

Chapter 39. Six Minute Walk Test (6MWT)

39.1 Introduction

This MOP chapter is designed to guide the performance of the 6-minute walk test (6MWT) using standardized procedures and techniques in order to provide accurate test results in a safe testing environment for participants enrolled in the PVDOMICS study. The 6MWT is a practical simple test to perform that does not require exercise equipment. The 6MWT measures the distance that a participant can walk quickly on a flat hard surface in a period of 6 minutes (the 6MWD).

The 6MWT evaluates the global and integrated responses of all body systems involved during exercise. It does not provide specific information on the function of each of the different organs and systems involved as is possible with the cardiopulmonary exercise test. Most participants do not achieve maximal exercise capacity during the 6MWT, and instead, choose their own level of intensity.

The primary measurement of the procedure is distance walked in 6 minutes. Use of supplemental oxygen is documented and heart rate and oxygen saturation by pulse oximetry (SpO2) is recorded and may be useful information. No attempt is to be made during the test to determine the optimal level of supplemental oxygen with exertion; rather, supplemental oxygen is used to insure adequate oxygenation during the procedure. Changes in 6MWT distance are a standard accepted measure of function and/or drug efficacy in pulmonary arterial hypertension.

Only one 6-minute walk test is performed for the PVDOMICS Study. No historical data is accepted. Participants will have only one attempt to complete the test. If the participant is unable to complete the test, record available information on Form 133-6MWT and enter the data into the database.

On 06/18/2018, the DCC provided each center with one Masimo oximeter, lanyard, and forehead probe that must be used prospectively. Each clinical center is responsible for replacing any lost and/or damaged piece(s) of equipment. Clinical centers may opt to purchase an additional set of equipment. Contact the Jose Ramos at the PFT Core (pvd-lungcore@bio.ri.ccf.org) for supplier contact information.

39.1 Technologist/Coordinator Training and Experience

It is not mandatory for the person conducting the 6MWT for the PVDOMICS Study to be a pulmonary function technologist (see also section 39.3.1). In some cases, it may be the study coordinator. Regardless, the individual who conducts the 6MWTs will be trained using this standard protocol, and should be supervised for several tests before performing them alone.

39.2 Participant Preparation

Table 1: Pre-Test Instructions	
•	Wear loose-fitting, comfortable clothing and shoes suitable for exercise
•	Participant should use their usual walking aid(s) during the test (cane, walker, rollator etc.)
•	A light meal is acceptable before early morning or early afternoon tests.
•	Medication holds are not specifically required for 6MWT

The participant should rest ten minutes prior to start of test and have not done vigorous exercise within 2 hours prior to test. It is recommended that 6MWT be performed BEFORE CPET.

39.3 Contraindications and Safety

Table 2: Contraindications for Performing the Test	
Absolute contraindications	Unstable angina in the previous month
	Myocardial infarction in the previous month
Relative contraindications	Severe untreated arterial hypertension at rest (180 mmHg systolic, 100 mmHg diastolic)
	Resting pulse rate > 120/minute
	See below for SpO2 requirements (pre-test procedure -Section 39.4)

1. Stable exertional angina is not an absolute contraindication for the 6MWT, but participants with this disorder should perform the test with their anti-angina medication at the ready.
2. Medications to treat asthma and angina will be available, including supplemental O₂ and albuterol (metered dose inhaler or solution for nebulizer). Sublingual nitroglycerin should be available. A telephone or other means will be readily available to enable a call for help, and the medical director of the PFT laboratory will establish the appropriate location for the crash cart.

Table 3 Reasons for Immediately Stopping the Test - Do Not Restart
Chest pain
Intolerable dyspnea
Leg cramps, staggering
Diaphoresis, pale or ashen appearance
Near syncope, syncope, dizziness, light-headedness or feeling faint
Oxygen saturation drops $\leq 80\%$ while walking

If a test is stopped for any of the reasons listed above, the participant should sit or lie supine as appropriate. The following should be obtained based on the judgment of the assessor: blood pressure, pulse rate, SpO₂ and a physician evaluation. Oxygen should be administered as appropriate.

