PLANTAR PRESSURE

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1. Background and rationale

In MOST, we will assess foot plantar pressure during both relaxed standing and self-paced walking. Our goal will be to characterize each participant's left and right foot mechanics, including the extent of foot pronation (flattening) and supination (arching) during typical activities. In order to make this characterization accurately, we will use the Emed-X plantar pressure platform (Novel, Inc) and its attendant database software. At the start of the exam, a digital still camera will be used to capture a single photograph of the dorsum of both feet in sitting. The photograph will allow subsequent identification of structural foot deformities such as bunions, bunionettes, and hallux valgus. During the exam, a digital video camera will synchronize with the pressure platform in order to capture the sagittal plane motion of the foot and ankle during the walking trials. The videos will allow subsequent identification of relevant motion impairments, including ankle equinus and functional hallux limitus.

With a densely packed array of four high quality capacitance pressure sensors in every square centimeter (6,080 sensors in total) and a sampling speed of 100 Hz, the Emed-X (manufactured by Novel, Inc.) is the premier device of its kind for detecting local foot pressures. Sophisticated data analysis software (available at Boston University [BU] and the Hospital for Special Surgery [HSS]) will allow MOST investigators to convert the average plantar pressure measurements obtained over five walking trials (five footprints from the left foot + five footprints from the right foot = 10 trials total) into accurate measures of overall foot pronation and supination during walking. We will use a simplified two-step protocol during all walking trials (a single step is taken on the walkway before stepping onto the active area of the pressure platform) since it has been shown to greatly expedite data collection without significantly compromising the validity of measures that have been averaged over multiple trials. In addition, we will perform a single brief trial during relaxed bipedal standing so that we can characterize foot pressure and alignment during stationary upright postures.

The Emed-X system consists of a 700 L x 403 W x 19 H mm plantar pressure platform (sensor area 475 L x 320 W mm^2) embedded within a 3668 L x 806 W x 71 H mm walkway. The platform connects directly via cable to the USB interface of a notebook computer. Pre- configured database software operating in the "Simple Mode" will facilitate the acquisition and storage of all trial data into a dedicated file for each participant. De-identified files can be uploaded to the secure data gateway and accessed by BU and HSS sites for further analysis. Basic elements of the data can be summarized and color printed at the clinic sites for the participant to keep as a souvenir (color printer must be accessible from the personal computer running the database software).

2. Equipment, supplies, and facilities

Hardware from Novel, Inc. includes

- Emed-x sensor platform
- Walkway – 3668 L x 806 W x 71 H mm.
- Sony Vaio notebook computer – Windows XP and USB interface

- Canon digital video recorder with platform cable interface and computer interface via IEEE1394/Firewire cable (included) (For photos illustrating correct connection of cables to video camera, see Appendix 4.)
- Video camera tripod
- Power Strip and USB Hub (for extra USB ports)

Other needed hardware

- Sony black Cyber-shot H10 digital still camera, model DSC-H10/B
- Sony portable AC power adapter for Cyber-shot camera, model AC-LS5K
- Vaddio expandable camera wall-mount
- Color printer—dedicated for printing color reports as participant souvenirs
- 2 USB to USB extension cables
- Power cord extension cable
- two plastic cord protectors

Software from Novel, Inc. includes:

- Emed-x/R data collection software
- Database medical software

Connectivity

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

Clinic supplies

- Small folding table–for notebook computer
- Two chairs- one with no armrests
- Disposable isopropyl alcohol wipes–recommended for disinfecting active area of platform
- Isopropyl alcohol in spray bottle–alternative for disinfecting active area of platform
- Cloth towels–soft and non-abrasive, for disinfecting walkway and/or platform
- Cavicide disinfectant in spray bottle–for disinfecting walkway
- Photocopier–Souvenir reports will be printed onto preformatted paper rather than blank paper. The preformatted paper must be periodically copied from a master template.

Installation equipment

- 10 colors of Basic acrylic paint and paint brush – to paint starting lines on walkway
- Masking tape
- Paper laminate – for signage to mark finish lines, and for protective cover over footprints marking appropriate location for standing under digital still camera.
- Dense red construction paper – for finish line signage
- Phillip's head power screwdriver – for installation of Vaddio camera wall-mount
- Leveler – to find level floor area for placement of Emed platform
- Steel plate – 32" W x 5'L x 1/8"H, to construct an even surface for the Emed platform

Facilities

A quiet room with a hard, smooth, and reasonably *level* (not sloping) and *even* (not undulating) floor measuring at least 18’ in length and 12’ in width is needed to accommodate all necessary hardware. The pressure platform will be recessed into a walkway so that the walking surface and the active area platform remain flush and level. The walkway is 12 feet long and 32 inches wide (see Fig. 1).

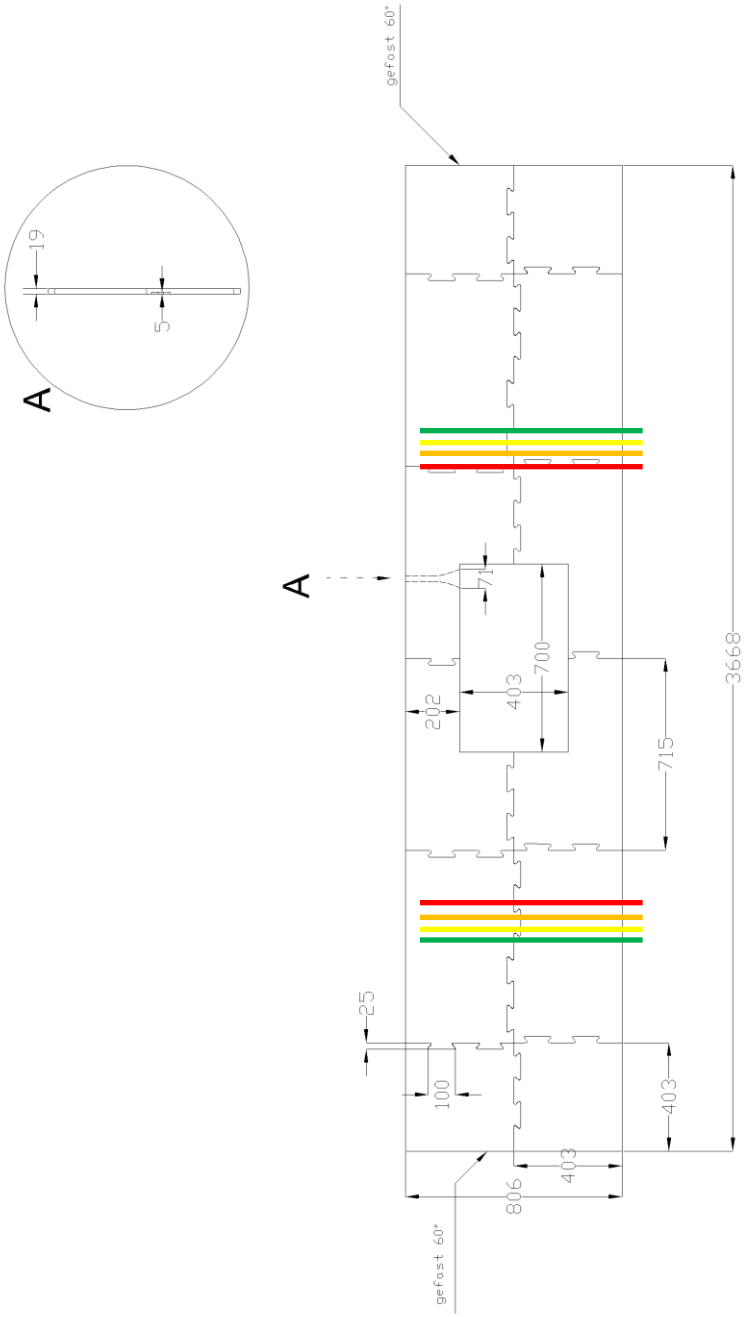

Figure 1. Dimensions of walkway into which the Emed platform is recessed. Ten lines are painted on either side of the platform to mark possible starting lines for initiation of the two-step protocol for collection of a walking footprint (only four lines are depicted). The first painted line is 13 inches from the thinnest blue border of the platform. Thereafter, a possible starting line is marked every 3 inches.

2.1 Service and maintenance

Maintenance
Emed database medical software was purchased along with an annual maintenance contract for 2008-2009 and 2009-2010 grant fund years. The Emed platform will be shipped to the Novel factory once per year for annual calibration. Novel will provide a replacement platform for the clinic to use during the calibration period so that there is no delay in study exams.

Contact for maintenance:

Susan Diekrager, Executive Vice President
Novel Electronics, Inc.
964 Grand Avenue
St Paul, MN 55105

tel 651.221.0505
fax 651.221.0404
susandiekrager@novelusa.com
www.novelusa.com

2.2 Shipping

The original shipping carton and all materials inside are needed to safely ship the Emed-X platform to Novel, Inc. in Munich, Germany for annual maintenance and calibration. Cables do NOT need to be included when shipping the platform and can remain in place at the clinic. The approximate dimensions of the shipping carton are 30.5”L x 20.5”W x 7.5”H.

To prepare the Emed platform for shipping, complete the following steps using the plastic bag, Styrofoam protectors, and the same cardboard carton in which the Emed was originally delivered:

1. Place the platform into the clear plastic bag in which it came.
2. Slide the rectangular Styrofoam protector around the platform. Start this at the bottom and move it up toward the middle of the platform.
3. Fit the two Styrofoam end protectors snugly to the edges of the platform.
4. Place the platform in the carton with the sensor surface DOWN.
5. Ensure to properly protect the power plug by wrapping it in bubble wrap.
6. Mark the carton fragile.
7. Contact Susan Diekrager of Novel, Inc. (contact information above) to arrange shipping.

2.3 Cleaning

The clinic floor, the blue foam walkway, the blue metal and black rubber exposed surfaces of the plantar pressure platform, and the clear plastic laminated footprint markers for the still photograph should all be regularly cleaned and disinfected in order to maintain a safe and sanitary environment for barefoot testing.

Emed platform – Disposable alcohol towel wipes are the preferred tool for cleaning the active black rubber area of the pressure platform after each participant exam. The disposable wipes offer assurance

that the amount of alcohol applied during frequent cleaning will be precisely regulated. Excessive alcohol can damage the exposed rubber surface. However, if done with caution, a spray bottle can be used to dampen a soft, non-abrasive washable cotton cloth with isopropyl alcohol or Cavicide. Always dampen the cloth first. Use the cloth to wipe the platform clean.

NEVER SPRAY ALCOHOL OR OTHER FLUID DIRECTLY ONTO THE PLATFORM!

Walkway – Spray a clean, soft, and non-abrasive cotton cloth with a residue-free household disinfectant or Cavicide and wipe the exposed surface of the blue foam walkway after each participant exam.
Laminated footprint markers – Dampen a cotton cloth with alcohol or Cavicide and wipe footprints after each participant exam.
Clinic floor – The floor should be regularly cleaned with a household disinfectant and mop. It is not recommended that the typical facility cleaning staff be allowed to freely clean the floors without supervision.

2.4 Hardware installation

One day of onsite staff training and assistance with installation was included in the cost of the Emed-X system. Onsite setup of the equipment, pre-configuration of the database software, and training and certification of the UAB and UI staff for execution of the study protocol will be provided by Maria Pasquale of Novel, Inc. along with Drs. Gross and Hillstrom of the MOST study. See section 6. for training and certification information.

If the video camera needs to be disconnected from the Emed platform and reconnected, see Appendix 4 for photo illustrations of correct connection of cables to the Emed platform.

2.5 Contact for training

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St Paul, MN 55105

tel 651.221.0505
fax 651.221.0404
MariaPasquale@novelusa.com
www.novelusa.com

2.6 Preferences set during installation of software

Initial preferences were set up prior to installation of the software. Unneeded data fields were removed and additional data fields were added in order to simplify use of the software by clinic examiners.

Please notify the study coordinator immediately if you find that any of the preferences have been inadvertently changed during the course of the study.

2.7 Calibration

Calibration of the Emed-X will be performed annually. There is a hardware maintenance agreement to cover the costs of calibration, which is performed at the end of each grant year by the engineers of Novel, Inc. at the factory in Germany. During a 2-year period of data collection, only a single calibration will be performed at the end of year 1. A loaner device can be made available to the clinic sites by Novel, Inc. in order to allow continuation of the study during the period of time that the purchased device is away. Contact Susan Diekrager to make arrangements:

Susan Diekrager, Executive Vice President
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964 Grand Avenue
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3. Safety issues and exclusions

3.1 Exclusion criteria

- Participant brings a walker or crutches to 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 straps) to the clinic visit and reports using the brace more than half the time when walking outside the home (see Figures 3A and 3B)
- Inability to walk safely over short distances without using a cane or an orthotic knee brace
- 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
- Any amputation of the lower extremity other than the toes
- Difficulty walking or standing upright because of a stroke, Parkinson's disease, or other neurological condition whose onset was less than 6 months ago
- 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
- Open wounds on the plantar surface of either foot are identified during a brief barefoot visual inspection

3.2 Stopping rules

- If the participant develops chest pain or dizziness during the test, do not complete testing.

- If the participant says that they cannot continue due to severe knee, foot, or back pain do not complete testing.

4. Participant preparation

4.1 Ask exclusions questions at the start of the GAITrite exam

Criteria for exclusion from the plantar pressure exam are, in all but one instance, identical to criteria for exclusion from the GAITrite exam. Therefore, a shared GAITrite and Plantar Pressure Exclusions form is to be used in place of two separate forms.

All exclusion questions that are common to the GAITrite and plantar pressure exams should be asked one time only.

There is only one criterion for exclusion from the plantar pressure exam that is *not* shared with the GAITrite exam and therefore must be uniquely assessed during the plantar pressure exam. This criterion is met when one or more open wounds are identified on the plantar surface of the participant's bare feet.

