose their balance.

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Cone in center and about 1 foot (12 inches) in front of (short of) the line for 6-minute walk

Cone to side and about 1 foot (12 inches) past the line for 20-meter walk



**4. Walking course set up**

20-meter walk. For consistency between field centers, the walking course length will be 20 meters and should be laid out in an unobstructed, dedicated corridor. Fluorescent orange traffic cones should be used to indicate the beginning and end of the walk. The cones should be placed about 1 foot (12 inches) past (beyond) the start and finish line and to the side so that the participant does not slow down during the walk. Measuring from the center of each line, place the lines 20 meters apart. Cones should be carefully placed so that they do not create a tripping hazard for the participant. Place a 1/2 meter length of bright cloth tape across the floor to mark the start and end of the course. Participants are to walk in the *clockwise direction*.

6-minute walk. The 6MWT will be performed, along a long, flat, straight, enclosed corridor with a hard surface that is seldom traveled.

The walking course should be 20 meters in length. The length of the corridor should be marked every 3 meters. The turnaround points should be marked with a cone (such as a small orange traffic cone). The cones should be centered to the line and about 1 foot (12 inches) in front of (short of) the line so the participant can walk around the cone. A starting line, which marks the beginning and end of each 40-meter lap, should be marked on the floor using brightly colored tape.

NOTE: Participants can walk *either clockwise or counter clockwise*, whichever is natural for them.

Cone to side and about 1 foot (12 inches) past the line for 20-meter walk

Cone in center and about 1 foot (12 inches) in front of (short of) the line for 6-minute walk

## **5. Participant preparation**

### **5.1 Footwear**

To eliminate the effect of different footwear on test performance these tests should be performed in comfortable walking shoes with minimal or no heels and non-slippery soles.

### **5.2 Blood pressure and foot size**

Blood pressure should be measured during the clinic visit some time prior to the walks. See Operations Manual, Chapter 3D, Blood Pressure. Blood pressure measurement results will be on the Participant's Results Summary Report.

Foot length, in mm, is measured along with height and weight. Foot length is needed for reading center analysis and will be provided by Coordinating Center. See Operations Manual, Chapter 3R, Standing Height & Foot Length.

## **6. Approach to standardizing the walk performance tests**

The walks are administered by a certified examiner. Since motivation and level of understanding can have a significant impact on performance, the exams should be administered strictly according to the protocol and in the following sequence:

1. Determine whether any exclusions or special test procedures apply.
2. Explain the procedure to the study participant making sure that key points from the suggested script are conveyed.
3. Demonstrate key aspects of the procedures using suggested script.
4. Ask the participant if they have any questions.
5. Re-explain the procedure briefly using suggested script.
6. Start recording activity monitor data.
7. Ask the participant to perform the procedure.
8. Administer 20-meter walk followed immediately by the 6MWT.

### **6.1 Instructions and encouragement**

Use the script provided to make sure that all key points are covered when you describe the test and how to perform it properly. You should not provide additional description or encouragement beyond the key points provided by the standard scripts.

### **6.2 Demonstration**

It is very important that the examiner demonstrate correctly what the participants are being asked to do. Experience has shown that participants follow more closely what the examiner does rather than what they say. If the participant indicates that they do not understand the instructions, demonstrate it again along with the verbal instructions.

## **7. Determine eligibility for the walks**

1. Describe the tests.

NOTE: The postural sway measurement should not be performed if the participant is using usual walking aids (e.g., cane). Usual walking aids (e.g., cane) may be used for both the 20-meter and the 6MWT if believed to be necessary for safety. Neither the postural sway test nor the walks should be performed by a participant who needs the assistance of another person to transfer or walk, OR is using a walker or crutches. See Section 3. Safety Issues and Exclusions for more information.

Script: "First we will assess your balance while you are standing quietly. Then we're going to use our walking course to observe your usual walking speed and see how far you can walk in six minutes. You will walk back and forth in this hallway.

"Do you feel it would be safe for you to try to walk up and down this hallway?"

Record the participant's response.

2. If the participant is willing to attempt the walk, ask the exclusions for the 6MWT.

Script: "Have you had any of the following during the previous month? Chest pain, pressure or tightness; Myocardial infarction/heart attack."

Record the participant's response.

3. If yes to either question, or the previously measured systolic blood pressure is greater than 199 mm Hg systolic, do NOT perform the 6MWT. You can still perform the 20-meter walk.
4. If the participant is eligible for at least the 20-meter walk, describe the purpose of the monitors that will be worn during the walks.

Script: "During these tests, we are asking you to wear 3 movement monitors - one on your lower back and one on each ankle. The monitors will collect data while you are walking about your pace, stride, and many other aspects of how you move when you walk."

5. Fit the Opal monitors on the participant as described in Appendix 3.

## **8. Opal activity monitors**

Participants will wear the Opal activity monitors (accelerometers) during postural sway and both walks. See Appendix 3 for detailed instructions for programming, fitting and recording the Opal monitors for the walks.

## **9. POSTURAL SWAY AND 20-METER WALK**

### **9.1 Description**

The 20-meter walk test measures the time it takes for the participant to walk 20 meters at their usual walking pace on a standardized course. There are two trials of the 20-meter walk.

Before performing the 20-meter walk, a test of balance during quiet standing with eyes open then with eyes closed will be performed.

If the postural sway test will not be performed, skip down to item #9.2.6 below.

### **9.2 Administration**

1. Describe the postural sway measurement.

Script: “First we will assess your body movement while you are standing quietly, first with your eyes open for about 30 seconds and then with your eyes closed.”

2. Describe eyes open component of the postural sway measurement.

Script: “Please stand with your feet apart approximately shoulder width and arms at your side. Look straight ahead. Try not to move your feet and maintain this position for 30 seconds with your eyes open. If you feel like you are about to lose your balance, take a step or reach out to me to steady yourself.”

NOTE: Although the risk of falling during quiet standing is extremely low in the ambulatory participants who will perform this exam, the examiner should remain close enough to the participant to extend an arm and assist them if they begin to lose their balance.

3. Once the participant is ready, start the Opal activity monitors. After the 5-second count down in the Opal software, say,

Script: “Begin.”



Start the timer and click the Annotation #1 key on the Logitech remote at the same time (see Appendix 4 for a diagram of the keys) and record for at least 30 seconds, but no longer than 45 seconds. Stop the timer and click the Annotation #2 key after 30 or more seconds have elapsed. If the participant takes a step or reaches out to the examiner before 30 seconds have elapsed, immediately press the Annotation #2 key to indicate the end of this assessment.

