



Manual 32
Physical Function and Endurance Procedures
ARIC Visit 10

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Physical Function and Endurance Procedures

Table of Contents

1	<u>PHYSICAL FUNCTION, ENDURANCE, WEIGHT LOSS, AND ZENO GAIT MAT</u>	3
1.1	<u>Overview</u>	3
1.2	<u>Administration of SPPB and Gait mat</u>	4
2	<u>PHYSICAL FUNCTION (PFX FORM)</u>	7
2.1	<u>Short Physical Performance Battery (SPPB)</u>	7
2.2	<u>Administration of the SPPB Single Chair Stand</u>	9
2.3	<u>Administration of the SPPB Repeated Chair Stands</u>	10
2.4	<u>Administration of the SPPB Standing Balance</u>	11
2.5	<u>Administration of Usual Walk (PFX and ZGM)</u>	14
2.6	<u>Training and Certification for SPPB</u>	18
2.7	<u>Grip strength</u>	20
2.8	<u>Training and Certification for Grip Strength Assessment</u>	23
2.9	<u>Physical Function Results</u>	24
3	<u>THE ZENO GAIT MAT</u>	25
3.1	<u>Administration of Gait Mat Tests</u>	25
3.2	<u>Report Generation</u>	32
3.3	<u>Processing, Analyzing and Exporting</u>	34
4	<u>ZENO GAIT MAT (ZGM FORM)</u>	48
4.1	<u>Administration of Quiet Standing and Limits of Stability</u>	48
4.2	<u>Administration of Usual Pace walk ON THE MAT</u>	49
4.3	<u>Administration of Single Cognitive Task</u>	51
4.4	<u>Administration of Dual Task</u>	52
4.5	<u>Administration of Short Fast Pace Walk</u>	53
4.6	<u>Training</u>	54
4.7	<u>Quality Control and Video Uploads</u>	55
5	<u>TWO MINUTE WALK (TME AND TMW FORM)</u>	58
5.1	<u>Administration of the TMW</u>	58
5.2	<u>Safety Issues and Exclusions</u>	60
5.3	<u>Assessment of test eligibility and exclusion criteria</u>	61
5.4	<u>Training and Certification for the TMW</u>	64
5.5	<u>Quality Control</u>	65
5.6	<u>Quality Assurance/Certification Checklist</u>	65
6	<u>REFERENCES</u>	69

1 PHYSICAL FUNCTION, ENDURANCE, WEIGHT LOSS, AND ZENO GAIT MAT

1.1 OVERVIEW

This abbreviated objective measure of physical function is based on previous epidemiologic studies of aging, such as the Established Populations for Epidemiologic Studies of the Elderly (EPESE), Framingham Heart Study, the Cardiovascular Health Study, Women's Health and Aging Study, Health ABC, and the Baltimore Longitudinal Study of Aging, that incorporated physical function assessments. The original core battery described below includes grip strength and the Short Physical Performance Battery (SPPB) which consists of chair stands, a usual-paced 4-meter walk, and balance tests. Endurance was added at Visit 6 along with questions about weight loss. At Visit 8, the Zeno Gait Mat was implemented for participants at in-person study visits. As with earlier visits, prior to SPPB training, all examiners should review this manual and the QxQ and complete the online training module for the National Institute on Aging SPPB (see Section 2.6 for more information).

Existing studies have established bi-directional relationships between mobility and cognitive function,¹⁻⁶ especially executive function⁷⁻¹⁴ and processing speed.^{13,15} Some studies have shown that cognitive impairments precede mobility decline,^{1,2} while others have demonstrated that impaired mobility precedes cognitive decline in older adults.^{3,5} A meta-analysis review supports the hypothesis that gait speed changes likely precede cognitive changes and incident dementia, particularly for non-Alzheimer dementia.⁽⁴⁾ In addition, even subtle changes in gait that are not visible to the eye are predictive of important clinical outcomes including mild cognitive impairment, dementia and falls.¹⁶⁻¹⁸ Performance on dual tasks (concurrent physical and cognitive tasks such as walking while performing calculations) may be particularly sensitive to incident cognitive changes.¹⁹ To date, however, the relationship of cognition with mobility is poorly understood.

ARIC and other studies have reported associations between cardiovascular risk factors and brain structural abnormalities that are also linked to cognitive and physical decline (i.e. functional decline). These risk factors are also associated with reduced cardiovascular fitness or endurance. In turn, endurance has been associated with brain structure and cognition in a small study.²⁰ Cardiovascular endurance may suffer substantial decline prior to the development of recognizable cognitive- or mobility-related difficulty, particularly in sedentary or cognitively impaired individuals, and may be an early indicator of impending functional limitation. The assessment of endurance in the ARIC cohort was added at Visit 6 to elucidate temporal relations of mid-life cognitive change to late-life endurance and provide an opportunity to examine relations of late-life cardiovascular endurance with late-life cognitive outcomes in the ARIC-NCS cohort.

Although maximum treadmill-based testing with measured oxygen consumption is considered the "gold-standard" method for ascertaining endurance and cardiovascular fitness, this

approach may be unsuitable for many older adults. With increasing age, the proportion of even apparently healthy ambulatory older persons who can satisfactorily complete a treadmill exercise test decreases markedly, from 30% in those aged 75 to 79 years, to 25% in persons aged 80 to 84 years, to 9% for those over 85 years.²¹ This is especially problematic in longitudinal studies of the aging process in which change in fitness and exercise capacity with age and disease progression are of great interest.

The American Thoracic Society's 6-Minute Walk Test is a widely accepted measure of submaximal level of functional capacity in clinical and research settings, but time constraints often limit its use in large studies. The Two Minute Walk is adapted from the 6-Minute Walk Test Protocol and is the recommended measure of sub-maximal cardiovascular endurance in the NIH Toolbox Endurance Domain.²² Validation and reliability studies of the Two Minute Walk have been reported in participants aged 3-85 years of age. The distances covered during the Two Minute Walk and the 6-minute walk are reliable between sessions (intraclass correlation coefficients = 0.888 and 0.917, respectively); the distances during the Two Minute Walk and 6-minute walk are highly correlated ($r=0.968$).¹⁰ The Two Minute Walk records the distance one is able to walk on a 50-foot course (out and back) in two minutes. The participant's raw score is the distance walked in two minutes, reported in feet. This score can be used as a raw measure or converted to the Toolbox normative scale scores. Studies indicate that approximately four minutes is required to complete the Two Minute Walk, including test instructions and practice.

Unintentional weight loss is an important risk factor in older adults that may be a marker of metabolic, psychiatric, neurologic, and other medical disorders, is associated with mortality, and is also considered a component in the frailty syndrome.²³ Fifteen to twenty percent of adults 65 years or older have unintentional weight loss when followed five to ten years; rates are higher in nursing home residents.²⁴ The most widely used definition of frailty defined involuntary weight loss as a loss of at least 10 pounds in the prior year or, at follow-up, of 5% of body weight in prior year by direct measurement of weight.²³ Objective measures improve classification of weight loss compared to subjective reports of weight loss and will be available in the ARIC exams. Objective assessments will be repeated using previous ARIC protocols; subjective reports will reflect methods used in the Cardiovascular Health Study.

1.2 ADMINISTRATION OF SPPB AND GAIT MAT

a. Summary of SPPB and Gait mat testing

Starting in ARIC Visit 8, the 4m usual pace walk SPPB component will be duplicate administered on the Zeno gait mat in addition to the new gait mat tests (Quiet standing, Limits of Stability, dual task, and short fast pace walks [the distance of the mat]). Chair stands, balance testing, and grip strength do not use the mat. The SPPB 4m walk will be completed off the mat

on the PFX form using a stopwatch and the usual pace walks on the ZGM form will be completed on the mat.

Table XX. Core Gait mat tests and SPPB

Test name:	Core gait mat	Off the gait mat
	Recorded on ZGM form	Recorded on PFX form
Usual pace 4-meter walk		X
Usual pace walk	X [†]	
Quiet standing and Limits of Stability	X	
Dual task walk	X	
Short fast pace walk	X	
Chair stands		X
Standing balance testing		X
Grip strength		X
Two Minute Walk (TMW)		X

b. SPPB and Gait Mat Administration Overview

Since motivation and level of understanding can have a significant impact on performance, each component of the exam should be administered strictly according to the protocol in the following sequence:

- Explain the procedure to the study participant making sure to adhere to the script.
- Demonstrate the procedure, using the script.
- Ask the participant if they have any questions.
- Re-explain the procedure briefly using the script.
- Ask the participant if they think it would be safe to perform the procedure.
- Begin timing with the stopwatch for the 4m usual pace walk with participant's first movement
- Begin all timed procedures on the mat with the words, "Ready? Go!".
- Make sure both feet are only partially on the active sensor area marked by the colored tape before beginning the walking and balance tasks on the mat. Correct foot placement on the mat is critical as reaction time can only be captured if the feet are properly placed on the sensors of the mat before beginning the walking task.
- Use the gait mat clicker on the word "go" for tests administered on the gait mat to capture participant's reaction time between "go" and when they begin the walk.

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

Demonstrate each maneuver correctly. Experience has shown that participants follow more closely what the examiner does rather than what they say. If the participant indicates they do not understand the test maneuver, demonstrate it again rather than solely relying on repeating the verbal instructions.

Limit practice trials for each test to those described in the individual measurement procedures. Allow the participant to rest between tests if out of breath or fatigued. If a test is not attempted because the participant refuses or if the test is not administered due to technical problems, staffing problems or similar unrelated issues, record "Participant refused or technical problems". If you or the participant considers the test unsafe or if they cannot physically complete the test, record "Not attempted, unable, or unsafe" on the scoring form.

Footwear: To reduce effects of different footwear on test performance, the participant should wear tennis shoes or comfortable walking shoes with minimal, blunt heels or no heels. High heels alter a participants gait and balance and pointed heels can damage the gait mat. The participant may perform the tests in non-slip socks if appropriate footwear is not available.

The chair should be placed on a non-skid surface (e.g., low pile carpeting if available) with the back of the chair against a wall for stability. There should be adequate room in front and on the sides of the chair for the examiner and participant to move freely.

c. Safety Issues and Exclusions – SPPB & Gait Mat Procedure

Safety issues and exclusions for the walking, balance, chair stands, and gait mat procedures are described here. Grip and TMW safety issues and exclusions can be found in those respective sections.

The large majority of participants should be able to attempt each performance test whether in the home or in the clinic exam. Walking aids may not be used for the chair stands, standing balance tests, or limits of stability test (Gait mat), but may be used for the timed usual pace, short fast pace, and dual task walks if participants cannot walk the distance without aids. Crutches, casts or other immobilizing devices alter the participant's usual mobility; if present, do not test the participant and note the reason test was not performed as "Other", with a text explanation in the comment field.

The decision to not assess a participant due to safety concerns can be based on the examiner's observations of the participant in the home or clinic or safety concerns expressed by the participant or proxy. However, all participants who do not have a physical function assessment should still have the PFX form completed to document the reason the test is missing. If the participant or the proxy expresses concerns about safety, the examiner should describe the test and demonstrate the test. The examiner should discuss with the participant and/or proxy their specific concerns about attempting the test, including physical problems and known disabilities.

Then the examiner should ask the participant and/or proxy if they think it would be safe to do the task. If the examiner, participant, or the proxy has concerns about safety, the task should not be done. The reason for not attempting a test should be recorded as “Not attempted” and the reason not attempted should be “Safety concerns”.

For the walking and balance tests, the examiner stands next to, and slightly behind the participant and positions his/her hands very close to either side of the participant’s trunk at the hip or waist level without touching the participant. The examiner should be ready to place both hands on the participant to stabilize them if necessary. If the participant loses balance, the examiner should catch the participant with both hands at the trunk to stabilize them. If the participant begins to fall, the examiner should reach under the participant’s shoulders from behind and slowly ease them down to the floor, rather than try to catch the participant while standing still. This strategy should protect both the participant and examiner from injury. Note that the examiner should avoid stepping on the gait mat unless necessary to stabilize a participant. No one should step on the black band along the long edge of the mat unless required for safety; this may mean that the examiner stands more behind or more to the side of the participant.

If the participant falls and is not injured, the examiner should have the participant get on their knees or on all fours, place a chair next to the participant, and have the participant support themselves on the chair as he/she helps to lift the participant under the shoulders. The examiner should not try to lift the participant from the floor by him/herself.

Additional safety information specific to the gait mat are provided in section 3.1.g

2 PHYSICAL FUNCTION (PFX FORM)

2.1 SHORT PHYSICAL PERFORMANCE BATTERY (SPPB)

A direct assessment of physical performance is standard practice in epidemiologic observational studies of health and disease. The most commonly used assessments, such as the SPPB, were initially designed to differentiate function in older adults. The SPPB is a well-known and validated lower extremity performance measure that predicts adverse outcomes including mortality, falls, nursing home placement, and incident disability in older adults.

a. Equipment: SPPB

- Digital stopwatch (repeated chair stands, standing balance, short walk tests)
- Standard chair: straight back, flat, level, firm seat; seat height 45 cm at front (single and repeated chair stands).
- Colored tape to mark walking course (see drawing included in description of walking tests). Masking tape, paper tape, or other tape that does not leave residue is recommended.
- 4-meter (13 feet, 1 ½ inch) measuring tape or lightweight pre-measured chain, rope, or measuring tool to mark the walking course. Use meters for measurement.

b. SPPB Component Overview

The SPPB includes three components described in the following sections:

1. Chair Stands
2. Standing Balance
3. Usual Pace Walk

A 4m Usual Pace walk will be done off the gait mat on the PFX form. Results for the 4-meter usual pace walk, standing balance testing, and chair stands are always recorded on the PFX form. Two additional trials of the Usual Pace Walk should be completed on the Zeno gait mat according to the instructions in Section 3 and recorded on the ZGM form, unless the gait mat is not operational or a participant refuses to use the gait mat

c. SPPB Administration Overview

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

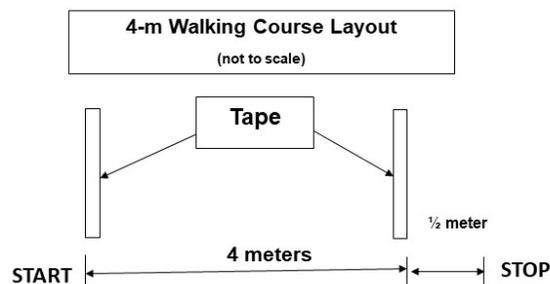
Limit practice trials for each test to those described in the individual measurement procedures. Allow the participant to rest between tests if out of breath or fatigued. If a test is not attempted because the participant refuses or if the test is not administered due to technical problems, staffing problems or similar unrelated issues, record “Participant refused or technical problems”. If the examiner, a proxy, or the participant considers the test unsafe, record “Not attempted” on the scoring form, go to the next question and record “Safety concerns”. If a test is attempted, but cannot be completed or scored, record “Attempted, unable” on the scoring form.

- The chair, described in “Equipment”, should be placed on a non-skid surface (e.g., low pile carpeting if available) with the back of the chair against a wall for stability. There should be adequate room in front and on the sides of the chair for the examiner and participant to move freely.
- The standing balance test should be performed with the participant standing a little less than an arm’s length from a wall to provide an additional source of support should loss of balance occur.
- 4-meter Walking course: The short walks at usual speed in the clinic should be conducted on a 5-meter (about 16 feet) path laid-out in an uncarpeted, unobstructed, low traffic corridor at least 122 cm (about 4 feet) wide. Five meters includes room on each end. See Figure 2a. The start and finish lines will be marked by tape on the floor. Allow an additional ½ meter on each end (or at least one end for home visit) of the walking course. For the first trial, the participant starts at one end, walks past the tape on the other end. For

Figure 2a. 4-Meter Usual Pace Clinic Walking Course



Figure 2b. 4-Meter Usual Pace Optional Home Walking Course



the second trial, the participant starts where they ended the first trial and walks back. The course for the gait mat is described in section 3.1.a.

For home visits, the course should be the same at the clinic if space allows. Low carpet, but not shag carpet, is allowed. The distance can be shortened to a 4.5-meter space (about 15 feet), allowing the participant to walk past the line of one end with the extra space (Figure 2b). For the 2nd trial, the participant would return to the same starting position as the first trial so that they have room to walk past the tape at the end of the course. Use a pre-measured lightweight chain, folding measuring stick, or other tool to measure the course.

2.2 ADMINISTRATION OF THE SPPB SINGLE CHAIR STAND (V10 CLINIC VISITS)

This test does not use the gait mat. Results are recorded on the PFX form.

This is a test of ability to stand up from a standard chair without using one's arms. This task is also used to screen for the ability to do repeated chair stands. Walking aids including canes may not be used. Although you will demonstrate the repeated chair stands, it is not necessary to demonstrate the chair stand for the single chair stand. Do, however, show the participant how to cross their arms on their chest. If participants' mobility is limited primarily to transferring from bed to chair or chair to bed, ask the participant if they think they can safely attempt the task after demonstrating the single chair stand. Examiner should stand in front of the participant for safety if the participant attempts the chair stand.

Make sure the participant's feet are squarely on the floor in front of them. The participant should be seated in a position which allows them to place their feet on the floor with knees flexed slightly more than 90 degrees so that their heels are somewhat closer to the chair than the back of their knees. Feet should remain on the floor during testing. Stand in front of the participant (with arms extended, if appropriate) for the participant's safety when performing the chair stands.

Say to the participant "This is a test of strength and stability in your legs in which you stand up from a chair without using your arms. Fold your arms across your chest, like this, and stand when I say GO, keeping your arms in this position. Any questions? Ready, Go!"

If the participant's arms unfold, or they put one or both hands down on the chair to push up, or their feet come off the floor during testing, remind them to keep their arms folded snugly across their chest with feet on the floor and ask them to repeat the chair stand. It is OK for the participant to move a little forward in the chair before standing, but knees and hips should be flexed to approximately 90 degrees before standing. If the participant cannot rise without using arms, say "OK. Try to stand up using your arms to push off."

a. Scoring the SPPB Single Chair Stand

Score as follows:

- If the participant refuses to do the test, probe for the reason to determine if the reason is due to a physical problem with weakness or balance. It is important to distinguish reasons that are related to one's ability to stand from an unrelated cause. "Participant refused or technical problems" should generally be reserved for reasons that have no

relationship to what is being measured and could be lack of interest or lack of time, for example. Technical, staffing, and environmental problems that result in a participant not being assessed are included in the category with refusals.