4.2 Identify knee braces, shoes, shoe inserts, and assistive walking devices

The following algorithm is used to determine whether to exclude a participant from both the GAITrite and plantar pressure exams based upon habitual use of an assistive walking device or orthotic knee brace (see GAITrite and Plantar Pressure Exclusions form in section 7). The algorithm requires the examiner to distinguish canes and walking sticks from crutches and walkers, and orthotic and ligament support knee braces from neoprene knee sleeves and patellar tendon straps. Figures 2A, 2B, and 3A, 3B will assist the examiner in making these important distinctions.

Additional non-exclusionary algorithms are used to characterize shoe stability, and to identify and distinguish supportive and non-supportive shoe inserts. Supportive shoe inserts include arch supports and heel wedges, while non-supportive shoe inserts include cushioning insoles and viscoelastic heel pads or heel cups. Figures 4A and 4B illustrate how these different categories of shoe inserts are distinguished.

A B

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.

A B

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

A B

Figures 4A (top row) and B (bottom row). **Shoe inserts.** Contoured or molded foot orthoses, arch supports, and inclined heel wedges ("Supportive" inserts, Figure 4A, top) are distinguished from flat or non-contoured gel or foam insoles, viscoelastic heel pads, and heel cups ("Cushioning" inserts, Figure 4B, bottom).

4.2.1 Assistive walking device and knee brace assessment

Participants that bring a walker or crutches with them to the clinic (see Figure 2B) are excluded from testing (see exclusion criteria). Participants that *bring* a cane or walking stick (see Figure 2A) or *wear* an orthotic or ligament support knee brace (see Figure 3A) are questioned to determine the extent of their dependency on the device. Note that the participant must be *wearing* the knee brace in order to trigger the following questions. These questions are not triggered if the participant is wearing a neoprene knee sleeve or patellar tendon strap (see Figure 3B).

"When you leave your home, do you use a cane/knee brace more than half the time when you walk?"

If YES for either the cane or the knee brace, exclude from testing.
If NO for both the cane and knee brace, ask:

"Are you able to walk safely over short distances without using a cane/knee brace?"

If NO for either the cane or the knee brace, exclude from testing
If YES for both the cane and knee brace, perform exam without the device.

4.2.2 Shoe insert assessment

During scheduling, participants are instructed:

> 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."

The participant may also wear a shoe insert along with these sneakers or walking shoes. If so, the presence and type of insert must be determined at the start of the plantar pressure exam.

In contrast to the GAITrite exam, in which the participant continues wearing their shoes (along with any inserts that the shoes may contain), the plantar pressure exam requires that the participant completely remove their shoes and socks and perform the exam barefoot. Consequently, the ideal time for the examiner to assess the participant's shoes (see shoe stability tests below), and to identify any shoe inserts that are present (shoe insert assessment), is just after the participant has removed their shoes and socks at the start of the plantar pressure exam.

Questions 2a and 3a of the Plantar Pressure data collection form ask the examiner to identify and *characterize shoe inserts in the following manner for both the right and left shoes*:

- Supportive = a contoured or molded foot orthosis, arch support, or heel wedge is present in the shoe (see Figure 4A).

- Cushioning = a flat or non-contoured gel or foam insole, or a non-wedged heel cup or viscoelastic heel pad is present in the shoe (see Figure 4B).
- Both = both supportive and cushioning inserts are present in the same shoe
- Other = unable to characterize the insert that is present in the shoe

4.2.3 Shoe assessment

The examiner will characterize the participant's shoes by performing three shoe stability tests (Figures 5 to7). Since the left and right shoes of a matching pair are expected to perform identically, the shoe stability tests can be performed on one shoe only. By default, we will *perform all three shoe stability tests on the left shoe only*. If for some reason the left shoe cannot be easily tested (e.g., it is excessively dirty), the examiner can test the right shoe instead with only minimal alterations to the written protocol.

Shoe stability tests
After removing all removable inserts from the shoe, the examiner characterizes shoe stability by performing the following three shoe stability tests on one shoe only (by default, the left shoe):

1. Bend test

The examiner positions the shoe perpendicular to the floor with the anterior toe box contacting the ground and the palm of the examiner's right hand ready to press down on the posterior heel of the shoe (Figure 5). The examiner applies approximately 5 lb of force longitudinally through the shoe by pressing it down against the floor. There are four possible results (Figure 5) which will characterize the shoe as either:

a. Rigid = there is no observable bend in the shoe.
b. Supportive = the shoe bends, but the bending remains isolated to the toe box and does not include the arch (midfoot) area of the shoe.
c. Flexible = the shoe bends and the bending extends beyond the toe box into the arch (midfoot) area of the shoe.
d. Not tested/Other

The examiner will record the result of the bend test in the appropriate section (Question 1a.) of the Plantar Pressure data collection form.

2. Twist test

The examiner holds the shoe in both hands so that the sole of the shoe is parallel with the ground. The examiner's left hand cups and stabilizes the heel of the shoe while their right hand grasps the toe box (Figure 6). The examiner then applies approximately 5 lb of torsional force (5 Nm or torque) to the shoe using the right hand to twist the toe box in a counterclockwise direction (Figure 6). There are four possible results which will characterize the shoe as either:

- Rigid = there is no observable twist in the shoe between the toe box and the heel.

- Supportive = the shoe twists, but the amount of twist is only sufficient to rotate the toe box less than 45 degrees (an imaginary line connecting the medial and lateral sides of the toe box makes an angle of less than 45 degrees with a line parallel to the sole of the shoe in the region of the heel).
- Flexible = the shoe twists, and the amount of twist is sufficient to rotate the toe box greater than or equal to 45 degrees (an imaginary line connecting the medial and lateral sides of the toe box makes an angle of greater than or equal to 45 degrees with a line parallel to the sole of the shoe in the region of the heel).
- Not tested/Other

The examiner will record the result of the twist test in the appropriate section (Question 1b.) of the Plantar Pressure data collection form.

3. Pinch test

The examiner places the shoe on the hard surface of a table or holds it upright with the left hand. The toes of the shoe are pointed away from the examiner so that the examiner is looking at the posterior heel of the shoe. The part of the posterior heel that is halfway up from the midsole of the shoe is known as the "heel counter" (Figure 7). Using the right index and middle fingers on the medial side of the heel counter, and the right thumb on the lateral side of the heel counter, the examiner pinches the heel counter using approximately 5 lb of force (Figure 7). There are five possible results which will characterize the shoe as either:

- Rigid = there is no observable narrowing of the heel counter ("narrowing" is defined as collapsing inward at the sides in response to examiner's pinching of the heel counter).
- Supportive = the heel counter narrows, but the amount of narrowing is not sufficient to allow the medial and lateral sides of the heel counter to make contact.
- Flexible = the heel counter narrows, and the amount of narrowing is sufficient to allow the medial and lateral sides of the heel counter to make contact.
- No heel counter present = the shoe has no heel counter, e.g., it has only a strap, or like many flip flop sandals, it has neither a heel counter nor a strap.
- Not tested/Other

The examiner will record the result of the pinch test in the appropriate section (Question 1c.) of the Plantar Pressure data collection form.

SHOE STABILITY TESTS

Figure 5. Bend test. Apply 5 lb of force by pressing the toe box of the shoe down against the floor. The response is graded as: 1) Rigid = no observable bend, 2) Supportive = the shoe bends, but the bending remains isolated to the toe box and does not include the arch (midfoot) of the shoe, or 3) Flexible = the shoe bends and the bending extends into the arch of the shoe.

Figure 6. Twist test. One hand cups and stabilizes the heel of the shoe while the other grasps the toe box. Apply 5 lb of torsional force to twist the toe box in a counterclockwise direction. The response is graded as:
1) Rigid = there is no observable twist in the shoe, 2) Supportive = the shoe twists, but the amount of twist is only sufficient to rotate the toe box < 45 degrees counterclockwise, or 3) Flexible = the shoe twists, and the amount of twist is sufficient to rotate the toe box $\geq$ 45 degrees counterclockwise.

Figure 7. Pinch test. With the right index and middle fingers and the thumb, the examiner applies 5 lb of pinching force to the heel counter. The response is graded as: 1) Rigid = there is no narrowing of the heel counter,
2) Supportive = the heel counter narrows, but the narrowing is not sufficient to allow the medial and lateral sides of the heel counter to make contact, 3) Flexible = the heel counter narrows, and the amount of narrowing is sufficient to allow the medial and lateral sides of the heel counter to make contact, or 4) No heel counter = no heel counter is present (there may be only a strap).

4.3 Removal of shoes and socks

All measurements are recorded with the participant barefoot. The participant is initially instructed to sit "side saddle" in an armless chair that is positioned directly in front of the wall with the mounted still camera. The participant's initial side saddle position on the chair allows the examiner to inspect the participant's feet for open wounds and perform the shoe stability tests without disturbing the position of either the chair or the camera. The examiner should provide assistance when needed to help the participant safely remove their shoes and socks. Similar assistance may be necessary to help the participant replace their shoes and socks after the exam is complete. The floor of the exam room should be hard and smooth so that injuries to the participant's bare feet are avoided. A strict schedule of cleaning the floor, walkway, platform, and laminated footprint markers should be adhered to throughout the duration of the study (see section 2.3 on cleaning).

4.4 Collection of foot photograph

After inspecting the feet for open wounds and completing the shoe stability tests, the examiner instructs the participant, who has been seated side saddle, to turn 90 degrees in the chair in order to sit facing forward. The participant will now be facing the same wall on which a Sony digital still camera (Figure 8, left) is mounted on an expandable arm (Figure 8, center). The expandable camera mount has been installed so that the camera, which is to remain in a fixed position at the end of the fully extended mount, maintains a focused view of two laminated colored footprint markers (see Appendix 3) on the floor beneath it. With assistance from the examiner, the participant will position both bare feet, with toes pointed straight ahead, directly over the laminated footprint markers (Figure 9). After the participant's feet have been properly positioned on the footprint markers, the examiner should verify that the viewfinder shows a clear view of the dorsum of both of the participant's bare feet (Figure 10). It is important that the tibias do not obscure a complete view of the dorsum of the feet. To ensure that they do not, position the participant and the chair so that *the knees have somewhat less than a 90 degree bend with the feet still positioned on the footprint markers.*

A single digital photograph is taken in this position. Once acquired, the photograph is immediately uploaded via USB cable into the participant's file within the Novel database (see section 5 for procedures). The computer end of the USB cable remains connected to the USB port of the laptop computer throughout the study. When not in use, the camera end of the USB cable is secured with Velcro to a nearby wall so that it will be immediately available whenever the examiner needs to plug it into the camera and upload a newly obtained digital photograph. Once transferred to the Novel database, the photograph should be deleted from the camera's memory card before the next participant is seen.

The camera will draw continuous power from a wall socket via a Sony AC adapter (Figure 8, right). There is no need to recharge the battery.

DIGITAL PHOTOGRAPH OF THE FEET IN SITTING

Figure 8. Camera equipment. A Sony Cyber-shot digital still camera (left) is mounted on an expandable camera mount (center). A single digital photo of the dorsum of both feet is acquired by leaving the mount fully expanded away from the wall so that the camera remains positioned over the seated participant's feet. A Sony AC adapter (right) provides continuous electrical power.

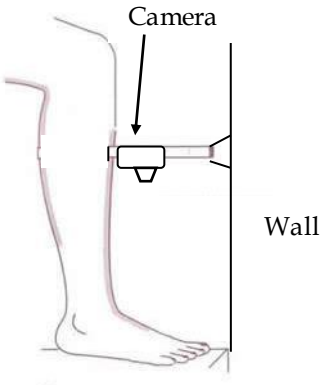


Figure 9. Position. The participant, initially seated side saddle in the chair, turns to face the wall on which the camera is mounted. Both feet are positioned on the footprint markers (see Appendix 3). The knees are bent less than 90 degrees so that the lower legs do not obscure a complete view of the dorsum of both feet.

Figure 10. Photograph. Turn the camera on by pressing down on the power button. Confirm that the dorsum of both feet and toes are fully visible in the LCD viewfinder. Acquire a single photo by pressing down on the shutter button.

4.5 Practice testing for walking trials

Establish ideal starting line
Practice testing is performed just prior to actual data collection in walking. A primary purpose of practice testing is to establish an ideal starting position from which the participant should begin walking so that their second step forward lands a footprint near the center of the active area of the Emed-X platform (recall the two-step protocol that is to be used in this study). Where an initial practice test fails to result in the desired second step in the center of the active area of the platform, the examiner will ask the participant to move their starting position slightly forward or backward. A set of ten possible starting lines are marked on the walkway with acrylic paint of varying colors. Once an appropriate starting line has been determined during practice testing, all subsequent walking trials should be initiated from a starting line of the same color. The ten possible starting lines appear in distinct colors on either side of the active pressure platform. Lines of the same color are the same distance from the active area of the platform. The first of these possible starting lines is 13 inches from the active platform. Thereafter, a starting line is painted every 3 inches.

Finish line
Successful performance of the two-step walking protocol requires that the participant continue walking forward several steps beyond the active area of the platform after landing a footprint on it. A finish line, common to all possible starting lines, is identified by a labeled sign (with the words "Finish Line" in large print) at either end of the 12-foot walkway.

The appropriate starting and finishing lines should be identified and pointed out to each participant during practice testing.

5. STEP- BY-STEP MEASUREMENT PROCEDURES

The following Step-by-Step Guide is accompanied by a detailed video. Examiners are encouraged to watch the video while following along. In the few instances where the video and written text conflict, the written text should take precedence.

1. **Verify that all power strips are turned on**
   The video camera and the Emed-X platform plug in to a surge protector power strip. *No attempt is made to utilize the power buttons on the devices themselves*. Instead, at the end of each day, the power to these devices is turned off simply by turning off their shared power strip. At the start of each day, the power strip must be turned on. Once turned on, the power can remain on for the duration of the workday.

