GAIT ASSESSMENT

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1. Overview

In MOST, we will assess the spatial and temporal characteristics of a participant's walking pattern. The spatial characteristics of interest include the base of support, step length, and the toe in or toe out orientation of the foot on the ground. The temporal characteristics of interest include the step duration, and the proportion time spent with the limb in stance vs. swing. We will accomplish this assessment using a device known as the GAITRite.

The GAITRite is a flexible rubber and vinyl carpet over which a participant walks. The GAITRite is 14' long and is embedded with an array of 16,128 pressure sensors that accurately record each footprint. Because the GAITRite is only ¼ inch thick and 36 inches wide, it is possible to roll the carpet up (42 lbs.) and store it in a wheeled plastic storage case (included) whenever it becomes necessary for facilities maintenance. However, for simplicity and consistency of data collection in MOST, we favor leaving the GAITRite undisturbed in a designated location on the clinic floor. This semi-permanent location should be well-lit, quiet, and uncarpeted (or very thinly carpeted) with minimal pedestrian traffic or outside interference. The edges of the GAITRite carpet should be taped to the hard, smooth floor in order to minimize any danger of catching a foot and stumbling. Periodically, the waterproof vinyl surface of the GAITRite should be wiped down with non-abrasive household disinfectant and a sponge mop.

Data from each walking trial is automatically passed from the walkway via USB cable to a password protected laptop computer (kept nearby on a folding table or countertop). The pre-installed GAITRite39 software facilitates the collection, verification, and storage of all trial data in a dedicated participant file in the GAITRite39 master database. A unique copy of the master database (file extension ".mdb") will be created for each separate week of data collection so that each week the entire database and all of its contents can be conveniently uploaded in a single zipped file to the Secure Data Gateway.

A clinic examiner should begin the GAITRite exam by securing a Velcro fastened elastic belt to the participant's pelvis and marking the location of the left and right anterior superior iliac spine (ASIS) using two brightly colored Velcro markers. Procedures for placing these markers are outlined in detail in both the written and videotaped protocol. Where obesity or the presence of a large abdominal pannus interferes with accurate placement of the markers, the participant is excluded from this portion of the exam, and the examination can proceed without an elastic belt.

The examiner selects "New Subject" from the opening screen of the GAITRite39 program and fills in three items of basic background information about the participant, including the study ID and acrostic, gender, and age. The examiner will enter "50" as a bogus age and female (F) as a bogus gender for all study participants since the actual age and gender will be recorded elsewhere. The participant will perform an initial practice trial followed by four actual trials (walking the length of the walkway four times) under each of two testing conditions: comfortably-paced ("normal") walking, and fast-paced ("fast") walking.

After entering and saving all necessary background information, the examiner selects "Auto suspend each trial" from the "Settings" menu. By conducting the exam in GAITRite's "Auto suspend" mode, all four trials in each test condition can be performed back-to-back without interruption or need for further input from the examiner. The participant simply walks the length of the walkway in one

direction, waits a brief moment while the GAITRite automatically resets, and then turns around and walks the length of the walkway in the opposite direction.

To begin data collection, the examiner should first activate the two USB video cameras by selecting "Open Video Capture 2 Camera" from the File menu. The view from each of the two cameras will quickly become visible on the computer screen. The examiner then clicks the "New Test" button followed by the "Start Walk" button. This will initiate actual video recording. If all necessary participant background information has been successfully entered, the GAITRite39 software flashes a quick series of confirmatory messages that all pressure sensors in the walkway have been activated and are functioning properly. A final message indicates that the participant may "Begin Walking" when ready. The collection of footprint data begins automatically at the instant that the participant's foot makes contact with the walkway.

Casual monitoring by the examiner is necessary during data collection. A verbal response is solicited from the participant immediately prior to each trial in order to verify that they are not experiencing any acute distress or shortness of breath. On occasion it may be necessary to repeat a trial if there are any blatant testing errors, such as when the participant strays off of the walkway during the performance of a walking trial.

2. Equipment and supplies

Walkway
- Walkway – platinum version GAITRite.
- Power Adapter, Network Control Box, USB cable – included with walkway
- Power Source – wall outlet with surge protector

Computer
- PC running Windows XP® or Windows Vista®
  The computer system must meet or exceed the following requirements:
  - Hard disk with 120MB available
  - 1GB RAM
  - CD-ROM/DVD drive
  - Four USB ports
  - Mouse
  - VGA display running at a minimum 1024 x 768 screen resolution
  - Windows Media Player® 9.0 or higher
  - Internet access for software updates and online support
- GAITRite39 Software

Connectivity
- Ethernet or secure wireless connection with high-speed internet—for data transfer

Video
- Philips webcam (included with GAITRite purchase)
- Logitech Quickcam Fusion webcam (included in Alabama shipment at no additional charge, ordered separately in Iowa [$40])

Clinic Supplies
- Chair – for participant to rest
- Folding table or countertop – for computer
- Velcro belt – marks pelvis so that it can be seen on video (supplied by Doug Gross)
- Brightly colored Velcro dots – attach to pelvic belt(supplied by Doug Gross)
- Color label/sticker will be placed over the lateral head of fibula landmark on both legs prior to the exam
- Residue-free household disinfectant in spray bottle—for disinfecting walkway
- Sponge mop – for cleaning walkway

Installation equipment
- Masking tape – to secure edges of walkway
- Colored plastic tape – to clearly mark the start and finish lines on the floor
- Two USB to USB extension cables
- Power cord extension cable
- Two plastic cord protectors

2.1 Maintenance, service, and cleaning

The GAITRite does not generally require much maintenance.
 Service
Hardware comes with a 20-month extended warranty to include annual cleaning and calibration, as well as parts and labor for needed repairs. UPS ground charges are paid both ways by CIR Systems. Shipping charges for a loaner walkway are the clinic's responsibility.

The extended service agreement includes software upgrades, and unlimited telephone or email support. Service needs should be communicated to:

Michael Rowling, President
MAP/CIR Systems, Inc. - GAITRite
60 Garlor Drive
Havertown, PA 19083
Phone: 610-449-4879
Fax: 610-853-2925
E-Mail: support@GAITRite.com
http://www.GAITRite.com

Cleaning

The exposed upper surface of the walkway is vinyl with square thread reinforcement, making it waterproof. Periodic cleaning prevents the build-up of dirt and other contaminants that may accrue as participants walk over it. The frequency of cleaning should depend on use. A weekly cleaning schedule will typically suffice.

- Exit the GAITRite39 program and shut off the computer.
- Unplug the Network Controller box, its power source.
- Moisten a clean cloth with household disinfectant. Do not use solvents or abrasives.
- Wipe the surface of the walkway.
- After applying disinfectant, moisten a second clean cloth with cold water and wipe the walkway again to ensure that no residue remains.
- Allow walkway to air dry completely before use.

NOTE: A weekly cleaning schedule will typically suffice. However, cleaning should be performed immediately if mud, snow, or water gets onto the walkway, as this could be a hazard!

2.2 Calibration

The spatial and temporal accuracy of the GaitRite should be verified quarterly at the clinic sites following "Procedures for Verifying Spatial and Temporal Accuracy of GAITRite" (Appendix 2). The MOST Quarterly GAITRite Spatial and Temporal Calibration Log (posted on the MOST website under Study Documents/Equipment Calibration) should be completed at the time of calibration.

2.3 Installation of software

GAITRite version 38 software (GAITRite39) will be pre-installed by Doug Gross or by the clinic coordinator with phone support from CIR Systems (Mike Rowling, CIR Systems). By default, the software will be installed in the "C:\GAITRite39" directory.

After inserting the installation CD, the following steps are followed:
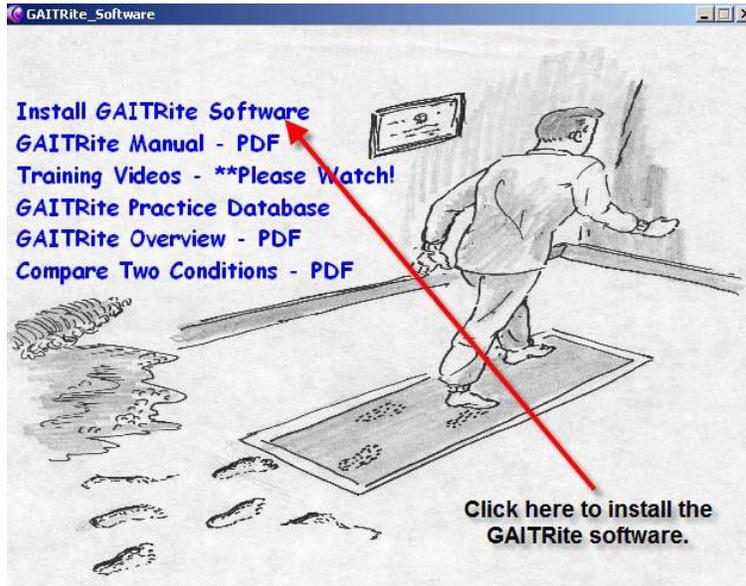
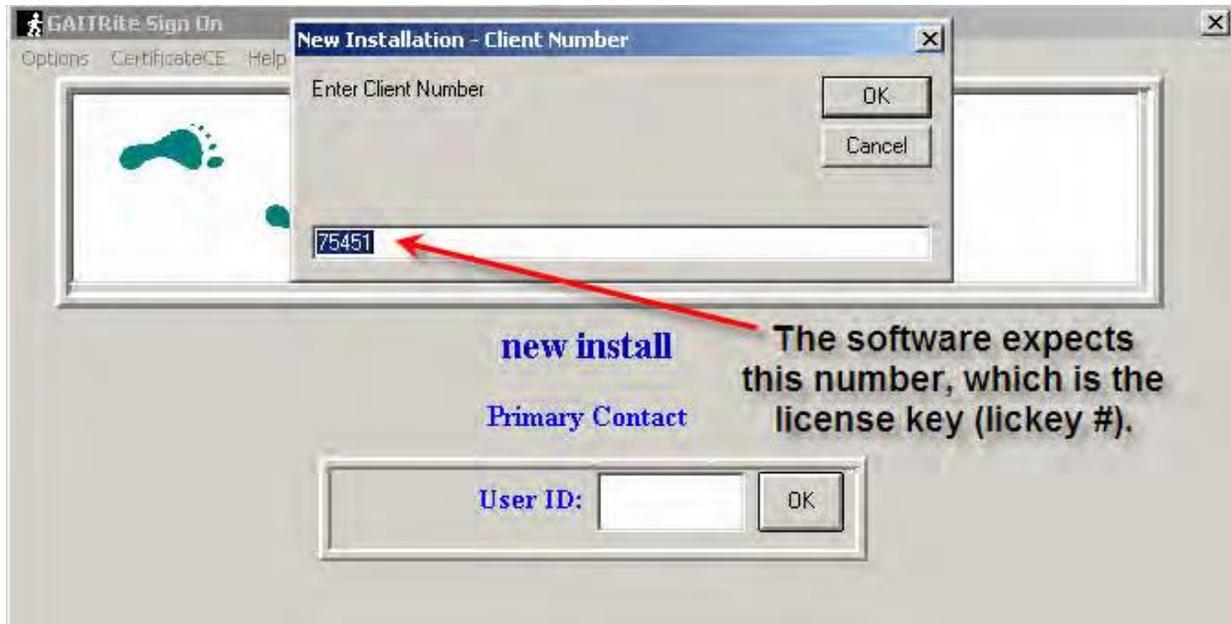**Step 1**: Click "Install GAITRite Software"
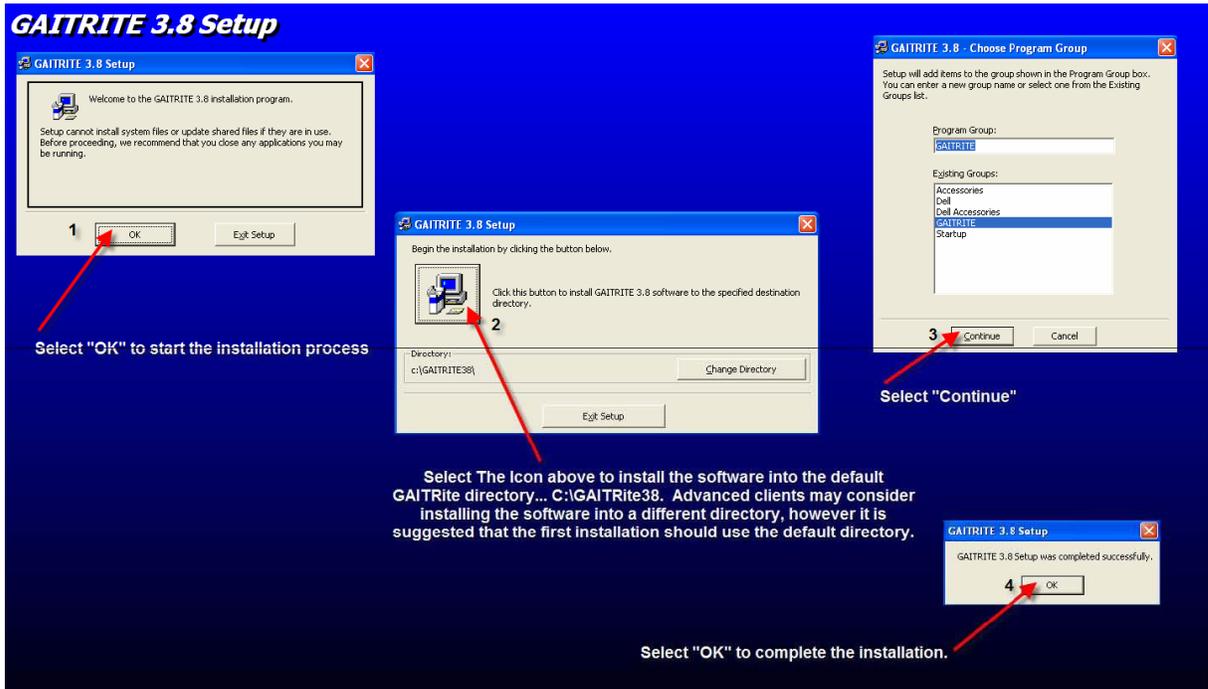
Step 2: Follow Prompts

Step 3: Enter Serial Number
Found on the Network Controller box. "K600G" is an example.