- If the procedure was not attempted because the participant was unable to physically perform the test, or they were considered unsafe, or for other reasons, score “Not attempted”, then go to the subquestion and record why the test was not attempted:
 - Participant unable due to weakness or balance (includes if the participant or proxy tells the examiner they are unable to stand without pushing or without assistance from a person or aid (such as a cane, lift chair or holding onto a support surface)). This response will be applicable to bedbound participants and some chair-bound participants who report only walking a few steps to transfer to another chair or bed.
 - Safety concerns (these can be concerns expressed by the participant or by the examiner). The examiner can demonstrate the single chair stand first, if safety is a concern, then ask “Do you feel safe doing this?”
 - Other problem (examples include recovering from fracture, sprains, amputation, cognitive problems)
- If the participant uses arms to stand up, score as "Rises using arms."
- If they stood up all the way without using arms, score as “Stands without using arms.” Go on to Repeated Chair Stands. Skip repeated chair stand for all other responses.

2.3 ADMINISTRATION OF THE SPPB REPEATED CHAIR STANDS (V10 CLINIC VISITS)

This test does not use the gait mat. Results are recorded on the PFX form.

Next the participant stands from a seated position five times as quickly as possible. Record the time it takes to stand five times. Say to the participant, “This time I want you to stand up five times as quickly as you can, keeping your arms folded across your chest.” With the next instructions, cross your arms over your chest and then rise while emphasizing “full standing position,” and sit while emphasizing “all the way down”: “When you stand up, come to a full standing position each time, and when you sit down, sit all the way down each time. I will demonstrate two chair stands to show you how it is done.” Count as you stand each time. Then begin the test. “When I say GO, stand five times in a row as quickly as you can without stopping. Stand up all the way and sit all the way down each time. Ready, Go!”

Start timing as soon as you say “Go.” Count: “1, 2, 3, 4, 5” as the participant straightens to standing position each time. Stop timing when the participant stands the final time.

If the participant is unable to complete the chair stands correctly (e.g., is not coming to a full stand, lifts feet off the floor), stop the procedure, repeat the demonstration, wait 1 minute, and begin the procedure again. If the participant stops before completing five stands, confirm that they cannot continue by asking: “Can you continue?” If they say yes, continue timing for up to 1 minute. Otherwise, stop the stopwatch and record the number of chair stands that were completed. If 5 stands have not been completed by 1 minute, stop the test and record “Attempted, unable to complete 5 stands” as well as the number completed.

a. Scoring the SPPB Repeated Chair Stands

If the participant refuses to do the test for non-physical reasons, score “Participant refused or technical problems.” “Participant refused or technical problems” should generally be reserved for reasons that have no relationship to what is being measured and could be lack of interest or lack of time, for example. Technical, staffing, and environmental problems that result in a participant not being assessed are included in the category with refusals. If the procedure was not attempted because the participant was unable to physically perform the test, they were considered unsafe, or for other reasons, score “Not attempted”, then go to the subquestion and record why the test was not attempted:

- Participant unable due to weakness or balance (includes if the participant or proxy tells the examiner they are unable to stand multiple times without pushing or without assistance from another person or an aid). This response will be applicable to some chair-bound participants. If participants transfer from bed to chair or chair to bed, ask the participant if they feel they can safely attempt the task. Examiner should stand in front of the participant for safety.
- Safety concerns (these can be concerns expressed by the participant or by the examiner). It is less obvious if the participant can do repeated chair stands for this response although observing the single chair stand will help inform the examiner’s impression. The examiner will have demonstrated the chair stands. If the examiner has concerns about safety, they can ask “Do you feel safe doing this?”
- Other problem (examples include fracture, sprains, amputation, cognitive problems).

If the participant attempted but was unable to complete five stands without using their arms, score as “Attempted, unable to complete five stands” and record the number completed without using arms.

If five chair stands were completed, record the number of seconds, to a hundredth of a second, required to complete five stands.

2.4 ADMINISTRATION OF THE SPPB STANDING BALANCE (V10 CLINIC VISITS)

This test does not use the gait mat. Results are recorded on the PFX form.

This is a series of timed, progressively more difficult, static balance tests. The level of difficulty increases as the lateral base of support decreases. The time (up to 10 seconds) that the participant can hold each position (i.e., side-by-side, semi-tandem, tandem) is recorded. Walking aids such as a cane or walker may not be used.

The standing balance test should be performed with the participant standing a little less than an arm’s length from a wall to provide an additional source of support should loss of balance occur.

For each stand, describe the position to the participant and then demonstrate it while facing the participant. After demonstrating, approach the participant from the front and off to the side away from the wall. The participant should use the wall for support; or, alternatively, the examiner may offer his/her arm for support if the participant is comfortable with this contact. The support surface (wall or examiner’s arm or both) can only be used for support while the participant gets in position. If the examiner is uncertain if this is safe to attempt, he or she can ask “Do you think

it would be safe to try this? I will stand here for support; you can let go of my arm [*or wall*] only when you feel ready.”

If they still feel they should not attempt it, record the appropriate response as “Not attempted”, record the reason for not doing the test, and move to the next test.

If the test was not attempted because the participant or the examiner did not think the participant was physically able (see below), or the examiner, proxy, or participant thought it was unsafe, or for other reasons, score “Not attempted”, then go to the subquestion and record why the test was not attempted:

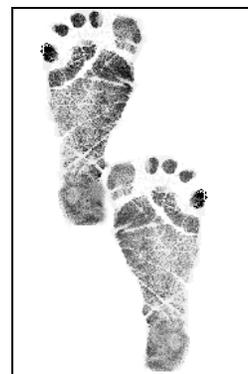
- Participant unable due to a balance problem (for example, participant or proxy might tell the examiner they are too unsteady or examiner observes unsteady gait when participant is walking or when standing)
- Safety concerns (these can be concerns expressed by the participant or by the examiner). If scoring this response, it is less obvious if the participant can do this balance test or not. If the participant was not observed walking, for example, but the examiner is aware that the participant is not very mobile, the examiner can demonstrate the task, then ask “Do you feel safe doing this?” as a safety screen.
- Other problem (examples include fracture, sprains, amputation, cognitive problems)

The same scoring principles also apply for the more difficult balance stands. The response “Participant refused or technical problems” should be reserved for refusals that are not due to balance problems, perceived difficulty of task, or safety concerns, such as lack of interest or “not enough time”. Technical, staffing, and environmental problems that result in a participant not being assessed are included in the category with refusals.

If the participant attempts the stand incorrectly, demonstrate it again. Time each stand. After 10 seconds for each stand, tell the participant to stop. If the participant loses balance before 10 seconds, record the number of seconds for which the stand was held. See figures for placement of feet for each type of stand. To maximize time allotment for testing, the balance tests begin with the semi-tandem stand. If this position cannot be held for 10 seconds, the examiner should record results of the semi-tandem stand then describe and demonstrate the side-by-side stand, which is easier, and mark the tandem stand as “Not attempted/unable.” If the semi-tandem position is held for ten seconds, the side-by-side position should be marked as “held for 10 seconds” and the tandem stand should be attempted.

a. *Administration of the Semi-Tandem Stand*

Begin by introducing the balance tests: “I’m going to ask you to stand in several different positions that test your balance. I’ll demonstrate each position and then ask you to try to stand in each position for 10 seconds. I’ll stand next to you to provide support if you lose your balance. Do you have any questions?”



Say, “First, I would like you to try to stand with the side of the heel of one foot touching the big toe of the other foot for 10 seconds. Please watch while I demonstrate. You may put either foot in front. You can use your arms, bend your knees or move your body to maintain your balance. Try to hold your feet in position until I say stop. If you lose your balance, take a step like this. Hold onto [*my arm or the wall*] while you get in position.” Allow the participant to hold your arm or touch the wall for support to get balanced. “When you are ready, let go.” If you or the participant feels this stand may be too difficult, probe for reasons and score as described above. Then start with the side-by-side stand instead (see Section 2.4.c.).

Stop the stopwatch if the participant takes a step or grabs for support, otherwise say, “STOP” after 10 seconds, record the response, then go to the Tandem stand.

If the participant is unable to hold the semi-tandem stand for at least 10 seconds, do not attempt the tandem stand, but instead perform the side-by-side stand, which is less difficult, and then go to the walking tests.

b. Scoring the SPPB Semi-Tandem Balance

If the participant refuses or if the test is not administered due to technical problems, staffing problems or similar unrelated issues, score “Participant refused or technical problems.” If the procedure was not attempted, go to the subquestions and record the reason for not attempting.

If the participant attempted the test but could not hold the position for at least 1 second, score as “Unable to attain position or hold for one second.” If the participant held the position for at least 1 second but less than 10 seconds, score as “Holds position ≥ 1 but less than 10 seconds” and record the time to 0.01 second on the PFX. If the participant held the semi-tandem stand for 10 seconds, score as “Holds for 10 seconds” and also score the side-by-side stand as “held for 10 seconds” on the PFX form.

c. Side-by-Side Stand

“Now, I would like you to try to stand with your feet together, side-by-side, for 10 seconds. You can use your arms, bend your knees or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop. Hold on to [*my arm or the wall*] while you get in position.” Allow the participant to hold onto your arm or the wall to get balanced. Say: “When you are ready, let go.” Start timing when the participant lets go. Stop the stopwatch if they take a step or grab for support. Record to 0.01 second the time the participant could hold this position. Say, “STOP” after 10 seconds.

d. Scoring the Side-by-Side Stand

If the participant refuses or if the test is not administered due to technical problems, staffing problems or similar unrelated issues, score “Participant refused or technical problems.” If the procedure was not attempted, score “Not attempted” and go to the subquestion to record why the task was not attempted. If the participant attempted the test but could not hold the position for at least 1 second, score as “Unable to attain position or hold for one second.” If the participant held the position for at least 1 second but less than 10 seconds, score as “Holds position ≥ 1 but less than 10 seconds” and record the time to 0.01 second. If the participant held the position for 10 seconds, score as “Holds for 10 seconds”.



e. Administration of the Tandem Stand

The Tandem Stand is only administered if the participant is able to hold the Semi-Tandem stand for at least 10 seconds. “Now I would like you to try to stand with the heel of one foot in front of and touching the toes of the other foot for 10 seconds. Please watch while I demonstrate. You may put either foot in front. You can use your arms, bend your knees or move your body to maintain your balance. Try to hold your feet in position until I say stop. If you lose your balance, take a step like this. Hold onto my arm while you get in position. When you are ready, let go.”

Start timing when the participant lets go. Stop the stopwatch if they take a step or grab for support. Record to 0.01 second how long participant is able to hold this position. Say, “STOP” after 10 seconds.

If the participant holds the position for 10 seconds, go to the walking tests. If the participant attempts the Tandem Stand and is unable to attain the position or cannot hold it for at least one second, go to the walking test. If the participant held the position for at least 1 second but less than 10 seconds, perform a second trial of the Tandem Stand. Say “Now, let’s do the same thing one more time. Hold onto [my arm or the wall] while you get into position. When you are ready, let go.”

f. Scoring of the Tandem Stand

If the participant refuses or if the test is not administered due to technical problems, staffing problems or similar unrelated issues, score “Participant refused.” If the procedure was not attempted, score “Not attempted” and go to the subquestion and record the reason the test was not attempted. If the participant attempted the test but could not hold the position for at least 1 second, score as “Unable to attain position or hold for one second.” If the participant held the position for at least 1 second but less than 10 seconds, score as “Holds position ≥ 1 but less than 10 seconds” and record the time to 0.01 second. If the participant held the position for 10 seconds, score as “Holds for 10 seconds”.

2.5 ADMINISTRATION OF USUAL WALK (V10 PFX: CLINIC AND HOME VISITS; V10 ZGM: CLINIC)

a. Usual Pace 4m (PFX Form):

The 4m usual pace walk will be timed with a stopwatch following the protocol below which was employed at prior ARIC visits. This will be offered in home visits beginning in visit 10. The 4m usual pace walks will be conducted separately from the usual pace walk in the Zeno mat protocol during Visit 10.

Because the 4m usual pace walk exam may be required throughout the visits, and to ensure valid comparisons to home visits, examiners must maintain proficiency in administering the task using a stopwatch. The 4m walk should be administered according to the following instructions and recorded on the PFX form.

PFX Time to walk 4 meters at the participant's usual pace is measured.

Say to the participant: "I'm going to ask you to do a short walk over this 4 meter course two times. You will walk at your normal or usual pace for two trials. I will demonstrate. Place your feet with your toes behind, but just touching the starting line, like this."



"Walk a few steps past the finish line." Demonstrate by walking to the other end of the course at your usual pace, making certain you walk past the finish line before slowing or stopping. "Do you think it will be safe to walk this short distance at your own pace?" If the participant has a cane, walker, or other aid, ask "Do you think it will be safe to try this without a cane or walker?" Participants are allowed to use canes or walkers if they need one for balance or safety. If they do not feel safe walking without a cane or walker, the examiner should acknowledge that they may use a cane or walker for this task and confirm the participant feels safe walking the 4 meters with their assistive device. The examiner should assure the participant that they will walk along with the participant. For example, the examiner can say, "You may use a cane or walker if you need to. Do you think it would be safe to try this walk with your [*cane / walker*]?" If they do not feel safe, do not attempt the walk.

Make sure the feet are in proper position. "Do you have any questions? When I say "Go", please walk at your normal pace. Remember to walk a few steps past the finish line." To start the test, say, "Ready, Go." Start timing with the participant's first movement.

Follow along a few paces behind and a little to the side of the participant so you can see when the foot crosses the finish line. Stop timing when the first foot fully crosses an imaginary plane extending vertically up from the ending line/tape. Record the time to the nearest 0.01 second.

Have the participant repeat the usual pace walk: "Let's try this one more time. Ready? Go."

Home Visits

The physical function assessment in the ARIC exam as well as more extensive measures of physical function have been safely and successfully carried out in the homes of older adults,¹⁻³ including in disabled older women.¹ Safety protocols for functional measures assessed during ARIC home visits employ the same safety protocols as in the clinic, which include published standards^{1,2} along with additional guidance specific for the ARIC cohort. The physical function assessment in home visits will only include the 4-meter walking test at visit 10.

The home environment can present situations not encountered in the clinic. This section addresses some additional aspects of the physical function assessment conducted during home

visits. If the assessment is not performed, the reason should be recorded. The responses on the form should be left blank.

Participants who are bedbound should not be approached for this test, but the PFX form should be completed. When “Type of Visit” is marked as a “Home Visit”, the questionnaire will skip to the usual gait speed question on the PFX form. Bedbound participants should be recorded as “Not attempted” and the reason that the test was not attempted should be marked as “Unable to walk short distance”. For other participants, examiners should observe the participant’s mobility and balance if they ambulate in the home during the visit. If the participant walks short distances in the home with or without a cane, rollator, scooter, or walker, they are generally safe to approach to assess their ability to perform the 4-meter walk test.

Examiners may not always have an opportunity to observe a participant’s mobility in the home prior to doing the walking test. In this situation, ask the participant questions about their mobility to determine how much they walk, if they use devices, if they are able to transfer out of a chair or bed, if they have unsteadiness, and so on. If participants report being able to walk across a small room, these participants are highly likely to be able to perform the 4-meter walk. For any participant whose ability to walk 4 meters is uncertain, in addition to talking to the participant and/or proxy in the home, the examiner should use the measuring tape of 4-meter chain or other measuring tool to show the distance the participant would be asked to walk. Ask the participant and/or proxy if they think it would be safe to walk this distance. Assistive devices are allowed during the 4-meter walk.

Some examples of questions that examiners could use to assess a participant’s mobility follow this paragraph and can be reworded as needed. Examiners should be cognizant of participant/proxy comfort with questions about potential physical limitations, but often questions such as these lead the participant or their proxy to disclose information about mobility or other challenges which they have never discussed with their healthcare providers. In such cases, the participant and/or proxy should be advised to discuss these with their healthcare team, who may be able to provide additional resources in the home. The following questions are not a complete list of questions, nor are they required for all home visits; rather, these should help guide examiners in gathering information that could help them assess safety related to the physical performance measures in participants for whom their mobility status is uncertain.

- “Do you ever walk outside your home?”
 - Participants who do this are usually good candidates for the 4-meter walk
- “Do you walk from room to room in your home?”
 - Participants who do this are usually good candidates for the 4-meter walk
- “Do you use a cane or walker to get around in your home?”
 - Participants who can walk around inside their home with or without an assistive device are usually good candidates for the 4-meter walk
- “Do you hold onto furniture or the walls for balance when you walk in your home?”
 - Participants who do this for balance and do not have a cane (or assistive device), or are unwilling to use one could be safety risks. Do not administer the walking test. Mark the form as “Not attempted” and then “Safety concerns”.
 - Participants who hold onto furniture or the walls for balance sometimes have a cane or other assistive device but do not always use it. Ask if they have a cane or

assistive device, as even participants with balance problems who use an assistive device are usually a good candidates for the 4-meter walk. If they are not willing to use an assistive device or do not have one, do not administer the test.

- “How do you get the kitchen and bathroom?” This may be helpful for seated participants who the examiner does not observe walking in the home. If they do not go to these rooms, asking “Where do you eat?” and/or “Do you have a bedside toilet?” can provide more information about their usual mobility status.
 - This provides information about whether a person can walk from room to room (definitely consider the 4-meter walk),
 - If they are limited to walking a few steps from where they sit or they only transfer from one position to another, e.g. chair to bed, or if they use motorized scooters in the home, probe further about walking ability to see if the participant can walk the distance of the course. If the participant or proxy describes an inability to walk this far, the participant response should be “Not attempted” and then “Participant unable to walk short distance”. If they think they can walk the distance but are concerned about falling, the test should not be attempted and the reason recorded as “Safety Concerns”.
- “Have you fallen inside your home in the past year?” If “Yes”, ask questions such as “How many times have you fallen? When was the most recent fall? Did you trip over something?” If the participant is having recurring falls or has fallen in the past month inside the home without tripping over an object, do not perform the 4-meter walk. Mark “Not attempted” and the reason should be marked “Safety concerns”. Use the comment box to provide additional text regarding concerns.
- “Have you had any “near” falls recently?
 - Near falls are not an exclusion criteria for the 4-meter walk but may help the examiner determine a higher state of risk if the participant reports currently having recurring near falls. Proceed with asking the participant if they think they can walk about 13 feet; the examiner may show the distance of the course and demonstrate the task.