2. **Instruct participant to sit side saddle in the designated chair and remove shoes and socks**
   A chair without armrests remains in position facing a wall upon which a digital still camera has been mounted. To avoid disturbing the position of either the camera or the chair, instruct the participant

to approach the chair from the side and sit down side saddle. Seated in this side saddle position, the examiner can assist the participant in removing their shoes and socks.

3. Perform shoe inserts assessment and shoe stability tests

The participant remains seated side saddle. Immediately after removal of a shoe (perhaps while the participant is still removing their socks) begin the shoe insert assessment and shoe stability tests.

An assessment is made of any shoe inserts that are present in the left or right shoes as outlined in section 4.2.2. Any shoe insert(s) present is characterized in the manner depicted in Figures 4A and 4B. The following are possible results:

a. **Shoe inserts (right and left separately)**

Does the participant have a shoe insert? If "Yes," What sort of insert it is?

- Supportive - a contoured insert is present
- Cushioning – a flat gel or foam insert is present
- Both Supportive and cushioning are present
- Not tested

The examiner records the results of the shoe inserts assessment in the appropriate section (Questions 2 and 3) of the Plantar Pressure data collection form.

After removing any removable shoe inserts, the examiner performs three shoe stability tests as described in section 4.2.3 and illustrated in Figures 5 to 7. The following are possible results:

b. **Shoe stability tests (left shoe only)**

i. Bend test

Select one of following:

- Rigid - no observable bend
- Supportive – bend in toe box only
- Flexible – bend extends into the arch
- Not tested/Other

ii. Twist test

Select one of following:

- Rigid – no observable twist
- Supportive – twists less than 45 degrees
- Flexible – twists greater than or equal to 45 degrees
- Not tested/Other

iii. Pinch test

Select one of following:

- Rigid – no observable narrowing of heel counter
- Supportive – narrows, but no contact of sides

- Flexible – narrows and sides contact
- No heel counter
- Not tested/Other

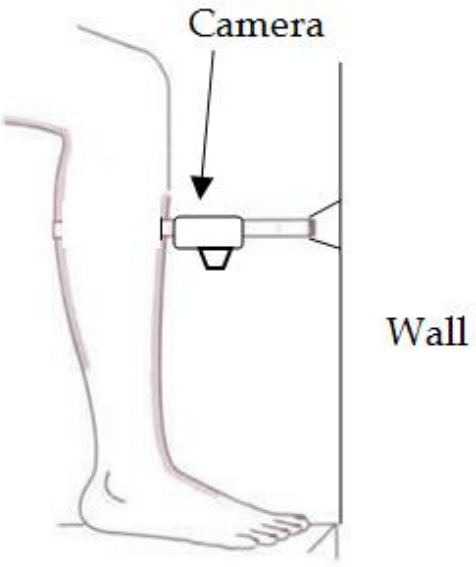
The examiner records the results of the shoe stability tests in the appropriate section (Question 1) of the Plantar Pressure data collection form.

4. Inspect feet for open wounds

In addition to the exclusions appearing on the shared GAITrite and Plantar Pressure Exclusions form, participants may also be excluded from the plantar pressure exam if they have any open wounds on the plantar surface of the feet. Quick visual inspection of the plantar surface of the feet is made while the participant remains seated side saddle in the designated chair.

5. Position for photograph

Upon inspection of the feet for open wounds, instruct the participant to turn 90 degrees on the chair in order to face forward. Complete the following steps:



a. Position the barefoot participant in the chair facing the wall on which the Sony digital camera is mounted.
b. Position the participant's feet on the laminated footprint markers (see Appendix 3).
c. With the expandable arm of the camera mount remaining fully extended, the camera will be centered over and pointing down at the dorsum of the participant's bare feet.
d. Verify that the participant is sitting far enough back in the chair so that the knees are bent less than 90 degrees and the lower legs do not obscure a complete view from above of the dorsum of both feet.

6. Acquire photograph

a. Turn the camera on by pressing down on the power button.
b. Confirm view of both right and left feet and toes in the LCD viewfinder as depicted.
c. Acquire a single photograph by pressing down on the shutter button.
d. Remove the camera end of the USB cable from where it is attached with Velcro to the wall, and plug it in to the camera's USB port (under plastic cover on the right side of the camera).
e. Instruct participant to turn 90 degrees in the chair to return to their original side saddle position. Instruct the participant to rise from the chair and begin making their way to the walkway.

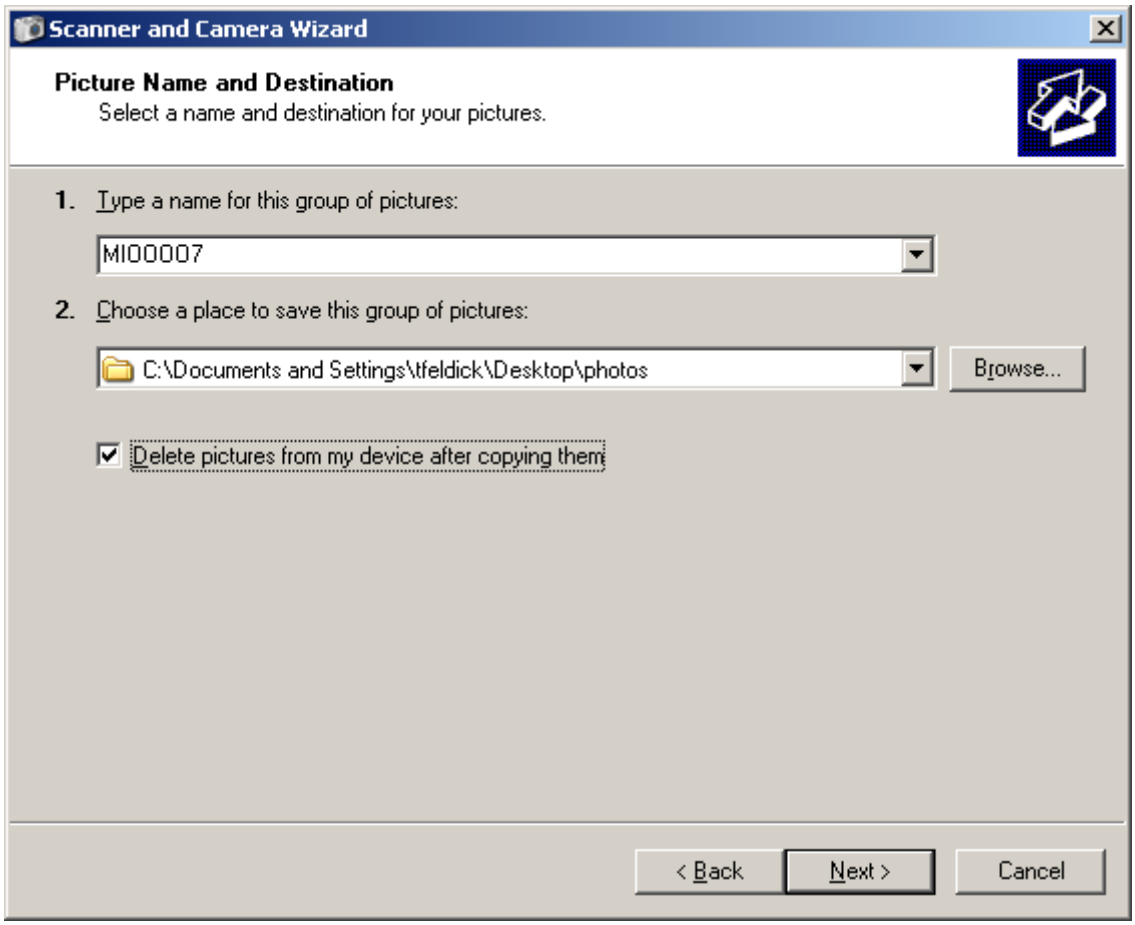
7. Upload photograph to folder on computer desktop

While the participant rises barefoot from the chair and makes their way to the walkway, complete the following steps to transfer the photograph from the camera to the computer.

a. After plugging in the camera end of the USB cable, the window above will appear on the computer screen.

Click 

.



b. Enter the participant's study ID in field 1 to name the photo.

Verify that Field 2 has defaulted to the folder named "Photos" on your Desktop. The directory address listed will end with

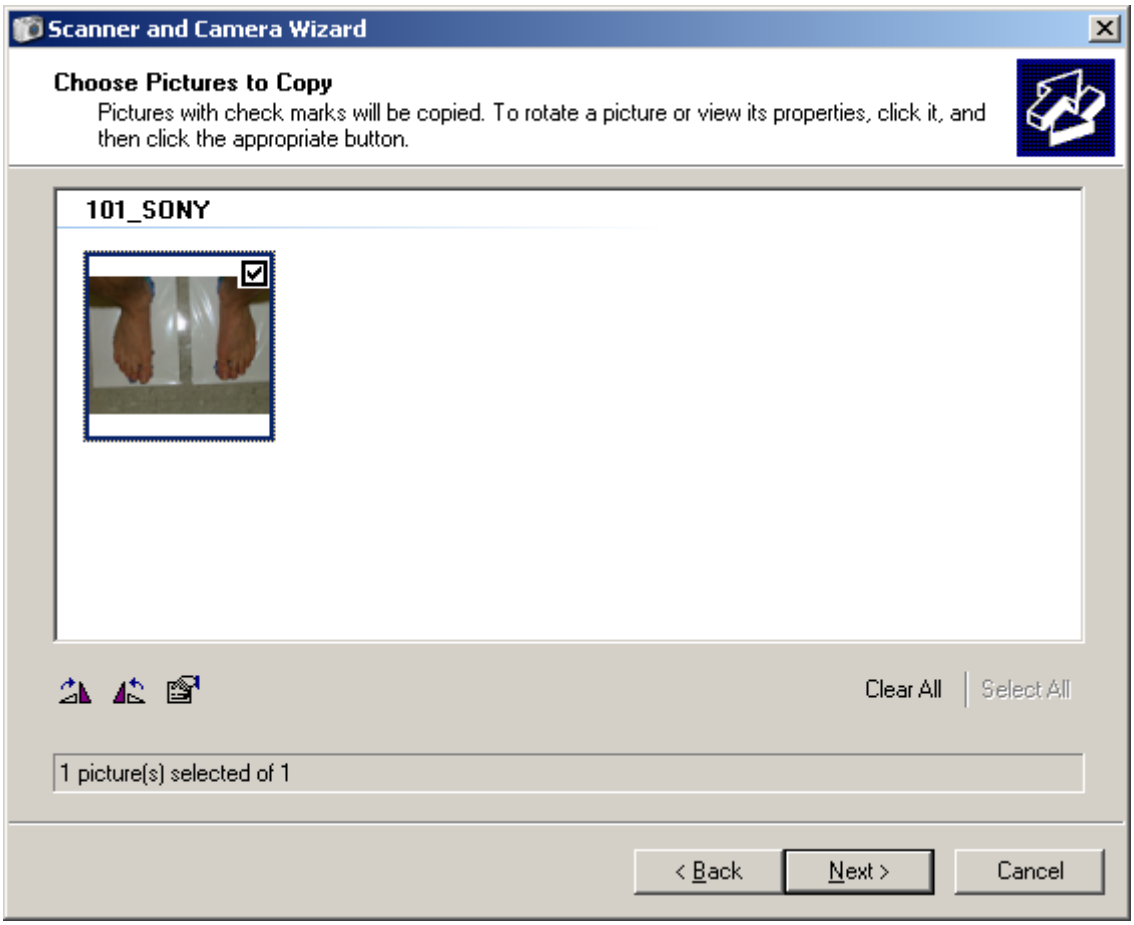
.

Check the box marked 

.

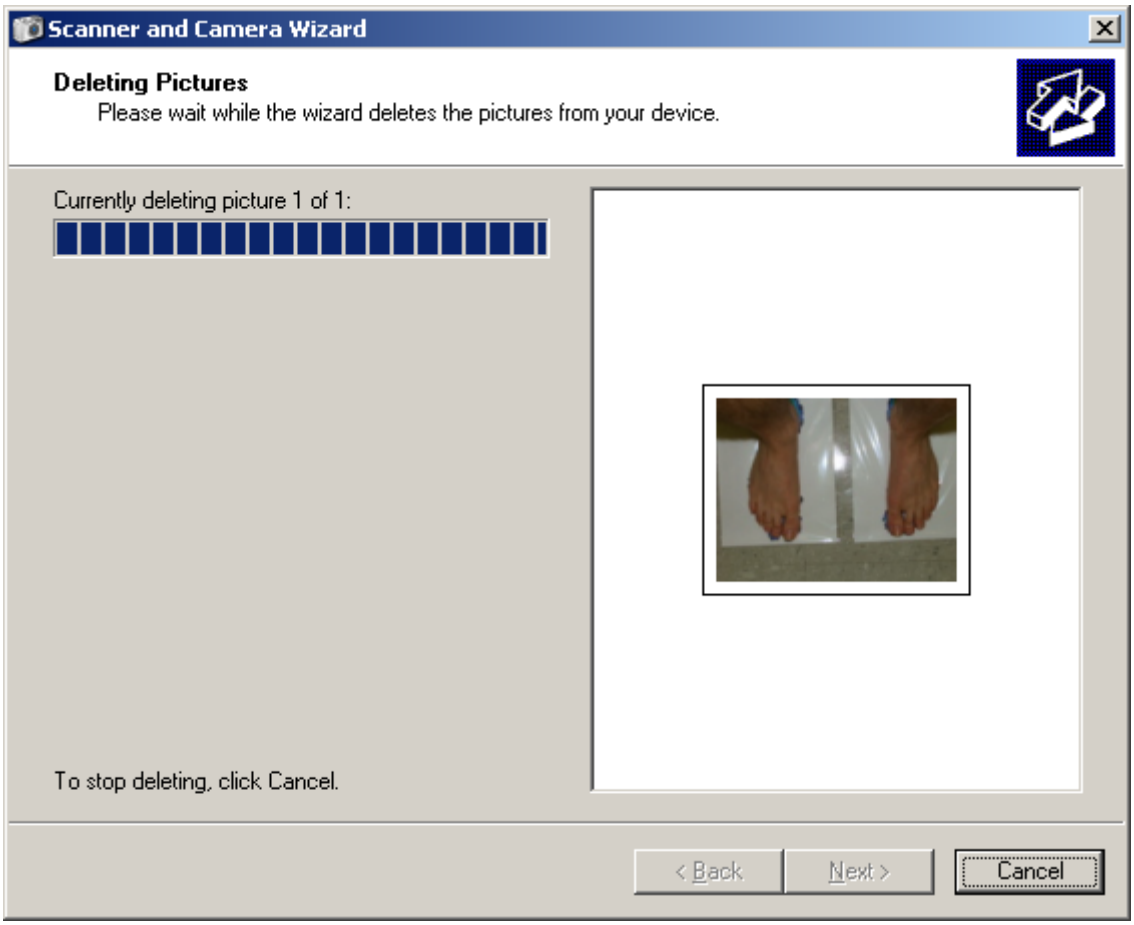
Click 

.