Step 4: Enter Client Number (lickey #)

A license key (lickey) file will be sent separately from CIR Systems. Upon receipt of the lickey file, the file should be immediately copied into the directory where GAITRite39 resides (C:\GAITRite39).

You can either enter the lickey # now, or you can bypass this step by leaving the field blank, selecting OK, and then selecting Cancel during subsequent prompts to re-enter lickey information.
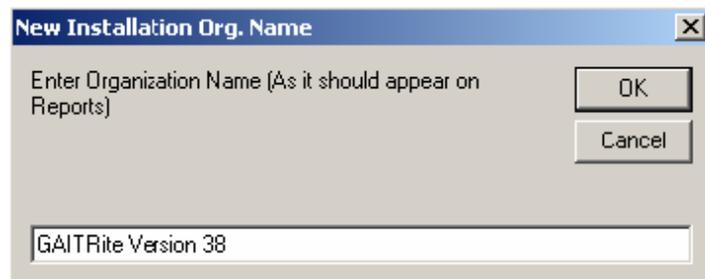
Step 5: Enter Organization Name

In Iowa, enter "University of Iowa." In Alabama, enter "University of Alabama."

Step 6: Enter User ID

Examiner:
1. Click the left mouse button three times in the User ID box, or
2. Type in the word "student" or "demo," and then click OK.

To perform software updates or reset preferences:
3. A User ID with security permissions (type "setup") allows entry into the profile module (located in the OPTIONS menu) where it is possible to carry out updates of the license key (likey), and/or reset the system preferences.

NOTE:
Left clicking three times in the User ID box is the preferred method of entering the GAITRite39 software for routine use by clinic examiners.

2.4 Connecting / disconnecting hardware

The following steps will be performed once at the start of the study, again a year into the study when the walkway will be sent away for factory calibration and maintenance, and following extraordinary circumstances when the GAITRite must be removed from its designated location on the clinic floor. Shutting off the computer and disconnecting the GAITRite from the wall outlet is required for weekly cleaning, but no additional hardware adjustments are necessary during routine use.

Connecting
- Make sure the computer is turned on and that the GAITRite39 software has been installed
- Unroll walkway
- Connect USB cable to USB port of computer
- Plug Power Supply cord into surge protector and then into an electrical wall outlet. Connect the other end of the power cord into the Network Controller box.
- Indicator lights on the Network Controller box verify that Power is on (green light on) and Program Status is off (yellow light off). The program status light will remain off until data collection has been initiated.
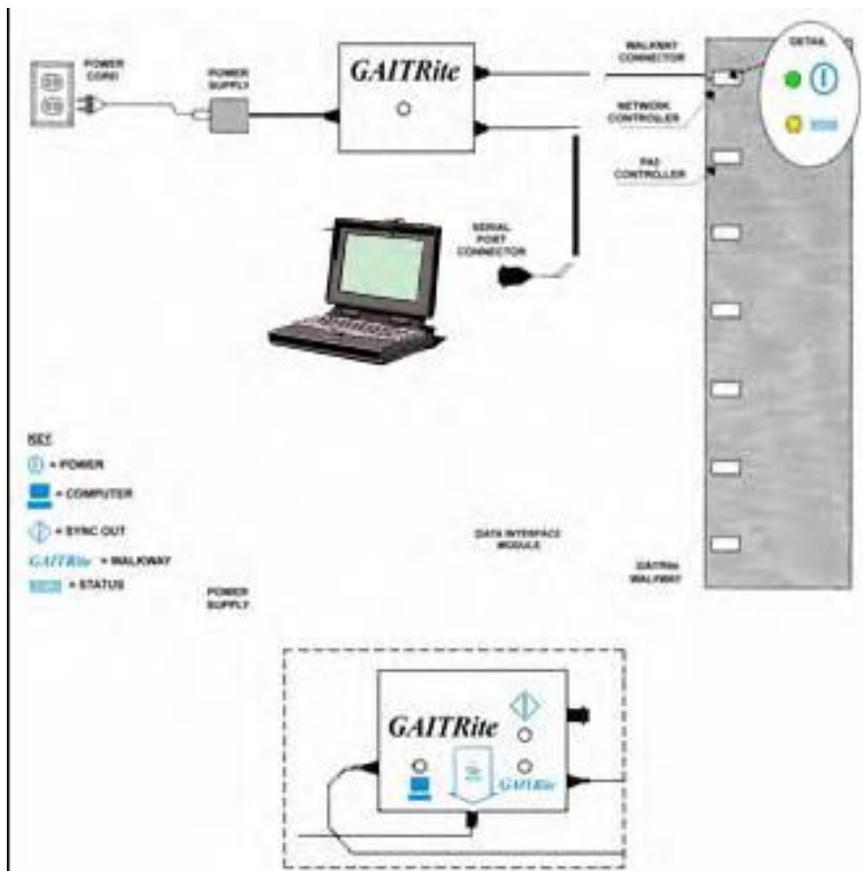

Figure 1. Hardware Connections

Disconnecting

- Exit GAITRite program and shut down computer.
- Reverse aforementioned connection instructions.
- Use the cardboard cylinder to roll up the walkway.
- Carefully place and secure rolled walkway (using built-in straps) in its wheeled storage case.

CAUTION:
Never attempt to move the walkway without first rolling it up. Once rolled up, always lay the plastic storage container on its side. Never stand it on end for any period of time, as this can cause the carpet to bend and develop creases!!!

3. Safety issues

The GAITRite assessment is generally safe and well-tolerated. Testing involves 10 trials (four trials plus one practice trial during each of two walking conditions) of indoor walking over 24' (14' walkway plus 5' between walkway and start/finish lines). The GAITRite is entirely non-invasive and will record footprints while the participant walks in their usual manner and in their usual footwear (consisting of their usual shoes and any shoe inserts or foot orthoses they contain). The GAITRite walkway does not come into direct contact with any part of a participant's skin.

The GAITRite has minimal thickness which causes it to rise 3 millimeters (1/4") from the surface of the floor. The raised edge of the walkway represents a minimal hazard to participants who drag their feet during walking. To reduce this hazard for all study participants, we will fix all edges of the walkway to the underlying floor using adhesive tape. All tests should be performed in well-lit conditions and under the supervision of a trained examiner. Because the bottom rubber surface of the walkway is fabricated to maintain a strong frictional hold on any smooth floor, injuries resulting from slipping or falling on the GAITRite have never been reported.

3.1 Exclusion criteria, stopping rules, precautions

Participants should not be tested on the GAITRite if they have any of the following:

Exclusion Criteria:
- Participant is using a walker or crutches at the clinic visit (see Figure 2B)
- Participant brings a cane or walking stick to the clinic visit and reports using the cane more than half the time when walking outside the home (see Figure 2A)
- Participant wears an orthotic knee brace (not including neoprene sleeves or patellar tendon straps) to the clinic visit and reports using the brace more than half the time when walking outside the home (compare Figures 3A and 3B)
- Surgery or an injury to the legs in the past 6 months that caused the participant to restrict weight bearing for a week or longer
- Inability to walk safely over short distances without using a cane or an orthotic knee brace
- Difficulty walking or standing upright because of a stroke, Parkinson's disease, or other neurological condition whose onset was less than 6 months ago
- Any amputation of the lower extremity other than the toes
- Hospitalized for cardiovascular or respiratory disorder in past 6 weeks

- Exhibits signs of vision, gait, or balance impairment, or signs of severe joint pain suggesting a possible safety risk *and*, when questioned, expresses uncertainty in the ability to safely walk short distances
- The participant has only "unacceptable" shoes (see section 5.3.2).

Stopping rules:

- If the participant develops chest pain, persistent shortness of breath, or severe dizziness during the test, do not complete the test.

- If the participant says they cannot continue with test due to increasing knee or back pain, do not complete the test.

Precautions/contingencies:
Participant appears mildly unsteady during practice testing:

- Fasten Velcro belt around participant's waist
- Tell participant:

  Script: "I am going to put this belt on your waist and follow behind you on the side of the walkway. This is just to be safe. Try to ignore me and walk as I have instructed."

- Repeat the practice test while providing a gentle contact guard and ready grip at the posterior midline of the Velcro belt. Should the participant stumble or begin to lose balance, pull them toward you and support them against your body.
- If unsteadiness continues and the participant appears to be at risk of falling, discontinue testing. If unsteadiness resolves, perform all subsequent tests while providing contact guard assistance. A second examiner may be needed to help operate the computer when it comes time to initiate data collection by clicking on the Start Walk button.

Glasses and hearing aids:
- Participants are permitted to wear glasses and hearing aids during the exam.

Figures 2A (left) and B (right). **Assistive walking devices.** Canes and walking sticks (Figure 2A, left) are distinguished from crutches and walkers (Figure 2B, right). Participants arriving with crutches or walkers are excluded. Participants arriving with a cane or walking stick are questioned about dependency.

Figures 3A (left) and B (right). **Knee braces.** Orthotic knee braces, including realigning and ligament support braces (fig. 3A, left) are distinguished from Neoprene sleeves and patellar tendon straps (Figure 3B, right). Participants wearing an orthotic knee brace are questioned about dependency.

Figures 4A (top row) and B (bottom row). Shoe inserts. Assessment is made of the presence and type of shoe insert during the Plantar Pressure exam. "Supportive" inserts (Figure 4A, top) are distinguished from "Cushioning" inserts (Figure 4B, bottom). During the Gait exam, the participant is permitted to wear their usual walking shoes or sneakers along with any kind of shoe insert that may be present in them.

4. Facilities requirements

The test area should consist of a clean, even, and reasonably level floor space (or very thin carpet with minimal plush) measuring *at least* 27'L x 6'W. Fourteen feet in length will be occupied by the walkway itself, while 5 feet of additional runway length is needed on both the near and far ends of the walkway for start and finish line placement (24 feet in total). An additional 3 feet of clean floor space is needed beyond one of the start/finish lines for placement of a video camera.

Six feet of floor space width is a minimum requirement. The walkway itself is approximately 3 feet wide, and an additional 3 feet is needed on the left or right side of the walkway at mid-length in order to accommodate a second video camera. Additional width may be required to accommodate placement of a folding table, laptop, and chair.

The floor of the test area must be clean and completely dry prior to unrolling and placing the walkway.

NOTES:

- *A minimum of 27 feet of open floor space is needed* to accommodate the total length of the GAITRite walkway and video cameras.

- The floor of the test area must be kept clean. Regular janitorial cleaning of the floor can occur without concern for the plastic colored tape that will remain adhered to the floor in order to mark the start and finish lines. However, *the video cameras should not be moved from the standard position where they have been situated!* This is important in order to maintain their consistent location, height, and orientation throughout the period of their use in MOST.

- The walkway, too, requires periodic cleaning in order to prevent the build up of dirt or other contaminants. *Cleaning of the walkway is performed separately from cleaning of the floor*, and should be done by hand using household disinfectant and a sponge mop (see cleaning instructions).

5. Testing Procedures

5.1 Preparation

Shoes
At scheduling, participants will be instructed to wear, or bring along, their own comfortable walking shoes or sneakers.

The following should be clearly explained to the participant PRIOR TO ARRIVAL:

Script: "Bring with you the walking shoes or sneakers that you would typically wear if you knew that you were going to be on your feet for a long while, such as when shopping, waiting in a long line, or taking a walk. Do not wear dress shoes, high heels, sandals, boots, or clogs."

- **Preferred:** Sneakers or walking shoes.
- **Acceptable for GAITRite:** Flats, loafers, hiking boots, sandals, flip flops, or clogs.
- **Unacceptable for GAITRite**: High heels, cowboy boots, steel-toed boots.

Placement in sequence of exams

Testing should follow a short period of warm-up. The 20-meter walk test is well-suited to this purpose and ideally should be performed immediately prior to the GAITRite exam. It is preferred that strength testing follow, rather than precede, the GAITRite exam if at all possible.

5.2 Overview

Duration

10 to 12 minutes, including:
- Background information − collection and recording
- Practice trials
- Instruction and testing.

Two walking conditions ("Normal" and "Fast")

Because the way that a person walks changes with the task they are performing, we will examine a participant's walking during two representative conditions, which are to be completed sequentially in the following order:

1. Comfortably-paced walking ("Normal")
2. Fast-paced walking ("Fast")

Rest breaks

If the participant becomes tired or needs a break, allow a short break *between conditions - not in the middle of a testing condition*, unless there is a perceived risk of falling, in which case the chair should be retrieved and positioned to allow the participant to sit down.