Some participants may not be able to undergo physical function assessments in the home due to the home environment and should be distinguished from those who did not undergo functional assessments for other reasons. Home environment reasons for not performing functional assessments include inadequate, unobstructed walking space (minimum is 4.5 meters), high-pile or shag carpeting, falls hazards such as thresholds on the floor or rugs that cannot or will not be moved, inability to place tape on the floor or participant preference to not use tape on the floor to mark the course, or clutter on the floor where the walking course would be laid out. These should be recorded as “Participant refused or technical problem”. Even though clutter is a safety concern, the safety issue is from the environment, not the participants inherent physical problem or safety risk, so environmental problems are reported in this category rather than “Safety concerns” category.

Scoring

“Participant refused or technical problems” should be reserved for refusals that are not due to walking or balance problems, perceived difficulty of task, or safety concerns; reasons such as lack of interest or “not enough time” are appropriate for the “refused” category. Technical, staffing, and environmental problems that result in a participant not being assessed are also included in the category with refusals.

If the procedure was not attempted because the participant or the examiner did not think the participant was physically able (see below), or the examiner, proxy, or participant thought it was unsafe, or for other reasons, score “Not attempted”, then go to the subquestion and record why the test was not attempted:

- Participant unable due to difficulty walking (for example, participant is bedbound, does not walk more than a couple steps to transfer to another seat/bed, participant or proxy tells the examiner they are too unsteady, or examiner observes unsteady gait when participant is walking)
- Safety concerns (these can be concerns expressed by the participant or by the examiner). It is less obvious if the participant can do this balance test for this response. If the participant was not observed walking, for example, the examiner can demonstrate the task, then ask “Do you feel safe doing this?”
- Other problem (examples include fracture, sprains, amputation, cognitive problems)

2.6 TRAINING AND CERTIFICATION FOR SPPB

A training video for the SPPB is available online. Note that the video does not include training on grip strength. Instructions for downloading the video (“Instructions – pdf”) and the demonstration video (“CD (Download and Execute – (.exe)) can be found at <https://www.nia.nih.gov/research/labs/leps/short-physical-performance-battery-sppb>. Click CD (Download). Go to the Downloads directory and click sppb_cd. This may take you to the D: or E: (or another) drive. Go to that location and click the application file labelled Start [ start]. It should open and play the video. The file may be found under “This PC” in the directory of files. Right click on it and will either allow you to “Run” or “Open” it as a virtual disk to your computer’s hard drive. If you do not have that option, you will have to burn a CD. This video should be reviewed prior to initial training session and every 6 months. Training will include:

- Watch the video for the SPPB
- Read and study the manual and the QxQ
- Attend ARIC training session on performance test administration techniques, or be trained at the ARIC field center by an experienced examiner
- Practice on other staff or volunteers
- Discuss problems and questions with local expert or QC officer

Certification will include:

- Complete training requirements
- Recite exclusions

- Conduct exam on two volunteers:
- According to protocol, as demonstrated by completed QC checklist
- Times agree within ± 0.5 second of QC officer or designated personnel for SPPB and 6 inches for 2-minute walk.

The following elements must be demonstrated successfully for certification:

CHAIR STANDS

- Back of chair against a wall
- Script correctly and clearly delivered
- Correctly demonstrates two stands, emphasizing full stand and return to complete sit
- Says "Ready? Go" for each test
- Records timed measure within 0.5 seconds of QC officer or designated personnel
- Counts each chair stand and records stand if less than 5
- Records and explains unusual values
- Starts timing with "Go", stops with final stand or one minute
- If task was not performed, codes and explains reasons

STANDING BALANCE

Side-by-side stand

- Script correctly and clearly delivered
- Correctly demonstrates position
- Timing started coincident with participant release and stopped when participant takes a step or grabs for support
- Records timed measure within 0.5 seconds of QC officer or designated personnel
- If task was not performed, codes/records reasons

Semi-tandem stand

- Script correctly and clearly delivered
- Correctly demonstrates position
- Timing started coincident with participant release and stopped when participant takes a step or grabs for support
- Records timed measure within 0.5 seconds of QC officer or designated personnel
- If task was not performed, codes/records reasons

Tandem stand

- Script correctly and clearly delivered
- Correctly demonstrates position
- Timing started coincident with participant release and stopped when participant takes a step or grabs for support
- Records timed measure within 0.5 seconds of QC officer or designated personnel
- If task was not performed, codes/records reasons
- Repeat (second trial), if necessary

4-METER WALK

- Script correctly and clearly delivered
- Correctly demonstrates
- Toes touching start line
- Timing started coincident with participant's first movement
- Time stopped when the first foot crosses an imaginary plane extending vertically up from the ending line/tape
- Repeat (second trial)
- Records timed measure within 0.5 seconds of QC officer or designated personnel
- If task was not performed, codes/records reasons

2.7 GRIP STRENGTH

This test does not use the gait mat. Results are recorded on the PFX form.

The grip strength assessment should be performed after the SPPB components and before the TMW, providing a rest period prior to the TMW. Grip strength is a commonly used measure of upper body skeletal muscle function, has been widely used as a general indicator of frailty and, in the absence of other measures of strength, is a good marker of global muscle strength. Grip strength is often measured in the dominant hand or in both hands and the best result used in analyses. This assessment is modified slightly to accommodate time restrictions while maximizing physical function measurements; overall, it is focused on measuring maximal strength. Grip strength in the participant's preferred hand,⁴ usually the dominant hand, will be measured using an adjustable, hydraulic grip strength dynamometer. Allowing participants to choose the best side should be comparable to either testing one's dominant hand, as most will choose the dominant hand, or to choosing the best result of bilateral testing. Allowing participant preference will permit participants to choose non-dominant side if medical or other conditions, e.g. stroke, have impaired the dominant hand and testing that side would not necessarily represent global muscle mass or strength.

For grip strength, the participant should be seated at a standard height table at or just below shoulder level with the elbow extended at approximately 180 degrees or next to a table with an adjustable tray table attached.

a. Exclusions

Grip strength exclusion is limited to those who have had surgery on both hands or both wrists in the previous 3 months. If only one side is affected, test the unaffected side. The test can be performed if the participant has a current flare-up of pain in their wrist or hand, for example arthritis or tendonitis. Be sure to record this information on the data collection form.

b. Equipment

Jamar Hydraulic Hand Dynamometer, which registers maximum kilograms of force during a trial, with adjustable handgrip.

Mouse pad or small rolled towel for wrist support

Table with adjustable height (moveable tray table preferred)

c. Equipment Checks

Every six months: Check the calibration of the grip strength dynamometer by hanging 4-5 kg and 10 kg (or about 10 and 22 lb) weights across the handle using two Velcro straps, one strap on each side of the dynamometer handle, or one wide strap that covers the whole handle. Lift the weights slowly from the floor while they are strapped to the dynamometer handle and record the maximum kilograms registered. The lifting motion should be very slow and smooth, and the weight should remain evenly distributed between the two sides of the handle. Repeat the procedure three times and record each result.



Average the three calibration trials. The dynamometer should be accurate within ± 2 kgs for the average of the three calibration trials. If the result is outside the ± 2 kg range after following the Troubleshooting tips below, you must send the dynamometer to the manufacturer for repair and recalibration. **DO NOT attempt to recalibrate the dynamometer yourself.** Calibration problems can be caused by dropping the dynamometer or by leaks in the hydraulic system.

Troubleshooting Tips:

If any of the measurements for any of the weights are outside of the acceptable range (± 2 kg), remove the weight and turn the dynamometer position to zero. Perform the procedure again for that weight, and verify if the result is in the acceptable range. Check the positioning of the weight on the dynamometer. The position of the weight can affect the reading.

If the result is still outside of the acceptable range, take all the weights off the handle, turn the dynamometer off and then notify the PI or designated person. If readings within the acceptable

range still cannot be obtained, a backup device, if available, must be used and the malfunctioning device sent to the company for repair or must be replaced. A dynamometer cannot be used if it does not calibrate properly.

d. Administration of the Grip Strength

The participant should be seated at a standard height table or on a seat with a moveable tray table attached.

"The next test I'll ask you to do is the grip strength test. This device is used to measure the strength in your hand. Even when you squeeze the grip bars as hard as you can, the bars will not feel like they are moving much at all. Before starting, I will ask you a few questions to make sure it is safe for you to do this test."

Determine if the participant has an acute or recent flare of arthritis in the hand that will be tested. Ask, "Do you have any pain or arthritis in either hand or wrist?" if participant answers "Yes", ask, "In which hand or wrist is the pain or arthritis?" Record response. Next ask, "Has the pain or arthritis in your hand(s) or wrist(s) gotten worse recently?" Record response. "Will the pain or arthritis in your hand(s) or wrist(s) keep you from squeezing as hard as you can?" Record response. Pain or arthritis that has gotten worse recently is not an exclusion for this test.

"Have you had any surgery on your hands or wrists in the past three months?" Record response. If the participant says "No", proceed with test; if they answer "Yes," ask them which hand or wrist was operated on, record response, and do not test that hand.

The examination is done with the participant seated facing a table which is at a comfortable level between the shoulder and waist while seated. Extend the arm to be tested in front of participant at or just below shoulder level with the elbow extended at approximately 180° and the elbow and forearm resting on the table (**Figure 2.2**). Place a mouse pad or comparably sized rolled towel under the wrist. The dynamometer is held perpendicular to the table in the hand to be tested, just off the table edge. Correct grip and participant positions are shown below. Demonstrate the correct grip and arm position while seated at the table.



Figure 2.2. Arm position



Figure 2.3. Arm Position



Figure 2.4. Grip Position



Figure 2.5. Mouse pad for wrist support

Ask "Which hand is your preferred or best hand to test for maximum strength?" This response determines which hand is tested unless this side was excluded in the previous screening questions. Record response on form. "Please extend that arm in front of your body and rest it on the table with your arm straight and wrist on the mouse pad. Grip the two bars in your hand like

this and squeeze gently to get the feel of it.” Demonstrate proper positioning of the dynamometer then place wrist strap around the participant’s wrist and position participant. Adjust the grip size until the participant is holding the dynamometer comfortably (this will almost always be the second setting). If the handle hits the participant’s hand distal to the second knuckle the grip size should be smaller. If the participant’s natural fingernails are hitting their palm the grip size needs to be larger. “Are the bars the right distance apart for a comfortable grip?” Readjust as needed prior to starting the test until a comfortable position is attained. Allow one submaximal practice trial to determine if the participant understands the procedure and that the grip size is appropriate.

When ready for the practice trial, say, “Now try it once just to get the feel of it. For this practice, just squeeze gently. It won’t feel like the bars are moving, but your strength will be recorded.” Show dial to participant after squeezing then reset to zero. “You’ll do this two times. When I say “squeeze”, squeeze as hard as you can. Ready? Squeeze! Squeeze! Squeeze! Now, stop.”

Perform two trials with 15 to 20 sec rest in between. After the first trial, reset the dial to zero, and say “Now, one more time. Squeeze as hard as you can. Ready. Squeeze! Squeeze! Squeeze! Now, stop.” Set the dynamometer to zero prior to each attempt. Record the kilograms from the dial to the nearest 2 kilograms onto the form. If the reading is exactly between two readings on the scale, round up to the next higher even number. Reset the dial to “0” after each trial.

e. Scoring of the Grip Test

Score as follows: if the participant refuses or if the test is not administered due to technical problems, staffing problems or similar unrelated issues, score “Participant refused.” If the participant was unable to perform the test, score “Unable to do.” If the participant was excluded due to recent surgery, record “Excluded”. If the participant completed only 1 trial, record “Did 1 trial”; if he/she completed both trials, record “Did 2 trials”. Round to nearest even kg; if exactly between two readings on the dynamometer, round to the next higher even number. For example, if the reading is midway between 26 and 28, record 28. Round readings that are less than half way between two even numbers down; round readings that are more than half way round up. Reset the dial to “0” after each trial.

2.8 TRAINING AND CERTIFICATION FOR GRIP STRENGTH ASSESSMENT

Study coordinators are responsible for training new staff using certified examiners based on standardized QxQ instructions.

The examiner requires no special qualifications or experience to perform this assessment.

Training will include:

- Read and study the manual
- Attend ARIC training session on performance test administration techniques (or observe administration by experienced examiner)
- Practice on other staff or volunteers
- Discuss problems and questions with local expert or QC officer

- QC officer or designated person may review video of 2 performances if necessary

Certification will include:

- Complete training requirements
- Recite exclusions
- Conduct exam on two volunteers:
 - According to protocol, as demonstrated by completed QC checklist
 - Kilograms agree within ± 2 kilograms of QC officer for grip strength

QC elements required for certification are:

- Participant is asked about recent surgery on hands
- Participant is asked about pain and arthritis in hands
- Participant is asked to place arm at or just below shoulder level with the elbow extended at approximately 180 degrees
- Recording dial reset to zero after sub maximal practice and each trial
- Appropriate hand placement and grip adjustment if needed
- Appropriate position of participant and dynamometer
- Reviews and correctly completes form

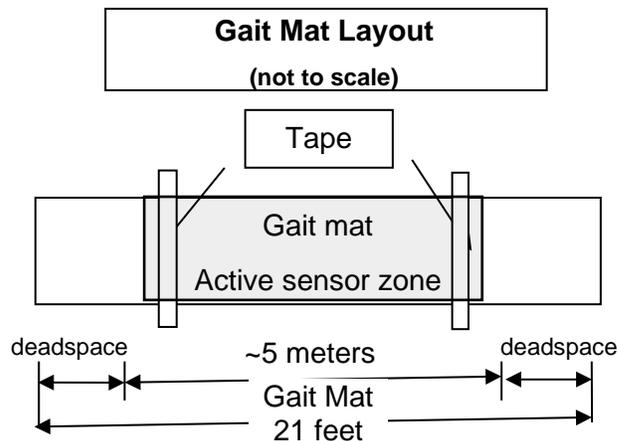
2.9 PHYSICAL FUNCTION RESULTS

Chair stand and balance results will be sent to participants as a part of the Visit 10 Summary of Results Report. The results letter template can be found in Appendix 1 (Section 6.2). The Maintaining Your Mobility handout (Section 6.3) should be provided to participants at the end of the visit.

3 THE ZENO GAIT MAT

3.1 ADMINISTRATION OF GAIT MAT TESTS

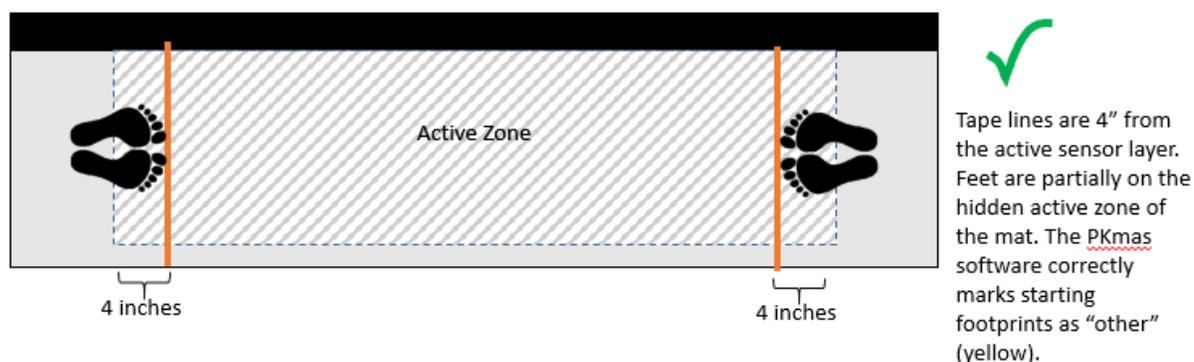
a. Walking Course



- **Gait mat:** The usual pace, dual task (usual pace plus serial subtractions), short fast pace walks, quiet standing, and limits of stability should be conducted on the gait mat. The start and finish lines will be marked by painter's or other colored tape on the mat corresponding to where the participant's starting foot will be partially in the active sensor zone of the mat. Participants will stand on the mat to begin each test with their toes lined up behind the tape and facing the long end of the mat (except QS and LOS) such that the front ball of their feet is on the active zone underlayer of the mat but their heels are not; the active zone underlayer is not visible from the top layer of the mat and the participant is unaware of its placement. Instruct participants to walk off the end of the mat before slowing or stopping each test. The black sensor band along the long edge of the gait mat should be placed against a wall and study staff and participants should avoid stepping on that area unless necessary for safety.

Place colored tape across the mat at each end of the active zone (2 marks). The tape should mark just past where the sensors begin under the mat. There are two layers of the gait mat, a top cover layer (visible) and a sensor layer that lies below the cover layer with an active zone that collects pressure information. Place the tape 4 inches into the active zone to ensure the feet are detected by the mat. The participant's toes are positioned just behind the tape such that approximately half the participant's feet are standing on the hidden active zone at the starting position (Figure 3.6). Participants at the starting position have both of their feet entirely on the top surface of the mat, but are partially standing on the active zone.

Figure 3.6



If the gait mat experiences a technical failure during any test such that the mat cannot be used for any further testing, record "Attempted, technical difficulties with mat" on the ZGM. If the technical issue can be resolved in time for another test, do not save the failed walk and repeat the test where possible.

b. Gait mat equipment

- Zeno Walkway™ Gait Mat
- Camera (synched to the gait mat, angled down to capture from chest height and below). When connected correctly, the gait mat will automatically record video once "Start Walk" is clicked.
- Clicker/signal with extended cord (connected to the gait mat)
- Colored tape to mark 4" into the start of the active zone on both ends of the mat (see above schematic)
- Notebook computer with PKMAS software
- Cart or table for Notebook, mouse, camera and a surface to which the camera can be attached.
- Clock displaying seconds, visible from testing area

To set up the ProtoKinetics Zeno Walkway™ Gait Mat and PKMAS software, a full manual is available at each field center in PDF format on the company provided Notebook.

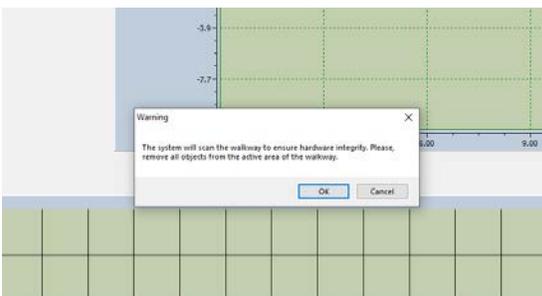
The correct way to connect the Notebook to the mat is shown below:



When connected successfully, only the green light above the "Power" button will be on.

c. Equipment checks

Every time the software starts up, the PKMAS software checks the sensors of the gait mat. The process takes approximately 10 seconds. If it registers a problem, check that there are no objects on the mat and run the check again.