4. Reset the timer but leave the Opal activity monitors recording and describe the postural sway with eyes closed measurement.

Script: “Now please continue to stand quietly in this position. When I say “Begin”, close your eyes. Try not to move your feet and maintain this position for 30 seconds with your eyes closed. If you feel like you are about to lose your balance, take a step or reach out to me to steady yourself.”

5. Once the participant is ready, say,

Script: “Begin.”

Once the participant has closed their eyes, start the timer and click the Annotation #1 key on the Logitech remote at the same time. Record for at least 30 seconds. Stop the timer and click the Annotation #2 key after 30 or more seconds have elapsed. Leave the Opal activity monitors recording. If the participant takes a step, reaches out to the examiner, or opens their eyes before 30 seconds have elapsed, immediately press the Annotation #2 key to indicate the end of this assessment.

6. Describe the 20-meter walk.

Script: “You may open your eyes now. Now we want to measure your usual walking speed over this 20-meter course.

You will start behind this line. When you have walked all the way past the orange cone I want you to stop. Do not slow down until you have passed the cone.”

7. Demonstrate how to walk past the cone. Emphasize that the participant needs to walk past the orange cone before slowing down.
8. Position the participant so that their toes are just touching the starting line.

Script: "Now when I say 'Go,' I want you to walk at your usual walking pace. Any questions?"

9. Start the test by saying,

Script: "Ready, Go."

10. You will need to walk a few steps behind the participant. Click the Annotation #1 key on the remote. Begin timing with the first footfall over the starting line and stop with the first footfall on, or over, the finish line.

11. When the participant reaches the 20-meter mark, stop timing, and record the time elapsed on the form (in field labeled "Trial 1").

12. Reset the stopwatch and have the participant repeat the 20-meter walk by walking back in the other direction.

Script: "OK, fine. Now turn around and when I say 'Go,' walk back the other way at your usual walking pace. Be sure to walk past the cone before slowing down. Ready, Go."

13. When the participant reaches the finish line, stop timing, and record the time it took to complete the second trial form (in data field labeled "Trial 2").

- a. Press the green Stop button on the Opal remote to end data collection for the 20-meter walk (Appendix 3, Section 4.3).

### **9.3 Scoring**

1. Participant can use a cane, if needed, during the 20-meter walk. Record whether or not a walking aid was used.

2. Ask the participant:

Script: "Did pain during the exam affect your ability to do this exam?"

3. If a test is not attempted because the participant refuses or cannot understand the instructions, record "Participant refused."

4. If a test is attempted but cannot be completed or scored, record "Attempted, unable."

5. If the examiner or participant deems the test unsafe or beyond the participant's ability, for whatever reason, record "Not attempted/unable" on the scoring form. Record a reason why the test was not attempted on the Follow-up Clinic Visit Procedure Checklist.

### **9.4 Alert values**

None.

## **10. 6-MINUTE WALK TEST**

### **10.1 Description**

This is a test of how far a participant can walk in 6 minutes. It is a test of functional ability and endurance.

### **10.2 Administration**

#### **1. Preparing for the test**

The 6-minute walk test (6MWT) should be done immediately after the 20-meter walk. The participant should sit at rest in a chair, located near the starting position. During this time, make sure that clothing and shoes are appropriate.

The Opal activity monitors should remain on the participant during the 6MWT. See Appendix 1 for the Borg Scale, and Appendix 2 for Key Parts of 6MWT Protocol and Script.

#### **2. Instructions**

Script: "The object of this test is to walk as far as possible for 6 minutes at a speed you can safely maintain. You will walk back and forth in this hallway. Six minutes is a long time to walk, so you will be exerting yourself. You may get out of breath or become exhausted. You are permitted to slow down, to stop, and to rest as you feel necessary. You may lean against the wall while resting, but resume walking as soon as you are able.

You will be walking back and forth around the cones without pausing at either end. You should turn briskly around the cones and continue back the other way without hesitation. Now I'm going to show you. Please watch the way I turn without hesitation."

#### **3. Demonstrate**

Position the participant behind the starting line and to the side so the examiner can demonstrate turning around the cone. The examiner should stand a few feet in front of the starting line facing the participant.

Demonstrate by walking around the cone at the end of the course where the participant is resting. Walk and pivot around a cone briskly.

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Script: "Are you ready to do that? I am going to use this counter to keep track of the number of laps you complete. I will click it each time you turn around at this starting line.

Remember that the object is to walk as far as possible for 6 minutes at a speed you can safely maintain, but don't run or jog."

4. Set the lap counter to zero and the timer to 6 minutes. Assemble all necessary equipment (lap counter, timer, data collection forms) and move to the starting point.
5. Start the Opal recording for the 6-minute walk trial.

After 5 seconds:

Script: "Start now, or whenever you are ready."

As soon as the participant starts to walk, start the timer.

6. During the walk

Do not talk to anyone during the walk. Use an even tone of voice when using the standard phrases of encouragement. Watch the participant. Do not get distracted and lose count of the laps. Each time the participant returns to the starting line, click the lap counter once. Let the participant see you do it. Exaggerate the click using body language, like using a stopwatch at a race. NOTE: a **lap is considered 40 meters** (walking forwards for 20 meters, and then back for 20 meters).

After the first minute, when the participant is close enough to hear you, say the following (in even tones):

Script: "You are doing well. You have 5 minutes to go."

When the timer shows 4 minutes remaining, tell the participant the following:

Script: "Keep up the good work. You have 4 minutes to go."

When the timer shows 3 minutes remaining, tell the participant the following:

Script: "You are doing well. You are halfway done."

When the timer shows 2 minutes remaining, tell the participant the following:

Script: "Keep up the good work. You have only 2 minutes left."

When the timer shows 1 minutes remaining, tell the participant the following:

Script: “You are doing well. You have only 1 minute to go.”

Do not use other words of encouragement (or body language to speed up).

When the timer is 15 seconds from completion, say this:

Script: “In a moment I’m going to tell you to stop. When I do, just stop right where you are and I will come to you.”

When the timer rings (or buzzes), say this:

Script: “Stop!”

Press the green Stop button on the Opal remote to end data collection for the 6-minute walk (Appendix 3, section 4.4).

Walk over to the participant. Consider taking the chair if they look exhausted. Mark the spot where they stopped by placing a bean bag or piece of tape on the floor.

#### 7. Stopping the test before completion

If the participant stops walking during the test and needs a rest, say this:

Script: “You can rest and lean against the wall if you would like; then continue walking whenever you feel able.”