5.3 Administration

5.3.1 Determine contraindications

Use the questions and other criteria on the GAITRite and Plantar Pressure Exclusions form and the GAITRite data collection form to determine if the participant is eligible for the test.

5.3.2 Verify appropriate footwear

- **Acceptable for GAITRite:** Sneakers, walking shoes, flats, loafers, hiking boots, sandals, flip flops, clogs.
- **Unacceptable for GAITRite**: High heels, cowboy boots, steel-toed boots.

If participant is wearing shoes that are unacceptable, but has brought with them shoes that are acceptable, they should be instructed to change prior to the GAITRite exam. If the participant is not wearing and has not brought shoes that are acceptable, the participant must be excluded from the GAITRite exam.

If a participant is excluded from the GAITRite exam on the basis of unacceptable shoes, the examiner should indicate this by choosing "No" in response to Question #2 on the GAITRite data collection form ("Was the normal-pace walk test administered?") and "No" in response to Question #3 ("Was the fast-pace walk test administered?").

5.3.3 Place label on lateral head of fibula

The lateral head of the fibula will have been marked with an "X" bilaterally at the anatomic landmarking stations. Apply a colored label/sticker over the center of the "X" on both legs. These markers will help investigators identify these landmarks during future analysis of the gait assessment.

5.3.4 Secure Velcro belt to participant's pelvis

A Velcro belt and a supply of brightly colored Velcro dots will be available in the exam room.

The Velcro belt will be fastened to the participant's pelvis as shown in Figure 6. Two Velcro dots will then be adhered to the belt over the right and left anterior superior iliac spines (ASISs) (Figure 8). The purpose of the dots is to clearly mark the location of the ASISs so that their position during walking can be determined from the video recording.

Note:
Because similar Velcro belts are often prescribed to women in order to improve stability in the pelvic joints during the last trimester of pregnancy, we are confident that our belts can be appropriately situated on the pelvis even in the presence of moderate obesity or a moderately large abdominal pannus (see Figure 5). However, where severe obesity or the presence of a very large abdominal pannus does interfere with accurate placement of the belt or the markers, the participant can be excluded from this portion of the exam, and the examination can proceed without an elastic belt.

To properly position the Velcro belt and situate the Velcro dots, please perform the following steps:

1. If the participant has an abdominal pannus (overhanging belly) that is obscuring the anterior pelvis, please instruct them:

    Script: "Put both hands on your belly, like Santa Claus does when he laughs, and lift your belly up towards the ceiling and away from your belt line."

2. With the abdominal pannus now safely out of the way, fasten the Velcro belt around the pelvis at the approximate level of the waist band of the undergarments (see Figures 5 and 6)

Figure 5. The Velcro belt is positioned just underneath any abdominal pannus at the level of the waist band of the undergarments.

Figure 6. The Velcro belt is fastened to fit snugly over the bones of the pelvis and covering the right and left ASIS.
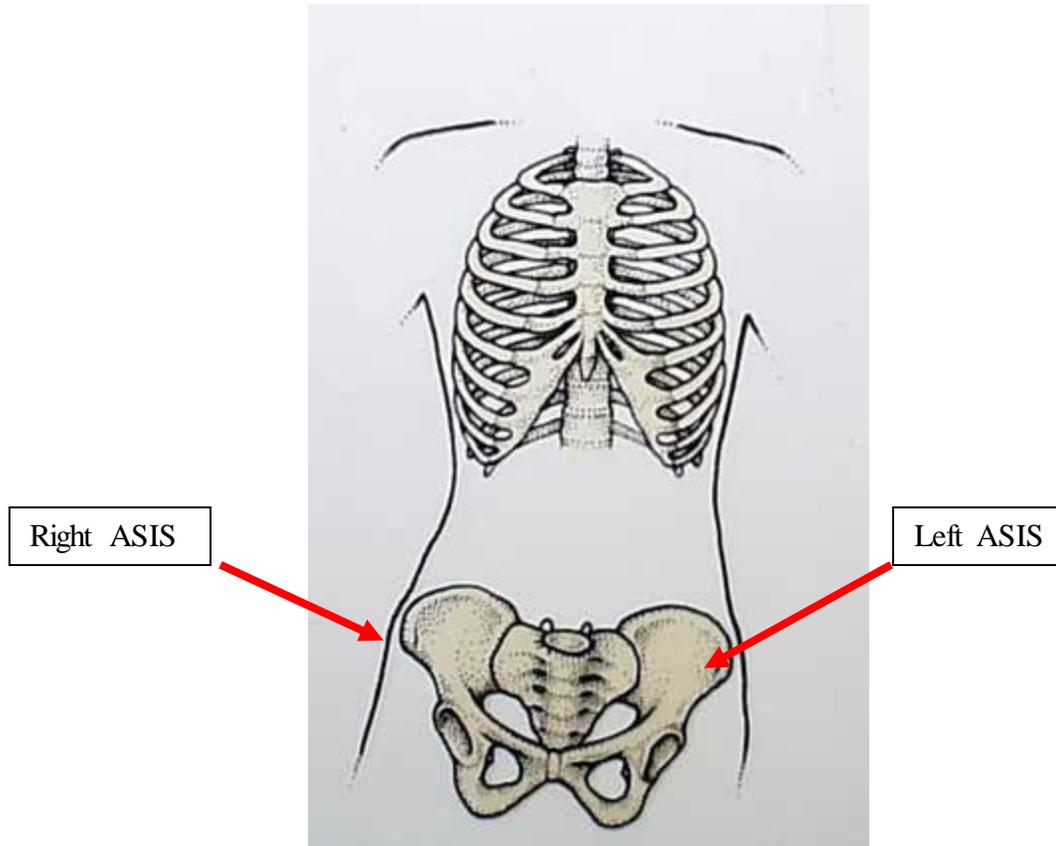
3.   The anterior superior iliac spines (ASISs) are protruding knobs of bone at far right and left sides of the anterior pelvis at the approximate level of the belt line (see Figure 7).

Using your thumbs, palpate the right and left ASISs (see Figure 8).

If you have trouble locating the ASISs, tell the participant:

Script: "Please rest your hands on your hips."

Since a person resting "hands on hips" generally places the hands on the bony pelvis (the right left ileum), you can usually find the right and left ASIS just underneath the fingertips of each hand.

4.   Attach one Velcro dot to the belt over the right ASIS, and a second Velcro dot over the left
       ASIS.

Figure 7. The ASISs are protruding knobs of bone at far right and left sides of the anterior pelvis at the approximate level of the belt line of the undergarments.

Figure 8. Attach one colored Velcro dot to the belt at the right ASIS, and a second colored Velcro dot at the left ASIS.

5.3.5 Operating GAITRITE39 software

Make sure the computer is turned on.

Open the GAITRite software by clicking the [GAITRite.Exe CIR Systems Inc. icon] icon on the desktop.
You will be greeted by the **GAITRite Sign On** screen (pictured below).

Complete the following steps:
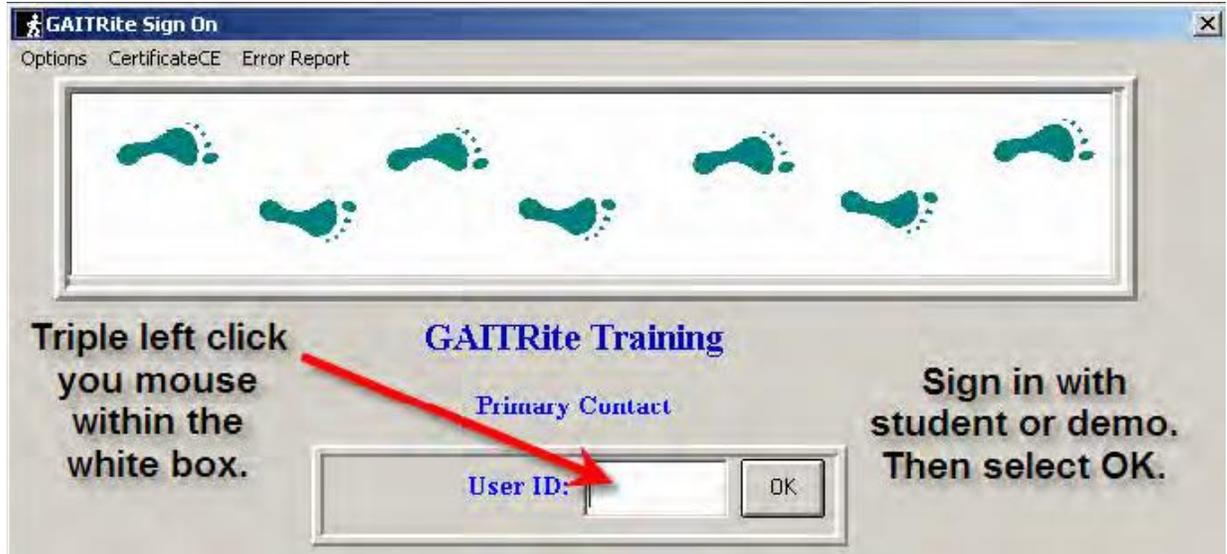
Step 1: Sign on by left clicking three times within the white box labeled User ID.

Step 2: Click on the "**New Subject**" button. At the prompt, verify your intention to register a new participant by clicking on "**Yes**."

Step 3: Begin registering a new participant by entering all of the required information (highlighted in red). Information about leg length (highlighted in blue), while needed for certain calculations, will be entered by Doug Gross at a later time.

Enter only:
1. Study ID #
   Enter 5 digit study ID# in field labeled "Patient: Last"
2. Acrostic
   Enter 4 letter acrostic in field labeled "Patient: First"
3. Age
   Enter the bogus age of "50" for all participants in the field labeled "Age"
4. Gender
   Enter the bogus gender value "F" for all participants in the field labeled "Gender"
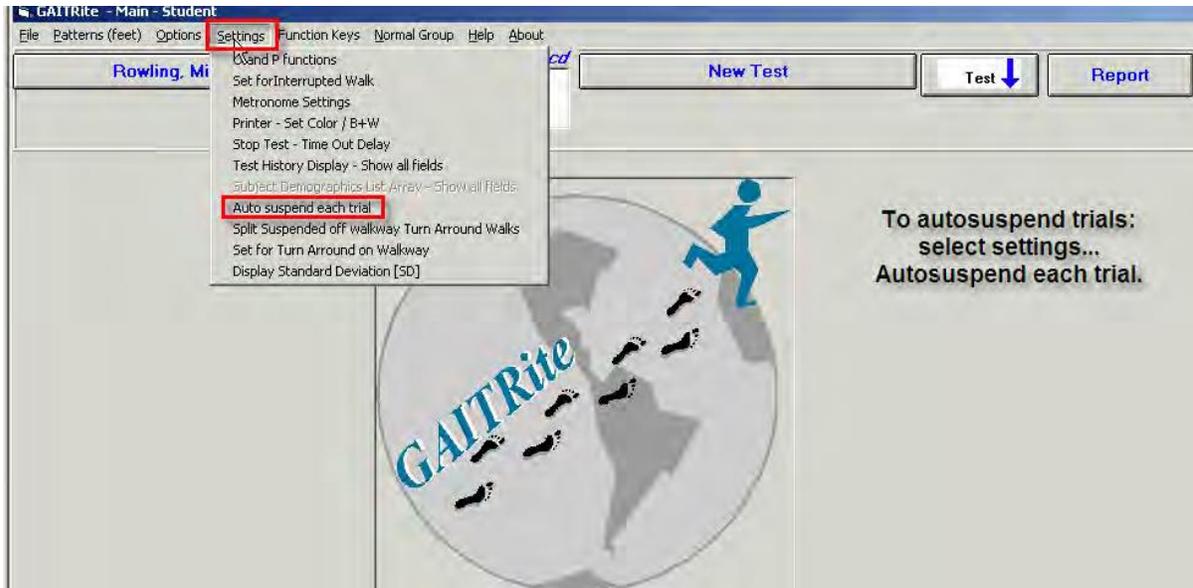
Step 4: After entering the required information (as shown above), click the [Save] button to save the participant background data into a new record for that participant.