**DO NOT RESTART THE TEST IF IT IS STOPPED
FOR ANY REASON NOTED IN TABLE #3.**

39.3.1 Test Supervision

- a. Physicians are not required to be present during all tests. The physician ordering the test, supervising laboratory physician or the laboratory's standard operating procedure should define whether physician attendance at a specific test is required. Call the physician PI for approval if you are unable to reach a resting pre-test O₂ saturation $\geq 92\%$, or if other contraindications are present.
- b. Technologists must be trained in at least Basic Life Support by attending an American Heart Association accredited program. Advanced cardiac life support training is desirable.
- c. The person(s) conducting the 6MWT must be trained to recognize these problems and the appropriate responses. If a test is stopped for any of the above reasons, the participant should sit or lie supine as appropriate depending on the severity of the event and the test giver's assessment of the severity of the event. Activation of the institution's emergency response system may be required. The following should be obtained based on the judgment of the test giver: blood pressure, pulse rate, and a physician evaluation. Oxygen should be administered as appropriate.
- d. Pulse oximetry **should be monitored continuously** during the walk.

39.4 6MWT Testing Procedures

Pre-Test Procedure	
Appropriate order	Check for a complete physician's order
Demographics	Identify the participant using two separate identifiers and record demographic information
Discuss test with participant	Briefly explain the purpose of the test in a manner that is understood by the participant.
Participant preparation	Measure blood pressure.
	Check for contraindications to testing
	Have the participant stand
	Place the provided Masimo pulse oximeter probe on finger or forehead (See note 1 on page 39.4); and record resting SpO ₂ and pulse rate. Ensure participant is on Room Air for 5 min, if possible, before checking SpO ₂ . If the participant is prescribed > 4L O ₂ at rest please <u>GET APPROVAL FROM PI PRIOR TO REMOVING O₂</u> . Measure and record resting room air SpO ₂ , and record resting SpO ₂ and O ₂ delivery method/cannula type while on O ₂ (If needed) (See below regarding O ₂ use during walk).
	Explain and record the Borg scale: see Appendix 1
	The technologist should be trained in pulse oximetry applications, quality assurance and limitations.

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If supplemental oxygen is to be used, ensure that the participant is familiar with pulling an E cylinder trolley (rather than pushing it). An alternative method that may be used is to adapt a rollator to accommodate an oxygen cylinder trolley, in which case it can be pushed like a walker. The participant should not carry their oxygen. **Please convert participant from their own oxygen system to an E cylinder** to be pulled or pushed using a rollator. Oxygen should be administered as a continuous flow, as opposed to “on demand (pulse)”. The test administrator should not pull the oxygen cylinder for the participant.

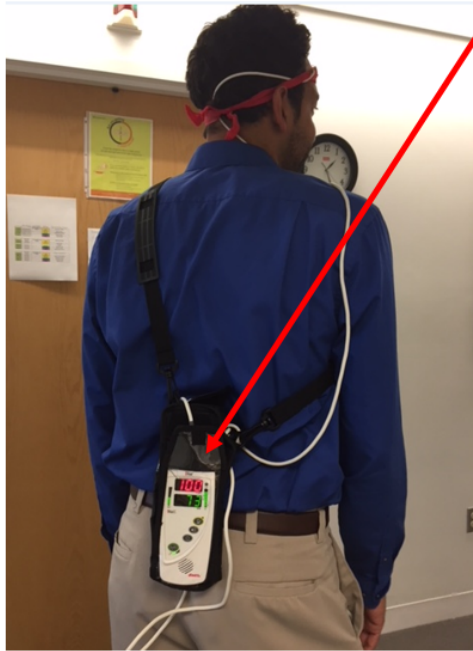
IF THE ROOM AIR REST PRE-TEST O₂ SATURATION IS $\leq 88\%$, THEN TITRATE THE O₂ SATURATION TO $\geq 92\%$ BEFORE WALKING THE PARTICIPANT (SEE NOTE BELOW). IF ROOM AIR REST O₂ SATURATION IS $\geq 89\%$, THEN WALK PARTICIPANT ON CURRENT O₂ REQUIREMENT (PRESCRIBED OR USED DURING PRIOR 6MWT).