Every time the mat is unrolled or shifted, make sure that the starting lines (one at each end of the mat) align with the start of the active sensor zone. Check that the edges of the mat are not curled or lifting away from the floor to present a tripping hazard. Lifting edges can be taped down to the floor.

For more details and troubleshooting, see the full manual in PDF format on the company-provided Notebook.

d. Starting and stopping tests on the Zero Gait Mat

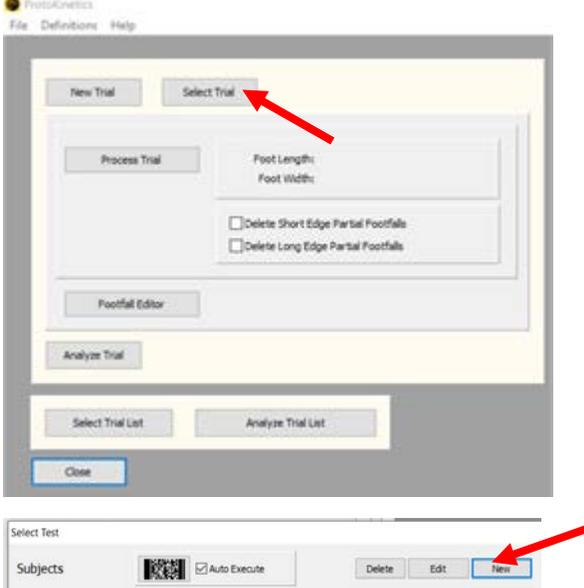
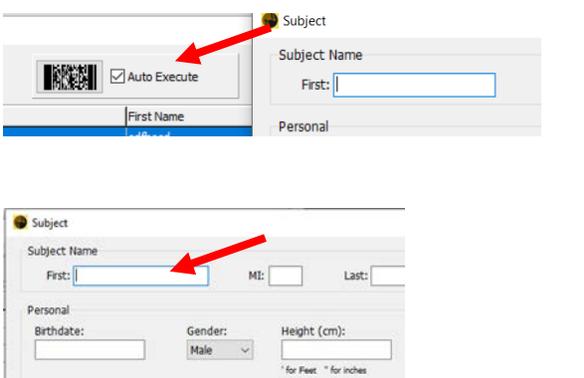
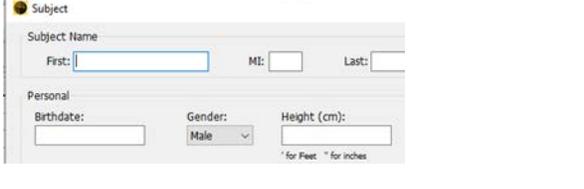
To start the software, sign in to the Notebook using the password protected login information. Open the PKMAS software and login again.

Log in to software

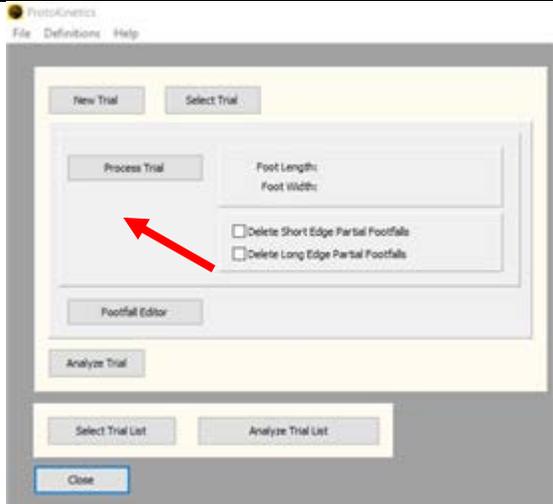
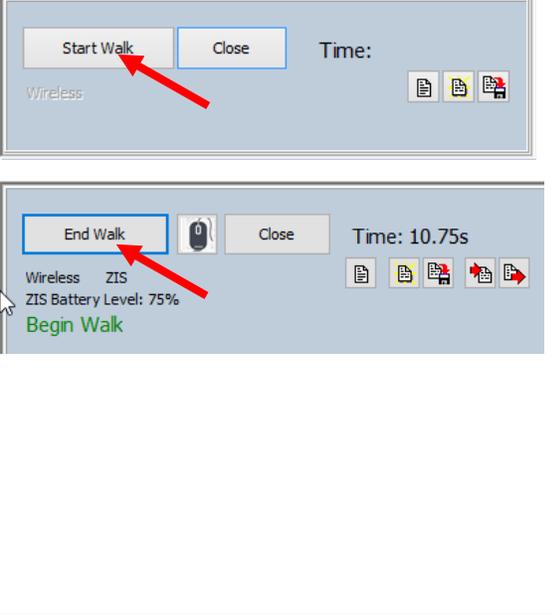
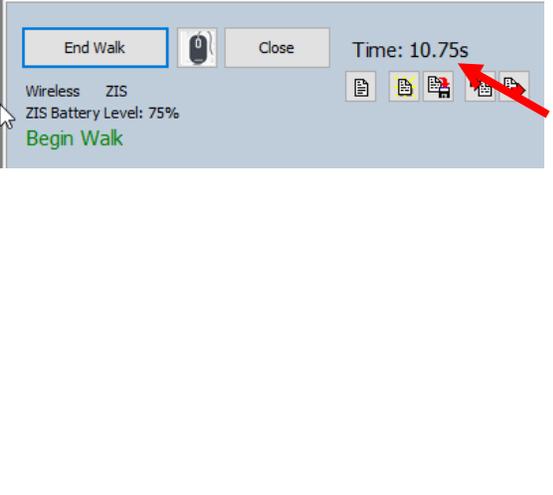
	<p>To log in to the software, enter the username and password provided by your ProtoKinetics representative. If you are unsure about the user name and password, begin by trying the following:</p> <p>username: admin password: pkmas</p>
--	--

To enter a new participant:

	To enter a new participant, click "Select Trial".
--	---

	<p>Click “New” participant.</p>
	<p>There are two options for entering the SubjectID</p> <ol style="list-style-type: none"> 1. Scan in the participant by selecting the barcode option “Auto Execute”. Opening a new participant and scanning a barcode with a connected scanner will automatically population the “First” name category. 2. Type in their SubjectID manually in the “First” name category. <p>The cursor is automatically in the “First” field option. From this screen, one can either manual type in the SubjectID to the “First” field or can scan a barcode and automatically enter the number in this field. The following screen will appear. <u>Fill in the ppt id in “First” name field.</u></p>
	<p><u>Additional information such as gender is not needed.</u> Naming of participants must be consistent in order for exported files to be named correctly. The software automatically selects “Male” as the gender; there is no need to correct this.</p>

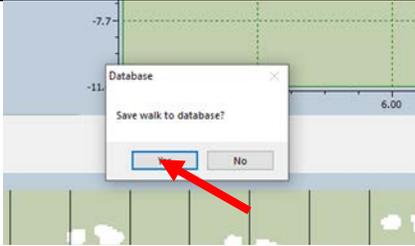
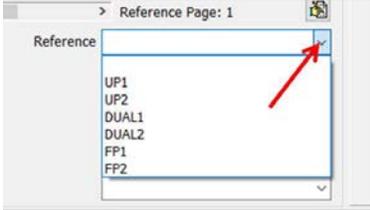
To start a new test:

	<p>From the PKmas home screen, select “New Trial”.</p> <p>NOTE: Check that the correct participant is highlighted when selecting “New Trial”. The software does not automatically select the last participant added.</p>
	<p>To start recording for a new test, make sure the participant is in position and click “Start Trial” in the upper left side corner dialogue box.</p> <p>NOTE: “Start Trial” must be selected <i>before</i> the mat can collect any data. Click “Start Trial” well before directing a participant to begin moving. It is better to be early than late in clicking “Start Trial”</p> <p>Once one clicks “Start Trial,” the button changes its text to read “End Trial”</p> <p>NOTE: Previous versions of the PKmas software use “Start Walk” and “End Walk” rather than “Start Trial” and “End Trial” (see left image); these are equivalent terms.</p>
	<p>After a brief delay, the “Time:” field will start counting up when the mat begins collecting data. Do not start the test until the time begins counting. If the participant is not standing on the active zone, the sensors are not picking up any extraneous data. It is better to start the data collection earlier and give part of the script while no one is on the mat than to start too late and miss data collection. As a general rule, however, read all instructions, demonstrate the test to be performed, and ask the participant if they have questions. When they are ready, select “Start Trial”. Once the timing begins, instruct the participant to begin.</p>

Gait Mat Filenames for Each Test*

Gait mat test	File Name
Usual pace walk	UP1, UP2
Quiet Standing & Limits of Stability (from PKmas preset list of filenames)	QS and LOS
Dual task walk	DUAL1, DUAL2
Short fast pace walk	FP1, FP2

Saving walks:

	<p>The mat will automatically prompt a save with the following box after “End Trial” is selected. Walks must be saved using only the filenames in the manual and available in the drop down list.</p> <p>Click “yes” if it is a good trial, according to the manual’s instructions.</p>
	<p>If the trial was a gait trial, use the Reference drop down list to select the file name for this test (e.g. UP1, UP2). If the trial was a QS and LOS balance trial, use the Protocol drop down list to select “QS and LOS”.</p> <p>Trial names only need to be added to the Reference List once per site. See the list below for what Reference name to use for each test.</p>

e. Cleaning the Zeno Gait Mat

Keep cleaning Lysol or Clorox (or similar, **non-bleach**) wipes near the mat. Bare feet are not allowed on the mat. The mat should be examined daily and cleaned as needed while it is disconnected. Wiping the mat with a dry mop or similar may be adequate on a daily basis with wipes at least weekly (can be on an extended handle, such as Swiffer), depending on use. The mat should not be in contact with standing water. A damp mop on the surrounding floor is fine.

Care of the mat should be discussed with personnel in clinic areas responsible for cleaning, including after-hours cleaning staff.

f. Storing the Zeno Gait Mat

When the mat is rolled for storage, keep the gait mat in the two carrying cases provided by the company.

If the mat is left out, alert all clinic staff, environmental services staff, and any other facility staff who work in the area to avoid walking on the mat. Use verbal communication and signs placed in easily visible areas around the mat. If barriers are allowed in the space around the mat, these could be placed around the mat or at either end and/or along the side. ALWAYS avoid stepping on the black strip on the long edge of the mat. Do not roll tables, carts, gurneys etc. over the mat; these will damage the mat.

When the mat is unrolled on the ground in a high-traffic area that is likely to result in pedestrian traffic on the mat when not in use, it should be kept covered by a rubber mat cover to protect the sensors and gait mat surface. Avoid stepping on the mat for non-testing purposes whenever possible. One example of a 3 foot by 20 foot rubber mat that be rolled up when not in use is the ClimaTex 9G-018-36C-20 Scraper, 36x20 Floor mat.

g. Safety Issues and Exclusions –Gait Mat Procedure

Safety was covered in Section 1.2.c. Additional safety measures for the mat include:

- Mat cables should be secured in a safe manner to avoid risk of tripping. Adhesive tape can be utilized to affix cables to the floor.
- For safety, prepare the participants by pointing out any tripping hazards posed by the perimeter height of the walkway and the routed cables.
- The test area must be large enough to provide ample space at the beginning and end of the walkway for the participant to safely start and finish the walk.
- When lifting, packing or relocating the Zeno walkway, make sure that you observe proper lifting for heavy items, 60-120 Lbs.

Walking aids may not be used for the limits of stability test, but may be used for the usual pace, dual task, and short fast pace walk. Ask participants who arrive with walking aids if they think they can do this short walk without the device when showing them the course. Often, participants who have aids will feel very comfortable and are quite capable of walking the gait mat without a walking aid when they see the length of the course. In these cases, the exam should be done without the aid.

Crutches, casts, prosthetics, or other immobilizing devices alter the participant's usual mobility; if present, do not test the participant and note the reason the test was not performed. Exclusion from any performance test is also based on examiner assessment or participant concerns that the test would be unsafe. In the latter case, the examiner should describe the test and discuss with the participant his/her specific concerns about attempting the test, including physical

problems and known disabilities. The reason for not attempting a test, or inability to perform a test are recorded on the data form.

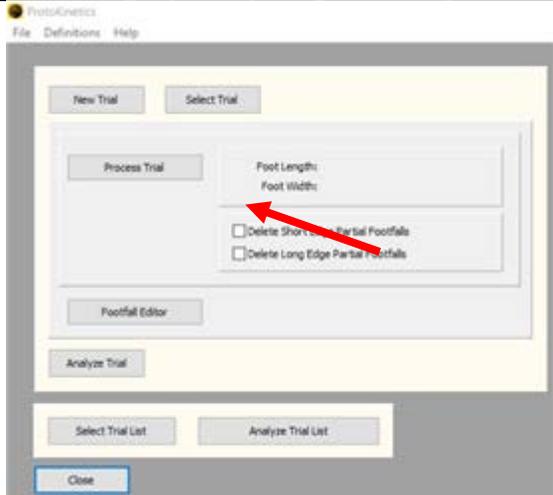
Examiner position is the same as for the SPPB testing. The examiner should avoid stepping on the gait mat unless necessary to stabilize a participant. No one should step on the black band along the long edge of the mat unless required for safety; this may mean that the examiner stands slightly behind or to the side of the participant.

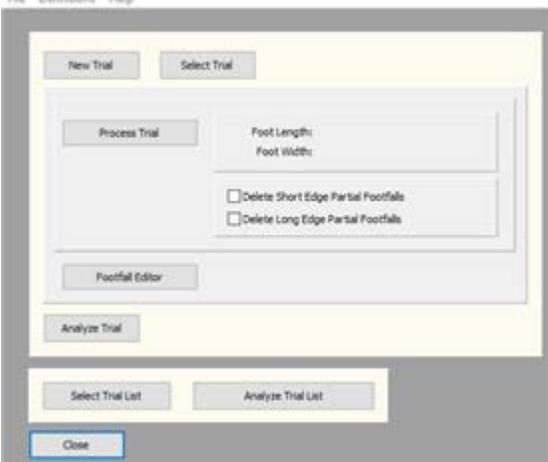
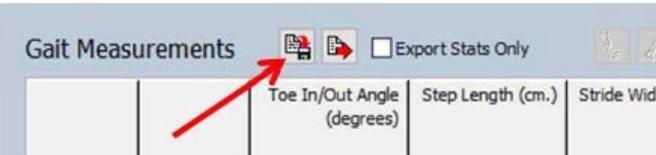
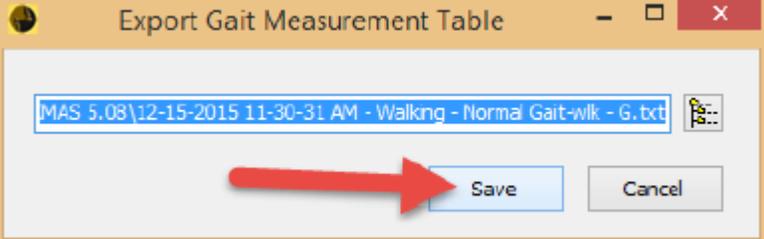
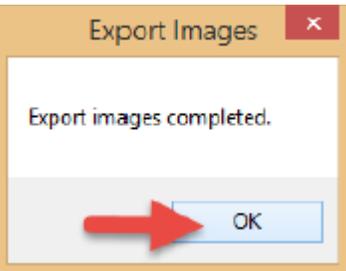
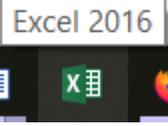
3.2 REPORT GENERATION

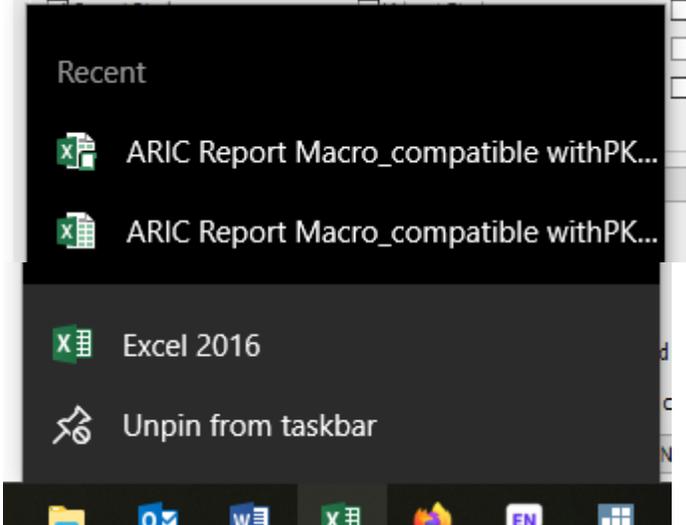
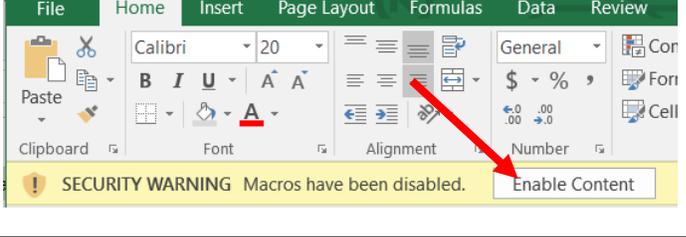
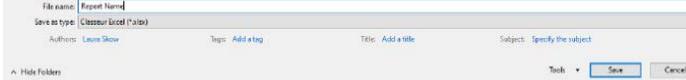
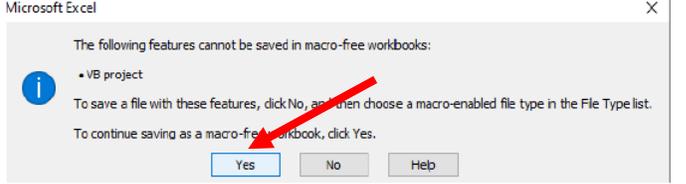
The Gait Mat Notebook Excel macro program will provide a printout of gait speed. After the walks are analyzed, generate reports using the instructions below. Reports can be given to participants the day of their clinic exam to take home. In the event that a day-of report is not feasible, reports can also be included with the neurocognitive report, with the accelerometry report, or sent alone, as needed by the study site. See Appendix 1 for an example Gait Mat report.

Script in final report:

- A. Walkway image with footfalls and script
 - a. "Small changes in how people move and walk may help identify those at risk of developing problems with physical and thinking abilities. Special mats like this one can detect small, but important, movements of the body that we would not see otherwise. This is what your footsteps look like when you walked across the mat. Right footprints and left footprints are marked in different colors. Any partial footprints or walking aids are marked in yellow."
- B. Gait speed
 - a. "This is your walking speed. Gait speed, or how fast you walk, is a way to describe how people move. A gait speed of less than 0.6 meters/second indicates that you walk slower than expected for people over the age of 65."