You will be brought to the Testing screen (shown below).
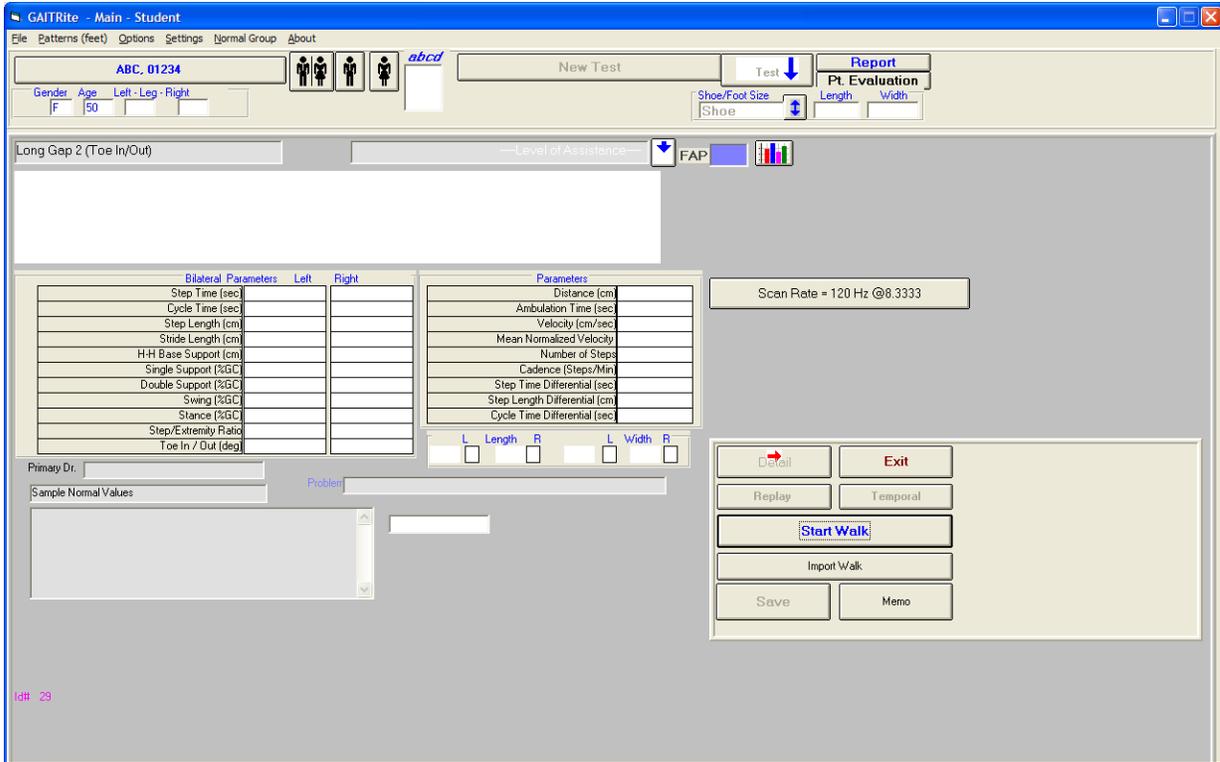
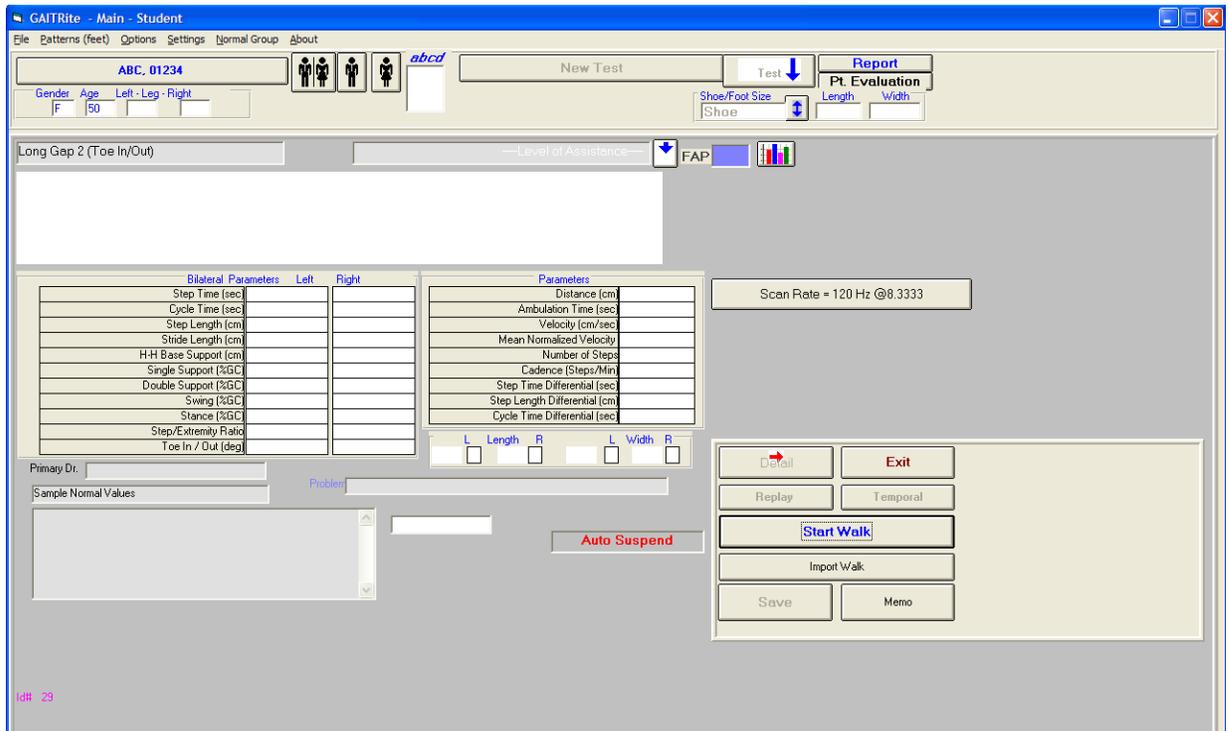**Step 5:** At the Testing screen (shown above), click the [Exit] button to go back to the Main screen (see below).

**Step 6:** Now on the Main screen. Select "**Auto suspend each trial**" from the drop down "**Settings**" menu.

Step 7: After selecting "**Auto suspend each trial**", click on the [New Test] button.

You will be brought back to the Testing screen (see below).

Step 8: On the Testing screen again, you should first **verify** that the words appear as shown above.

If these words do not appear as shown, click "Exit" to return to the Main screen and repeat Steps 6 and 7.
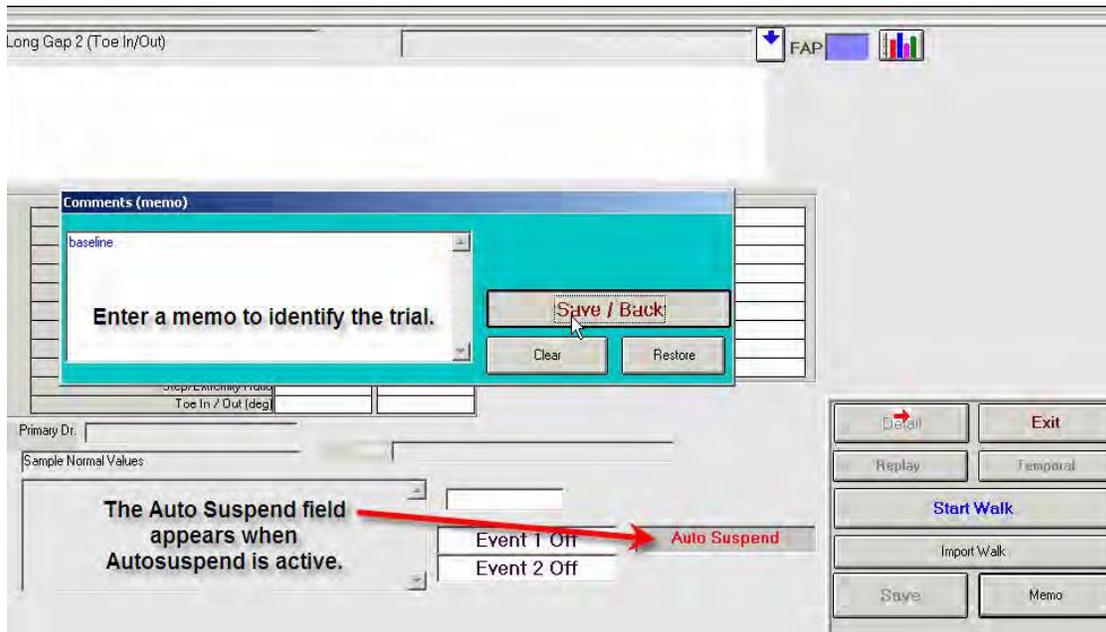
Step 9: Click the [Memo] button to enter a memo that will identify the testing condition under which the subsequent four trials will occur.

The first test condition (consisting of four trials) is self-paced ("**Normal**") walking. The second test condition (consisting of four trials) is fast-paced ("**Fast**") walking.

Step 10: Identify the test condition

After clicking the Memo button (above), the following pop-up window will appear:

- Enter the Test Condition ("normal" or "fast")
    1. Enter "**NORMAL**" (as depicted) when preparing to examine the participant in the first test condition (consisting of four back-to-back trials). Recall that in the first test condition, the participant is instructed to walk at a "normal" or self-paced walking speed.
    2. Enter "**FAST**" (not depicted) when preparing to examine the participant in the second test condition (consisting of another four back-to-back trials). Recall that in the second test condition, the participant is instructed to walk at a "fast" walking speed.

- Click the [Save / Back] button to save your entry. The pop-up Memo screen (shown above) will disappear from sight and you will return to the Testing screen (shown below).
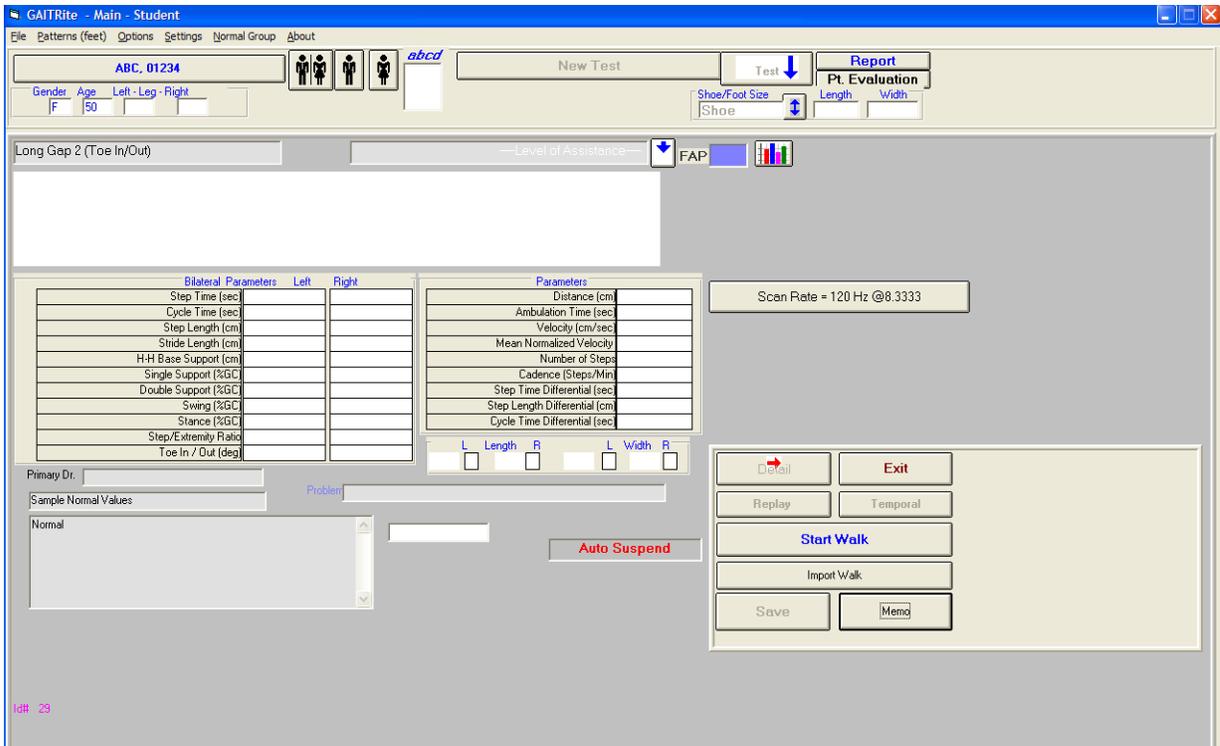
Step 11: Now back at the Testing screen, **verify** that the [Memo] button appears with a **bold outline**, and that the contents of the Memo that you just entered appear in a field at the bottom left corner of the screen, as in the following example for the "Normal" testing condition:
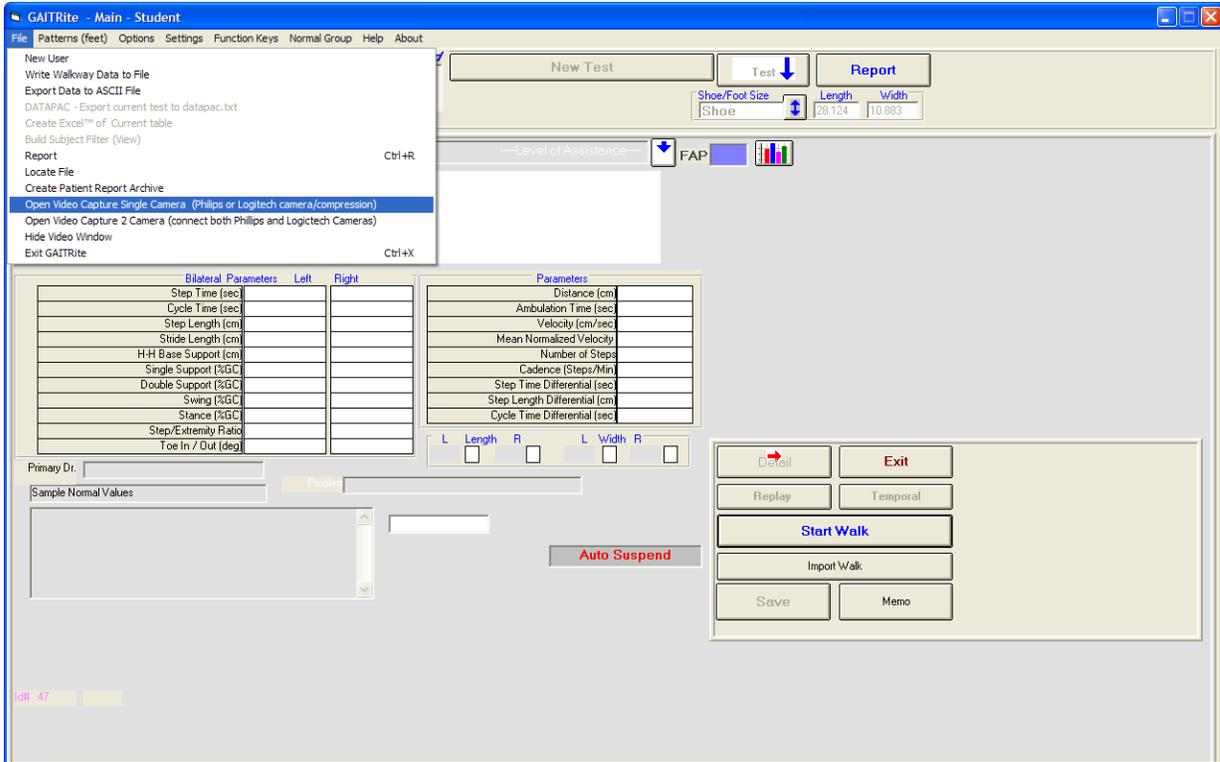
Step 12: Open video capture

Go to the **File** menu and select:

"**Open Video Capture 2 Camera (connect both Phillips and Logitech cameras)**"

Two pop-up windows entitled "Video Preview 1" and "Video Preview 2" like the one shown below, will appear. The images are the views from the two video cameras, which have now been activated.