Record baseline heart rate and SpO₂ at rest after 5 minutes or when the SpO₂ has been stable for 2 minutes, whichever comes first. Record the oxygen device, liter flow and the use of a walking aid.

Note 1: Use the provided Masimo oximeter and strap (lanyard) in all participants. In participants with peripheral vascular compromise including Scleroderma, Raynaud’s, etc., use the provided forehead probe and secure the probe with self-adhesive gauze (e.g., Coban) or headband (not provided by DCC). It is recommended that the device be positioned in such a manner that the participant cannot read the O₂ saturation and heart rate values (i.e., hip or back) **(SEE PAGE 39.5)**. The device should be positioned in such a manner that the technician can read the O₂ saturation continuously at a minimum of two times for each lap **(SEE PAGE 39.5)**.

Unless participant is staggering or a fall risk, the technician SHOULD NOT walk with the participant. Participants with congenital PH and associated hypoxemia can perform 6MWT if pre-test O₂ saturation is $\leq 89\%$ and test may continue if SpO₂ falls to $\leq 80\%$, at the discretion of the physician PI. If the participant has congenital PH and associated hypoxemia, and if unable to titrate up SpO₂ to $\geq 92\%$, it is recommended to perform 6MWT on O₂ level that has been prescribed or used on previous 6MWT. There is no upper limit of O₂ administration mandated for the 6MWT. If any concern arises in the pre-test 6MWT period, contact PI.

Placement of Masimo Oximeter and Strap (lanyard)



Positioning of the Masimo forehead probe and lanyard

1. The lanyard should be placed across the patient's body with the oximeter readout on the back of the patient which will remove it from their view.
2. The cord coming from the oximeter to patient's forehead should be clipped to the patient's shirt/blouse (as shown Pic. 2) to avoid the cord from dragging or becoming a tripping hazard.
3. The cord should run behind the patient's ear and should be positioned between the hairline and the eyebrow (may have to slightly move to improve signal strength).



6MWT Protocol continues on next page

6MWT Procedure	
Before Starting	Complete the first part of the worksheet/report
	Set the lap counter to zero and timer to 6 minutes
	Take the participant to the starting point of the walk. This may be the end of the walk track or it may be a point in the hallway marked with the distance to the end of the hallway the participant will be walking toward when the test starts. If the latter is the case, record that distance (starting residual).
	Make sure that the oxygen probe (finger or forehead) is giving a steady pulse oximetry reading and that the participant cannot see the O2 saturation/heart rate values.
	Instruct the participant by reading the instructions as follows (hearing impaired participants may benefit from written as well as verbal instructions): <i>“The object of this test is to walk as far as possible for 6 minutes. You will walk back and forth in this hallway between the markers, as many times as you can in 6 minutes.</i> <i>I will let you know as each minute goes past, and then at 6 minutes I will ask you to stop where you are.</i> <i>Six minutes is a long time to walk, so you will be exerting yourself. You are permitted to slow down, to stop, and to rest as necessary. You may lean against the wall while resting, but please resume walking as soon as you are able.</i> <i>Remember that the objective is to walk AS FAR AS POSSIBLE for 6 minutes, but don’t run or jog.</i> <i>Do you have any questions?”</i> If the participant is unfamiliar with the test, it is a good idea to demonstrate how you would like the participant to walk around the cones/markers as it is important that they do not cut the lap distance short by turning before or at the markers.
	While standing at the starting point, tell the participant: <i>“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, but don’t run or jog. When the 6 minutes are up I will tell you to stop. I want you to stop right where you are and I will come to you. Start now, or whenever you are ready.”</i>
Testing	Position the participant at the starting point.