Do not stop the timer. If the participant stops before the 6 minutes are up and refuses to continue (or you decide that they should not continue), wheel the chair over for the participant to sit on, discontinue the walk, and note on the data collection form the distance, the time stopped, and the reason for stopping prematurely.

Reasons for stopping the test include the following: 1) chest pain, 2) intolerable dyspnea, 3) leg cramps, 4) staggering, 5) diaphoresis, 6) pale or ashen appearance, 7) the participant says they are finished and can’t go, or don’t want to go any further.

If a test is stopped for any of these reasons, the participant should sit or lie supine as appropriate depending on the examiner’s assessment of the severity of the event and the risk of syncope. The following should be obtained based on the judgment of the examiner: blood pressure, pulse rate, oxygen saturation, and a physician evaluation. Oxygen should be administered as appropriate.

### **10.3 After the test and scoring**

1. Congratulate the participant on good effort and offer a drink of water.

2. Record the number of laps completed from the lap counter.
3. Record the additional distance covered (the number of meters in the final partial lap) using the markers on the wall as distance guides.
4. If the test was ended before 6 minutes, record the time elapsed at the end of the test.
5. Ask if the participant experienced symptoms during the test.

Script: “How do you feel? Is there anything that is bothering you now?”

Record the symptoms described.

6. Ask the participant to grade their current breathing level using the Borg Scale. Then ask the participant to grade their current level of fatigue using the Borg Scale
7. Record if the test was ended before 6 minutes, and if so, ask the participant why they felt they could not continue.
8. Record if the participant paused or rested during the test, and if so, ask the participant why.
9. Record whether a walking aid was used during the test, and whether supplemental oxygen was administered during the test.
10. If the participant did not complete the walk, record the reason why.
11. Remove Opal activity monitors.

#### **10.4 Alert values**

None.

### **11. Quality assurance**

#### **11.1 Training and certification**

The examiner requires no special qualifications or experience to perform this assessment. Training should include:

- Read and study manual
- Attend MOST training session on techniques (or observe administration by experienced examiner)

- Practice on other staff or volunteers
- Discuss problems and questions with local expert or QC officer

### **11.2 Certification requirements**

- Complete training requirements
- Conduct exam on two volunteers while being observed by QC officer
  - According to protocol, as demonstrated by completed QC checklist

### **11.3 Quality assurance checklist**

#### **Postural sway**

- Opal activity monitors correctly programmed and place on participant prior to beginning the postural sway exam
- Main points of script correctly and clearly delivered (eyes open trial)
- Timer started and Annotation #1 key on Logitech remote clicked at the same time
- Annotation #2 key on Logitech remote clicked after 30 or more seconds have elapsed
- Timer reset
- Opal activity monitors left recording
- Main points of script correctly and clearly delivered (eyes closed trial)
- Timer started and Annotation #1 key on Logitech remote clicked at the same time
- Annotation #2 key on Logitech remote clicked after 30 or more seconds have elapsed

#### **20-meter walk**

##### **Trial 1:**

- Opal activity monitors correctly programmed and placed on participant prior to beginning walks
- Main points of script correctly and clearly delivered
- Correctly demonstrates
- Toes touching start line
- Instructs participant to walk at their usual pace
- Opal activity monitor recording started at correct time for the 20-meter walk
- Timing started coincident with participant's first footfall over the starting line and Annotation #1 key clicked on remote
- Timing stopped with first footfall **on or over** the finish line
- Time recorded correctly on data collection form

##### **Trial 2:**

- Resets stopwatch for second 20-meter walk
- Again, instructs participant to walk at their usual pace
- Opal activity monitor recording stopped at correct time for the 20-meter walk
- Timing started coincident with participant's first footfall over the starting line
- Timing stopped with first footfall on or over the original starting line
- Time recorded correctly on data collection form
- Reviews form for completeness
- Correctly saves a copy of the Opal data file into the weekly folder

**6-minute walk test**

- 6-minute walk test performed immediately after 20-meter walk
- Exclusions assessed correctly
- Main points of script correctly and clearly delivered
- Correctly demonstrates
- Participant positioned at the starting line
- Opal activity monitor recording started at correct time for the 6-minute walk.
- Timer started as soon as the participant starts to walk
- Opal activity monitor recording stopped at correct time for the 6-minute walk.
- Correct number of laps counted, and time stopped at 6 minutes
- Correct number of meters in the final partial lap calculated
- All post-walk questions on data collection form completed correctly
- Reviews form for completeness
- Correctly saves a copy of the Opal data file into the weekly folder

**12. Data collection forms**

Please see the Overview of the 144-month Follow-up Visit Operations Manual for an overview of the data collection forms, information on whether each form is in REDCap or TeleForm, and where the forms can be accessed on the study website.



### Appendix 1 Response Card for Borg Scale for 6-Minute Walk Test

#### The BORG Scale

- 0 Nothing at all
- 0.5 Very, very slight (just noticeable)
- 1 Very slight
- 2 Slight (light)
- 3 Moderate
- 4 Somewhat severe
- 5 Severe (heavy)
- 6
- 7 Very severe
- 8
- 9
- 10 Very, very severe (maximal)

## **Appendix 2 Key Parts of 6-Minute Walk Test Protocol and Script for Examiners**

(See Section 10.2 for Entire 6-Minute Walk Test Protocol and Script)

*Say* "The object of this test is to walk as far as possible for 6 minutes at a speed you can safely maintain. You will walk back and forth in this hallway. Six minutes is a long time to walk, so you will be exerting yourself. You may get out of breath or become exhausted. You are permitted to slow down, to stop, and to rest as you feel necessary. You may lean against the wall while resting, but resume walking as soon as you are able.

You will be walking back and forth around the cones without pausing at either end. You should turn briskly around the cones and continue back the other way without hesitation. Now I'm going to show you. Please watch the way I turn without hesitation."

*Demonstrate.*

*Say* "Are you ready to do that? I am going to use this counter to keep track of the number of laps you complete. I will click it each time you turn around at this starting line. Remember that the object is to walk as far as possible for 6 minutes at a speed you can safely maintain, but don't run or jog."

"Start now, or whenever you are ready."

*Start timing as soon as the participant starts to walk. Track the number of laps completed.*

*Follow script in section 10.2 during the walk.*

*When the timer is 15 seconds from completion say* "In a moment I'm going to tell you to stop. When I do, just stop right where you are and I will come to you."

*Say* "Stop!" when 6 minutes is up. Walk over to the participant. Consider taking the chair if they look exhausted. Mark the spot where they stopped by placing a bean bag or a piece of tape on the floor.