By sustaining a left click on the blue title bar of the pop-up window, you can drag the window to anywhere on the screen that is most convenient for you (see below, where the window has been placed in the bottom left corner of the screen).
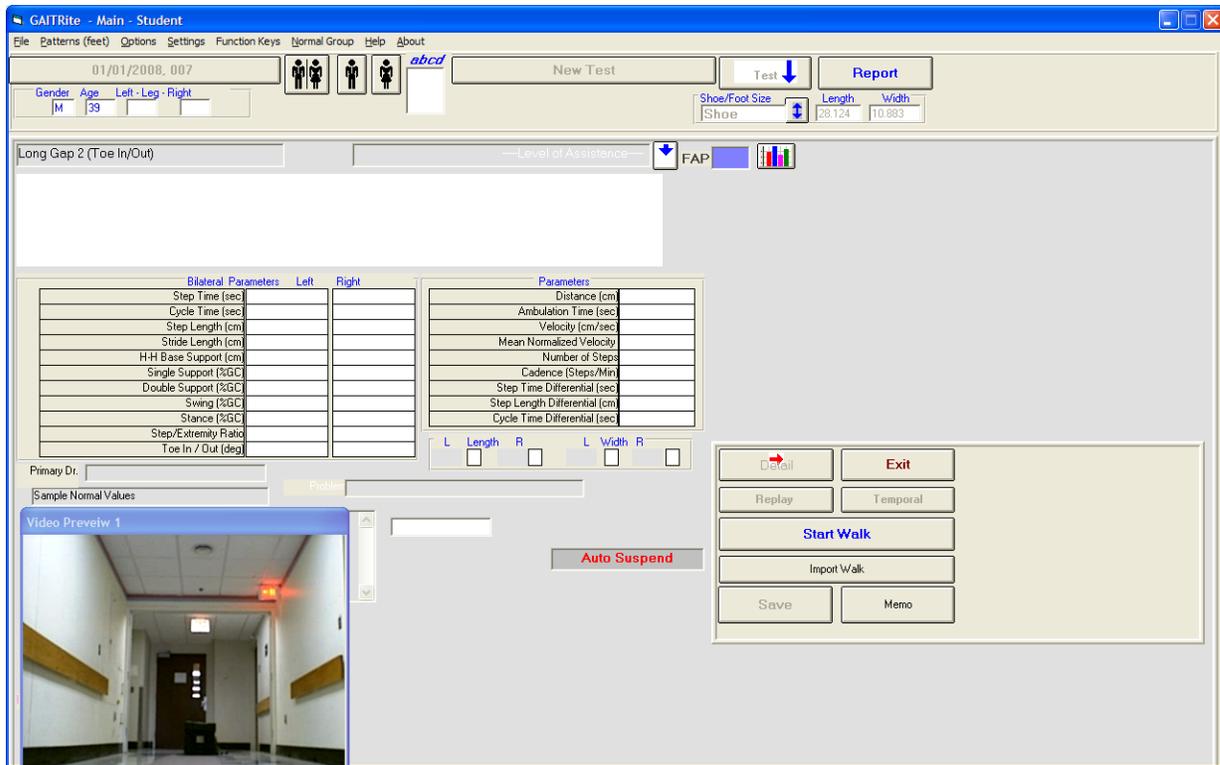
Step 13: Explanation and practice trial

- Show the participant where the start / finish lines have been marked with colored tape on the floor.
  - A line of colored tape 5' ahead of the leading edge of the walkway will serve as the starting line. A line of colored tape 5' beyond the distant edge of the walkway will serve as the finish line.
  - On the examiner's instruction, the participant will complete one trial by walking straight forward from the starting line, over the walkway, until they have crossed the finish line on the opposite end. The participant then turns around and awaits the examiner's next command before beginning a second trial of walking in the opposite direction to where they began.
  - The line of colored tape that served as the starting line during the first trial, will serve as the finish line during the second trial, and vice versa. Four trials will be completed in total for each test condition ("normal" and "fast").

- Tell the participant:

  Script: "When I say 'begin walking,' you will begin walking from where you now stand. Pass over the walkway until you cross the finish line on the opposite end. Once you've crossed the finish line, turn around and await my next instruction to begin walking back."

Script for practice trial of normal-paced walk:

> Script: "You should walk in your usual way, and at a pace that feels comfortable and unhurried."
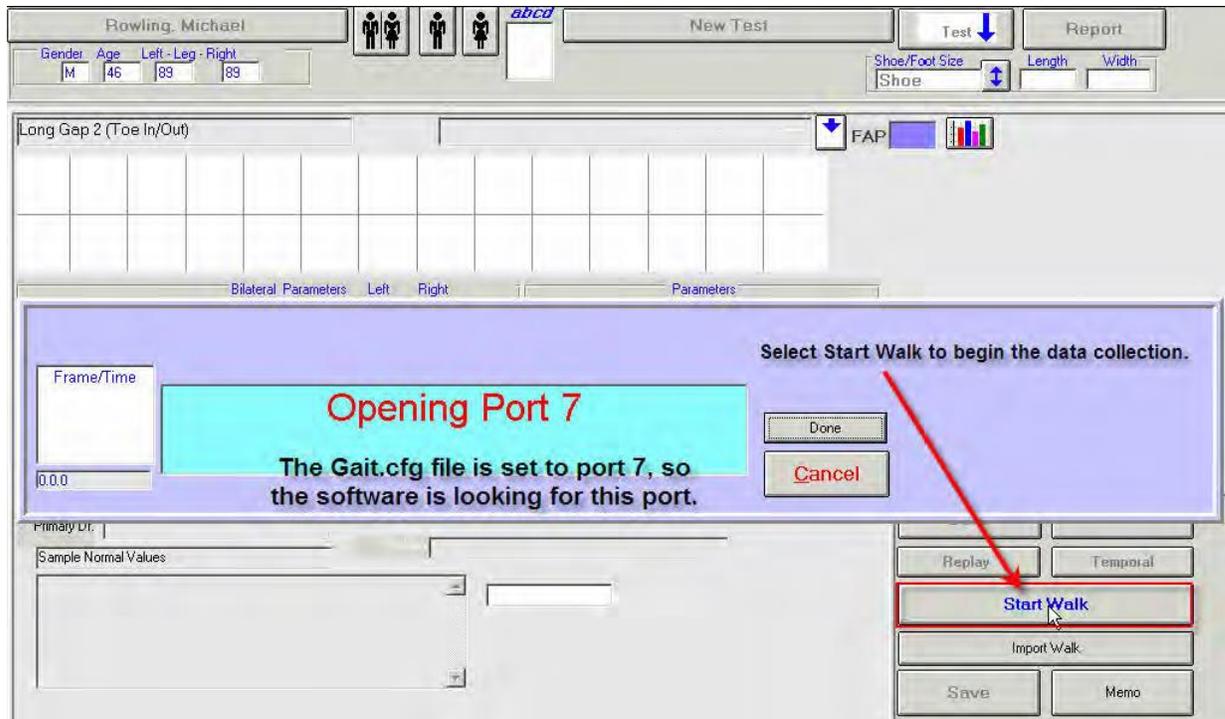
> Script: "Ready? . . . .Begin walking."

After the four sets of normal-pace walk tests are completed, a fast-pace practice trial is done:

Script for practice trial of fast-paced walk:

> Script: "In a moment, I will once again instruct you to begin walking. This time you should walk in your usual way, but at a faster pace, as if you were late for an important meeting."

> Script: "Ready? . . . .Begin walking."

- Observe as the participant completes the practice trial by walking the length of the walkway in one direction from the starting line to the finish line. If the participant is seen to stray off of the walkway, or is otherwise walking in a way that is inconsistent with the instructions that you have given, repeat Step 13 from the beginning in order to perform a second practice trial.

- If no problems are evident during the practice trial, proceed to Step 14.

Step 14: Begin testing

1. Issue instructions:

- Prior to testing under the **first test condition** (normal walking speed), issue the following instructions:

   Script: "In a moment, I will once again instruct you to begin walking. Again, you should walk in your usual way, and at a pace that feels comfortable and unhurried."

   "Ready? . . . .Begin walking."

- Prior to testing under the **second test condition** (fast walking speed), issue the following instructions:

   Script: "In a moment, I will once again instruct you to begin walking. This time you should walk in your usual way, but at a faster pace, as if you were late for an important meeting."

   "Ready? . . . .Begin walking."

   Note:
   If this is the first of the four trials under the test condition ("Normal" or "Fast"), complete Step 14.2 below.

   If this is the second, third, or fourth trial under the test condition ("Normal" or "Fast"), skip Step 14.2 below, and proceed to Step 14.3.

2. When the participant indicates their readiness to begin, click the
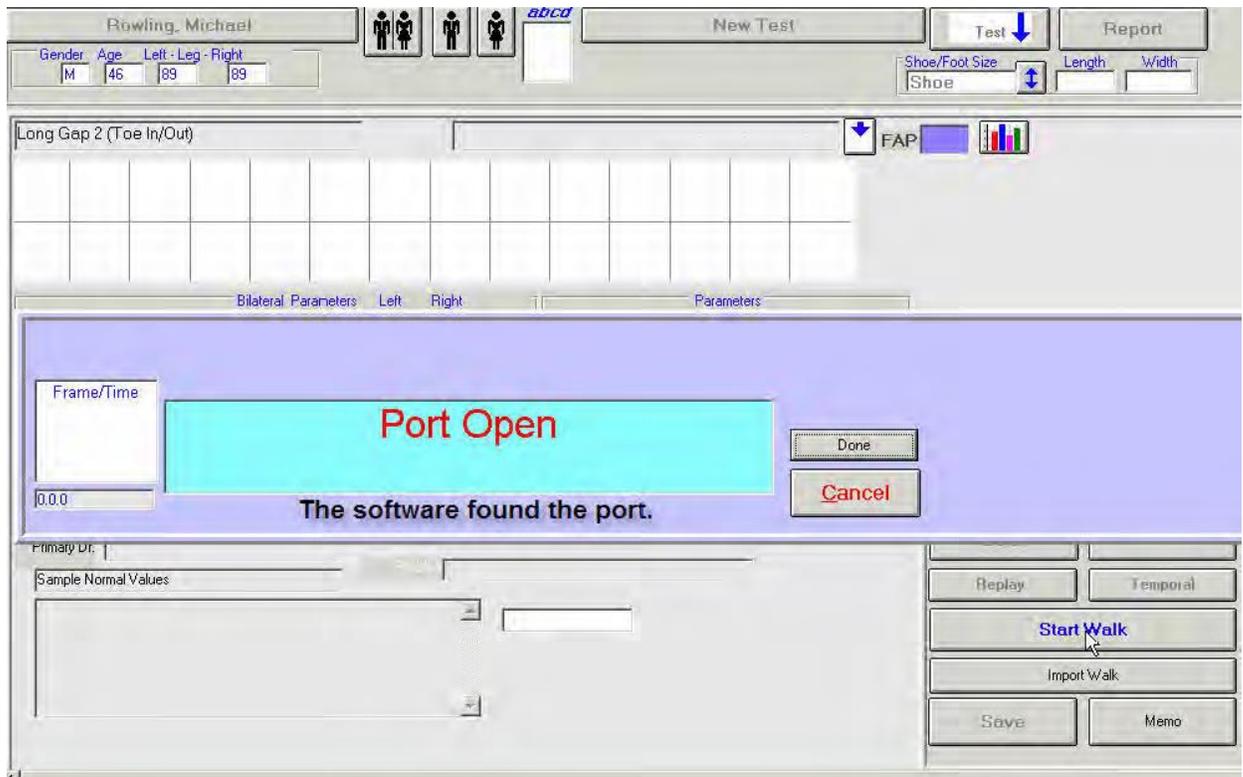
   | **Start Walk** | button.