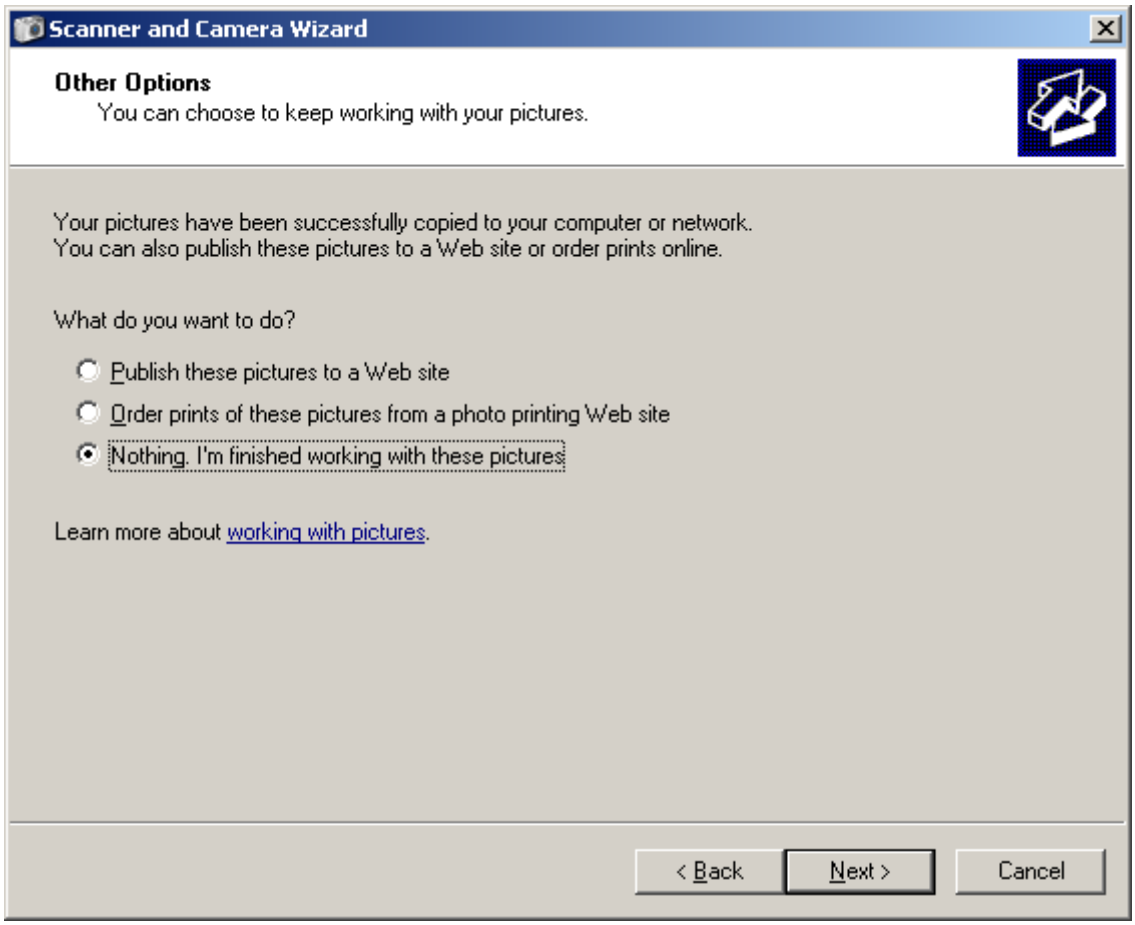


c. Verify that a  appears in the box in the upper right corner of the image just acquired. If any other images appear, uncheck these boxes by clicking over them.

Click  .



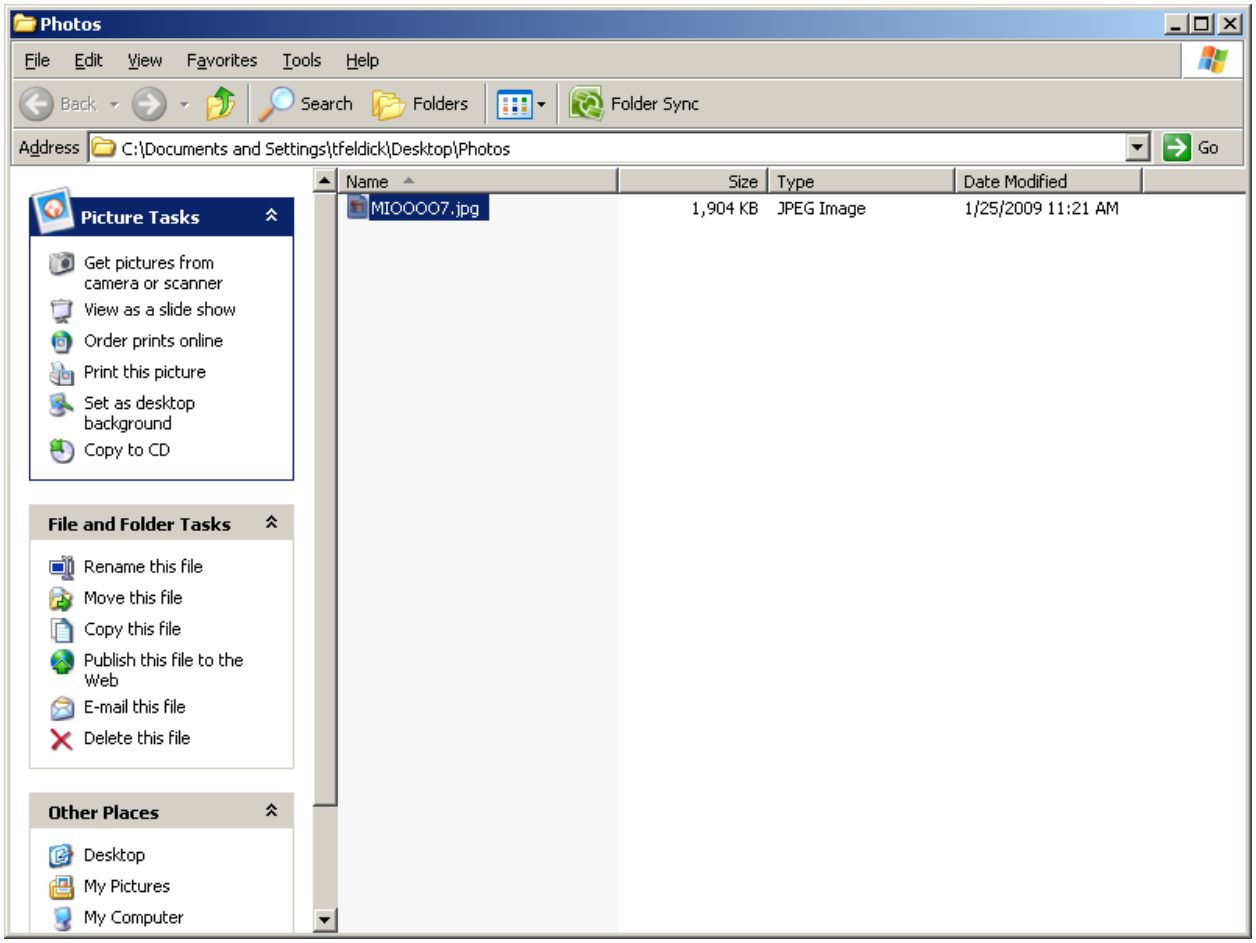
d. The screen above will appear only briefly and requires no action by the examiner.



e. When the screen above appears, click 

.

f. Click  to complete the procedures for uploading the photograph.



g. A window will appear showing you the contents of the folder named "Photos" (located on the Desktop) in which the photo now resides.

Close this window by clicking the ☒ in the upper right corner.

8. Open Novel database software

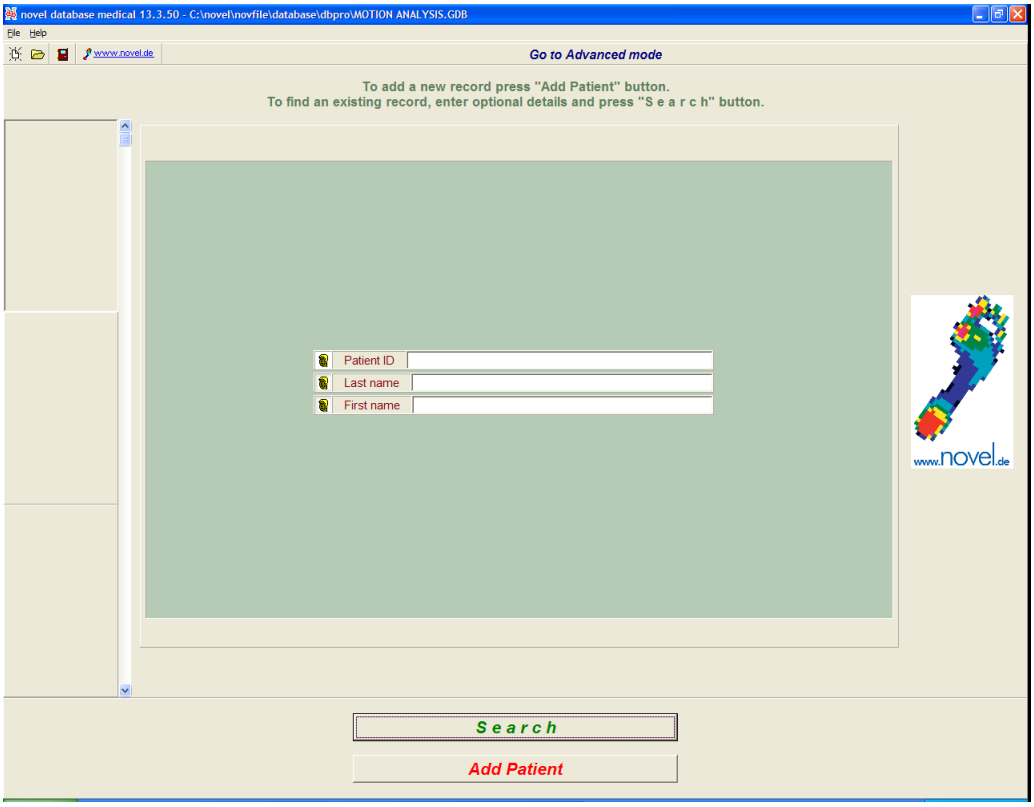
The Novel equipment is delivered along with a hardlock key that must remain connected to the USB port of the computer in order for the software to run.

Click on the Novel Database software icon 

on the desktop to open the Novel database software.

9. "Simple Mode"

The following screen will welcome you to the Novel database software running in Simple mode.



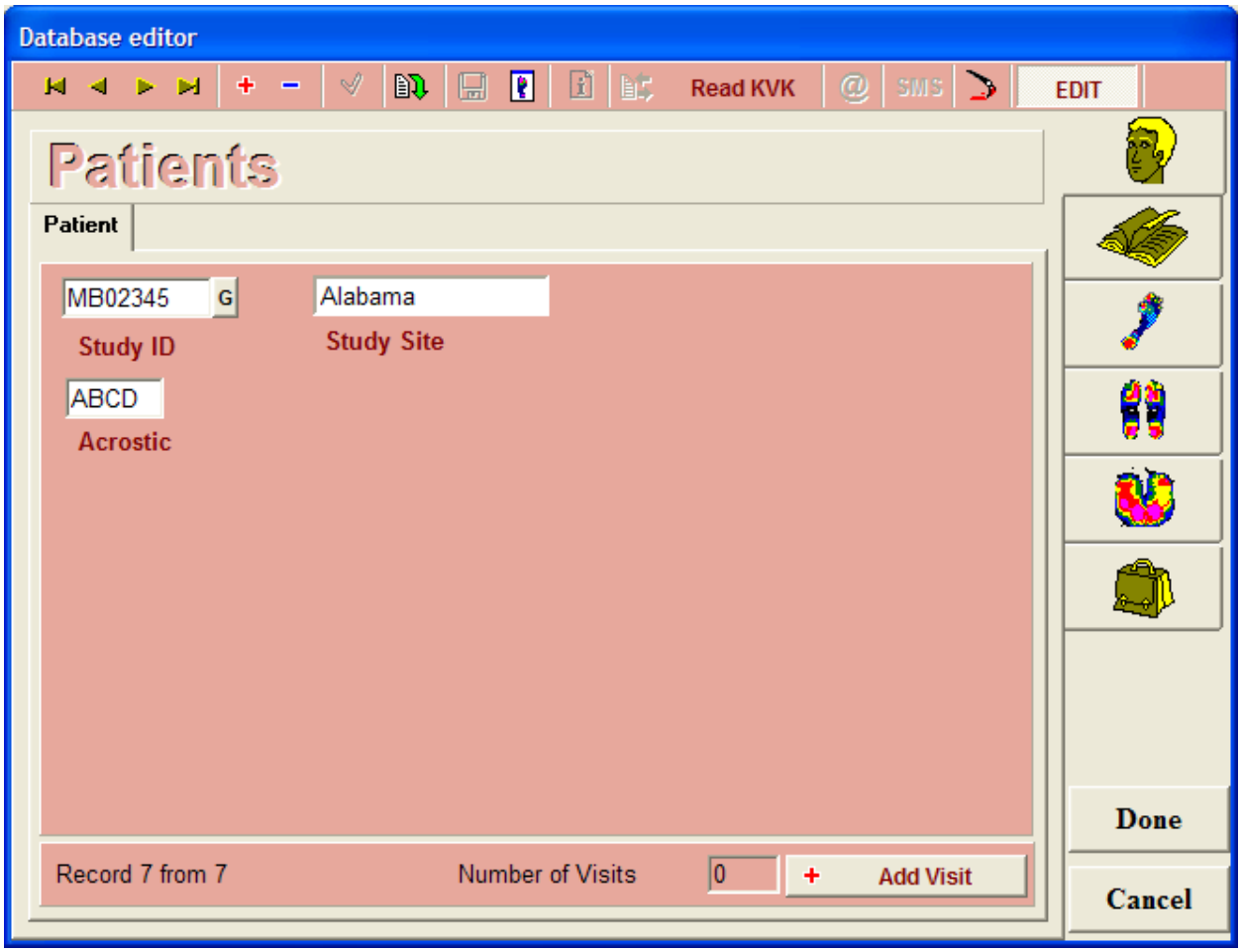
10. Add Participant (Patient)

As the choices on the screen indicate, you may either:

(A) Add a participant by clicking on the Add Patient button, or

(B) Find an existing record by entering the Patient ID and then clicking the Search button.