Generating a participant gait mat report using the Excel macro	
	<p>Click "Select Trial" from the PKmas home page and open usual page 1 for the relevant participant.</p> <p>Note – this will bring you back to the PKmas home page</p>

	Click "Analyze Trial"
	In the Gait Measurements window, click the "export to file" icon.
	Do not change the name of the file. Click Save.
	Next, click the "Export Images" icon in the test navigation pane.
	Verify that you are exporting the carpet display. A message will indicate that the images have been exported. Click "OK"
	On the computer Taskbar, right light on the Excel Icon and select "ARIC Report Macro"

	
	<p>NOTE: When opening the “ARIC Report Macro” in Excel, some computer security settings will automatically try to block the macro from working (left). Click “enable content” to allow the macro to work correctly.</p>
	<p>When the blank report opens, press the “Ctrl” and then the “t” key together.</p> <p>Select the appropriate file by participant ID (should be the most recent exported) and click “Open”</p>
	<p>Enter the appropriate file name and click Save.</p>
	<p>A pop-up will appear stating you will be saving a macro-free workbook. Click “yes”.</p>
	<p>Print the report & distribute to participant.</p>

3.3 PROCESSING, ANALYZING AND EXPORTING

Once a participant’s gait mat tests have been completed and saved, the files need to be processed and analyzed before a participant report can be generated. The data are then exported as .txt files before they can be transferred to the central QC center via upload to the Hopkins OneDrive. Process, analyze, and export participant walk files each day (at least every two days). Twice-a-month (biweekly), transfer data files from the Notebook laptop at each field

center to a secure server on the Johns Hopkins University OneDrive folder “GaitQC”. Each site has received a secure link to the OneDrive folder “GaitQC” from the Hopkins team and should save the email where the link was delivered. Contact Dr. Laura Skow (lskow1@jhmi.edu) at Johns Hopkins University if this link cannot be found. For the first month of the study visit, sites also transfer the entire PKData folder (includes video files and PKmas raw, unprocessed database files) twice-a-month (biweekly) into the site-specific “QC” sub-folder for archiving and for Gait Mat team QC. After the first month of the visit, the PKData folder is uploaded at least once a month.

Note, Gait Mat data collected as a part of ARIC Generation 2 should be uploaded to the same site-specific QC folders in OneDrive that are used for ARIC visits.

Twice-a-month

- Upload new participant walk files (batch export txt files for gait statistics and gait footfalls)
- Upload new participant QS & LOS individual txt export files
- *For the first month of the study visit only, copy the PKData folder into the site-specific QC sub-folder (details below)

Monthly

- Copy the PKData folder (including videos and PKmas raw database) to the OneDrive site-specific QC subfolder.
 - Note: this folder may take a long time to upload and should be done after the last participant is finished for the day. Each PKData folder upload replaces the previous upload (i.e. a newer upload includes all of the data up to that point, including previous data).

The Gait Mat team at Johns Hopkins will review data files for errors including file upload issues, unreadable files, improper marking of footfalls, and other data collection protocol issues. The Gait Mat team will work with staff at the field enters to resolve any issues and may request updated files to be uploaded to OneDrive. They will email the Coordinating Center at the end of each month when data files have passed QC and are ready to be downloaded from OneDrive and stored as SAS datasets with the rest of the V10 data.

There are three tasks that have to happen before gait mat data can be uploaded to the “GaitQC” OneDrive folder. For the QS and LOS tests, these three tasks all happen test-by-test. For the walks, processing happens test-by-test but analyzing and exporting are done in batches.

- I. **Process:** Checks that footprints on the mat are correctly identified.
 - a. All tests on the gait mat have to be processed individually before they are analyzed.
- II. **Analyze:** Calculates gait measurements based on the processed footprints.

- a. All of the walk tests can be analyzed in one batch; QS&LOS tests are analyzed individually.
- III. **Export:** Saves the gait mat data in a file type that can be uploaded to the central OneDrive and used without the PKmas software.
- a. All of the walk tests can be exported in one batch; QS and LOS files exported individually. Video files for the walks are copied into the “GaitQC” OneDrive folder in batches.

Gait mat test	Processed test-by-test	Analyzed and exported test-by-test	Analyzed and exported in a batch (can be multiple participants, multiple tests in one batch)	Video exported*
QS and LOS	X	X		
Usual pace walk(s)	X	(Report)	X	X
Dual task walk(s)	X		X	X
Short fast pace walk(s)	X		X	X

*For sites that have IRB approval and participant consent for video recording.

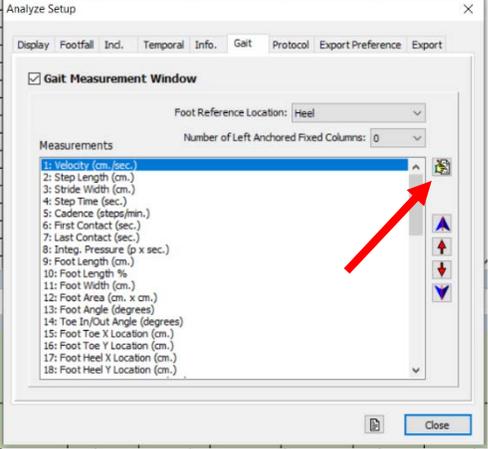
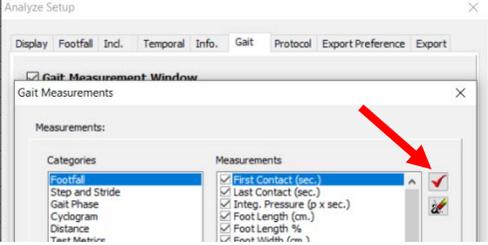
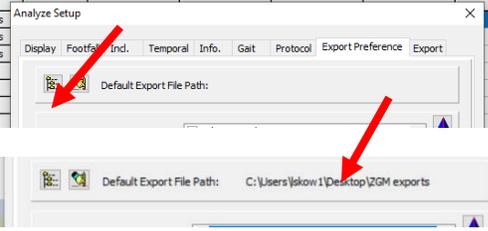
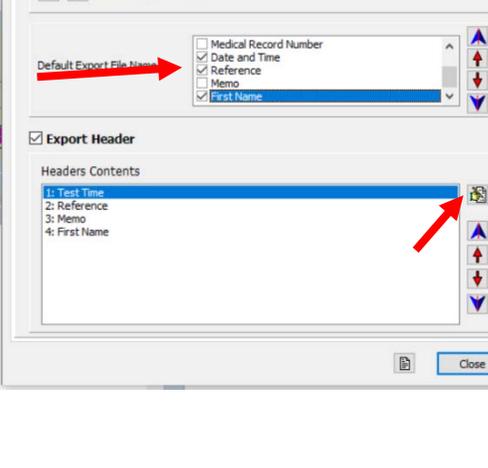
The following has instructions for six task types:

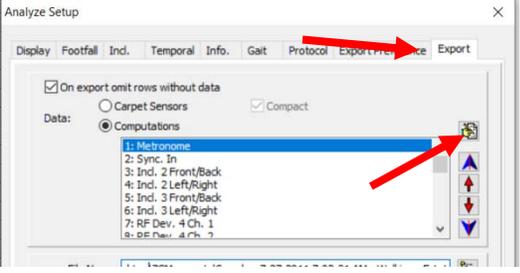
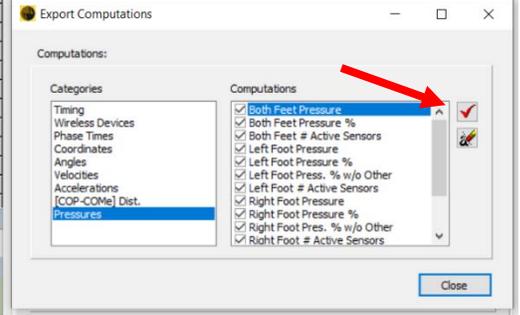
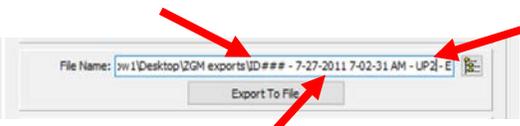
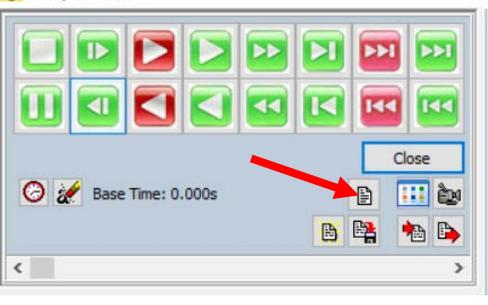
1. Setting up exporting preferences (only done once per site)
2. Processing tests
3. Analyzing and exporting the balance tests and QS and LOS
4. Analyzing and exporting the walks in batches via Test List feature
5. Video file exporting for the walk tests
6. Uploading txt and video files to the Hopkins OneDrive folder “GaitQC”

a. Before exporting to txt file for the first time

The Exporting Preferences need to be set the first time a study site exports any gait mat information. Once they have been set for a site, they do not need to be re-set; using the “Export to file” button will automatically use the set Export Preferences.

Setting up Exporting Preferences – only needs to be set up once per site	
	<p>Click the file icon for preferences in the Analyze Trial screen.</p>

 	<p>In the Gait tab, Select “Foot Reference Location” to “Heel”. Check that all measurements are analyzed.</p> <p>Make sure all the measurements are selected for all categories.</p>
	<p>Go to “Export Preferences” tab.</p>
	<p>Set “Default Export File Path” to folder on the Notebook/laptop. This folder will be where all exports go to be later uploaded to the Hopkins OneDrive.</p> <p>The file path will now appear to the right.</p>
	<p>Set “Default Export File Name” to have:</p> <ol style="list-style-type: none"> 1. “First” name (the field where a participant’s ID was entered) 2. Date and Time 3. Reference <p>The file name will have the following structure:</p> <p>Drive:\\ZGM exports\ID##### - 7-27-2011 7-02-31 AM – UP2.txt</p> <p>Verify that the “Header Contents” includes Test Time, Reference, Comment 1, First Name, Full Name, Age, Gender, and Partition Line.</p>

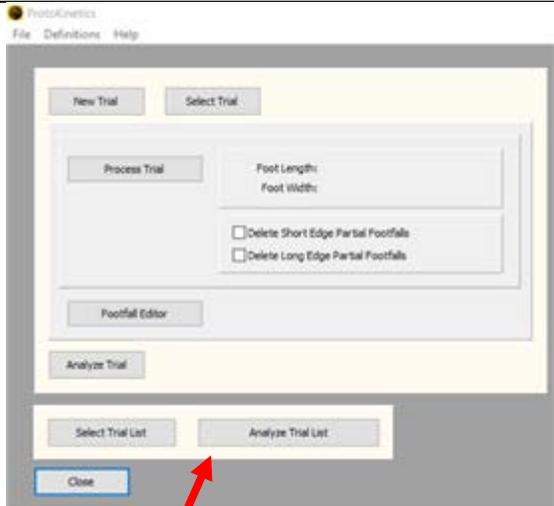
	<p>NOTE: The fields Full Name, Age, and Gender are blank. They are needed to generate the EasyReport to participants using Version 5 of PKmas</p> <p>Fields can be added by following the second red arrow shown to the left.</p>
 	<p>In the “Export” tab, select all Computations to export.</p>
	<p>Verify that the default file name has the participant’s ID, the date, and the name of the test.</p> <p>The file to the left was a mock participant on July 27, 2011 completing the usual pace walk, trial two, with the participant ID of ID###.</p> <ul style="list-style-type: none"> • Participant ID: “ID###” • Date: “7-27-2011” • Test name: “UP2”
	<p>Return to the PKmas homescreen. Open a different test and open Process Trial.</p> <p>Verify that the export settings have automatically changed for the new test.</p> <p>The default export settings now load automatically.</p>

b. Processing Tests

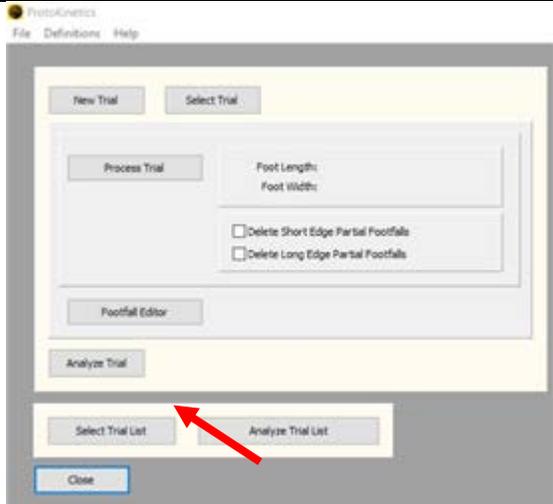
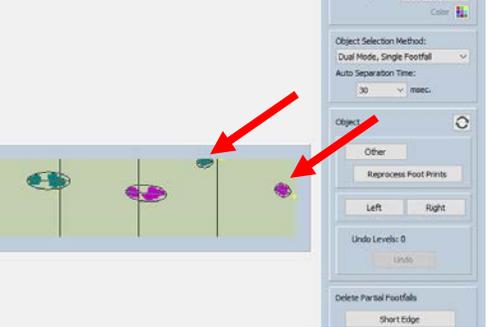
The goal of processing a test is to verify that all the footprints have been correctly identified and labeled by the mat. Examiners should check that Right vs. Left footprints have been identified correctly, that partial footprints due to the participant not stepping fully on the active zone (include the starting standing footprints) are labeled as “Other”.

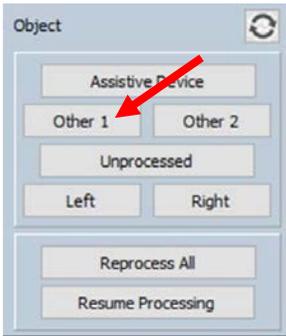
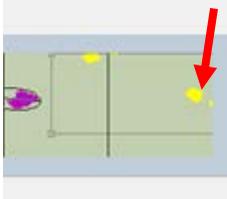
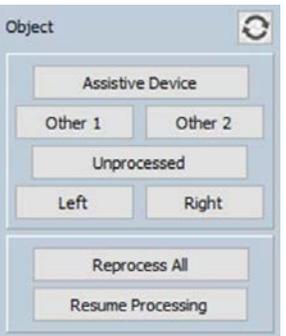
While processing the data, the participant will have a wait period. Other examiners may interact with the participant during this time (e.g. administer questionnaires, perform other tests etc.) If grip strength is best performed elsewhere due to gait mat placement, this processing time can serve as a replacement rest period prior to the TMW.

The data must be processed to create the participant report. Give the report to the participant at the end of the clinic exam. To process a walk after the participant completes testing, use the following steps. All tests must be processed individually. Processing the tests must be done before the datafiles can be exported.

Processing tests – all trials of all tests must be processed one-by-one			
		Select the trial to process.	
1	U	11/21/2015 9:28:35 AM	
2	U	11/21/2015 9:27:50 AM	
3	U	11/21/2015 9:27:02 AM	
4	U	11/21/2015 9:26:12 AM	
5	P	11/21/2015 9:25:24 AM	

Tests that have not been processed have the Type “U” (from “Unprocessed”). Tests that have been processed say “P”, including balance tests.

	<p>Select "Process Trial".</p>
	<p>Check the footprints are labeled correctly on the mat. Check that walking aids have been labeled "Assistive Device". If the examiner stepped on the mat, label their footprint(s) as "Other 1".</p> <p>Right and Left footprints are labeled in green and purple. Yellow marks are things the mat has recognized as incomplete footprints.</p> <p>NOTE: For the walks, the participant starts with their feet half-on, half-off the active zone. Those standing footprints should be labeled "Other 1" in yellow.</p>
	<p>In the walk to the left, there are two incomplete footprints at the right edge of the mat that the PKmas software incorrectly identified as "Right" and "Left" instead of "Other1".</p>

		<p>Move the grey selection box so that it surrounds the partial footprint(s) that need to be relabeled. Click “Other” in the dialogue pane to label the footprints as “Other”.</p> <p>Select the “Left” or “Right” buttons to label the footprints and left or right.</p>
		<p>The selected footprints are now yellow, showing that PKmas has now correctly labeled them as “Other”.</p> <p>This process is the same for labelling examiner footprints as “Other” and for labelling walking aids as “Other”.</p>
		<p>Exit the Processing screen by clicking “Close”. The file is now ready to Analyze and Export.</p>

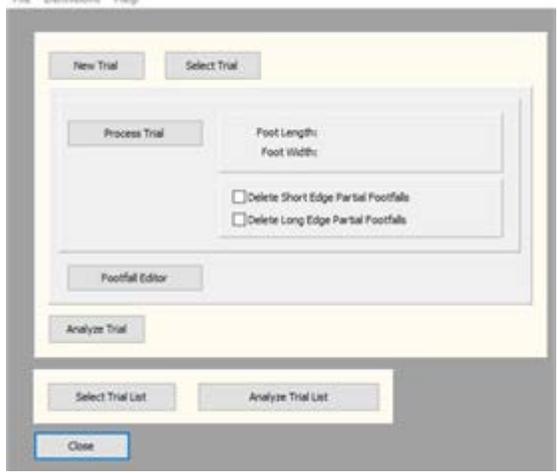
c. Analyzing and Exporting

i. Analyzing and Exporting the QS and LOS

The QS and LOS test must be exported individually. For the QS and LOS, the examiner exports the “QS and LOS Table”.

NOTE: Walk tests—usual pace, dual task, and short fast pace—can also be analyzed and exported one-by-one according to these same instruction pattern, but the “Gait Measurements”

table is exported. The walk tests can also be exported in batches for faster processing, using the Test List feature shown later.