*If the participant stops walking during the test and needs a rest, say* "You can rest and lean against the wall if you would like; then continue walking whenever you feel able." *Do not stop the timer. If the participant stops before the 6 minutes are up and does not want to continue (or you decide that they should not continue), wheel the chair over for the participant to sit on, discontinue the walk, and note on the data collection form the distance, the time stopped, and the reason for stopping prematurely.*

## **Appendix 3 Using the Opal Activity Monitors During the Walks**

### **1. Background and rationale**

In healthy individuals, gait parameters are essentially symmetrical with only minor deviations. However, presence of musculoskeletal impairments leads to gait asymmetries in lower limb kinematic and kinetic parameters, such as stride time, stance time and swing time.

The Opal inertial system (APDM Inc.) will be used to quantify spatial and temporal measures during over-ground walking (e.g., cadence, stride time, stride length, swing time, stride time variability, asymmetry). Three Opal monitors will be used simultaneously: one will be placed on each ankle and one on the lower back. The data will allow us to determine the left-right gait asymmetry.

### **2. Equipment and supplies for the inertial system Opal**

1. Laptop computer (for required specs, see Opal User's Guide, Section 3).
2. Mobility lab software (download from website; for installation instructions, see Opal users guide, Section 3).
3. Movement monitors (4 - 3 for use and 1 for backup in case of problems). Monitors should be marked with "B" for lumbar/back, "R" for right shin/ankle and "L" for left shin/ankle. Label each monitor with "Top" in an easily seen location.
4. Belts to attach monitors to waist (1 - elastic) and ankles (2 - velcro).
5. Docking station for three monitors (docking station power must come from a wall plug).
6. Hand-held remote with USB receiver.
7. Wireless access control point.
8. Supplies for sanitizing ankle belts if placed directly over skin (TBD).

### **3. Safety issues and exclusions**

1. None for wearing the Opal monitoring devices.
2. Participant must be eligible for the 20-meter walk. The monitors should be used on the 20-meter walk even if the 6-minute walk is not done.

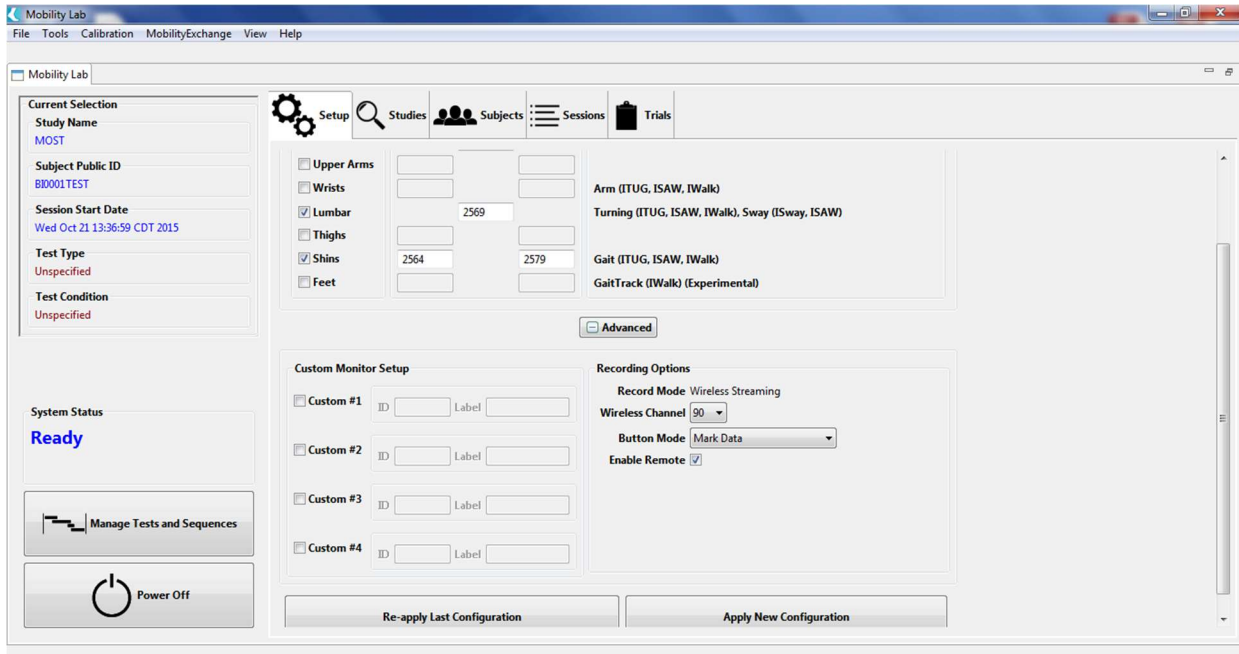
### **4. Administration**

**IMPORTANT:** Study the **Opal Mobility Lab User's Guide** to become familiar with all aspects of the Opal operation and procedure.

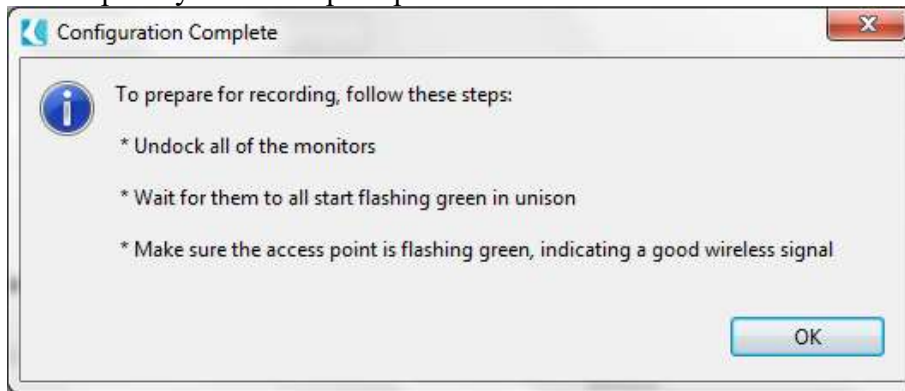
The Opal monitors will be worn by the participant during the 20-meter walk and the 6 minute walk.