Begin plantar pressure examination for a new participant by clicking Add Patient. (choice A)



11. Enter participant (Patient) information

Enter:

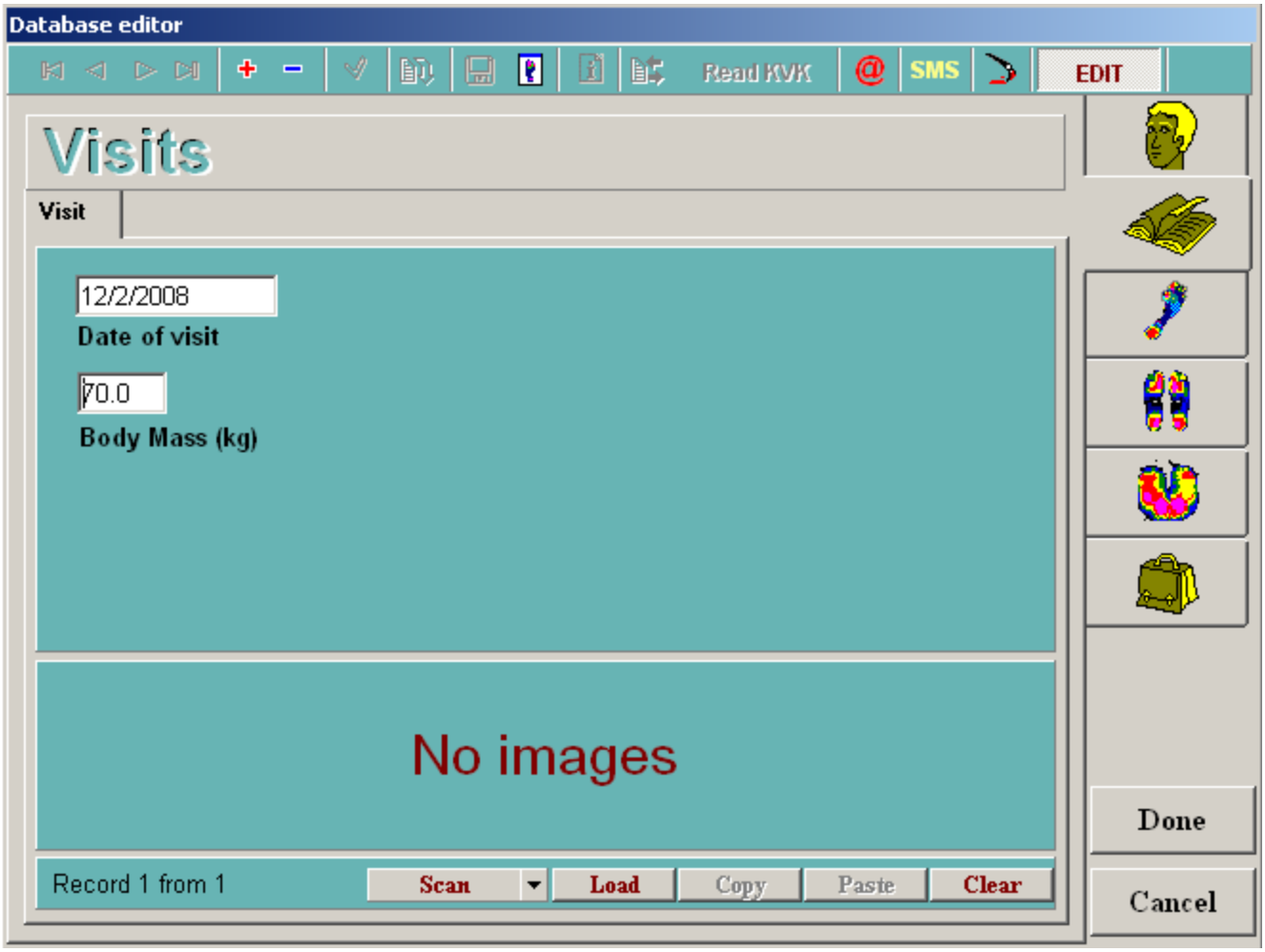
a. Study ID
MOST ID consists of two letters ("MI" for Iowa or "MB" for Birmingham) followed by five numbers.

b. Acrostic
MOST acrostic consists of four letters.

c. Study Site
Select either "Alabama" or "Iowa" from dropdown menu

12. Add Visit

Click + Add Visit button (bottom right)



13. Enter visit information

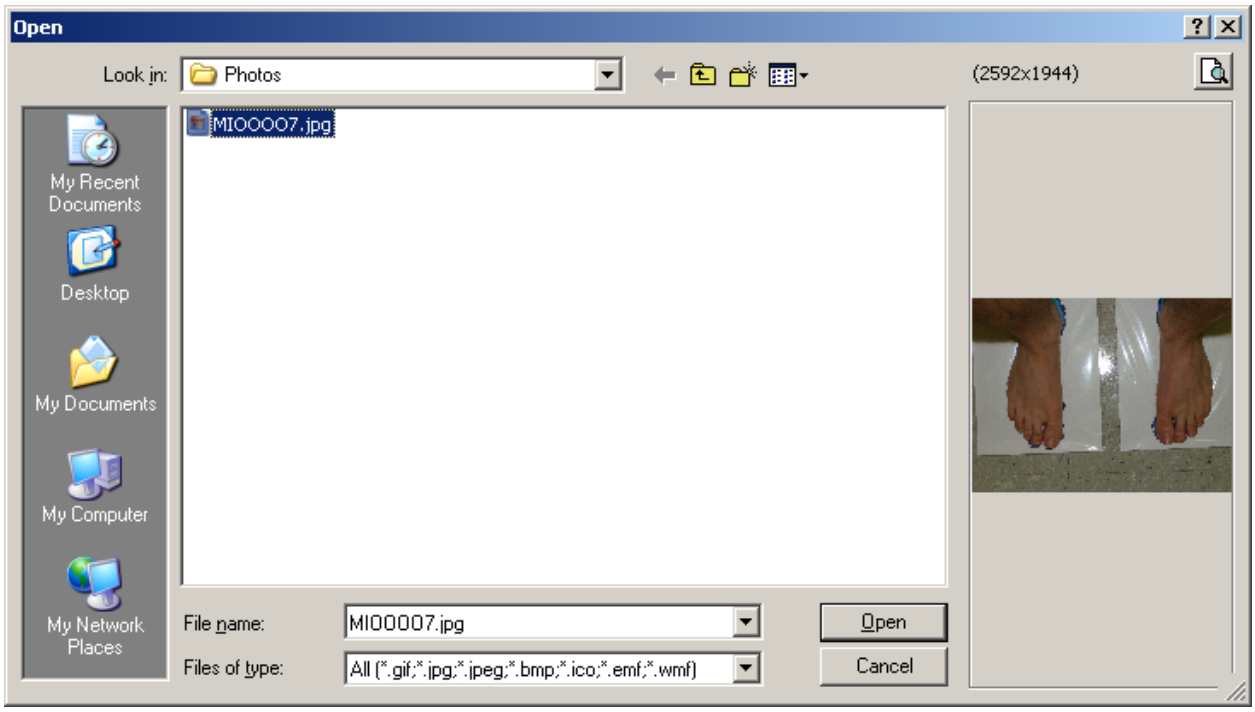
a. **Date of visit**
   Filled in automatically

b. **Body Mass (kg)**
   Enter weight in kilograms from current Clinic Visit Workbook

NOTE: Leave the Visits window open until after the next step is complete

14. Load photograph into the participant's visits information within Novel Database

a. Click the Load button at the bottom of the Visits screen (see step 13, above)

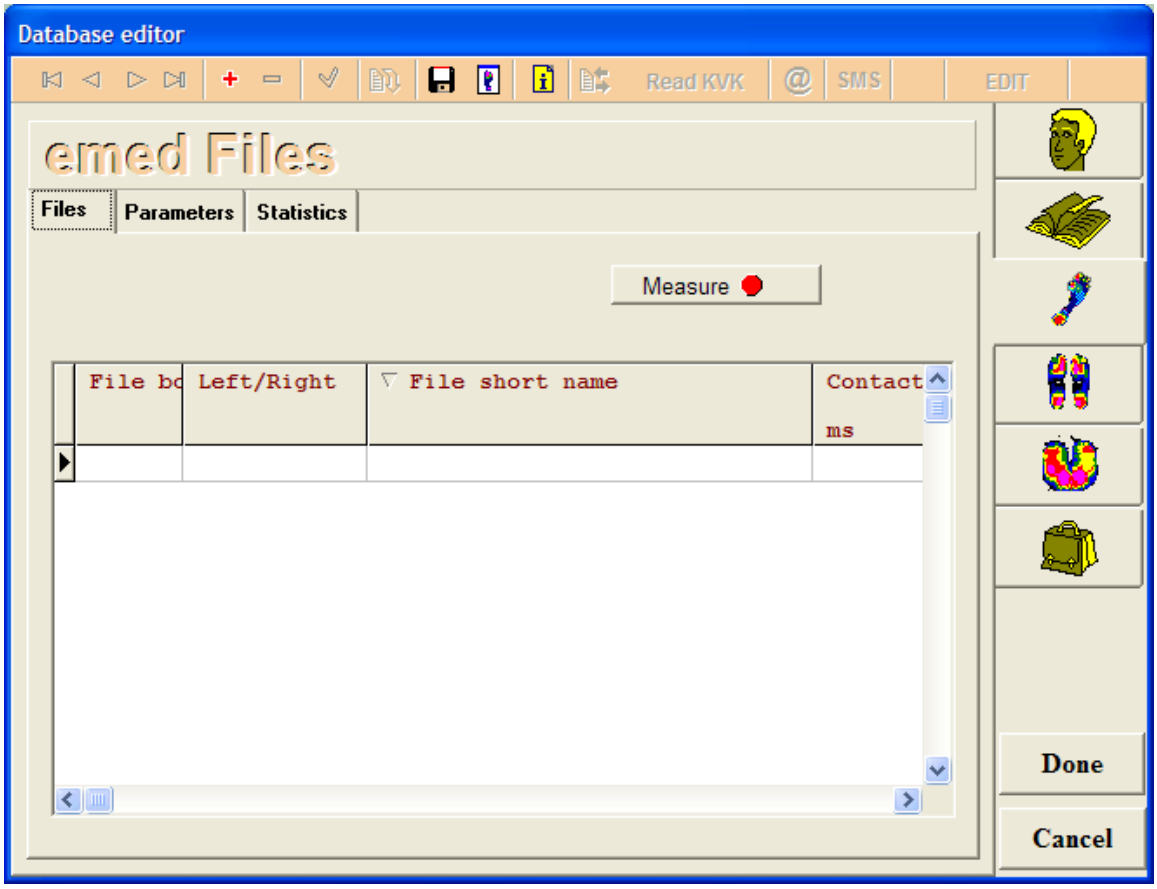


b. By default, the contents of the Desktop folder named "Photos" will appear (if not, the folder can be found by clicking over the Desktop icon in the right hand column).

c. Select the .jpg file whose name is the participant's study ID (e.g MIOOOO7.jpg) and click Open. The photo will display in the Visits screen of the Novel Database, as shown below:

15. Prepare for the Emed data collection

a. Click the  tab.



16. Perform practice walking trial(s)

One or more practice walking trial(s) are performed in order to: 1) familiarize the participant with the testing procedures and 2) establish the correct starting position from which to begin all subsequent walking trials (see section 4.4).

1. Position participant
   The participant is instructed to stand on the walkway at one of the painted starting lines. Begin at the starting line that, given the participant's approximate step length, is estimated to be two steps in front of the active black rubber area of the Emed platform.

2. Perform practice trial(s)
   One or more practice trials may be necessary to verify that the chosen starting line results in a well-placed footprint near the center of the active black rubber area of the Emed platform on the participant's second step forward.

1. Instruct participant.

Script: "When I instruct you, take a step forward with your (left / right) foot and begin walking down this walkway in your usual manner and at a pace that feels comfortable and unhurried to you.

"You should continue walking forward until you have crossed the finish line at the far end of the walkway.

"Ready?
"Begin walking."

2. Observe participant walking
   Determine whether or not the participant's second step forward lands fully within the active black rubber area of the Emed platform.