   This will initiate video recording and prepare the walkway for data collection (which is initiated when the first footprint is made on the walkway).
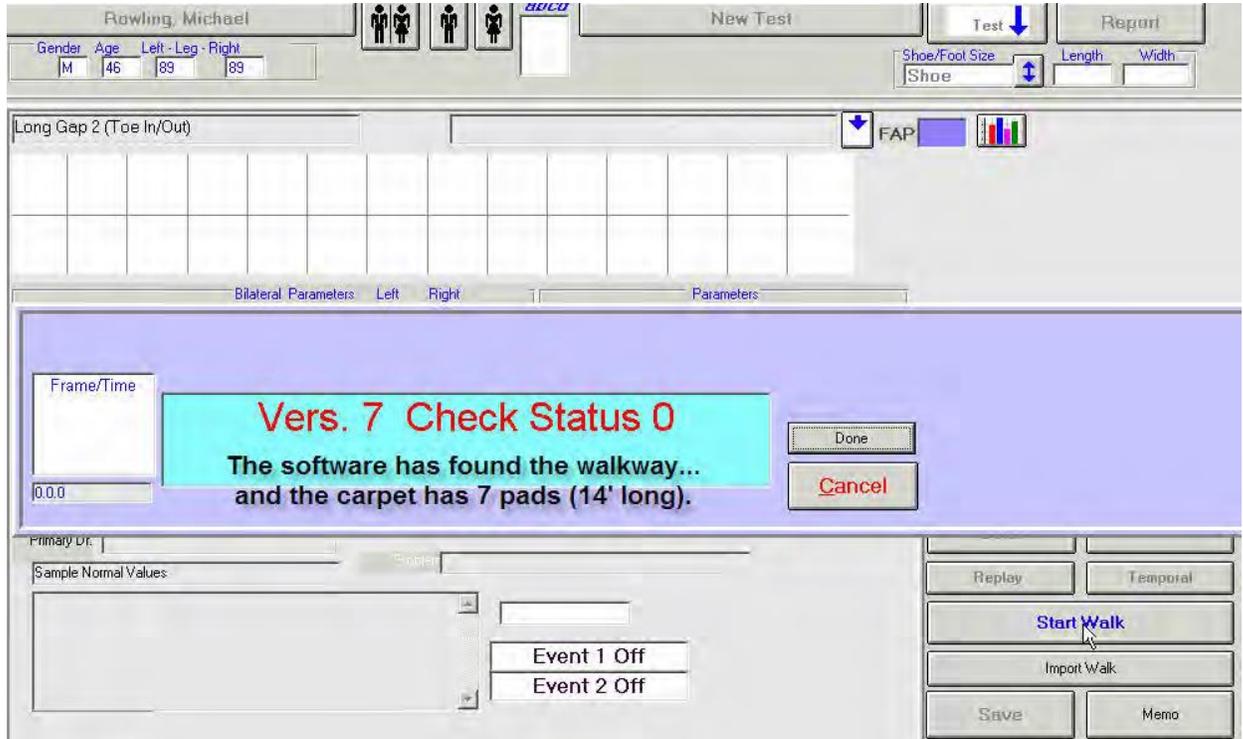
3. Allow the GAITRite a brief period of time to verify that:
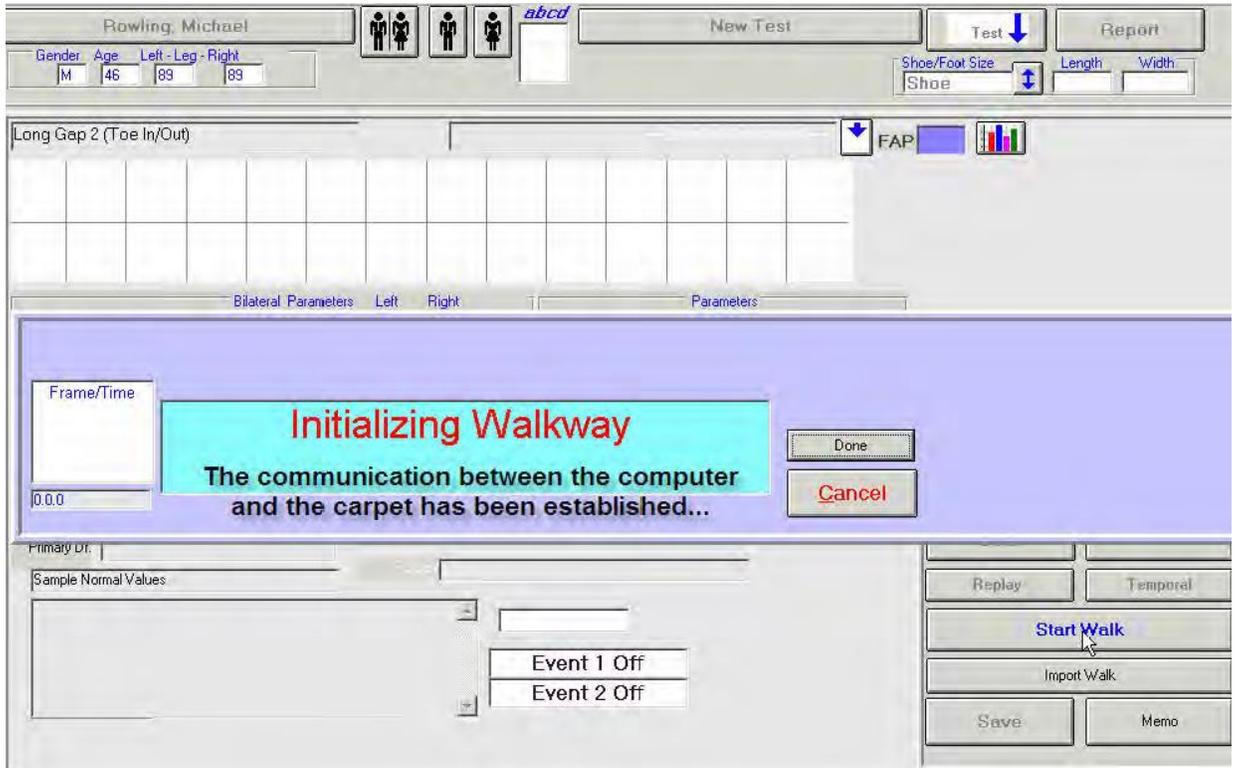
   1. The port is open.
      You will briefly see the following message: Port Open

2. The software has identified the walkway.
   You will briefly see the following message: Vers. 7 Check Status 0

3. The software is communicating successfully with the walkway.
   You will briefly see the following message: Initializing Walkway

4. GAITRite is ready to collect data.
   You will see the following message, which will remain until the participant's foot makes initial contact with the walkway: **Begin Walking**

4. Tell participant,

   Script: "Begin walking."

Step 15: Perform additional back-to-back walking trials under that condition
In response to your instruction, the participant will walk the length of the walkway before stopping at the marked finish line (marked in colored tape).

1. Tell the participant,

   Script: "Please turn around and wait at the marked line."

2. The GAITRite system will quickly process the data just collected, before once again cycling through the same process (see Step 14.3) of verifying that the port is open, the walkway has been identified, and communication with the walkway has been established.

3. When the GAITRite system has finished processing the data just collected (seconds later), you will again see the following message, which will remain until the participant's foot makes contact with the walkway: **Begin Walking**

5. **Repeat Steps 14.3 through 15**
   Repeat Steps 14.3 through 15 until four trials of walking have been completed for that testing condition ("Normal" *or* "Fast").
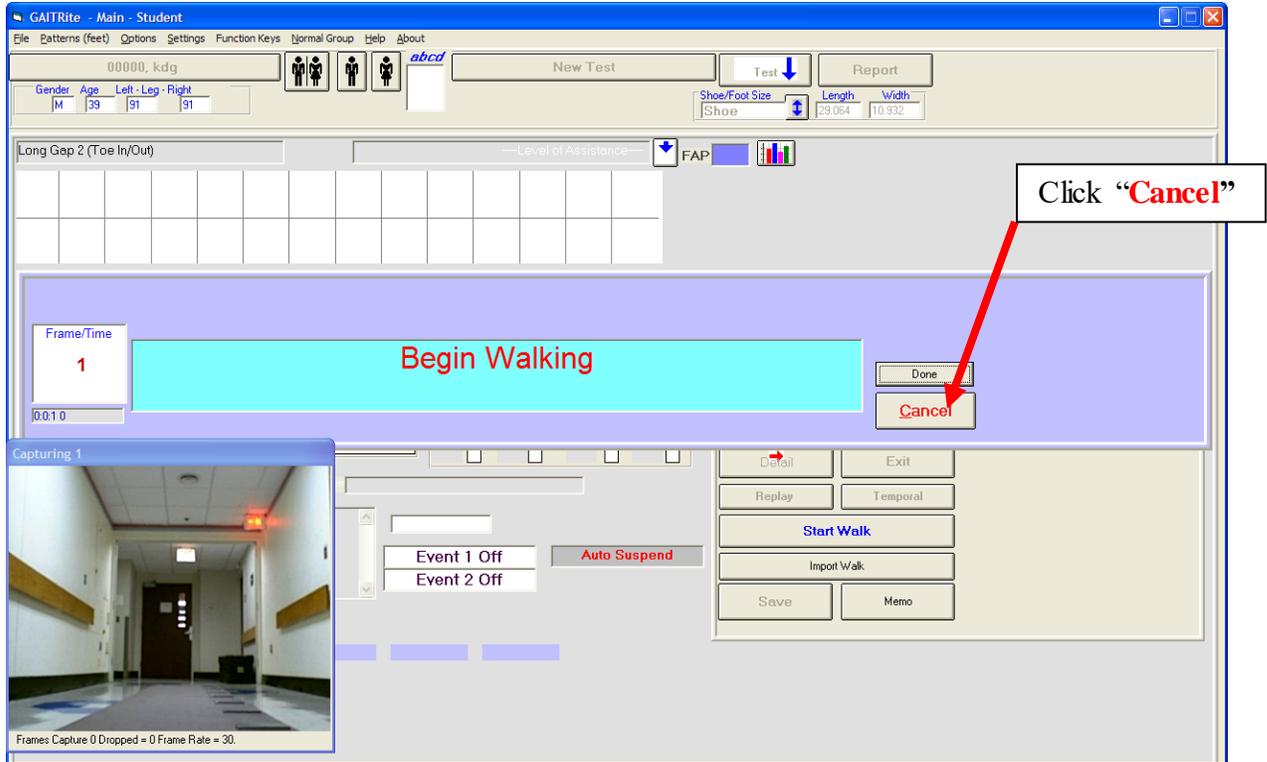
Step 16: Click the Cancel button

Click "**Cancel**" when all four trials have been completed under that testing condition ("Normal" *or* "Fast").

Repeat steps 9-16 and go to step 17 (omit Step 12 since camera is already activated) to complete data collection under the second test condition ("Fast" walking).

Step 17: Question regarding pain during testing

Question #4 on the data collection form guides the examiner through a short series of questions regarding pain during testing. Although this question is asked after the fast-pace walk, and NOT after the normal-pace walk, the question pertains to both the normal and fast pace walk. Administer these questions to the participant and record the responses on the data collection form:

4. During this test, did you experience any pain in your joints or muscles?

○ Yes   ○ No   ○ Refused or unable to answer

a. Where was the pain located?
(Examiner Note: Mark all that apply.)   ○ Back

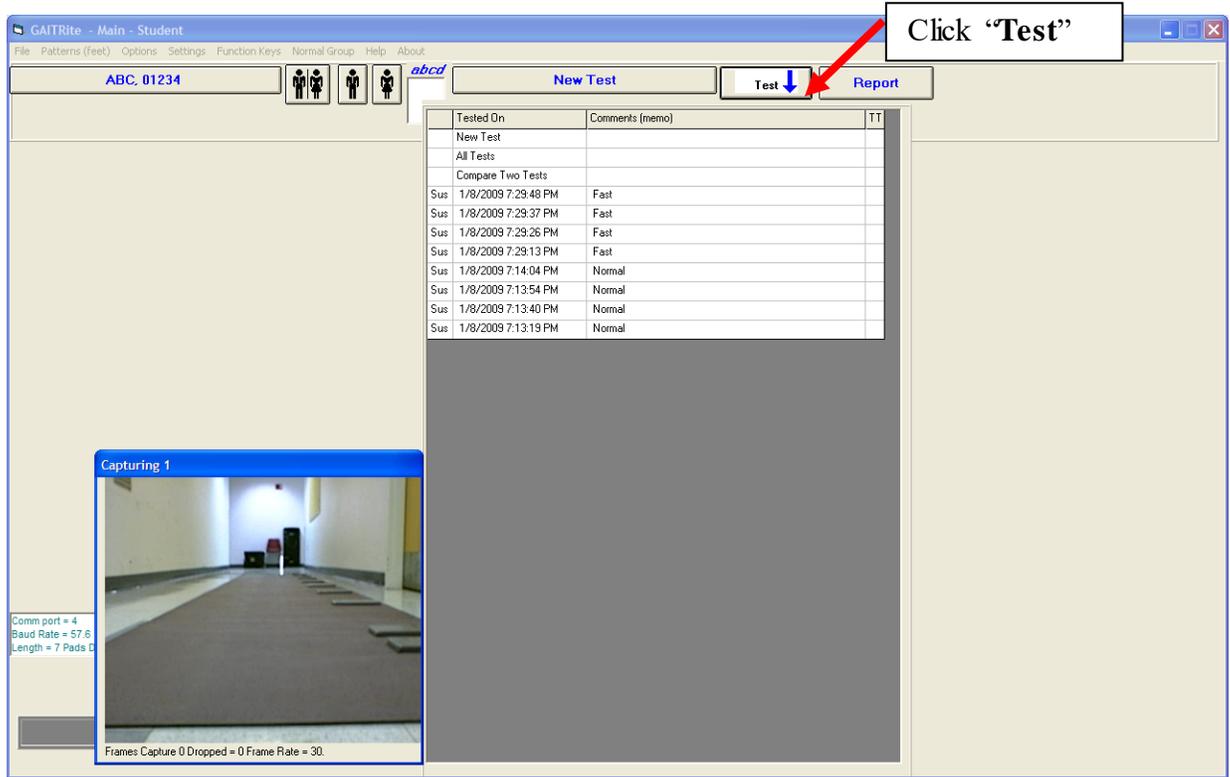| Left side	Right side
○ Buttock	○ Buttock
○ Hip	○ Hip
○ Thigh	○ Thigh
○ Knee	○ Knee
○ Leg	○ Leg
○ Ankle	○ Ankle
○ Foot	○ Foot
○ Other *(Please specify:* _____)	○ Other *(Please specify:* _____)

b. Was the pain typical of what you usually feel during this kind of activity?