#### **4.1 Equipment preparation**

1. The hardware should be set up as described in Section 4.1 of the User's Guide.
2. Plug the Wireless Access Control Point into the computer. Plug in the USB receiver for the handheld remote.
3. Connect the 3 monitors to be used in the walking test to the docking station. The docking station power adapter must be connected to a wall plug when more than one monitor is docked. The light on the monitor should turn dark blue when connected.
4. Start the Mobility Lab software.
5. Open "Set-Up" in the tab bar.
6. Configure the monitors for data collection
  - a. Specify body sites (Lumbar, Right Shin, Left Shin) and the ID of the monitor you will place in each location. (**IMPORTANT:** Always use the same monitor, labeled "B" - Lumbar, "R" – Right Shin, and "L" – Left Shin, for each of the 3 body sites to avoid error.)
  - b. Under "Advanced" configuration (See User's Guide Section 4.3), Record mode should be set to "wireless streaming", Wireless Channel to "90" at UAB and "20" at UI, Button Mode at "Mark Data" and Enable Remote to "checked".
  - c. If you get an error indicating that the wrong monitors are docked, make sure the monitor IDs that are entered in the left column match those that are etched onto the back of the monitor cases.
  - d. The screen should look something like this:



- e. Once you are done choosing your configuration options, click the “Apply New Configuration” button in the Configuration panel at the bottom of the screen. This will create a new configuration and save it for future use.
- f. The configuration of the Opal sensors is saved from the last time they were used (wireless channel, sensor numbers, etc.), but it is necessary to run through the configuration at the beginning of each subject because in addition to setting the mode, etc., this synchronizes the sensors.
- g. At this point you will be prompted to undock the monitors:



Click OK.

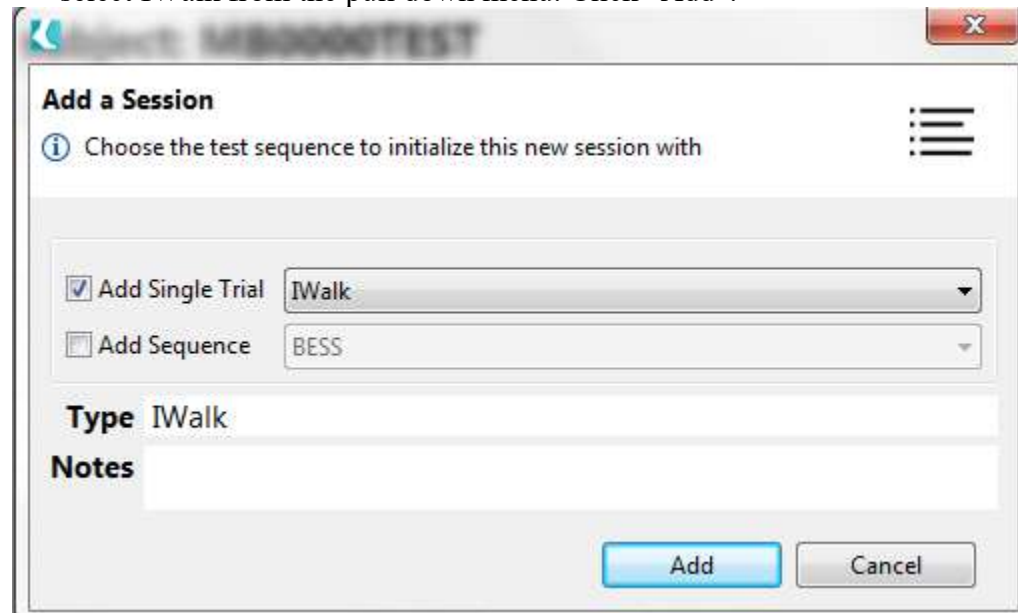
- h. The system status panel on the left of the screen should indicate “Ready”

IMPORTANT: Once the monitors start flashing green in unison and the access point is flashing green, the monitors are synchronized and there is a good wireless signal.”

7. Click the "Studies" tab in the tab bar. Select study name: MOST. [See User's Guide Section 5.1 on creating the MOST study name]

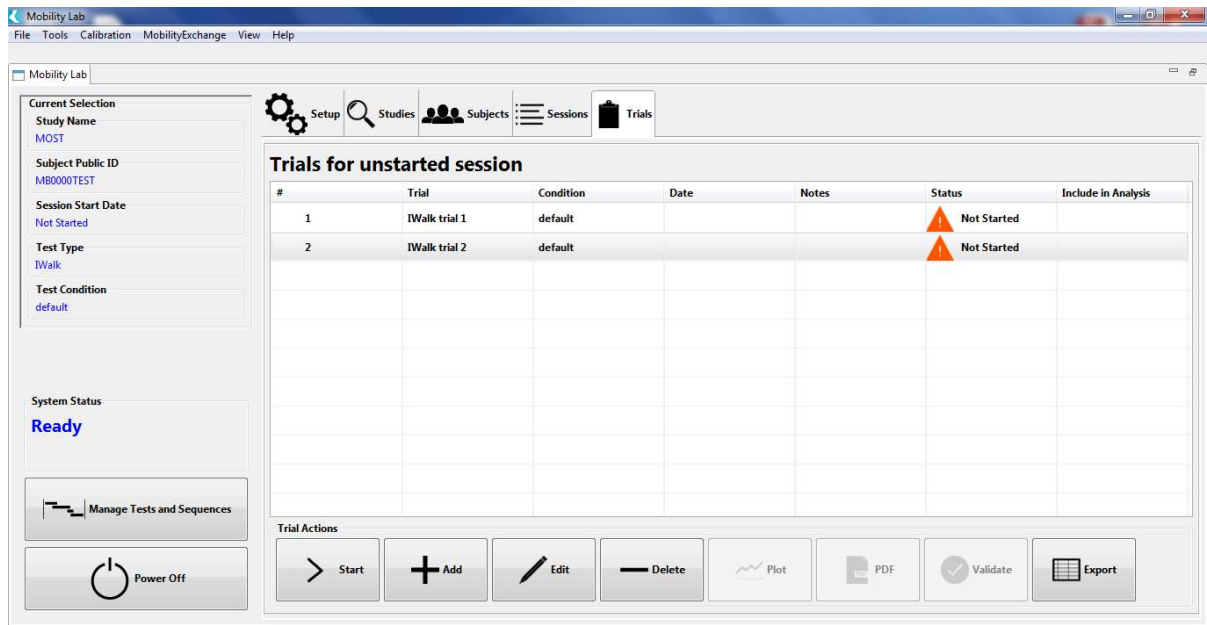


8. Open the "Subjects" tab.
  - a. Click on the “Add” button to add a new participant. Enter the MOST Participant ID and Acrostic in the “Public ID” column. [See User's Guide Section 5.2]
  - b. NOTE: the participant’s height (cm) does NOT need to be entered into the software. The Coordinating Center will send participants’ height data to the reading center at a later date.
9. Open the "Sessions" tab. [See User's Guide Section 5.3]
  - a. Click on the “Add” button to add a new session and select a single trial and select IWalk from the pull down menu. Click “Add”.



10. Open the "Trials" tab. [See User's Guide Section 5.4]
  - a. “IWalk Trial 1” will automatically appear in the first row of the Trials window. Add a note for Trial 1 that this is the “20m” trial.