3. Perform additional practice trial(s) as necessary
   i. If a well-placed footprint is *not* made on the active black rubber area of the Emed platform on the participant's second step forward, then an additional practice trial should be performed.

   ii. Begin an additional practice trial by instructing the participant to begin at a new starting line. If the previous practice trial results in the second step forward landing partially or completely beyond the active black rubber area of the Emed platform, then a subsequent practice trial should be initiated from a starting line that is a *greater* distance from the platform. If the previous practice trial results in the second step forward landing partially or completely before the active black rubber area of the Emed platform, then a subsequent practice trial should be initiated from starting line that is a *lesser* distance from the platform.

   iii. Additional practice trials are performed until an ideal starting position is identified. Once an ideal starting position has been determined, all subsequent data collection trials will begin from a starting line of the same color.

17. Perform 10 walking trials (five left footprints, five right footprints)

The Emed data collection software will begin in the dynamic mode  (number 1 in Toolbar Buttons below). Once the software has initialized you will see the 

message and hear a computerized voice say, "Let's go."

The software will begin data collection once the foot hits the platform and continue for 3 seconds. The software will automatically begin the next trial once the previous trial has finished and saved.

Use the following ***two-step protocol*** to collect five left footprints and five right footprints during 10 trials of walking at the participant's comfortable self-selected pace.

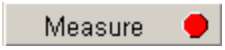
a. Instruct participant.

Instruct the participant to begin the first of five trials by initiating with a step forward with the ***left foot***. A right plantar pressure footprint is captured. After repeating this over the first five trials, instruct the participant to begin the next five trials by initiating with a step forward with their ***right foot***. A left plantar pressure footprint is acquired. Ten trials will be completed in all, yielding five footprints of the right foot, and five footprints of the left foot.

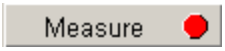
Script: "When you hear the computerized voice say, 'Let's go,' please take a step forward with your right foot and begin walking down this walkway in your usual manner and at a pace that feels comfortable and unhurried to you.

"You should continue walking forward until you have crossed the finish line at the far end of the walkway. After you cross the finish line, turn around and place your toes at the same colored start line and wait for instructions to 'Begin walking.'

"Ready?"

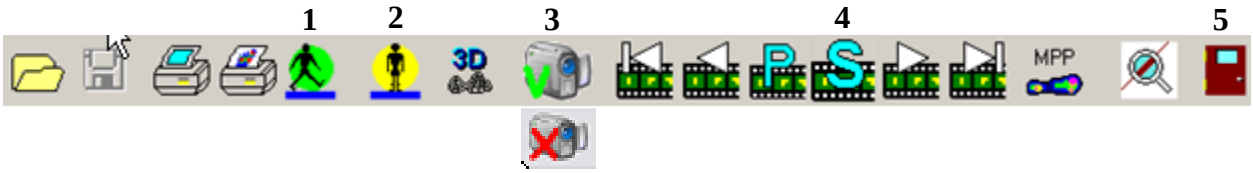
b. Click the 

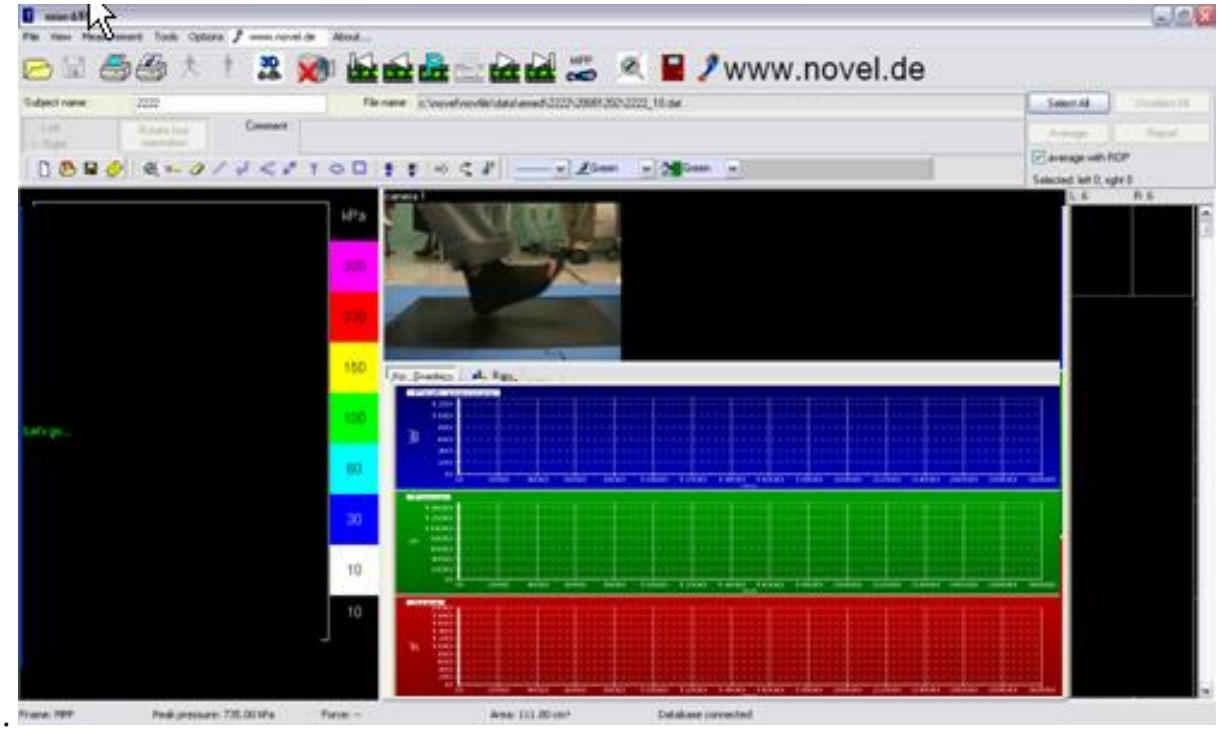
button to begin collecting plantar pressure measurements.

NOTE FOR STEP 21: When preparing to collect data for additional repeated walking trails, click the  button (see number 1 in toolbar depiction below) instead of the 

button.

Novel Emed-x Toolbar Buttons:





c. Ensure that video is being collected

   i. Once the Emed data collection software begins, you should see a video window, as shown in the screen capture above. When you see the image of the foot coincident with the first step, the video is filming the trials.

   ii. If you do NOT see the video window, click the  button (number 3 in the toolbar buttons listed above) to initialize the video recording.

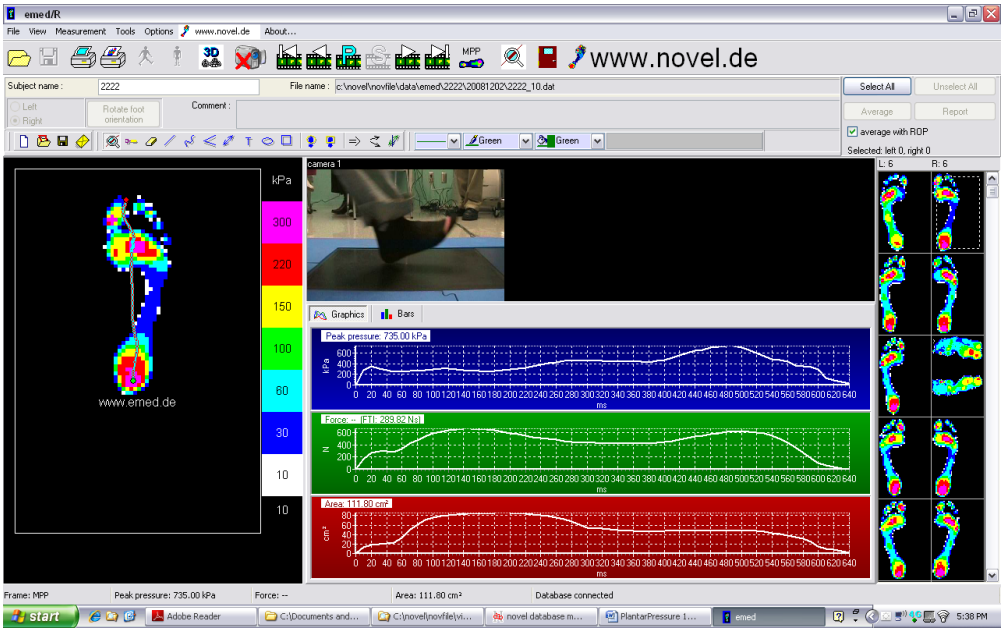
d. Once the software has initialized you will see the 

message and hear a computerized voice say, "Let's go."

e. Perform the next walking trial until 10 trials in total have been collected. Immediately following completion of one trial, the software will save the data (the footprint appears in the right-hand column), and ready itself for the next trial. Position the participant at the same color starting line, but facing the opposite direction on the walkway. Repeat steps 17a through e until ten walking trials have been collected (five left footprints and five right footprints).

18. Stop collecting walking data

After data has been successfully collected for 10 trials of walking (five left footprints and five right footprints), wait to hear the "Let's go" message a final time and then click the  button (toolbar button number 4 listed above).



19. Identify any incomplete or distorted footprints

Each acquired footprint appears in the right hand column of the data collection screen soon after it is collected. The examiner should pay close attention to verify that a complete (see a., below) and undistorted (see b., below) footprint is acquired from each of the 10 walking trials.

a. Incomplete footprints

A "complete footprint" is one in which the second step forward leaves a footprint completely within the active black rubber area of the platform without encroaching upon any of the non-active blue borders of the platform. If the software detects that the participant has hit the edges of the platform during a walking trial, a chime will sound and a message will appear warning you of this. If the participant has hit an edge of the platform this should be considered an "incomplete footprint."

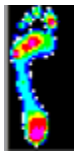
Note that in some cases (i.e., a "shuffle" walker) you may see more than one footprint resulting from the same walking trial When one of the two footprints is incomplete because it landed partially on the inactive blue metal border of the platform, and the other footprint is complete because it landed completely within the active black rubber area of the platform, the complete footprint can still be retained (see step 20 below).

Note: *Not infrequently, a well-placed footprint in the active black area of the platform is acquired with insufficient plantar pressure under one or more of the lesser*

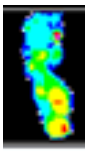
toes to generate an imprint of all four lesser toes. The absence of one or more lesser toes from the imprint is not a sufficient justification for rejecting an entire footprint as "incomplete."

b. Distorted footprints

A footprint can become distorted when a participant drags or twists the foot on the active black rubber surface of the platform. Identifying a footprint as "distorted" is necessarily subjective. In comparison with an undistorted footprint, the edges of a "distorted" footprint are often fuzzy and the color gradations within the footprint often appear blurry and poorly delineated, as the following examples indicate:



Undistorted Footprint

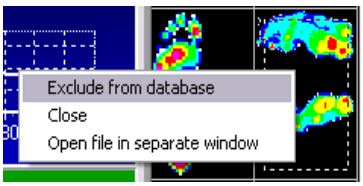


Distorted Footprint

Note: Time is saved when the attentive examiner is able to take mental note *during the trials* of which footprints (recorded one after another in the right hand column) have either incited the software to chime a warning message, or are otherwise to be regarded as incomplete or distorted. Without interrupting the flow of the exam, the examiner can simply anticipate that the distorted or incomplete footprint will later be excluded from the database (step 20 below), and that an additional trial must therefore be performed on that foot (left or right). This additional trial can be performed immediately without waiting until after the  button has been pressed. The additional trial will result in an excess of footprints initially appearing in the right-hand column. However, once the needed exclusions have all been made following completion of the trials (step 20 below), the desired total of five undistorted and complete left footprints and five undistorted and complete right footprints will be retained..

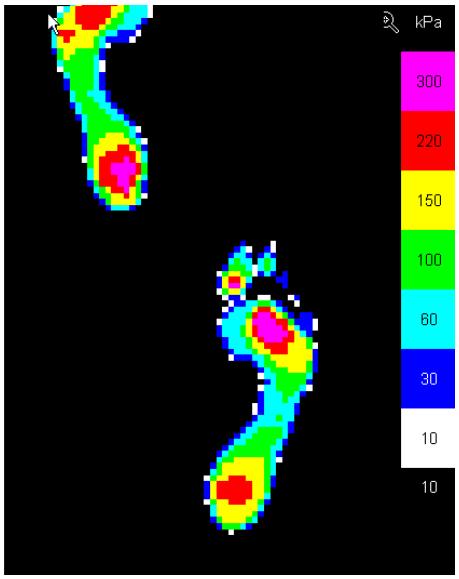
20. Exclude all incomplete or distorted footprints

If, after reviewing the acquired footprints in the right hand column, the examiner determines that one or more footprints is either incomplete or distorted, then the examiner should exclude those footprints from the database. To exclude a footprint, simply right click on the footprint and select "**Exclude from database**" from the dropdown menu.



21. If needed, perform post-processing for one complete and a second incomplete footprint

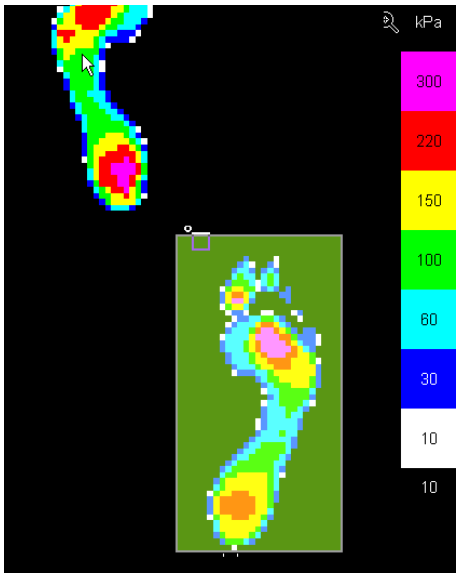
You may encounter "shuffle" walkers, or individuals whose stride length is so short that two steps hit the active black rubber area of the platform during the same walking trial. It is common that one of the two footprints will be complete and the other will be incomplete, such as shown in the trial below.