○ Yes   ○ No   ○ Refused or unable to answer

(Examiner Note: See list of areas with pain above. Do not ask the next question.)
c. Did the participant report pain in either knee?

○ Yes   ○ No

Show Card #27 and ask participant:

i. Please rate the knee pain that you had by pointing to the number on this card.
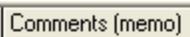
○ 0   ○ 1   ○ 2   ○ 3   ○ 4   ○ 5   ○ 6   ○ 7   ○ 8   ○ 9   ○ 10

Click "**Test**"

Step 18: Verify that all eight trials (four trials under each of two conditions) have been recorded

- Click the [Test ↓] button to see a drop-down menu.
  The menu should list all eight trials that have been recorded for that participant.

  As indicated in the far left column these trials have all been saved as Suspended Trials ('**Sus**' files).
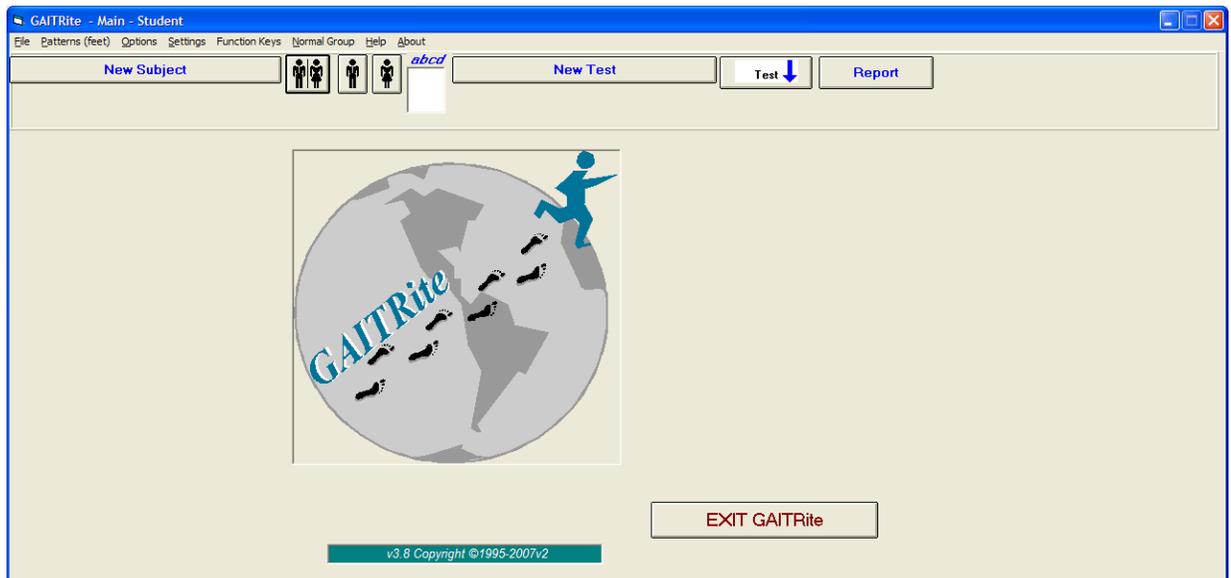
  Under the column labeled [Comments (memo)] on the right, you should verify that four of the eight trials are identified as "**Normal**" and the other four are identified as "**Fast**."

- After confirming that all eight trials are listed, click anywhere along the beige upper border (see below) of the drop-down menu to close the menu.
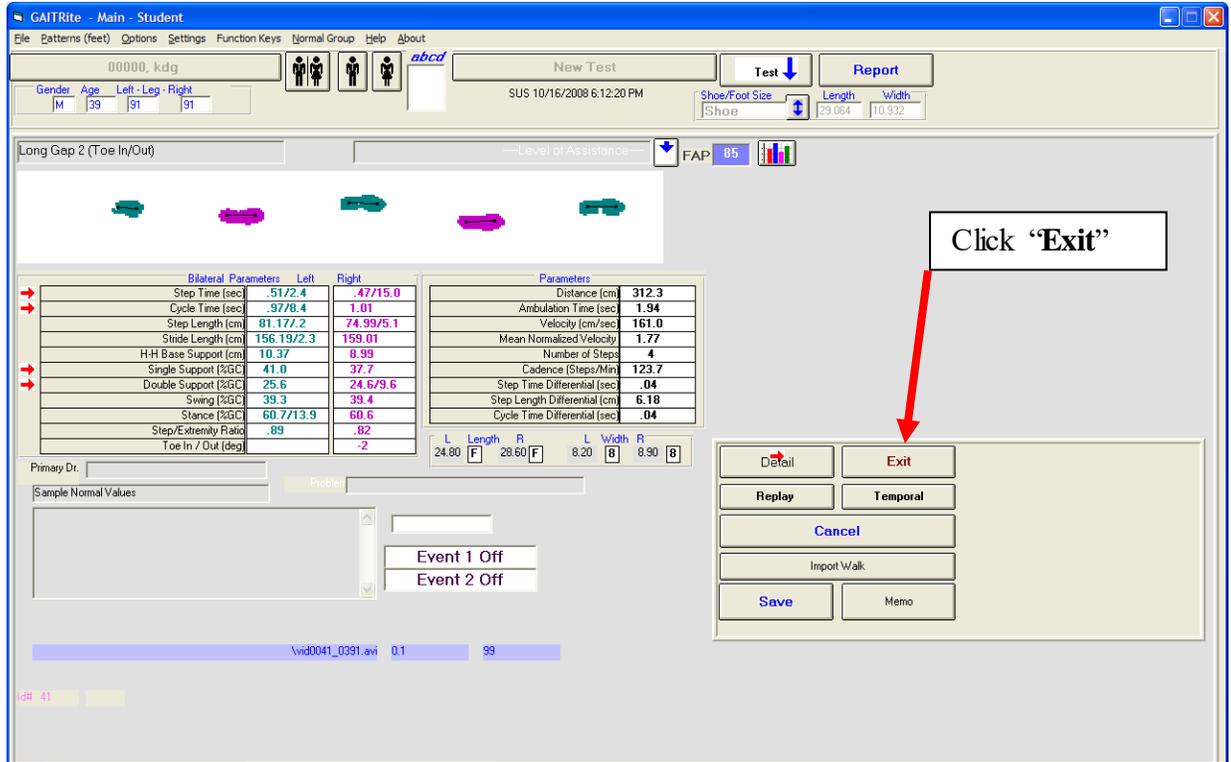
Step 19: Click the Exit **button.**

Step 20: Click the EXIT GAITRite **button**

REPEAT ALL STEPS 1-20 TO PERFORM DATA COLLECTION ON A NEW PARTICIPANT

6. Troubleshooting

It is not uncommon for the first and/or last footprints of a trial to fall half on and half off the active recording area of the walkway. Clinic examiners should not worry about this. Analysts at Boston University will edit each trial, and will identify and delete all partial footprints. If, however, a clinic examiner witnesses a trial in which the majority of footprints fall outside the active recording area of the walkway, then please continue with the protocol with the addition of one extra trial under that test condition ("Normal" or "Fast" walking condition). Nothing should be deleted. When analysts find that there are five trials under a test condition instead of the expected four trials, it will serve as a cue for them to look for and identify the unusable trial.

7. Quality assurance

7.1 Training and certification

Staff will be trained at the centralized training session by a master examiner. Training procedures will cover basic device and software operation and the fundamentals of testing, as well as study-specific procedures. Videotapes of exams will be also be provided for examiners to review. Examiners should practice on other staff members and themselves until consistency and efficiency are achieved. It is especially useful to practice on volunteers who are not knowledgeable about what to expect. Examiners will be recertified midway through the examination cycle.

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

- Attend training sessions
- Observe measurement by experienced examiner
- Read operations manual with goal of understanding
  - the proper use and cleaning of the GAITRite device
  - the proper operation of the GAITRite39 software
  - exclusions and safety considerations
  - detailed testing procedures
- Practice on colleagues and "naive" volunteers

7.2 Certification requirements

- Complete training requirements
- Recite exclusion criteria
- Demonstrate cleaning of GAITRite
- Conduct exam on two volunteers while being observed by clinic QC officer

7.3 Quality assurance checklist

☐ Exclusion questions asked from data collection form

☐ Participant information correctly entered on computer

☐ Elastic belt properly attached to participant's pelvis

☐ ASISs correctly identified and marked with colored Velcro dots

☐ Colored dots applied to center of "X"s over lateral heads of fibula

☐ Main points of script correctly and clearly delivered

☐ Toes touching start line

☐ Instructs participant to walk at normal pace for practice test

☐ Software properly set up for normal pace test

☐ Correct instructions given for four test trials at normal pace

☐ Instructs participant to walk at fast pace for practice test

☐ Software properly set up for fast pace test

☐ Correct instructions given for four test trials at fast pace

☐ Participant asked about pain after test

☐ Correctly completes data collection and exclusions forms

☐ Reviews forms for completeness

8. Data Collection Form

GAITrite and Plantar Pressure Exclusions

3398

Visit	MOST ID #	Acrostic	Staff ID#
O 60-month O 84-month			

(Examiner Note: Do not ask this question.)

1. Is participant using a walker or crutches?

     O Yes   O No

> Do NOT administer GAITrite or plantar pressure walk tests. Go to next test.

---

2. Does participant have a cane with them?

     O Yes   O No

> **a.** When you leave your home, do you use a cane more than half the time when you walk?
>   O Yes   O No   O Don't know
>
> > Do NOT administer GAITrite or plantar pressure walk tests. Go to next test.
>
> > **b.** Are you able to walk safely over short distances without using a cane?
> >   O Yes   O No   O Don't know
> >
> > > Do NOT administer GAITrite or plantar pressure walk tests. Go to next test.

---

3. Is the participant wearing an orthotic knee brace?
(Examiner Note: Do <u>not</u> include neoprene sleeve or patellar tendon strap.)

     O Yes   O No

> **a.** When you leave your home, do you use a knee brace more than half the time when you walk?
>   O Yes   O No   O Don't know
>
> > Do NOT administer GAITrite or plantar pressure walk tests. Go to next test.
>
> > **b.** Are you able to walk safely over short distances without using a knee brace?
> >   O Yes   O No   O Don't know
> >
> > > Do NOT administer GAITrite or plantar pressure walk tests. Go to next test.

GAITrite and Plantar Pressure Exclusions

32446

Visit	MOST ID #	Acrostic
● 60-month ○ 84-month	M	

MOST

---

4.   Has the participant had any amputation of the lower extremity other than the toes?

○ Yes   ○ No

↓

> Do NOT administer GAITrite or plantar pressure walk tests. Go to next test.

---

5.   In the past 6 weeks, have you had either surgery or an injury to your legs or feet that caused you to restrict weight-bearing for a week or longer?

○ Yes   ○ No   ○ Don't know/Refused

↓

> Do NOT administer GAITrite or plantar pressure walk tests. Go to next test.

---

6.   Do you have difficulty walking or standing upright because of a stroke, Parkinson's disease, or other neurological condition?

○ Yes   ○ No   ○ Don't know/Refused

↓

> 6a. Have you had this difficulty for 6 months or more?
>
> ○ Yes   ○ No   ○ Don't know
>
> > Do NOT administer GAITrite or plantar pressure walk tests. Go to next test.

Examiner Note: Observe participant for signs of impairment of vision, gait, and balance, or severe joint pain that might pose a safety risk for the GAITrite and plantar pressure tests.
If there is a safety concern, ask the participant if they feel they can safely walk short distances.
If necessary describe the tests in more detail.

7.   Is there a safety concern?

○ Yes   ○ No

↓

> *Ask participant:*
>
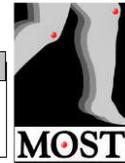> 7a. Do you think you can safely walk short distances?
>
> ○ Yes   ○ No   ○ Don't know
>
> > Do NOT administer GAITrite or plantar pressure walk tests. Go to next test.

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GAITrite

Visit	MOST ID #	Acrostic	Staff ID#
○ 60-month ○ 84-month			

MOST

1. In the past 6 weeks, have you been in the hospital overnight or longer for a heart or lung condition?

     ○ Yes   ○ No   ○ Don't know/Refused

> Do NOT administer GAITrite walk test. Go to plantar pressure test.