- b. Click “+Add” to add an IWalk Trial 2, and in the Notes section enter “6min” walk” and click “Add”. You will then see a screen similar to this:



- c. Select “IWalk trial 1” which should have “20m” in the “Notes” column and “Not Started” in the Status column.

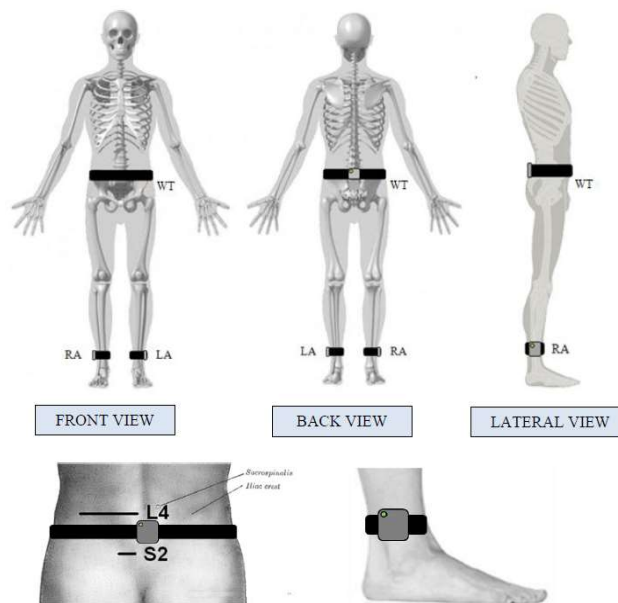
You are now ready to attach monitors to the participant.

#### 4.2 Attach monitors to the participant

1. Before placing the monitors on the participant, check to make sure that:
  - a. The “System Status” indicator on the left panel in Mobility Lab says “Ready”
  - b. The LED on the access point is blinking **green**, indicating a good wireless signal.
  - c. The LEDs on the monitors are all blinking **green** in unison, indicating that they are synchronized.
2. Insert the monitors into the holders.
3. The USB ports should be pointing down. The flashing green LED will be at the top left corner of the monitor and should be visible on the side of the monitor away from the body.



4. Attach the monitors to the participant in the configuration shown below, being careful to use the correct monitor for each location. The ankle monitor should be on the sides of the ankle, as shown.
  - a. The ankle monitors should be placed underneath any clothing.
  - b. The belt can be worn over clothing, but as little clothing as possible.

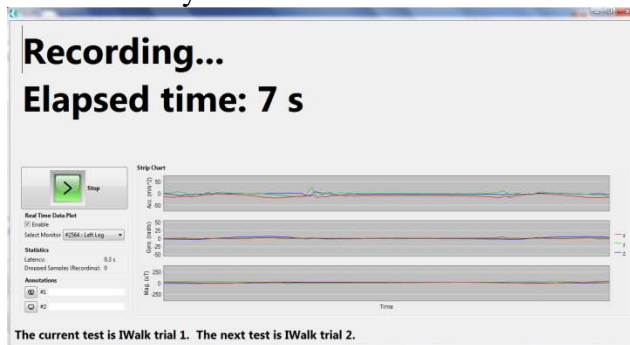


### 4.3 Starting and stopping the 20-meter walk trials

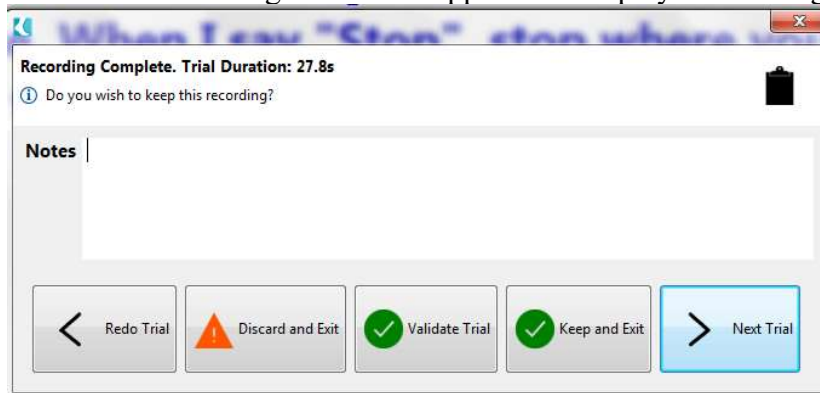
1. When the monitors are properly attached, ask the participant to walk over to the starting point for the 20-meter walk.
2. Select “IWalk Trial 1”. The current selection is displayed in the upper left panel. By default, the first incomplete trial from the first subject in the first study is selected.



3. Make sure the Enable Remote option is checked, enter "1" into the #1 textbox, and enter "2" into the #2 textbox.
4. Give the instruction for the 20-meter walk. (See Section 9.2 of this manual)
5. When the participant is ready to start the 20-meter walk, using the remote click on "Record". The "Recording" dialogue box will appear and the monitors will start recording data in about 5 seconds.
6. After a 5 second pause, start the 20-meter walk. Verify from the recording dialog box window that data are being collected by all three monitors, then follow the participant down the hallway.



7. When both trials of the 20-meter walk are complete, press the green Stop button on the remote.
8. The confirmation dialogue box will appear and display "Recording Complete."



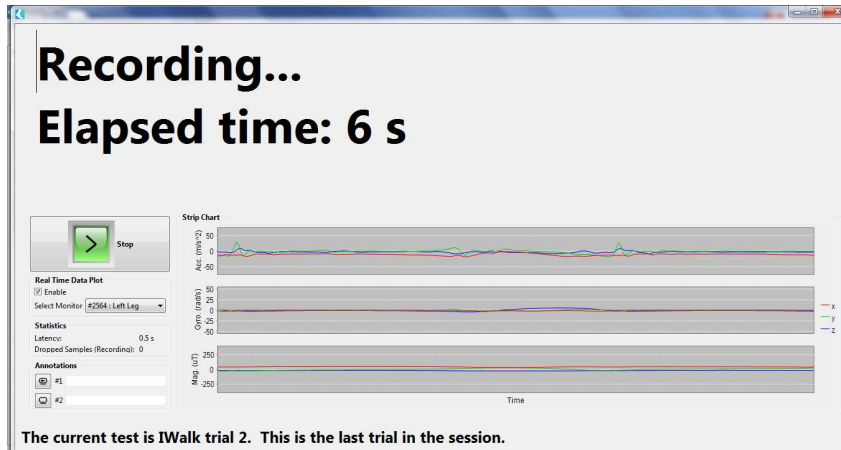
9. Record any notes that would indicate why a test may be **invalid**.
10. NOTE: you can validate the 20-meter walk trial now, or validate both the 20-meter and 6-minute walk trials at the end of the 6-minute walk.