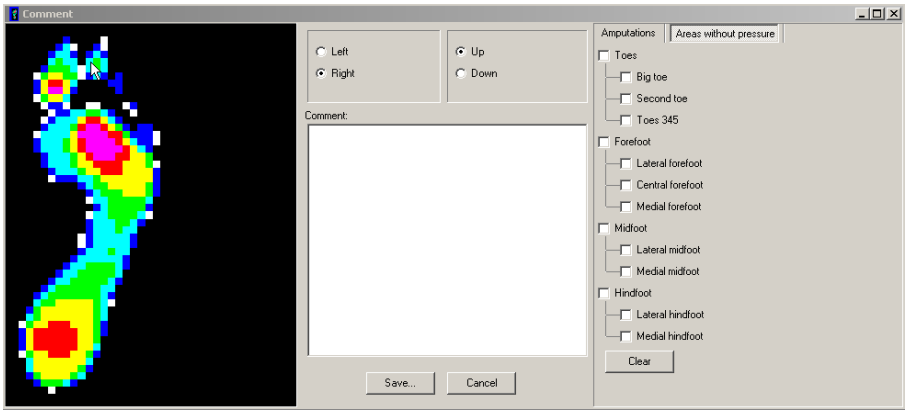
In this example there is one complete right step and one incomplete left step In this instance, the examiner should "crop out" and keep the right step, as described in the following steps:

a. Click on the  button

b. Draw a box around the complete footprint as shown below:



c. Click the ⇒ button and a Save As window will appear:



d. Click the Save... button

e. Exclude the original file with the two steps by following the procedures in Step 20 above.

22. Repeat walking trials if needed to replace excluded footprints

Repeat steps 17a through 21 as needed until five complete and undistorted footprints are acquired of the right foot and five complete and undistorted footprints are acquired of the left foot.

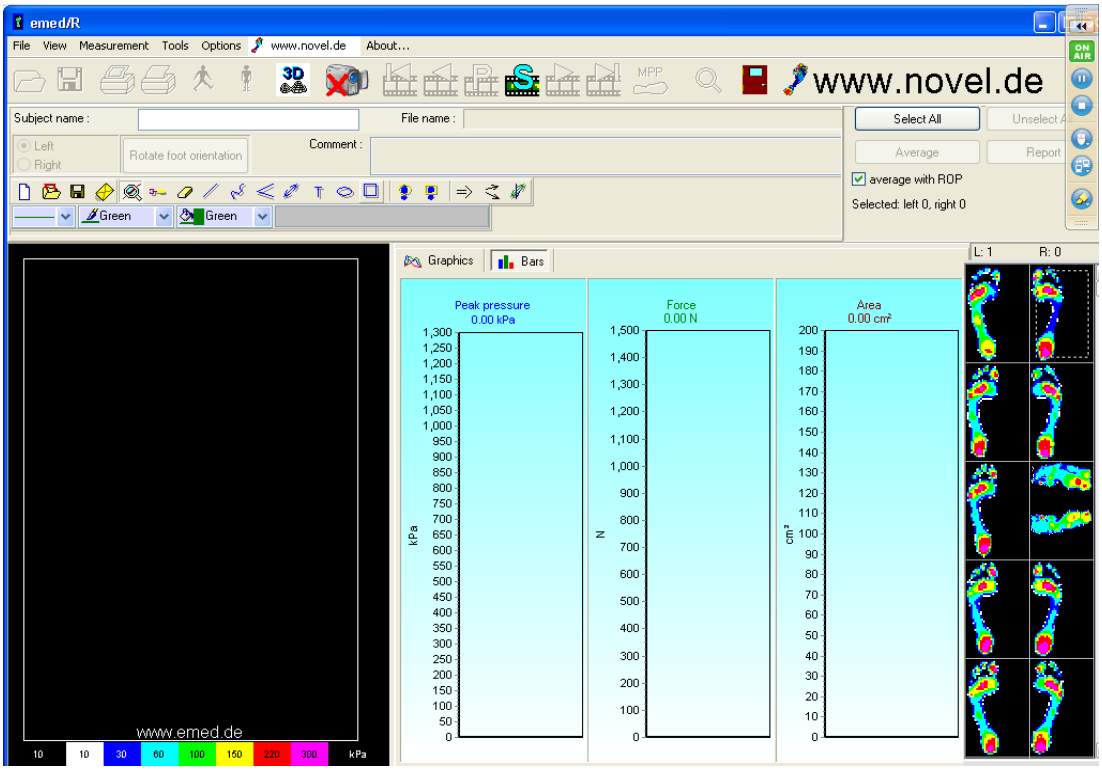
NOTE: When preparing to collect data on additional walking trails, click the  button (number 1 in Toolbar depiction above) instead of the Measure button (in step 17b).

23. Acquire single snapshot of plantar pressure in standing

Orient the participant perpendicular to the length of the walkway with their back to the video camera (on a miniature tripod on the floor). A brightly colored orange paper circle on a black background will remain thumb tacked to the wall in order to serve as a visual cue upon which the participant should fix their gaze during the trial. On 1/12/2010, lines were added to the Emed mat delimiting the area within which participants feet must fall for the standing posture photograph so that the view of the calcaneous is not obstructed.

a. Instruct the participant to stand to one side of, *but not on*, the platform.

b. Click the  button and wait to hear the "Let's go" message. You will see the following screen.



c. Instruct participant to stand on the active black rubber area of the platform

Script: "Step to the side and stand with both feet on the black area of the platform. Stand comfortably with both arms at your sides. Look ahead and focus your gaze on the bright orange circle on the wall."

d. Instruct participant to march in place

To ensure that the participant is standing with a normal angle and base of support, instruct the participant to march in place:

Script: **"**Remaining where you are, please begin marching in place.

"Good.

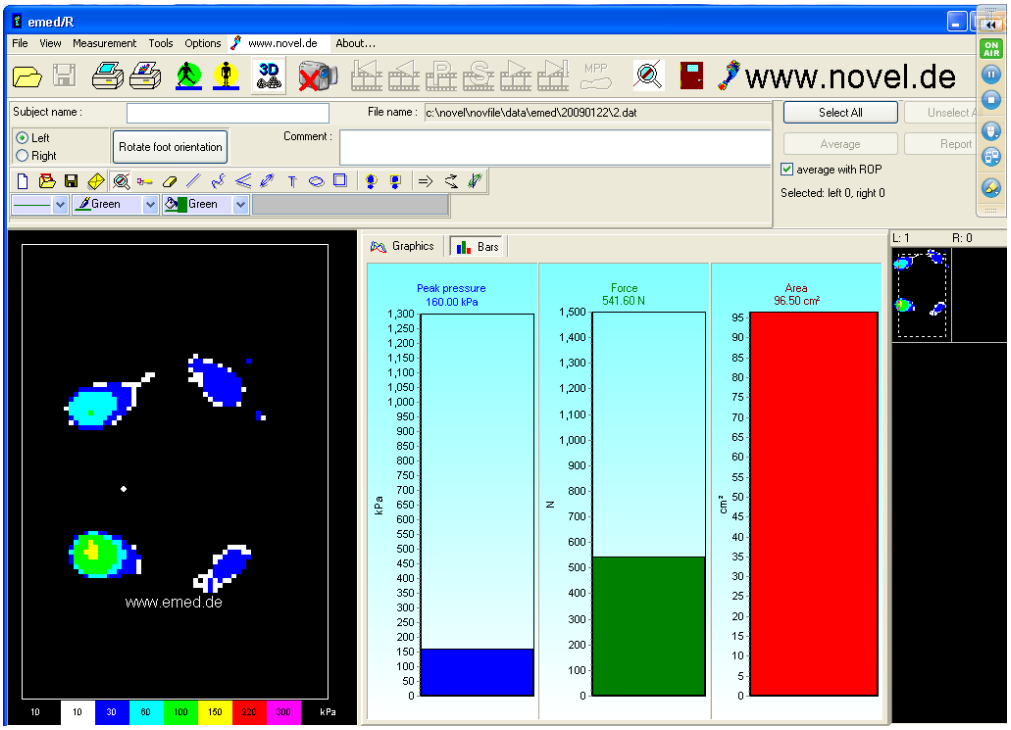
"When I tell you, stop marching and let your feet come to rest." (Wait 5 seconds)

"Stop marching.

"Please remain standing quietly with your arms at your sides and looking straight ahead at the bright orange circle on the wall."

e. Verify correct standing position
After 5 seconds of marching in place, the command to stop will generally result in a more relaxed standing posture with a normal angle and base of support. Verify that no part of the participant's feet (including toes) encroaches upon the non-active metallic blue border of the Emed platform or falls over the lines delimiting the area within which the feet must land to insure an adequate view in the photograph. If part of a foot strays from the active black rubber area of the platform, or over the lines, instruct the participant to move to a more central position on the platform and repeat the previous step (step d, marching in place).

f. Click the  button (number 4 in the Toolbar depicted in step 17) to obtain the standing plantar pressure imprint. You will now see the following screen:



g. Instruct the participant to remain standing in their current position. Acquisition of the standing foot photograph will (time permitting) occur in this position (see step 25 below)

24. Exit the Emed data collection software

a. You may now close out of the Emed data collection software by clicking the  button (number 5 in the Toolbar depicted in step 17).

25. Acquire a single still photograph from the video camera (time permitting)

It is a simple procedure to utilize the video camera to acquire a still photograph of the back of the participant's feet while they are standing and to include this photograph in the participant's Novel database file.

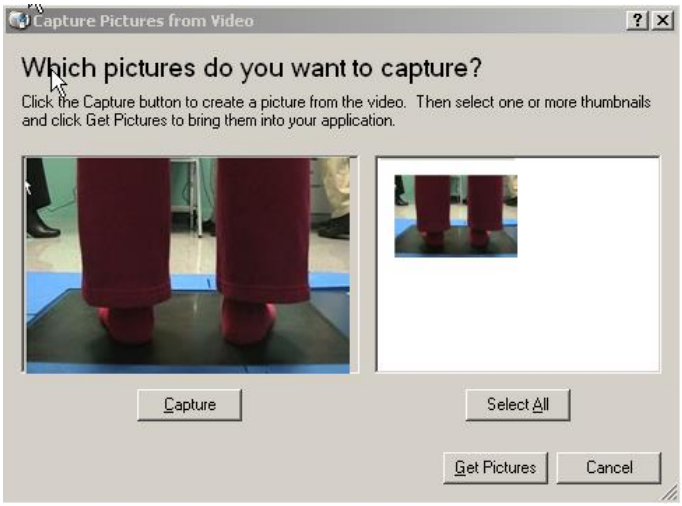
The participant should still be standing on the black rubber area of the pressure platform with their back turned to the video camera.

a. You should now see the database Editor screen again (see Step 15). Click on the visit tab  to return to the Visits window (see Step 13). Then click the 

button in the upper right hand corner of the Visits window.

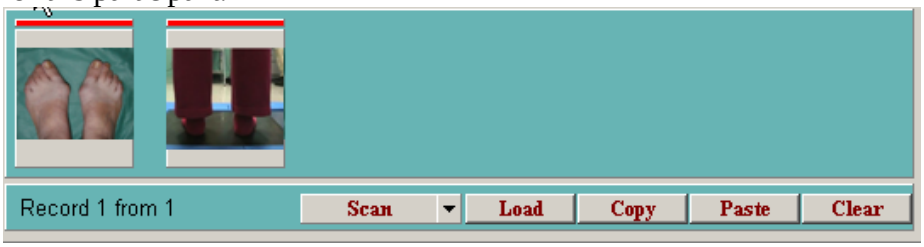
b. Click the 

button and the following screen will appear:



Click the Capture button and then select the picture on the right hand side of the window. Finally, click the Get Pictures button.

c. You will now see both the standing and the seated pictures within the Visit Information for this participant.



26. Instruct participant to sit down and put their shoes and socks back on

Data collection procedures for the plantar pressure exam are now complete.

27. Question regarding pain during the walking trials

After data collection on the walking trials is complete, the examiner inquires about pain or discomfort in the joints and muscles that the participant may have experienced during testing. The exact questions and answer choices appear in the context of an algorithm that guides their application on the Plantar Pressure data collection form (section 7.2). These questions appear here only in outline.

Script: "During the walking portion of this test, did you experience any pain or discomfort in your joints or muscles?" (yes / no/ refused or unable to answer)

If yes, ask the following:
"Where was the pain located?" (mark all that apply among areas listed)

"Was the pain or discomfort typical of what you usually feel during this kind of activity?" (yes / no/ refused or unable to answer)

Was pain located in either knee? (See list of areas with pain above)

If yes, show card #27 and instruct the participant:

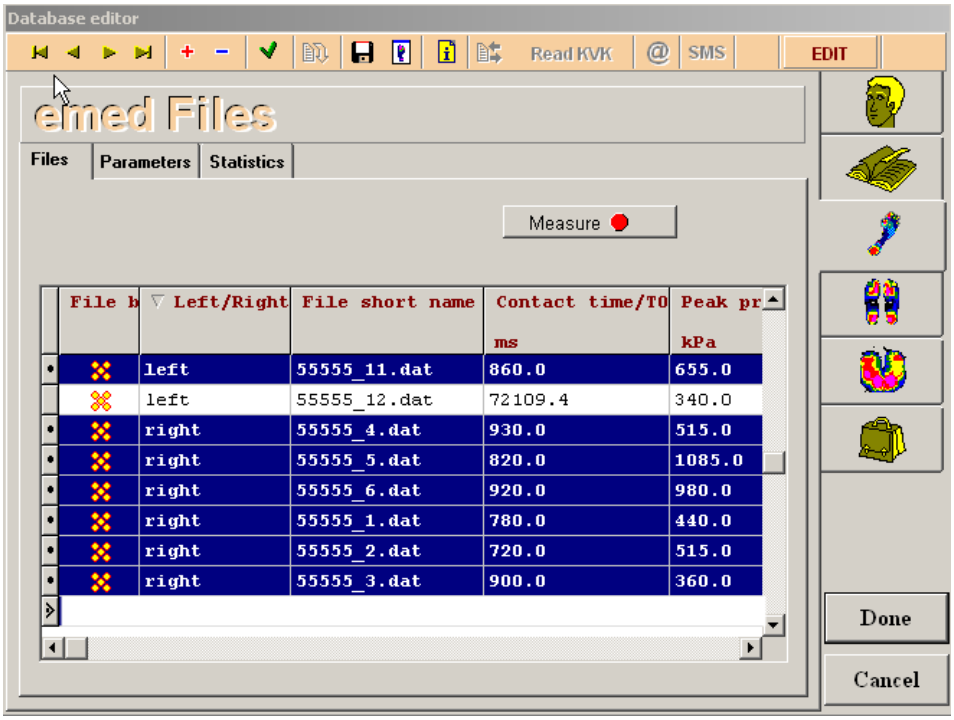
"Please rate the knee pain that you had by pointing to the number on this card."