	As soon as the participant starts to walk, start the timer. Do not walk with the participant. Pulse oximetry should be measured continuously.
	During the walk, do not talk to anyone else except the participant. Use an even tone of voice when using the standard phrases of encouragement. Watch the participant and do not get distracted. Each time the participant returns to the starting line, click the lap counter once (or mark the lap on the worksheet). Directly observe the O2 saturation/heart rate value twice per lap. IMMEDIATELY STOP THE TEST IF O2 SATURATION FALLS TO $\leq 80\%$.
	Standard phrases of encouragement: After the first minute, tell the participant: <i>“One minute has passed. You have 5 minutes to go”</i> When the timer shows 4 minutes remaining, tell the participant: <i>“Two minutes have passed. You have four minutes to go.”</i> When the timer shows 3 minutes remaining, tell the participant: <i>“Three minutes have passed. You are halfway done.”</i> When the timer shows 2 minutes remaining, tell the participant: <i>“Four minutes have passed. You have only 2 minutes left.”</i> When the timer shows only 1 minute remaining, tell the participant: <i>“Five minutes have passed. You have only 1 minute to go.”</i> When the timer is 15 seconds from completion, say: <i>“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.”</i>
	Walk the participant (if able) to the room where you started. When the participant sits down start the elapsed timer.
	Take a post-walk blood pressure, but be sure to notice the HR shown on the oximeter when the elapsed timer indicates the first minute has passed. Record the post-walk heart rate.
	Record the post-walk dyspnea score using the Borg scale. See Appendix 1
	During post walk recovery, record the heart rates and SpO2 at 1 and 2 minutes.
	Record the number of laps from the counter (or tick marks on the worksheet) and the additional distance covered (the number of feet in the first (if walk was started from any point on the 6m walk track other than the starting point) and final partial lap) using incremental markers on the wall or floor as distance guides.
	Calculate and record the total distance walked.
	Congratulate the participant on good effort, and offer a drink of water.

	Note: If the participant stops during the test, and needs to rest, say, “You can 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, or if O₂ SATURATION $\leq$ 80%, take a chair over the participant to sit on, discontinue the walk, and note on the worksheet the distance, the time stopped, and reason for stopping prematurely.
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39.5 Procedure Notes

1. Sources of variability

There are many sources of variability in this test including height, age, weight, disease, and musculoskeletal disorders. Procedural sources of variability will be controlled as much as possible.

2. Practice walks

Practice walks are not utilized for PVDOMICS. The technician can demonstrate if required.

3. Instructions and encouragement

The script provided in this document will be used to explain the test and instruct the participant. Standardized phrases of encouragement will be limited to declaring the elapsed time and the time remaining each minute during the test.

4. Supplemental O₂

See above section 39.4 for guidelines of oxygen administration. The type of O₂ delivery device/cannula will also be noted on the report. The participant should be transitioned to an E cylinder from their own oxygen system.

39.6 Equipment, Supplies and Location:

The 6MWT will be performed indoors, along a flat, long, straight, corridor with a hard surface with little traffic. Ideally, the walking course should be approximately 30 meters (100 feet) in length. Track lengths as low as 50 feet have been found to be acceptable.

The course will be marked with visible markers (e.g., traffic cones or marks on the floor). A starting line, which marks the beginning and end of each lap, will be marked on the floor. Incremental markers of distance on the floor or wall (e.g., every 10 feet) help to measure the distance walked. Record length of track utilized for testing.

The following equipment is used for the 6MWT:

1. Stopwatch
2. Mechanical counter or other method to count laps
3. Markers to identify the course
4. Borg Dyspnea Scale (appended to end of Form 133-6MWT)
5. Chair or wheelchair
6. Form 133-6MWT data form on a clipboard
7. Masimo pulse oximeter, lanyard and forehead probe (one set provided by DCC)
8. Self-adhesive gauze (e.g., Coban) or headband (not provided by DCC)
9. Sphygmomanometer and appropriate sized cuffs

- 10. Access to an automatic electronic defibrillator
- 11. Telephone

39.7 Test Data Reporting

Test results will be recorded on Form 133-6 Minute Walk and entered into the DCC database. The following items should be recorded on Form 133.