One-by-One analyzing and exporting – for QS and LOS	
	<p>From the PKmas home screen, select a test that has been processed and click “Analyze Trial”.</p>
	<p>For the QS and LOS, click on both the icon of a person with arrows pointing away from their feet to process the QS and the LOS respectively. If a participant did not complete the LOS, but DID complete the QS, select the standing icon without arrows (you may get an error if you select differently).</p> <p>Then select the “Export to file” icon on the “QS and LOS Table”. Do not export the “Gait Measurements” table for the QS and LOS.</p>
	<p>Verify that the default file name has the participant’s ID, the date, and the name of the test.</p>
	<p>The selected QS and LOS test has been exported as a txt file to the designated folder on the Notebook or laptop.</p>

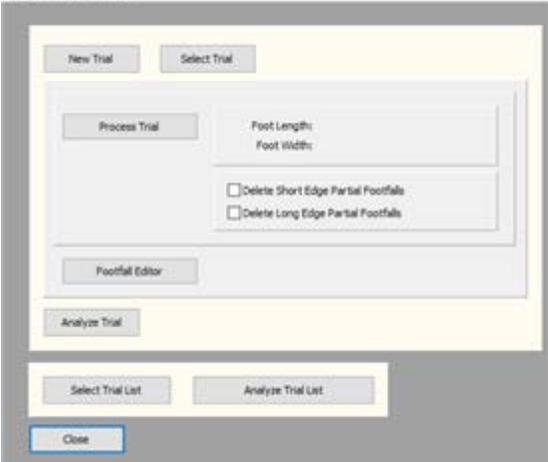
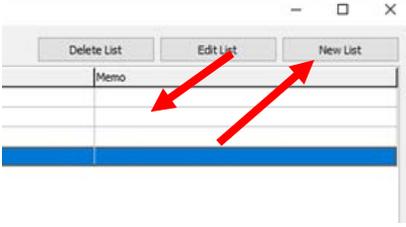
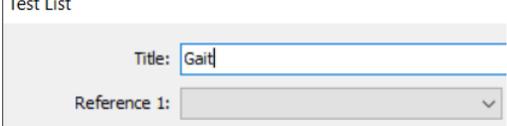
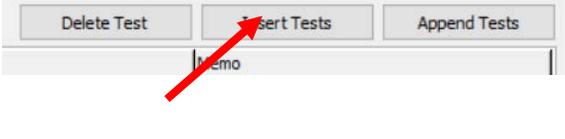
ii. Analyzing and exporting the walks in a batch via Trial List

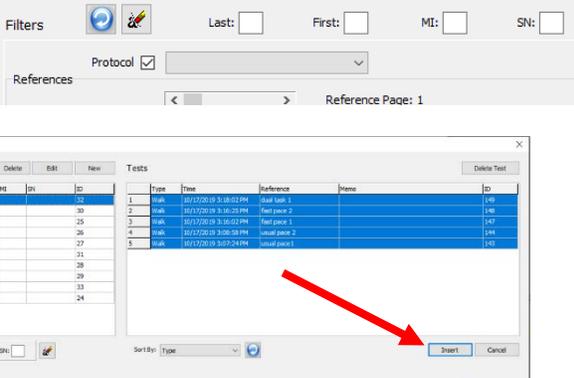
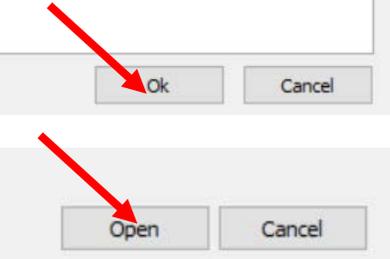
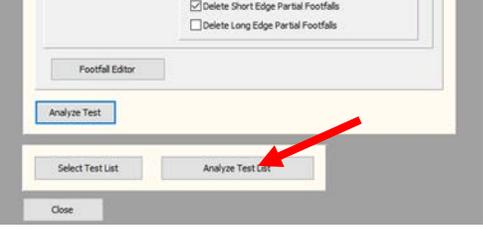
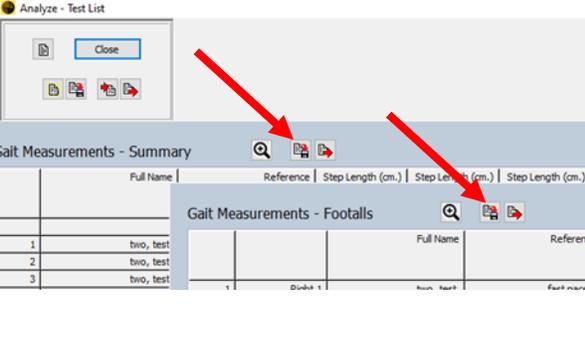
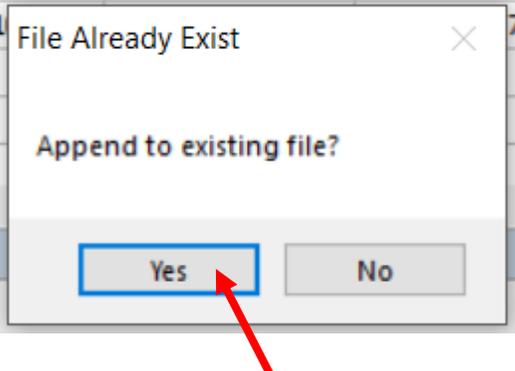
The three types of walk tests—usual pace, dual task, and short fast pace—can be analyzed and exported in a large batch. Multiple participants’ walks can be analyzed and exported in one

batch (i.e. all of the walks from participant X can be analyzed and exported in the same batch as all of the walks from participant Y) using the Trial List feature.

Analyzing many walks at the same time will take the software a few minutes. The more walks are in the Trial List, the longer this takes.

For additional information on Trial List exporting, see the “Using Trial Lists” pdf supplied by ProtoKinetics.

Batch analyzing and exporting via Trial List – for usual pace, dual task, and short fast pace walks	
	<p>From the PKmas home screen, click “Select Trial List”</p> <p>NOTE: Previous versions of PKmas software refer to the Trial List feature as the “Test List” feature; these are equivalent terms.</p>
	<p>Create a new Trial List by selecting “New List”</p> <p>Note: Delete old Trial Lists as they are exported. There should be only one active Trial List at a time.</p>
	<p>Title the new Trial List “Gait”. <u>Use the same title for all Trial List exports</u> so that new Trial List exports can be added to the same master file as old Test List exports.</p> <p>The Trial List feature saves participant IDs, dates, and test names within the file.</p>
	<p>Insert trials.</p> <p>Select which participants and which walk tests will be added to the new Trial List using “Insert Trial”.</p>

	<p>Check the Protocol Filter box and ensure that the dropdown to the right is empty. This will filter out the QS and LOS trials.</p> <p>Multiple tests can be selected at once by using the Shift key + dragging the cursor. Alternatively, multiple tests can be selected by holding down the Ctrl key and clicking each test one-by-one.</p> <p>Click “Insert” to add the selected tests to the Trial List.</p>
	<p>If an error has been made in adding tests, use “Append Trial” to add more tests or “Delete Trial” to remove tests from the Trial List.</p> <p>When all the walks have been added to the Trial List, select OK.</p> <p>Select the Trial List and click “Open”. PKmas redirects to the home screen.</p>
	<p>From the PKmas home screen, select “Analyze Trial List”</p> <p>NOTE: Once the Trial List begins analyzing, it cannot be stopped until it finishes. This can take several minutes and takes longer the more walks are in the batch.</p>
	<p>Two tables appear, a Gait Measures “Statistics” and a “Footfalls” table.</p> <p>Use the “Export to file” icons to export <u>both</u> tables.</p> <p>NOTE: Previous version of the PKmas software referred to the Gait Measures Statistics table as “Gait Measurements – Summary” (as left); these are equivalent terms.</p>
	<p>A dialogue box will now appear because the new Trial List has the same name as all the old Trial Lists. Select “Yes”. This appends (adds) the new Trial List to the end of the old Trial Lists, creating a master file.</p> <p>If this message does not appear, check that the new Trial List was named the same way as previous test lists.</p> <p>NOTE: Upload gait mat txt files to the Hopkins OneDrive twice-a-month (for both ARIC visits and ARIC Generation 2 visits). This helps the QC and</p>

	<p>the Coordinating Center and also protects examiner's time if a new Trial List accidentally is saved as a replacement instead of an appended file.</p> <p>If the new Trial List isn't appended to the existing file (if it replaced the old file), then the participants and walks since the last upload to OneDrive will have to be re-analyzed and exported.</p>
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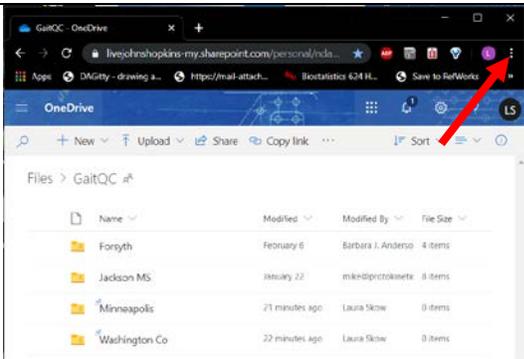
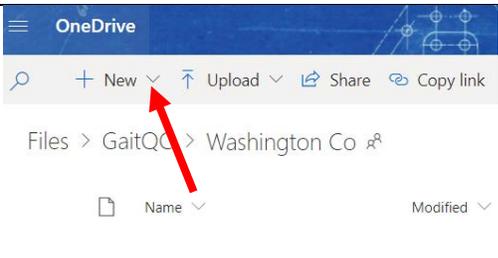
iii. Video exporting

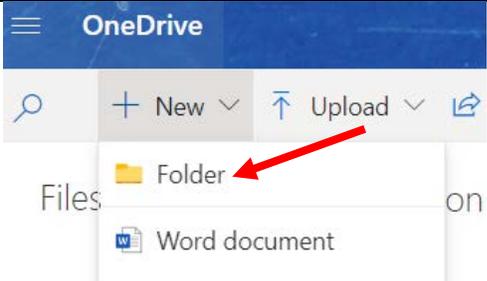
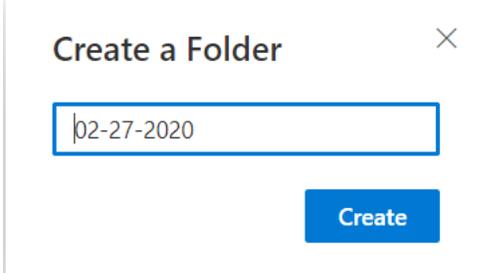
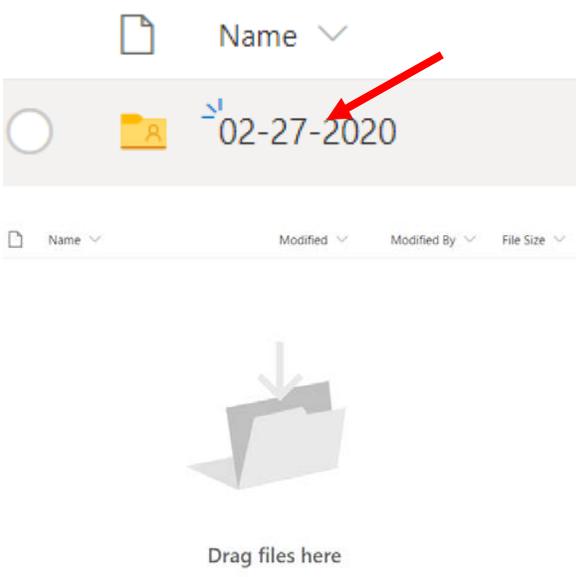
Video files are only exported for the walks and where there is site IRB approval and participant consent. PKmas automatically saves video files to the "Video" folder in the PKmas parent folder. The video files are transferred as part of the monthly PKData folder QC upload to the site's QC sub-folder on the OneDrive. There is no need to rename or sort the video files by participant; PKmas automatically assigns each video file with a unique serial code that is linked to the walk test export.

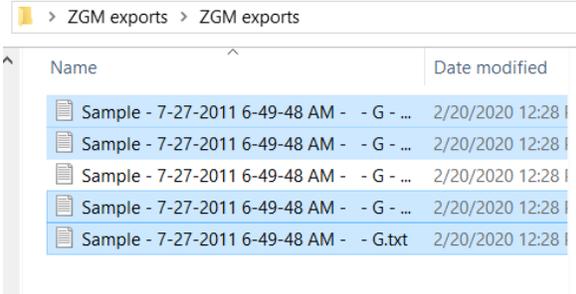
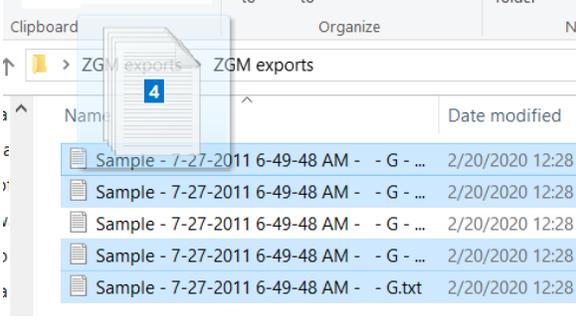
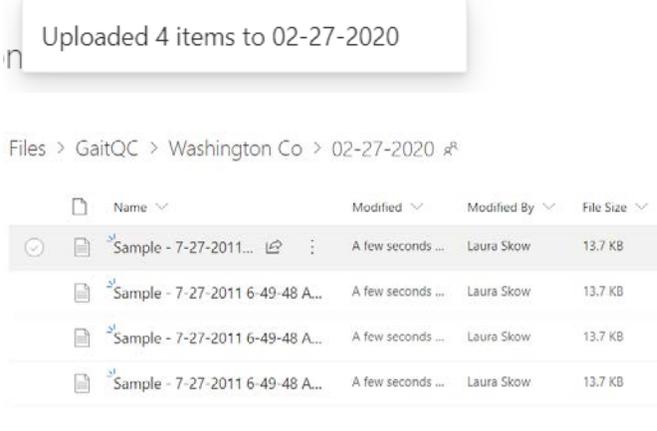
Copying video files to the OneDrive may take several minutes, and takes longer the more video files are being copied at once.

d. Transferring gait mat txt files into OneDrive.

Transfer the exported txt data files from the Notebook laptop at each field center to a secure server on the Johns Hopkins University OneDrive folder "GaitQC" at least twice a month. The same folder is used for both ARIC Generation 2 and ARIC Visits.

<p>Transferring from export folder to OneDrive</p> 	<p>Open OneDrive GaitQC. If convenient, this site can be bookmarked at the top of your browser by using the bookmark settings (red arrow).</p> <p>Click on your site's folder.</p>
	<p>Within the folder, select "+ New" option "New Folder".</p>

 <p>OneDrive</p> <p>+ New ▾ ↑ Upload ▾ ↗</p> <p>Files</p> <ul style="list-style-type: none">Folder ←Word document	
 <p>Create a Folder ×</p> <p>02-27-2020</p> <p>Create</p>	<p>Create a folder with the date of the file transfer in the format MM-DD-YYYY.</p>
 <p>Name ▾</p> <p>02-27-2020 ←</p> <p>Name ▾ Modified ▾ Modified By ▾ File Size ▾</p> <p>Drag files here</p>	<p>Click on the new folder.</p> <p>The folder is currently empty.</p>
 <p>ZGM exports</p>	<p>Open the export folder on the Notebook, where the .txt files have been exported from the PKmas software according to the instructions above.</p>

	<p>Select the files to be transferred to the OneDrive.</p> <p>NOTE: SHIFT + cursor drag will select multiple files that are next to each other at the same time. CTRL + cursor clicks will select multiple files that are not next to each other. These can be used in combination.</p>
	<p>Drag the selected files out of the export folder and into the new OneDrive GaitQC folder.</p>
 <p>Drag files here</p>	<p>NOTE: It will say "+ Copy" below the files. The files are not deleted from the export folder on the site Notebook or computer.</p>
	<p>A pop-up banner will show that the files are being uploaded and when they have been uploaded.</p> <p>The files are now uploaded into the GaitQC OneDrive.</p> <p>NOTE: OneDrive keeps a copy of versions of a document. If something is accidentally deleted or changed, the old version could be recovered within OneDrive under version history.</p>

4 ZENO GAIT MAT (ZGM FORM)

4.1 ADMINISTRATION OF QUIET STANDING AND LIMITS OF STABILITY

Using the gait mat, a participant's stable standing and ability to lean comfortably and safely is measured.

Ask the participant if they feel comfortable standing and rocking in place without a walking aid. If they do not, record this on the ZGM form and move to the next section. Walking aids cannot be used for Quiet standing or Limits of Stability testing.

a. Quiet Standing (QS) and Limits of Stability (LOS)

QS:

The participant's foot should have as much contact with the floor as possible. If they are wearing shoes with a heel or rigid sole, offer the participant socks with grippers (hospital slipper socks), or they can wear their own socks if they are comfortable from a safety perspective. The participant should stand on the mat in the active sensor zone, facing the end of the mat with the cables.

Say to the participant: "The next test will assess how you balance yourself. I will ask you to stand in place without moving for 30 seconds, and then to lean in four directions as far as you can comfortably and safely without lifting any part of your foot off the floor. It is important that you do not move your feet until I say it is time. If you feel unsteady, you should take a step to the side. Let me demonstrate what I've described."

Show the participant the quiet standing (can be less than 30 seconds but remind them they will stand for 30 seconds), then describe the rocking as you demonstrate it in each direction. Add "notice how I am not moving my feet as I go from standing quietly to rocking. Do you have any questions?" When ready to begin, say "To begin, I will ask you to stand facing me and march in place a few times." [Let the participant march in place 3-4 times.] "Now stop, stand quietly in place for 30 seconds. After 30 seconds, I will tell you when you which way to lean without moving your feet. I will let you know when you can move your feet."

Press "Start Walk" in PKMAS. When the mat begins collecting data, say "Ready? Time starts now." Stand next to the participant.

At the end of 30 seconds, do NOT stop the recording. Make sure the participant does not pick up their feet.

LOS:

Say to the participant: "Don't move your feet. Keep all the parts of your feet on the floor at all times. Rock forward, now back to the middle. Now rock to the right, keeping your entire foot on the ground. Return to the middle. Now lean to the left, back to the middle. Now rock backwards, only to where you feel comfortable, without losing balance, now come back to the center." If the participant leans out of order, e.g. left then right, you do not need to repeat the test.

When the participant has returned to the middle, stop the recording by clicking “End Walk” in PKMAS and say, “You can move your feet now”. Mark completion status for the QS and for the LOS on the ZGM. Regardless of completion status for QS and LOS, save the file as “QS and LOS” in the preset drop down list of tests.

4.2 ADMINISTRATION OF USUAL PACE WALK ON THE MAT

This test uses the gait mat. If the gait mat is not operational or if the participant refuses to use the gait mat, record so on the ZGM form and administer the usual pace walk according to section 2. “Administration of the SPPB 4 Meter Usual pace walk.” In V10, participants are to complete both the usual pace walk on the gait mat (ZGM) and the 4m usual pace walk off the mat (PFX)

a. Usual pace walk

Say to the participant: “I’m going to ask you to do a short walk over this gait mat two times. You will walk at your normal or usual pace for two trials. I will demonstrate. Place your feet with your toes touching the line, like this. Walk a few steps past the end of the mat.” Demonstrate by walking to the other end of the course at your usual pace, making certain you walk past the end of the mat before slowing or stopping.