11. If you choose to validate the 20-meter trial now, click on the "Validate Trial" button, then exit the dialog box by selecting 'Keep and Exit' back to the main screen to verify that it validated. [See User's Guide Section 9 for details] If you choose to validate at the end of the walks, use the remote to select the 'Next Trial' button to begin the 6-minute walk.
12. If the trial is **invalid**, an Invalid Trial dialogue box will appear. If possible, repeat one trial of the 20-meter walks, following the instructions above for OPAL data collection.
13. If the trial is **valid**, select the "IWalk trial 2" and click on "Start" in the confirmation dialogue box.

You are now ready to start the 6 minute walk.

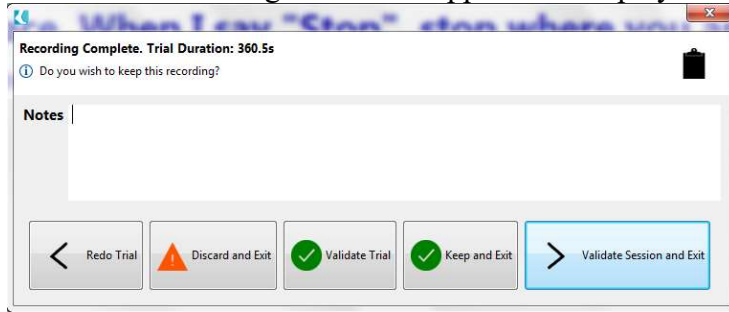
#### 4.4 Starting and stopping the 6-minute walk trial

1. If you validated the 20-meter walk, return to the "Trials" tab and manually start "IWalk Trial 2."
2. If you plan to validate the 20-meter and 6-minute walks at the end of the 6-minute walk, use the remote to automatically move to "IWalk Trial 2."
3. Begin the instructions for the 6-minute walk. (See Section 10.2 of the Operations Manual)
4. When the subject is ready to start the walk, be sure that "Recording" dialogue box is open to "IWalk Trial 2". Using the remote click on "Record". The monitors will start recording data in about 5 seconds.

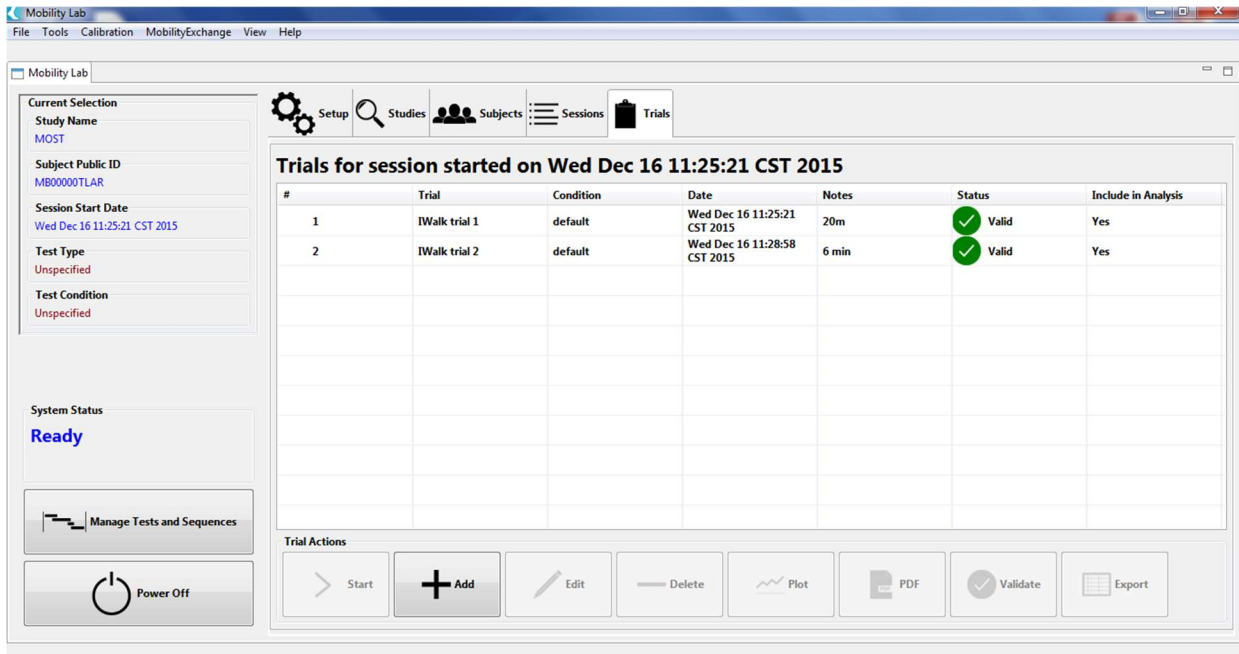


5. After a 5 second pause, start the 6-minute walk. Verify from the recording dialog box window that data are being collected by all three monitors.

6. During the 6-minute walk, periodically check the Recording dialogue box on the computer to verify that it is collecting data.
7. When 6-minute walk is complete, with the Recording dialogue box open, using the remote click on the green "Stop" button to end the data collection.
8. The confirmation dialogue box will appear and display "Recording Complete"

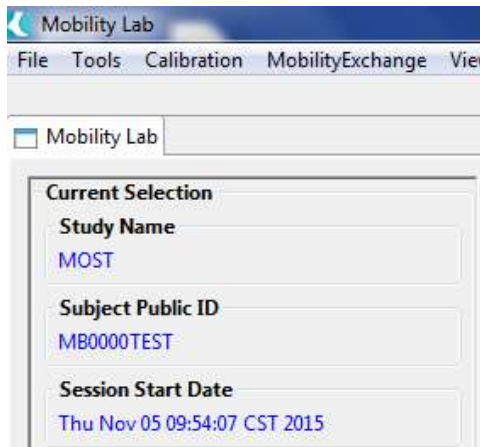


9. Record any notes that would indicate why a test may be **invalid**.
10. Click on the "Validate Trial" button.
11. If the trial is **invalid**, an Invalid Trial dialogue box will appear. Confirm the system defaults to "Include in Analysis" so that the invalid trial data for the 6-minute walk is saved.
12. If the trial is **valid**, click on "Keep and Exit" in the confirmation dialogue box.
13. If the 20-meter walk has not been validated yet, click "Validate Trial" for the 20-meter walk trial. You should now see a screen similar to the one below, and in this example both trials were recorded as valid.