- PVDOMICS Study ID, alpha code and date of test
- Resting variables
- Blood pressure, heart rate, Borg scale, and room air SpO₂, Oximeter probe site (finger, forehead)
- Exercise variables
 - o Total distance walked
 - o Oxygen usage if applicable
 - Liter flow (continuous or pulsed)
 - Delivery device (nasal cannula, other)
 - Mode of transport (pulled tank or pushed tank using rollator)
 - o Borg Dyspnea scale obtained immediately after walk
 - o Reason for early termination, if applicable.
 - o Cumulative time spent resting (breaks during walk), in seconds.
 - o Heart rate and SpO₂ obtained at 1 and 2 minutes after termination of the walk. Timer to begin when the participant is seated in a chair after the walk is terminated.

39.8 Reference:

1. Task Force Report, ATS/ERS Technical Standard. An official European Respiratory Society/American Thoracic Society. Technical standard: field walking tests in chronic respiratory disease. Eur Respir J 2014; 44: 1428-1446.

Appendix 39.1 Modified Borg Rating Scale for Perceived Dyspnea

0	Nothing at all
0.5	Very, very slight shortness of breath
1	Very mild shortness of breath
2	Mild shortness of breath
3	Moderate shortness of breath or breathing difficulty
4	Somewhat severe
5	Strong or hard breathing
6	-
7	Severe shortness of breath or very hard breathing
8	-
9	Extremely severe
10	Shortness of breath so severe you need to stop

MOP Chapter 39: PVDOMICS Six Minute Walk (6MWT)

Summary Sheet for Recent Changes to MOP Chapter 39 and Form 133-6MWT

1. Has the participant avoided rigorous exercise for 2 hours? (non-invasive CPET should be done afterwards if scheduled for the same day). If yes, reschedule the test.
2. Ensure that participant is not wheelchair bound, no medical conditions restricts walking, and is safe to perform six minute walk.
3. Is the participant using 4 liters or more of oxygen at rest? If so, ask supervising provider if the participant is safe to do a room air saturation. If not, then mark under Q4 on Form 133 PI feels performing 6MWT would jeopardize safety and do not perform 6MWT.
4. Start 10 minute rest period (if using oxygen, remove oxygen after 5 minutes-need oxygen off for 5 minutes to do room air saturation).
5. Check blood pressure, Borg dyspnea score and check room air saturation after ten minutes of rest. Make sure to mark the type of oximeter used (finger, ear or forehead). If any circulatory disorders (i.e. scleroderma) a forehead or ear probe must be used.
6. Pre-test oxygen saturation: To be performed during 10 min pre-test rest period
 - a. If oxygen saturation on room air or home O2 flow is 88% or less at rest, then add additional supplemental O2 to achieve a resting O2 saturation of 92% or greater (unless participant has congenital heart disease), then proceed with 6MWT as per MOP Chap 39.
 - b. If room air oxygen saturation is 89% or greater at rest, than perform 6MWT on room air or home O2 flow rate as prescribed, or O2 flow level as administered on prior 6MWT.
 - c. If unable to achieve a resting O2 saturation of 89% or greater with supplemental oxygen then contact physician provider for approval to perform 6MWT safely.
 - d. After making change in O2 administration wait for a minimum of 2 minutes after change to ensure O2 saturation is stabilized.
7. Record baseline Pre-test SpO2 Q12 on Form 133 (this is completed only if your participant is using oxygen for the 6MWT).
8. If using oxygen, you must convert participant to an E cylinder that can be pushed or pulled using a rollator.
9. **A continuous pulse oximetry reading is needed for all 6 MWT.** The pulse ox used should be less than 2 lbs in weight and transported by the participant using a lanyard, fanny pack or other carrying device. The participant should not be able to see the pulse ox readings. The person administering the 6WMT should be able to see the readings easily. Again, if the participant has circulatory issues a forehead or ear probe must be used.
10. Proceed with the test as per MOP Chapter 39. If the participant has chest pain, intolerable dyspnea, leg cramps, diaphoresis, is ashen, near syncope, syncope, falls or oxygen saturation drops to 80% or below, **STOP THE WALK IMMEDIATELY.** The supervising physician should be notified and emergency care provided as directed. Record the reason for test termination on Q22 on Form 133.