Make sure the participant’s feet are in proper position with the starting feet partially, but not fully, on the active zone of the mat.

If the feet are not being read by the mat, move the foot placement forward into the sensor area 1-2 inches more. When standing at the start of the test, a participant’s foot should be partially, but not fully, on the active sensor zone.

Say: “Do you have any questions? When I say “Go,” please walk at your normal pace. Remember to walk off the end of the mat without slowing down.” To start the test click “Start Walk” in PKMAS and verify that the collection has begun.

When the timer has begun, say, “Ready, Go,” and depress the clicker on the word “go.”

Observe the participant’s arm swing as he/she walks.

After the participant has left the gait mat, stop the trial in PKMAS by clicking “End walk”. Save the trial as “UP1” in PKMAS and record completion status on the ZGM form.

If the participant stepped outside the active sensor zone during the length of the walk, do not save trial. Re-do the test and record the repeat as trial 1, i.e. “UP1”.

Have the participant line up at the far side of the mat to do the second trial coming back. Have the participant repeat the usual pace walk: “Let’s try this one more time. Ready? Go,” and depress the clicker on the word “go.” If there are safety concerns about managing the software and walking with the participant during the 2nd walk, the second walk can be done with the participant returning the same end of the mat for trial 2. The examiner can select “Start Walk”, leave the clicker, and walk with the participant.

After the participant has left the gait mat, stop the trial in PKMAS by clicking “Stop walk”. Save the trial as “UP2” and record completion status and arm swing observations on the ZGM form.

If the participant stepped outside the active sensor zone during the length of the walk, do not save trial. Ask the participant to re-do the test and record as trial 2.

b. Scoring arm swing

For both trials, the examiner should observe the participant’s arm swing movements. At the end of the second trial, score according to the following guidelines. Arm swing scoring is subjective and captures presence or absence of arm swing in one or both sides. If the hands swing past the front and back of the body, record arm swing as “present”. If the hand(s) do not fully pass an imaginary horizontal plane in front of and behind the body, record “absent” arm swing.

The ARIC training video entitled Body Bradykinesia.mpg can be found on the ARIC website (Training > Visit 8/NCS). This training video was originally designed as part of a more extensive evaluation for movement disorders and includes information beyond arm swing examinations and scoring procedures. Although the video was designed to observe and score the body overall for speed of movement, poverty of movement, and amplitude of movements, it is being used to provide training only for arm swing movements. Bear in mind that in the video, the score could be abnormal despite a normal arm swing due to findings related to other body parts. Therefore, do not consider the scores in the video to reflect arm swing scoring; this is an example video of convenience.

The first two people in the video illustrate normal arm swings; they received scores of 0 and 1 for overall bradykinesia. The 3rd person, “Martha”, received a score of “2” for overall bradykinesia, but would also be rated as a normal arm swing as she entered room. “Sherman”, who received a score of 3 for overall bradykinesia, would be rated as absent arm swing in both arms; observe Sherman’s arms when he enters the room.

In the following video link (Stanford Medicine 25; Exam for Parkinson Disease), the patient undergoes a gait examination that includes observations about arm swing. The neurologist demonstrates an asymmetric loss of arm swing on her right and a normal arm swing on her left prior to the patient walking. Afterwards, observe “Larry” walking in the hall; you can see his arm swing exam at time 13:17 -13:43.

<https://www.youtube.com/watch?v=cxHpFWKIfGw&t=13m27s>

4.3 ADMINISTRATION OF SINGLE COGNITIVE TASK

This test does not use the gait mat but is required for the dual task gait mat walk. Responses are recorded on the ZGM form.

a. Subtraction by serial 3s

Participants may sit or stand for this task. Say to the participant: “Now I’m going to ask you to do a mental task. When I say “go”, please count backwards from 100 by 3s. I will tell you when to stop. Do you have any questions? Ready, go.”

Stop participant after seven answers or when they pass 79, whichever happens first.

Record the answers the participant gives in the ZGM form, regardless of if they are correct or not. A correct answer is 3 less than the previous answer, regardless of whether the previous answer was correct itself (e.g. “97, 91, 88” is “correct, incorrect, correct” = 1 error, 2 correct).

If the participant has 3 or more correct answers, mark “Yes, had 3 or more correct” in the ZGM form and continue on to the dual task. Use subtraction by serial 3 as the cognitive task in the dual task.

If the participant refuses the test, attempts and discontinues, or has fewer than 3 correct answers, mark so on the ZGM form and continue on to the “Subtraction by serial 2s” cognitive task.

b. Subtraction by serial 2s

Participants may sit or stand for this task. Say to the participant: “Let’s try another task. When I say “go”, please count backwards from 100 by 2s. I will tell you when to stop. Do you have any questions? Ready, go.”

Stop participant after seven answers or when they pass 86, whichever happens first.

Record the answers the participant gives in the ZGM form, regardless of if they are correct or not. A correct answer is 2 less than the previous answer, regardless of whether the previous answer was correct itself (e.g. “98, 91, 89” is “correct, incorrect, correct” = 1 error, 2 correct).

If the participant refuses or discontinues the test, mark so on the ZGM form and do not complete the dual task walk.

4.4 ADMINISTRATION OF DUAL TASK

This test uses the gait mat. Responses are recorded on the ZGM form.

The dual task combines a cognitive task (serial subtractions from 100) with a physical task (walking at usual pace).

If necessary, participants may use walking aids, such as a walker or cane. Ask participants who arrive with walking aids if they think they can do this short walk without the device when showing them the course. Often, participants who have aids will feel very comfortable and are quite capable of walking the gait mat without a walking aid when they see the length of the course. In these cases, the exam should be done without the aid.

Say to the participant: "When you are ready, we'll do another walk."

When the participant is rested, position them in the same place as for the usual pace walk. They will complete the same usual pace walk protocol, but this time they will simultaneously complete the serial subtraction that was used in the single cognitive task. If they were able to correctly give 3 or more correct responses to serial 3s, use serial 3s in the dual task. Otherwise use serial subtraction by 2s.

Say to the participant: "I'm going to ask you to walk over this mat while talking. Place both feet with your toes at the starting line, like this."

Make sure feet are in proper position in front of the tape line and on the active zone of the mat. To start the test click "Start Walk" in PKMAS and verify that the collection has begun.

When I say "Go", please walk at your normal pace while counting backwards by **[THREES OR TWOS]** starting with 100. Remember to walk off of the end of the mat without slowing down. Do you have any questions?"

Then say, "Ready? Go," and press the clicker on the word "go." The examiner walks slightly behind and to the side of the participant during each of the dual task walks. Responses can be recorded on paper rather than on the form during the dual task walks if the examiner prefers for safety reasons. After the walks, record all of the participant's responses for serial subtractions on the ZGM form.

After the participant has walked past the other end of the gait mat, stop the trial in PKMAS by clicking "End walk". If the examiner cannot safely monitor the participant and operate the clicker, leave the clicker with the Notebook after depressing the clicker. Examiners are not required to depress the clicker when participant ends the walks. Save the trial as "DUAL1" and record the walk on the ZGM form.

If participants veer off the sensor area or the examiner cannot hear responses during the dual task, the examiner should stop the test. As soon as the first cognitive response is not heard, the test should be stopped. Ask the participant to repeat the walking task and to speak up. The examiner should try to remain in close proximity to hear responses if possible. Do not repeat the first dual task more than once. The second dual task walk should not be repeated if the first trial was repeated. If the first trial was not repeated, then the 2nd can be repeated. A maximum of three walks can be completed: one partial and two full length trials. If answers cannot be heard during the recorded walk, record as "Attempted, responses unclear."

If participants stop walking or stop attempting subtractions during the dual task, stop the test and review the instructions but do not save the interrupted test in the software. If the participant cannot complete walking and serial subtractions simultaneously, mark "No, attempted, discontinued". Only save the walks if participant were attempting subtractions and walking for the complete length of the sensors.

Have the participant repeat the dual task walk.

Say: "Let's try this one more time." To start the test click "Start Walk" in PKMAS and verify that the collection has begun. Then say, "Ready? Go," The participant will now be at the end of the mat away from the Notebook. The examiner does not need to depress the clicker for the second walk in the dual task if it is not feasible to watch the participant, record responses, and use the clicker together. Write the subtraction responses on paper or on the ZGM form as the participant is walking. Responses can be transcribed to the data collection form after the participant has completed the test and left the area.

After the participant walks past the end of the gait mat, stop the trial in PKMAS by clicking "End walk". Record the trial as "DUAL2".

Participants may slow their pace, veer to the side, stop, or teeter during the dual task. The examiner should walk to the side and a little behind the participant to avoid setting the pace for the participant, but be prepared to provide stability if needed. If participants are upset with their performance, you may say the following or something similar to "It is not uncommon for people's walking patterns to change when they are also thinking about other things."

4.5 ADMINISTRATION OF SHORT FAST PACE WALK

Time to walk the length of the gait mat at the participant's fast pace is measured. This should always be given after all the usual pace and dual task walking tests are completed.

Participants may use walking aids, such as a walker or cane for this task. Ask participants who arrive with walking aids if they think they can do this short walk without the device when showing them the course. Often, participants who have aids will feel very comfortable and are

quite capable of walking the gait mat without a walking aid when they see the length of the course. In these cases, the exam should be done without the aid.

Say to the participant: “Finally, I’m going to ask you to do a fast walk over this gait mat. You will start with your feet behind and your toes touching this line like you did before. When I say ‘Go,’ you will walk down the mat fast as you can without running or hurting yourself. I will demonstrate.”

“Walk a few steps past the end of the mat.” Demonstrate by walking to the other end of the course at a fast pace, making certain you walk past the finish line before slowing or stopping.

Make sure the feet are in proper position with the toes lined up behind the line. “Do you have any questions? When I say “Go,” walk at a fast pace without running. Remember to walk a few steps past the end of the mat.” To start the test click “Start Walk” in PKMAS and verify that the collection has begun.

Say, “Ready, Go,” and press the clicker on the word “go.”

After the participant has left the gait mat, stop the trial in PKMAS by clicking “End walk”. Record the trial as “FP1”. If the participant stepped outside the active sensor zone during the length of the walk, do not save trial. Re-do the test and record as FP1. The participant may be allowed a short break before either of the fast pace walks.

Have the participant repeat the short fast pace walk:

Say: “Let’s try this one more time.” To start the test click “Start Walk” in PKMAS and verify that the collection has begun. Ready? Go,” and press the clicker on the word “go.”

After the participant has left the gait mat, stop the trial in PKMAS by clicking “End walk.” Save the trial as “FP2” and record on the ZGM form.

4.6 TRAINING

Usual pace and fast pace walks

- Camera captures arms and legs, up to chest level but not participant’s face
- Script correctly and clearly delivered
- Correctly demonstrates
- Both feet are behind the tape and partially in the active sensor zone
- Clicker marks “go” signal in the PKMAS software.
- Repeat (second trial)

- Partial footfalls, walking aids, and non-participant signals are marked as objects
- If the participant leaves the active sensor zone, the trial is repeated. If the participant leaves the zone again, the trial can be repeated or not according to the examiner's discretion.
- If task was not performed on the gait mat, codes/records reason
- If task was not performed, codes/records reasons

Quiet standing and Limits of Stability testing

- Script correctly and clearly delivered
- Correctly demonstrates position
- If task was not performed, codes/records reasons
- Saves files, regardless of completion status of QS and LOS, as "QS and LOS" from the preset drop down list of test names.

Single cognitive task and Dual task

- Camera captures gait but not participants face on dual task (no camera for single cognitive task)
- Script correctly and clearly delivered
- Correctly demonstrates
- Feet are lined up behind the tape with toes and pads of feet in the start of the active sensor zone
- Clicker is used when examiner alerts participants to begin, required only for the first trial
- Repeat (second trial, clicker not required)
- Records responses to serial subtractions on ZGM form and correctly determines administration of serial 3s versus serial 2s
- If task was not performed, codes/records reasons

Reports

- Uses Easy Reporting software to print participant's report on day of visit

Downloading and Saving Data

- Saves data files using appropriate filenames
- Uploads all data files to the designated secure server (JHU OneDrive "GaitQC")

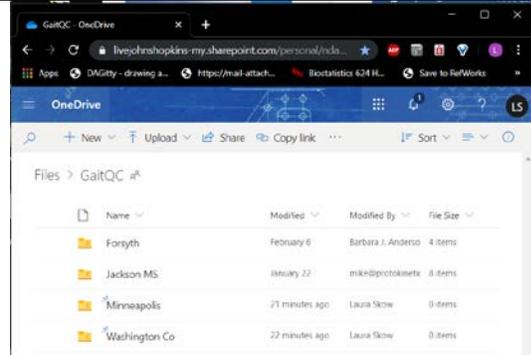
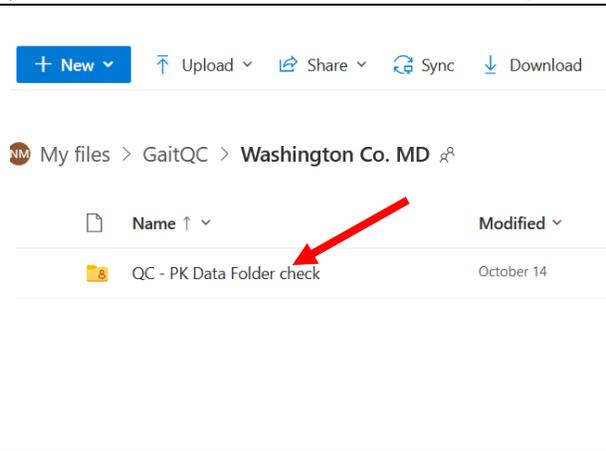
4.7 QUALITY CONTROL AND VIDEO UPLOADS

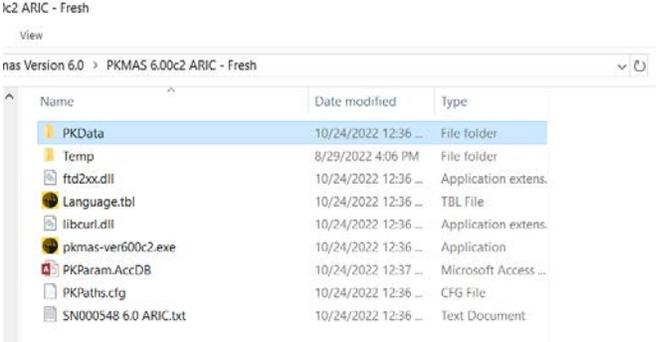
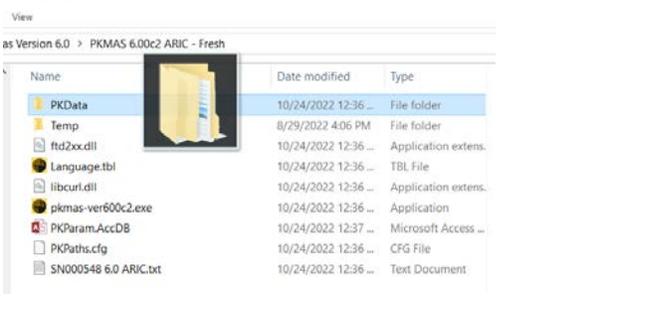
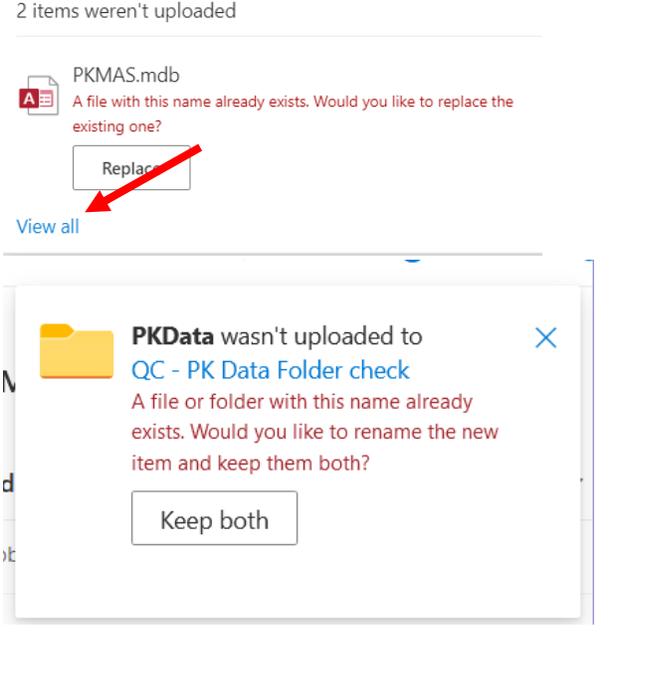
The data collected by each interviewer are reviewed by a ProtoKinetics representative early in Visit 10 and/or central ARIC staff. Data patterns suggestive of deviations from protocol are brought to the attention of the field center principal investigator, QC officer or designated personnel. Observation of the assessments then follows, with discussion of possible remedial actions with staff. Major deviations are brought to the attention of the Executive Committee.

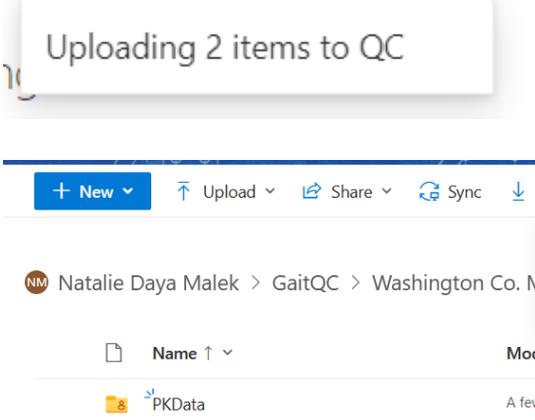
Copy the "PKData" folder (includes the videos files of participants and the PKmas database) into the Hopkins OneDrive under the QC folder twice-a-month (biweekly) for the first month of

the visit and at least once a month subsequently. The same QC folder and the same schedule should be used for ARIC Generation 2. The PKData folder allows ProtoKinetics and central ARIC staff to review raw unprocessed PKmas trials to check for any software or protocol issues.

Note: Copying the PKData folder into OneDrive may take a long time to upload and the computer may not be useable until the upload is completed. Consider uploading after the last participant is done for the day.