2. Was the normal-pace walk test administered?

     ○ Yes   ○ No

3. Was the fast-pace walk test administered?

     ○ Yes   ○ No

4. During this test, did you experience any pain in your joints or muscles?

     ○ Yes   ○ No   ○ Refused or unable to answer

   a. Where was the pain located?
     (Examiner Note: Mark __all__ that apply.)   ○ Back

Left side	*Right side*
○ Buttock	○ Buttock
○ Hip	○ Hip
○ Thigh	○ Thigh
○ Knee	○ Knee
○ Leg	○ Leg
○ Ankle	○ Ankle
○ Foot	○ Foot
○ Other *(Please specify:* _____)	○ Other *(Please specify:* _____)

   b. Was the pain typical of what you usually feel during this kind of activity?

     ○ Yes   ○ No   ○ Refused or unable to answer

     (Examiner Note: See list of areas with pain above. Do not ask the next question.)
   c. Did the participant report pain in either knee?

     ○ Yes   ○ No

     Show Card #27 and ask participant:

   i. Please rate the knee pain that you had by pointing to the number on this card.

     ○ 0   ○ 1   ○ 2   ○ 3   ○ 4   ○ 5   ○ 6   ○ 7   ○ 8   ○ 9   ○ 10

MOST Follow-up
Clinic Visit Workbook
K9

44167

Appendix 1 Data Transfer Procedures

The entire GAITRite database can be easily copied, renamed with that day's date, and uploaded to the Secure Data Gateway. (See chapter 7 Secure Data Gateway.)

During installation of GAITRite39
First enter the serial number, license key, and clinic name into the settings of GAITRite39 (see section 2.2). Then create a master copy of the file "gaitrite.mdb" by completing the following steps:
1. Copy the existing gaitrite.mdb file
2. Paste the copy of the gaitrite.mdb file into the same folder.
3. Rename the new "copy of gaitrite.mdb" to "gaitrite_new.mdb".

Weekly
Users must create a zip file containing the gaitrite database (gaitrite.mdb) and the contents of the video folder and then upload that zip file to the Coordinating Center. This can be done in an automated manner by running a specially written MS-DOS batch file, or manually.
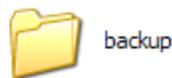
Automated Creation of Zip File for upload
Users can back up the data manually and create a zip file for transfer to the Coordinating Center using these instructions:

1. Go to the gaitrite folder (C:\gaitrite39):

 Click on the "Shortcut to GAITRite39" on the desktop

2. Open backup folder

3. Double-Click on the icon to run BackupGaitriteForTransfer.bat

4. When prompted, enter today's date (yyyymmdd format)

5. The program will create a .zip file for you and inform you that it has finished:

```
C:\WINDOWS\system32\cmd.exe
02/27/2009
Enter Today's Date [yyyymmdd]: 20090222
A subdirectory or file MB_G20090222 already exists.
Access is denied.
------------------------------------
copied gaitrite.mdb and video folder
------------------------------------
        1 file(s) copied.
A subdirectory or file video already exists.
------------------------------------------
created new empty gaitrite.mdb and video folder
------------------------------------------
 Files backed up. Press ENTER to continue, and remember to create compressed zip file
```

6. If you see the message shown above, press return to close the window

7. If you see any other message, contact the Coordinating Center

8. In the c:\gaitrite\backup folder, there will now be a new folder named after today's date (MB_Gyyyymmdd at Alabama, or MI_Gyyyymmdd at Iowa).

9. Right mouse click on the Mx_Gyyyymmdd folder and send to compressed zip folder
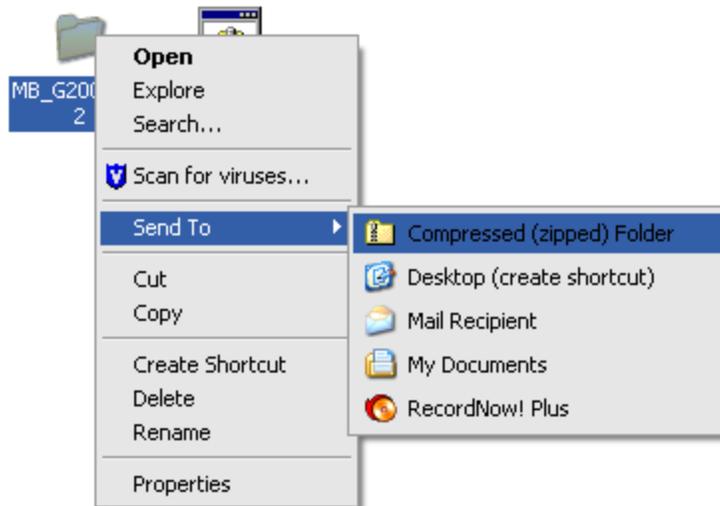
10. Upload this Mx_Gyyyymmdd.zip file to the Secure Data Gateway as per instructions in the Secure Data Gateway operations manual.

11. Collect data the following day as usual
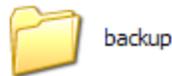
Manual Creation of Zip File for upload

Users can back up the data manually and create a zip file for transfer to the Coordinating Center using these instructions:

12. Go to the gaitrite folder (C:\gaitrite39):

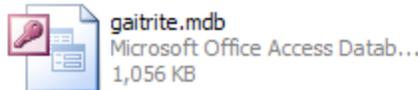 Click on the "Shortcut to GAITRite39" on the desktop

13. Open backup folder

14. Create a folder named after today's date (MB_Gyyyymmdd for Alabama, MI_Gyyyymmdd for Iowa):

15. Move (do not copy) "gaitrite.mdb" and "video" folder from C:\gaitrite39 into C:\gaitrite39\backup\Mx_Gyyyymmdd folder.
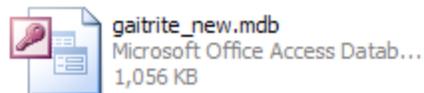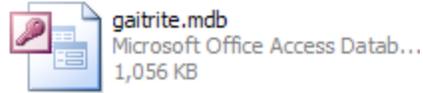
 and

Moved to

16. Copy "gaitrite_new.mdb" (resides in C:\gaitrite39)

17. Paste "gaitrite_new.mdb" into the same folder (C:\gaitrite39). It will now be named "copy of gaitrite_new.mdb"
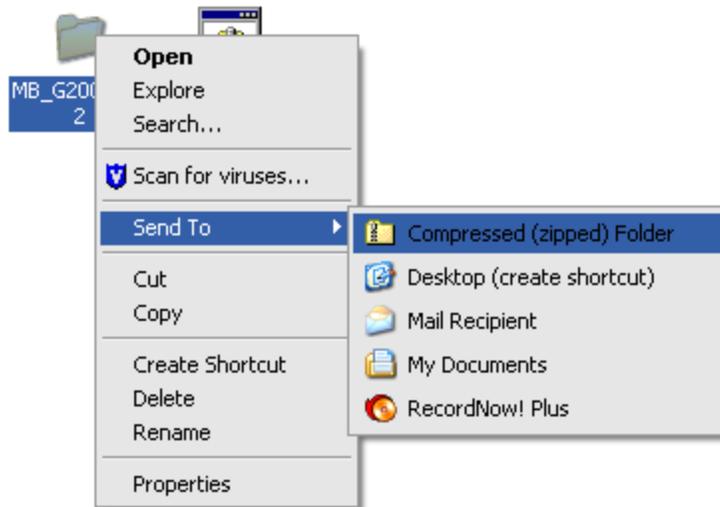
18. Rename to "gaitrite.mdb"

gaitrite.mdb
Microsoft Office Access Datab...
1,056 KB

19. Create a new video folder
      a.   Right click from within C:\gaitrite39
      b.   Select "New," "Folder"
      c.   Name the new folder "video"

video

20. Go to C:\gaitrite39\backup folder

21. Right mouse click on the Mx_Gyyyymmdd folder and send to compressed zip folder

22. Upload this Mx_Gyyyymmdd.zip file to the Secure Data Gateway as per instructions in Secure Data Gateway operations manual.

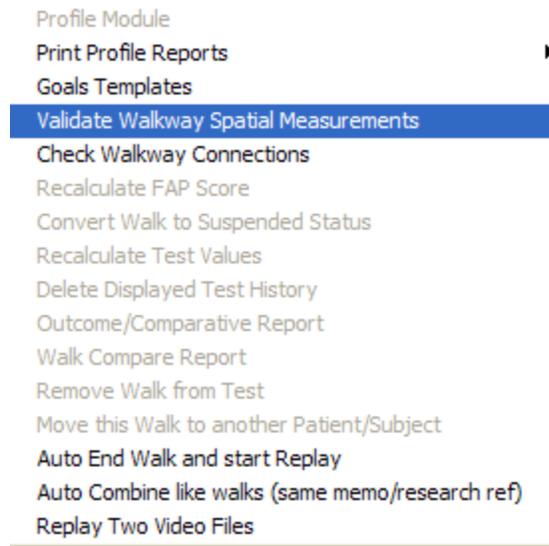23. Collect data the following day as usual

Appendix 2 Procedures for Verifying Spatial and Temporal Accuracy of GAITRite

The greatest threat to the accuracy of the GAITRite is not gradual decay in the performance characteristics of the walkway's instrumentation, but rather overt damage to the walkway by inappropriate shoewear or careless bending or folding. If overt damage to the walkway has occurred, it should be promptly reported to CIR, Inc. at support@gaitrite.com.

The following procedures should be followed every 3 months in order to verify to spatial and temporal accuracy of the GAITRite device.

1. Open GAITRite 3.9 and sign on in the usual manner by triple left clicking in the white box marked User ID

2. Click on the **Options** button at the top of the screen and select "Validate Walkway Spatial Parameters" from the drop down menu:

3. You will arrive at the following screen:

4. Follow these steps using colored adhesive dots:
   a. Place one adhesive dot somewhere within the active area of the carpet. Place a second adhesive dot at a diagonal 12-16 inches from the first adhesive dot (and still within the active area of the carpet).
   b. Use a tape measure to determine the linear distance (in centimeters) between the center points of the two dots.
   c. Click **Begin**.
   d. Using the dull end of a broom stick, apply moderate pressure over the first and then the second adhesive dot.
   e. Use a stopwatch to determine the time interval (in seconds) between when you begin applying pressure at the first dot and when you begin applying pressure at the second dot.
   f. The software will compute the linear distance in centimeters (first column) and the linear distance in inches (second column):

g.   The software will also compute the time interval (in seconds) between the applied pressures (third column):

h.   Verification of the spatial and temporal accuracy of the GAITRite is accomplished when the examiner's own measured results are closely comparable to the software's computed results for both linear distance and time interval variables. In MOST, measured and computed values should be within 1.5 cm. and 1.5 seconds to be regarded as accurate.

i.   If accuracy is not within 1.5 cm. and 1.5 seconds during the first trial, perform a second and third trial using the exact same methods.

j.   If, after 3 trials, accuracy is still not within 1.5 cm. and 1.5 seconds, then the carpet must be regarded as damaged or poorly calibrated and it should be returned to the manufacturer (see address below) for maintenance or replacement during the 2 ½ year period that it is under warranty following the date of purchase.

k.   Repeat steps 4a-4i at 3 or 4 different locations along the active area of the carpet in order to verify the spatial and temporal accuracy across the full length of the carpet.

Contact Info. for maintenance or replacement:
CIR Inc.
60 Garlor Drive
Havertown, PA., 19083
support@gaitrite.com

Appendix 3 Trouble-shooting

Run-Time Errors

On rare occasions, examiners have reported run-time error messages that interrupt a GAITRite examination. In the event of a run-time error, follow these steps in order to ensure that data from the previous trial is not lost:

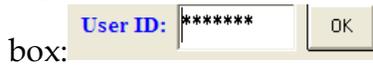1. A pop-up message will appear announcing that some kind of "Run-time error" has occurred:

   Click [OK].

2. The GAITRite software may be forced to shut down. If this occurs:

   a. Re-open the GAITRite software in the usual manner by clicking on the icon .

   b. Sign-in in the usual manner by triple left clicking in the User ID box:

   c. A pop-up message will appear saying "GAITRite did not close normally, Recovery data available, Recover Now". Click "**No**".
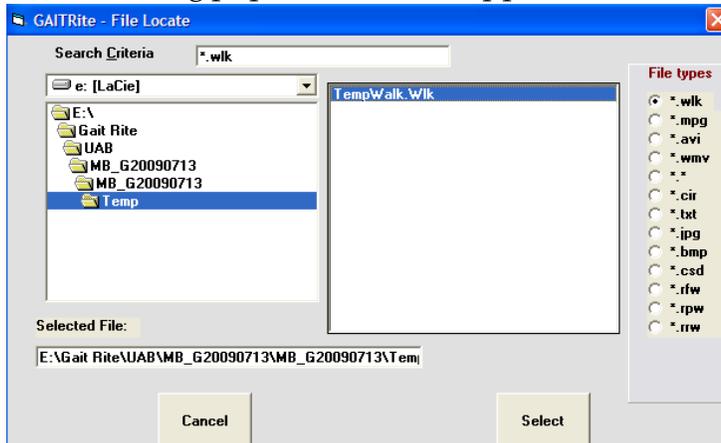
   d. Click on the All Patients icon to see a list of all subjects in the database.

   e. Select the current subject from the drop down list of All Active Subjects

3. Click [New Test]

4. Click [Import Walk]

5. The following pop-window will appear:

6. In the ![Temp] folder will be a file entitled "TempWalk.Wlk". Select this file by highlighting it and clicking Select.

7. The footprint data from the previous trial should load.

8. Click Settings and verify that "Auto suspend each trial" is checked.

9. Continue with exam as outlined in the written protocol.