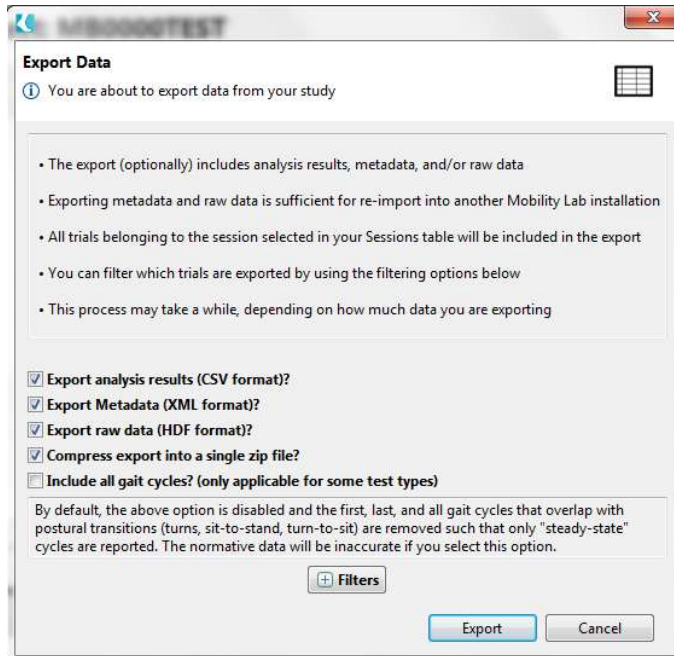


#### 4.5 Exporting the session data for the participant

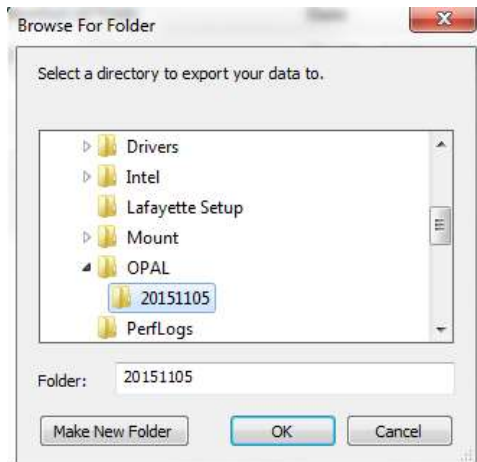
1. Select the “Sessions” tab and highlight the session that you just completed. Ensure that the correct Participant information appears in the “Current Selection” box at the top left of the program window.



2. Click the “Export” button in the bottom right of the program window and an “Export Data” dialog box will appear.
3. Ensure that all the check boxes are checked EXCEPT the last one (see below) and then click “Export”.

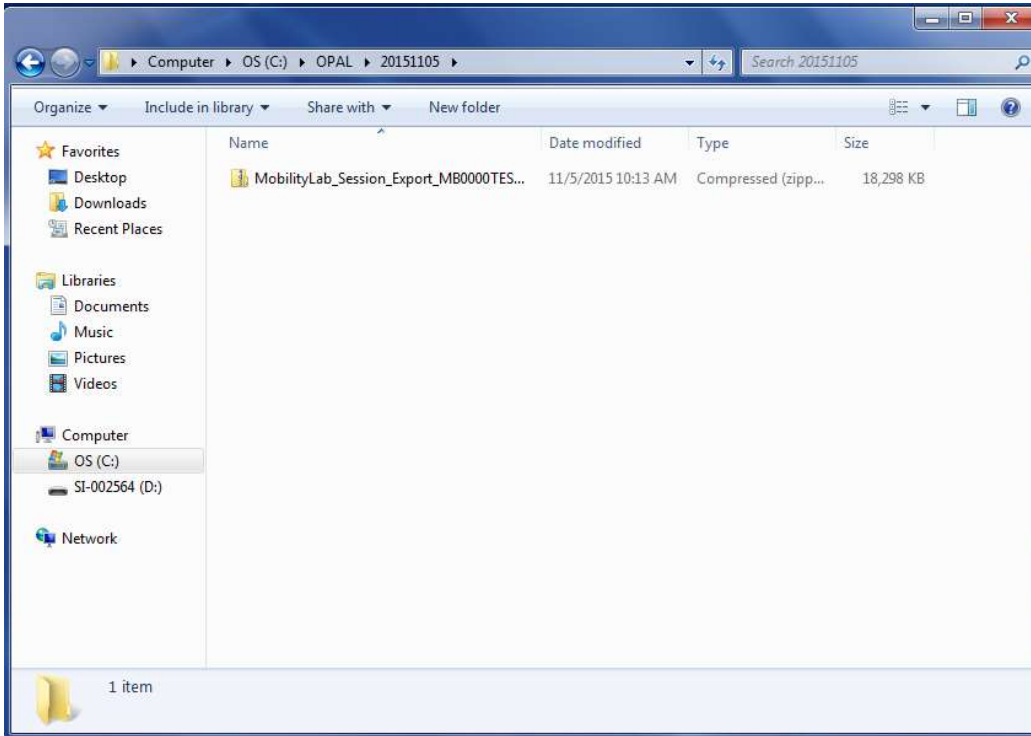


4. Choose the folder C:\OPAL\YYYYMMDD (where YYYYMMDD is the date of the Monday of this week) and this example would be for the first week of November 2015. If the folder does not exist, right-click on the C:\OPAL folder and chose "New->Folder" from the menu and enter YYYYMMDD as defined above for the folder name.



You can now exit the software or click on the "Subjects" tab to enter a new participant's data and start a new session.

To ensure that a participant's data is saved in the correct folder, in Windows 7, navigate to the folder you used in step (d) and double check a .zip file named after the correct participant exists, and in this example, you can see that a file for MB00000 TEST was created on 11/5/2015.



#### **4.6 Secure Data Transfers to UCSF**

At the end of the day where any sessions have been recorded the operator will need to check that the computer is left switched on and that files have synchronized to the UCSF ftp server. This is done by clicking on an icon in the bottom right of the screen. See Section 4 of the MOST Secure Data Transfer Operations Manual.

#### Appendix 4 Using the Logitech remote

When using the Logitech remote, please make sure the USB dongle is connected and the remote is turned on.

Pressing the start button will start the trial recording. Pressing the button again will end it. During the trial pressing on Annotation key #1 or key #2 will mark an event in the opal's annotation field.

It is important to stay at the range of the remote while pressing the annotation keys. In order to test the range it is possible for example to open a PowerPoint file and use the arrow buttons of the remote to change pages in the presentation.