Transferring from the PKData folder to OneDrive for QC	
	<p>Open OneDrive GaitQC.</p> <p>Click on your site's folder.</p>
	<p>Within the site folder, select the "QC – PK Data Folder check" folder.</p>
	<p>Open the PKmas software folder on the Notebook, where the pkmas .exe file is used to launch the application.</p>

	<p>Select the <u>PKData</u> file to be transferred to the OneDrive.</p> <p>Within the PKData folder are the video files and the raw software database files. You will be transferring all of these files when you transfer the PKData folder.</p>
	<p>Drag the selected PKData folder out of the export window and into the new OneDrive GaitQC folder.</p>
	<p>NOTE: It will say "+ Copy" below the files. The folder is not deleted from the export folder on the site Notebook or computer.</p>
	<p>NOTE: The folder may have previous versions of the PKData folder. If prompted by OneDrive, replace that folder with the new transfers. The new version copied over is an updated version of the previous files.</p> <p>If replacing the old folder is not an option, select "Keep both" and renamed the new file with the date, e.g. PKData-MM-DD-YYYY</p>

 <p>The screenshot shows a OneDrive interface. At the top, a white pop-up banner with a checkmark icon says "Uploading 2 items to QC". Below the banner is a navigation bar with buttons for "New", "Upload", "Share", "Sync", and "Download". The breadcrumb path is "Natalie Daya Malek > GaitQC > Washington Co. M". A table lists files with columns for "Name" and "Modified". One file is visible: "PKData" with a modified date of "A few".</p>	<p>A pop-up banner will show that the folder is being uploaded and when it has been uploaded.</p> <p>The folder is now uploaded into the GaitQC OneDrive.</p> <p>NOTE: OneDrive keeps a copy of versions of a document. If something is accidentally deleted or changed, the old version could be recovered within OneDrive.</p>
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5 TWO MINUTE WALK (TME AND TMW FORM)

Safety issues and exclusions for the TMW will be assessed on the Two Minute Walk Eligibility (TME) Form. **Staff must complete and save the TME form prior to completing the TMW form.** CDART will use the information gathered from the TME form to determine whether or not a participant is eligible to complete the Two Minute Walk. This eligibility information will be displayed in the TMW form. Please see section 5.2 below for details regarding the TME form and safety and exclusions.

5.1 ADMINISTRATION OF THE TMW

a. Administration of the Unintentional Weight Loss Questions

The goal of these questions is to document unintentional weight loss that has not been regained. In the first question, the participant is asked if s/he has lost 10 pounds in the past year. If the participant has not lost more than 10 pounds, record "No" and skip to question 3a. If the participant reports s/he has lost about 10 or more pounds, the response should be coded as "Yes" and the interviewer should then ask "About how much lower is your weight now than a year ago?" This will provide an estimate of weight loss in whole numbers. Record response and go to question 3. If the response to question 1 is "unknown", go to question 3 to ask if the participant was trying to lose weight.

b. Footwear

To reduce the effect of different footwear on test performance, the TMW should be performed in tennis shoes or comfortable walking shoes with minimal or no heels. The participant should be instructed during the pre-visit instructions to wear or bring comfortable walking shoes to the clinic.

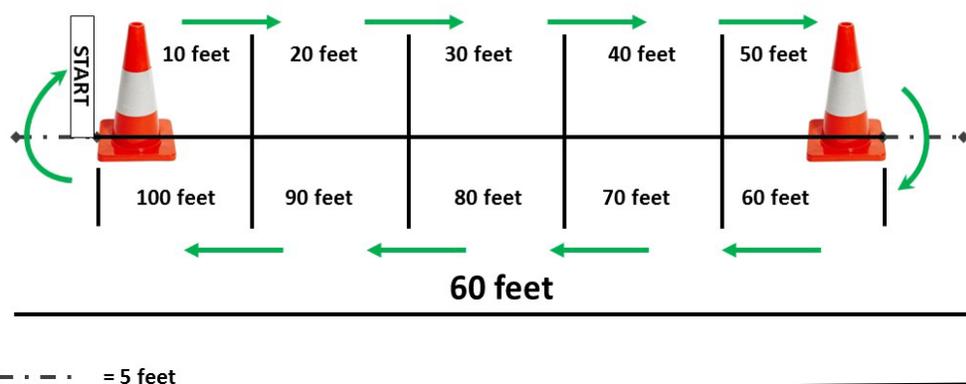
c. Course Set-up

For consistency, the walking course length will be 50 feet with an additional 5 feet on each end, laid out in an unobstructed, dedicated corridor. Use traffic cones to indicate the beginning and end of the course. The cones should lie fully within the 50 foot course (see Figure 4.7). Participants will walk in a clockwise direction. Place a 1.5 foot length of tape across the floor to the left of one of the cones to mark the start of the course.

Figure 4.7. Course set-up

Course Illustration

- 60-ft total space
- 50-foot walk, 10-ft intervals, 5 ft on each end



- **Gait mat.** Where possible, the two minute walk course should pass over the gait mat on one side of loop. Examiners should avoid stepping on the active sensor zone of the gait mat or on the black band along one side. If the two minute walk course takes the participant off the gait mat for half of the loop, then the examiner should walk behind the participant as a safety measure instead of next to and behind the participant. If the TMW is done on the mat, before beginning the walk, click "Start Walk" in PKMAS and verify that the collection has begun. Perform the two-minute walk as noted below. After the participant finishes, click "End walk" and save the trial as "tmw."

For easy access, the examiner should wear the stopwatch around his/her neck. To use the Ultrak 410 stopwatch (pictured at right), first press the reset button at the top left so the display shows **000 00"00**. To begin timing, depress the top of the right-hand button labeled START/STOP watch and press again at the bottom right to stop. The total time will appear on the primary display as minutes'seconds'hundredths of a second.

5.2 SAFETY ISSUES AND EXCLUSIONS

The Two Minute Walk Eligibility (TME) Form is used to assess safety issues and exclusions for the Two Minute Walk. The examiner must complete and save the TME form prior to completing the TMW form and administering the Two Minute Walk test. If there is an unclear answer to an exclusion question, the final decision to test rests with the medical supervisor. Any one of the following is cause for exclusion from the TMW and must be documented on the data collection form:



- Participants unable to complete the 4-meter walk without a walking aid
 - Use the results of the 4-meter walk trials from the PFX form. See section 5.2.a, 'Requires walking aid,' for using the information from the PFX and the rules for completing the partial PFX for ACHIEVE-enrolled participants.
- Resting heart rate < 40 or >110 beats per minute (bpm)
 - Use the results from the SBP form. See section 5.2.b, 'Heart rate and blood pressure,' for using results.
- Systolic blood pressure ≥ 180 or diastolic ≥ 120
 - Use the results from the SBP form. See section 5.2.b, 'Heart rate and blood pressure,' for using results.
- Cast or other immobilizing device on leg
- Self-reported angina (chest pain due to heart disease), heart attack, angioplasty, or heart surgery in the previous 3 months
- Seen or thought about seeing a health profession for new or worsening symptoms of chest pain or pressure, shortness of breath, or fainting in the previous 3 months
- Ziopatch alerts (1a, 1g) previously recorded for wide complex tachycardia >120 bpm sustained for more than 30 seconds or narrow complex tachycardia >180 bpm sustained for 60 seconds or more
- If any Ziopatch alert (1b-1e) was previously recorded for: 3rd degree heart block, Mobitz II 2nd degree AV block, pause > 6 seconds, or bradycardia < 40 bpm and sustained for > 30 seconds, then the participant must be asked if they have a pacemaker.
 - If response is "No" or "Uncertain", then exclude.
- Atrial Fibrillation documented from a variety of **sources*** and displayed in the CDART Participant Snapshot Report **requires a manual heart rate check.**

- If the manual heart rate is < 40 or > 110 bpm, this supersedes the Omron vitals and the participant is excluded. Section 5.2.c, 'Measuring heart rate' describes how to take a manual heart rate.

* **Sources** include the following.

- Self-reported treatment of atrial fibrillation in the past three months
- Ziopatch abnormality of atrial fibrillation or atrial flutter
- Ziopatch alert for atrial fibrillation
- Atrial fibrillation documented in ARIC by ECG or hospitalization codes

a. Requires walking aid

Some participants who complete the short walks without a walking aid may be uncomfortable and/or unwilling to attempt a longer walk, such as the TMW, without the walking aid. Use of a walking aid is not allowed in the TMW. The results of the 4-meter walk trials are pre-populated in the TME form if data are entered into the PFX form for the clinic visit. If data are not entered into the PFX form, consult the PFX data and unlock the TME item 2 to answer the question about the walking aid. The PFX results **must** be collected prior to the TME/TMW and on the same day as the TME/TMW for safety concerns.

For ACHIEVE-enrolled participants, the full PFX form is completed during the ACHIEVE annual visit. The rules for the administration of the partial PFX during a participant's ARIC abbreviated visit 10 are:

1. When the abbreviated visit 10 is on the **same** day as the ACHIEVE annual exam (and the ACHIEVE exam occurs first), the ACHIEVE staff should share the 4-meter walk results with the ARIC visit staff. The ARIC visit staff will unlock the TME item 2 and answer the 4-meter walk question.
2. When the abbreviated visit 10 is collected at **any time other than** the ACHIEVE annual visit, the 4-meter walk trials must be conducted during the ARIC visit 10. The PFX form in the "V10 / NCS" form group should be partially completed for items 0a, 0b, 0c, 7-8d.

b. Heart rate and blood pressure

Heart rate and blood pressure results are pre-populated into the TME form if data are entered into the SBP form for the clinic visit. If data are not entered into the SBP form, consult blood pressure data collected in the SBP form earlier in the clinic visit. Then unlock the TME items 3 and 4 to answer the questions about average resting heart rate, systolic blood pressure, and diastolic pressure.

c. Measuring heart rate

The participant should be seated comfortably with the forearm extended and palm facing up. Place your index and third fingers in the groove between the bone and the tendon over the radial artery, which is located on the thumb side of the wrist, as shown in the pictures below, using either approach. If you can't find the pulse, try moving your fingers around a bit or press a little harder.



Perry AG, Potter PA, Ostendorf WR (Eds.) 2018. *Clinical Nursing Skills and Techniques [9th ed]*. St. Louis. Elseiver. <https://www.cdc.gov/physicalactivity/basics/measuring/hearttrate.htm>.

Using a timer, clock, or watch that counts seconds, count how many beats you feel in 20 seconds. Start the count on a beat, which is counted as “zero” as the second hand (or seconds) begins the timing cycle. The next beat is counted as “one”. Note the last beat felt when 20 seconds passes then multiply this by 3. Use a calculator if it is too difficult to calculate by hand.

If the heart rate in 20 seconds is 13 or less, then the calculated bpm will be < 40; if the heart rate is 37 or higher, then the calculated bpm will be > 110. If the examiner is uncertain of the heart rate due to a weak or irregular pulse, make note of this finding in the comment field, mark the response for manual heart rate on the form as “Uncertain / unable to complete” and exclude the participant from the TMW test.

For most participants, full administration of the TMW should take no longer than 4-5 minutes.

5.3 ASSESSMENT OF TEST ELIGIBILITY AND EXCLUSION CRITERIA.

- 1) Review exclusion criteria above and record responses on the TME and TMW forms. **Remember the TME form must be completed and saved prior to completing the TMW form.** Before beginning the Two Minute Walk test, tear off a piece of tape that will be used to mark the participant’s stopping point on the course.
- 2) Provide a brief, general description of the TMW to participants who have no exclusion criteria. Examiner should have participant sit in a chair near the beginning of the walking course.

Script: “This is an activity that shows how physically fit you are by seeing how far you can walk in 2 minutes. I will ask you to walk as fast as you can until I ask you to stop. I know this is hard for some people so don’t worry if you have to slow down or rest. If you do stop or slow down, start walking again as soon as you feel you are ready to do so. Is there any reason you cannot do the walk? **[wait for response]** Does anything hurt or are you in pain?” **[wait for response]**

If participant does not feel he or she can do this task, note this on the record sheet and continue with another measure.

Script: “You and I will not talk while you are walking because this might make you walk more slowly. I will, however, let you know how much time you have to walk and when you are almost done.”

While demonstrating first part of the task, say:

Script: “You will start with your feet behind this line. When I say ‘Go,’ you will walk back and forth around the cones as fast as you can without running or hurting yourself. You will begin

after I say 'Ready, 3, 2, 1, Go!' As you pass the cone, do not stop or slow down. When I tell you to stop, stop where you are on the path until I come to you. If you stop before I say "Stop," I still need you to remain at that point if you are able."

Demonstrate task and say:

Script: "Watch me as I show you what you are going to do. You see that I am walking fast but not running and that I am not slowing or stopping when I pass the cone. When I say "stop", stop in place like this." (Stop where you are and stand still on the path.) If the gait mat is on one side of the course, say "You will only walk on the mat when walking this direction. Don't cross over to go back on the mat. Do you have any questions?" Answer questions as necessary.

Script: "Stand with your toes at the starting line. Ready, 3, 2, 1, Go!"

Start timing the participant when the first foot crosses the start line, before making first footfall. Examiner should begin marking off the number of cones on the data form as they are completed; all turns around the cone away from the start line should be odd numbers and all turns around the cone nearest the start line should be even numbers. The examiner should walk with the participant, slightly behind and just to the side of the participant.

The examiner should provide the following feedback: After 1 minute* say:

Script: "You are doing well. You have 1 minute to go."

*If participant is resting at one-minute reminder, encourage him/her to continue and change statement to:

Script: "You have only 1 minute left. Rest as long as you need; start walking again as soon as you feel able to do so."

When time reads 1:45, tell the participant:

Script: In a moment, I'm going to ask you to stop. When I do, just stop right where you are and I will come to you.

When five seconds remain, examiner should count down:

Script: "5, 4, 3, 2, 1, stop."

Stop the stopwatch, put a piece of tape on the floor behind the participant's heel that is on the floor at the end of the two minutes, and, if the walk was done on the Zeno mat, press "End Walk". Save as "TMW". Measure distance from the last cone passed to the edge of the tape that touched the participant's heel. Record the distance in feet on the data form. If the distance is 6 inches or more beyond a foot marker, round up. Otherwise, round down. If the participant stopped for a rest, mark this on the data collection form.



a. Scoring Process

The participant's raw score is the distance walked in two minutes, reported in feet or meters (and fractions thereof). This score can be used as a raw measure or converted to the Toolbox normative scale scores.

b. Interpretation

Cardiorespiratory and muscle endurance are important components of physical fitness and contribute to both performance and health status. Greater distance walked in the TMW is suggestive of better endurance. Normative scale scores are provided in the NIH Toolbox: (<http://www.nihtoolbox.org/WhatAndWhy/Motor/Endurance/Pages/default.aspx>).

For the endurance component of the NIH Toolbox Motor assessment, the fully adjusted scale score can be used in the interpretation of normative scores, because it takes into account gender, age, ethnicity and education differences. Thus, it provides a level playing field for evaluating participants' performance since differences in performance may exist as a function of some of these demographic variables (most notably, gender and age). When interpreting endurance normative scale scores, higher performance is indicative of better endurance. A fully adjusted scale score that is 2 SDs below the mean (scale score of 70 or below) is suggestive of motor dysfunction; further evaluation by a physician or physical therapist may be warranted. People with better endurance are able to complete daily tasks and are more physically fit to pursue leisure activities and accomplish higher-intensity workloads. The clinical significance of endurance, as measured by timed walk tests, to morbidity and mortality outcomes has been reported in healthy and clinical populations across the age span.

c. Symptoms during/after the TMW

Participants could experience symptoms during the walk. Mild symptoms could include feeling tired or flushed, dizziness, muscle soreness, cramping, or have other muscle or joint irritation. If mild symptoms occur, tell the participant to slow down. If chest pain/pressure/tightness occurs, quickly approach the participant, mark the stopping distance and record the time and distance. Assist the participant to a chair, or if necessary take a chair to the participant. If the participant confirms chest pain or pressure/tightness after resting for 5 minutes notify the nursing or medical staff on site. Symptoms of chest pain, tightness, or pressure with walking that do not resolve with rest are considered a medical emergency. Even if the symptoms resolve with rest this should be reported to the participant and with the participant's authorization to the physician of record as an alert. If the reason for stopping is chest pain, tightness, or pressure, discontinue the test and do not resume.

Except for chest pain/pressure/tightness, the test should not be stopped cold. Participants may resume walking from the marked stopping location if symptoms such as flushing, shortness of breath, cramping, or fatigue resolve and they are willing. Participants can resume walking at the faster pace or continue with the slower pace during the remainder of the walk after a rest period. Always record the reason for stopping the walk on the data collection form.

5.4 TRAINING AND CERTIFICATION FOR THE TMW

Study coordinators are responsible for training new staff using certified examiners based on standardized QxQ instructions.

The examiner requires no special qualifications or experience to perform this assessment.

Training will include:

- Read and study the manual
- Questions regarding unintentional weight loss questions will be addressed during central training and certification for the TMW will include administering these questions.
- Attend ARIC training session on performance test administration techniques (or observe administration by experienced examiner)
- Practice on other staff or volunteers
- Discuss problems and questions with local expert or QC officer
- QC officer or designated person may review video of 2 performances if necessary

Certification will include:

- Complete training requirements
- Recite exclusions
- Conduct exam on two volunteers:
 - According to protocol, as demonstrated by completed QC checklist
 - Distances recorded are within ± 1 foot of QC officer measurement

5.5 QUALITY CONTROL

The data collected by each interviewer are periodically reviewed by the QCC from quality control analyses performed by the CC. Data patterns suggestive of deviations from protocol are brought to the attention of the field center principal investigator and study coordinator.

Observation of the assessments then follows, with discussion of possible remedial actions with staff. Major deviations are brought to the attention of the QC Committee.

5.6 QUALITY ASSURANCE/CERTIFICATION CHECKLIST

Preparation

- Checks blood pressure and heart rate using vitals previously taken
- Reviews exclusion criteria:
 - Used walking aid for 4-m walk
 - SBP >180 or DBP > 120
 - Heart rate >110 bpm
 - Cast or immobilizing device on leg

- Clearly delivers key points from script for each test
- Correctly describes the test
- Correctly demonstrates walking the course (around the cone)
- Explains stop protocol
- Prepares a piece of tape to mark where participant stops

2-Minute Walk

- Instructs participant to walk as quickly as they can
- Encourages participant every lap
- Gives 1 minute warning
- Marks and records number of cones passed
- Offers rest period if needed and encourages resting participant to resume when ready
- Gives participant notice when 1:45 time elapsed and walks to participant at 2 minutes
- Places tape behind participant's heel
- Records whether or not the participant completed the walk and if not, why
- Reviews form for completeness
- Accurately measures and records distance
- Describes appropriate responses to symptomatic participants during TMW

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