Record responses to pain provocation questions on the Plantar Pressure data collection form (section 7.2)

28. Print a report for the participant

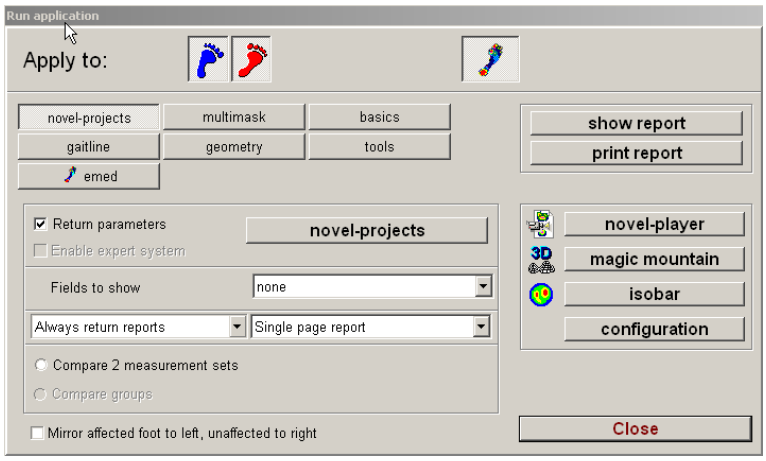
1. Click on the  tab and choose the  button

2. Using the Ctrl key on your keyboard, UNSELECT the trial in which the Contact time (4th column from left, below) is much longer than the other trials. This is the standing trial and *we do NOT want to include the standing trial in the printed report!*

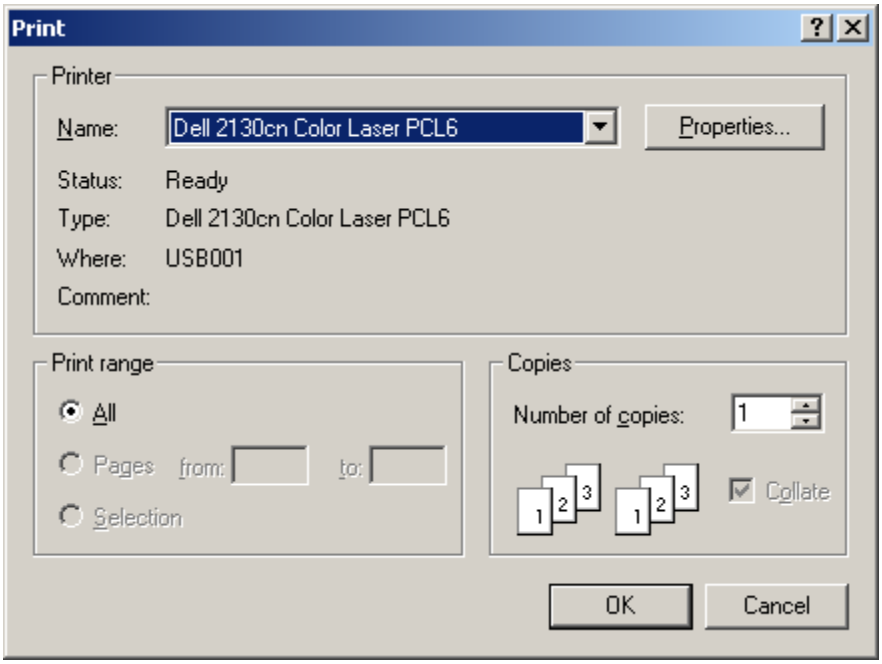


Note: Sometimes the standing trial will be listed as a Left trial (2nd column from left), other times it will be listed as a Right trial. Ignore this distinction.

3. Click on the "Run Application" button in the toolbar over the top of the screen, and then click the print report button



Note: The computer must be connected to the color printer.



4. Verify that the correct color printer is selected. Click OK.

5. Give the printed report to the participant. Explain that the printed report is intended to serve as both a souvenir and a source of information that may be shared with the participant's physician. The report includes a written explanation of the information included and the purpose that this information may serve. Appendix 2 provides an example.

26. Close the Participant's Editor Window

Once all data collection and printing is complete, click Close (on the window in step 25.3 above).

Then, click the Done button to complete the plantar pressure exam for this participant.

27. Delete the photo from the camera's memory card.

a. Unplug the USB cable from the camera and attach cable end to Velcro attachment on wall.
b. Press button marked "Menu" on camera.
c. Press enter button (located at center of four directional arrows) to approve the selection of the delete icon.
d. Confirm you intention to delete the photo by hitting the up arrow and pressing enter.
e. Turn the camera off by pressing down on the power button.

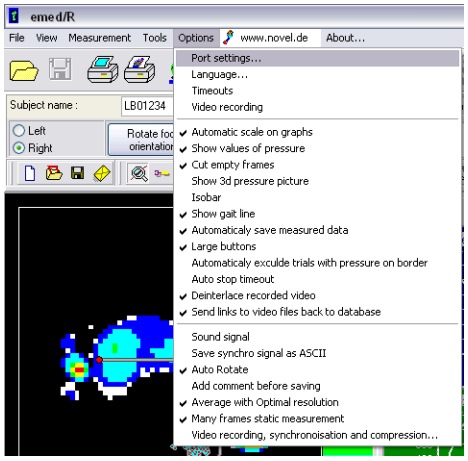
28. Close Database Medical Software (only at end of day)

This only needs to be complete at the end of the day. The Novel Database software can stay open in between study participants.

Select the  from the tool bar, or click File Menu | Exit to exit Novel Database software.

TIPS to Running the Novel Software:

1. If you receive the message "No Connection" within the Emed data collection software, Choose the Options | Port settings... menu item and click **OK** and the software will reinitialize the connection:



6. Quality assurance

6.1 Training and certification

A representative of Novel, Inc. (Maria Pasquale) along with Drs. Gross and Hillstrom will provide onsite training to the staff at each clinic. This training will cover basic machine operation and the fundamentals of testing, as well as study-specific procedures. Videotapes of the plantar pressure exam will also be provided for examiners to review. Examiners should practice on other staff members until reliable measurements 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:

- Observing execution of study protocol by an experienced examiner
- Reading MOST operations manual with goal of understanding:
  - the proper use of equipment
  - exclusions and safety considerations
  - detailed testing procedures
- Practicing on colleagues and "naïve" volunteers
- Attending training session

6.2 Certification requirements

- Completion of training requirements
- Recitation of exclusion criteria and stopping rules
- Demonstration of hardware cleaning and care
- Performance of exam on two volunteers under the observation of clinic QC officer
  - According to protocol, as demonstrated by completed QC checklist

6.3 Quality assurance checklist

- ☐ Exclusion questions asked and recorded on data collection form
- ☐ Assistive device, brace, and orthotics questions asked from data collection form
- ☐ Participant information correctly entered on computer
- ☐ Visit information correctly entered on computer
- ☐ Participant removes shoes and socks
- ☐ Feet inspected for sores
- ☐ Shoe insert assessment properly performed and results recorded on data collection form
- ☐ Shoe tests properly performed and results recorded on data collection form
- ☐ A seated foot photograph is obtained and properly stored in the database
- ☐ Script correctly and clearly delivered for walking tests
- ☐ Practice test administered properly, start line determined
- ☐ Five walking trials starting with left foot performed starting at correct start line
  - ☐ Computer screen shows video image of foot coincident with first step
- ☐ Five walking trials starting with right foot performed starting at correct start line
  - ☐ Computer screen shows video image of foot coincident with first step
- ☐ Footprints obtained from walking trials are reviewed for incompleteness or distortion.
- ☐ Edits and deletions are made where needed.
- ☐ Additional walking trials are performed as needed to replace deleted footprints
- ☐ Participant asked pain questions and responses recorded on data collection form
- ☐ Script correctly and clearly administered for standing test
- ☐ Verifies correct standing position
- ☐ Standing plantar pressure imprint obtained
- ☐ Footprints obtained from standing trial are reviewed for incompleteness or distortion.
- ☐ Edits and deletions are made where needed.
- ☐ Additional standing trials are performed as needed to replace deleted footprints
- ☐ A standing foot photograph is obtained and properly stored in the database
- ☐ Report printed for participant
- ☐ Participant's editor window closed on computer
- ☐ Reviews data collection form for completeness
- ☐ Correctly completes data collection form

7. Data collection forms

7.1 GAITrite and Plantar Pressure Exclusions form

All questions on the GAITrite and Plantar Pressure Exclusions form apply equally to the GAITrite exam and to the plantar pressure exam. The seven questions on this form should be asked one time only. There is no need to complete any portion of this form during the plantar pressure exam.

3398

GAITrite and Plantar Pressure Exclusions

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

(Examiner Note: Do not ask this question.)

1. Is participant using a walker or crutches?

○ Yes ○ No

↓

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

2. Does participant have a cane with them?

○ Yes ○ No

a. When you leave your home, do you use a cane more than half the time when you walk?

○ Yes ○ No ○ 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?

○ Yes ○ No ○ 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.)

○ Yes ○ No

↓

a. When you leave your home, do you use a knee brace more than half the time when you walk?

○ Yes ○ No ○ 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?

○ Yes ○ No ○ Don't know

↓

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

32446

GAITrite and Plantar Pressure Exclusions

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

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.

7.2 Plantar Pressure data collection form

In contrast to the GAITrite and Plantar Pressure Exclusions form, the questions on the Plantar Pressure data collection form pertain only to the plantar pressure exam. Therefore, all portions of the Plantar Pressure data collection form must be completed during the plantar pressure exam.

12554

Plantar Pressure

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

Examiner Note: Perform bend, twist, and pinch test on participant's shoe (left preferred).

1. Record type of shoe participant wore to clinic:

1a. Bend test
- O Rigid (no bend)
- O Supportive (bend in toe box; no bend in arch)
- O Flexible (arch bends)
- O Not tested/Other

1b. Twist test
- O Rigid (no twist)
- O Supportive (toe box twists <45 degrees)
- O Flexible (toe box twists ≥45 degrees)
- O Not tested/Other

1c. Pinch test
- O Rigid (no narrowing of heel counter)
- O Supportive (heel counter narrows - NO medial/lateral contact)
- O Flexible (heel counter narrows - medial/lateral contact)
- O No heel counter present
- O Not tested/Other

2. Does participant have an insert in their right shoe?
O Yes O No

2a. What sort of insert?
- O Supportive
- O Cushioning
- O Both supportive and cushioning
- O Other
- O Not tested

3. Does participant have an insert in their left shoe?
O Yes O No

3a. What sort of insert?
- O Supportive
- O Cushioning
- O Both supportive and cushioning
- O Other
- O Not tested

MOST Follow-up Clinic Visit Workbook KW

12554

18203

Plantar Pressure

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

(Examiner Note: Look at the bottom of the participant's feet.)

4. Does the participant have any open wounds on the bottom of either of their feet?

○ Yes ○ No ○ Don't know/Refused

Do NOT administer plantar pressure walk test. Go to next test.

5. Was the seated foot photograph acquired?

○ Yes ○ No

6. Were any walking trials performed?

○ Yes ○ No

7. Was standing photograph acquired?

○ Yes ○ No

8. Was posture data collected?

○ Yes ○ No

4340

Plantar Pressure

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

9. During the walking part of 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

Appendix 1 Data File Transfer

The data transfer and upload should occur once per week, on Wednesday, via the site manager. The site manager will follow these steps:

A. **Open Novel database software**

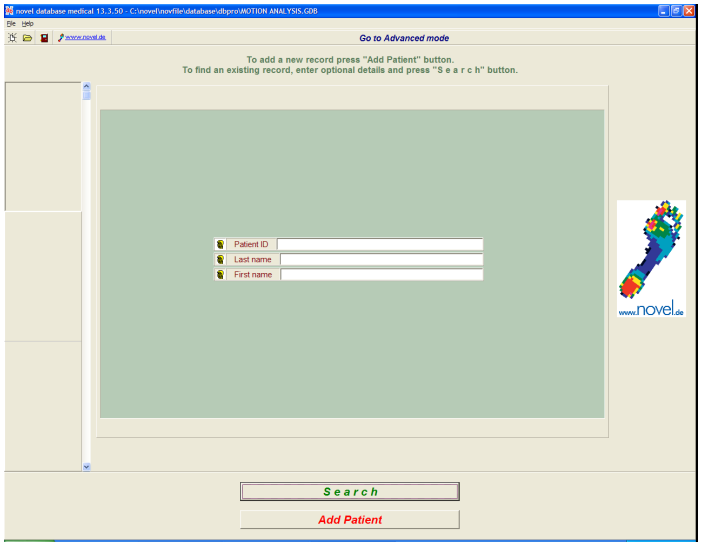
The Novel equipment is delivered along with a hardlock key that must remain connected to the USB port of the computer in order for the software to run.

Click on the Novel Database software icon 

on the desktop to open the Novel database software.

B. **"Simple Mode"**

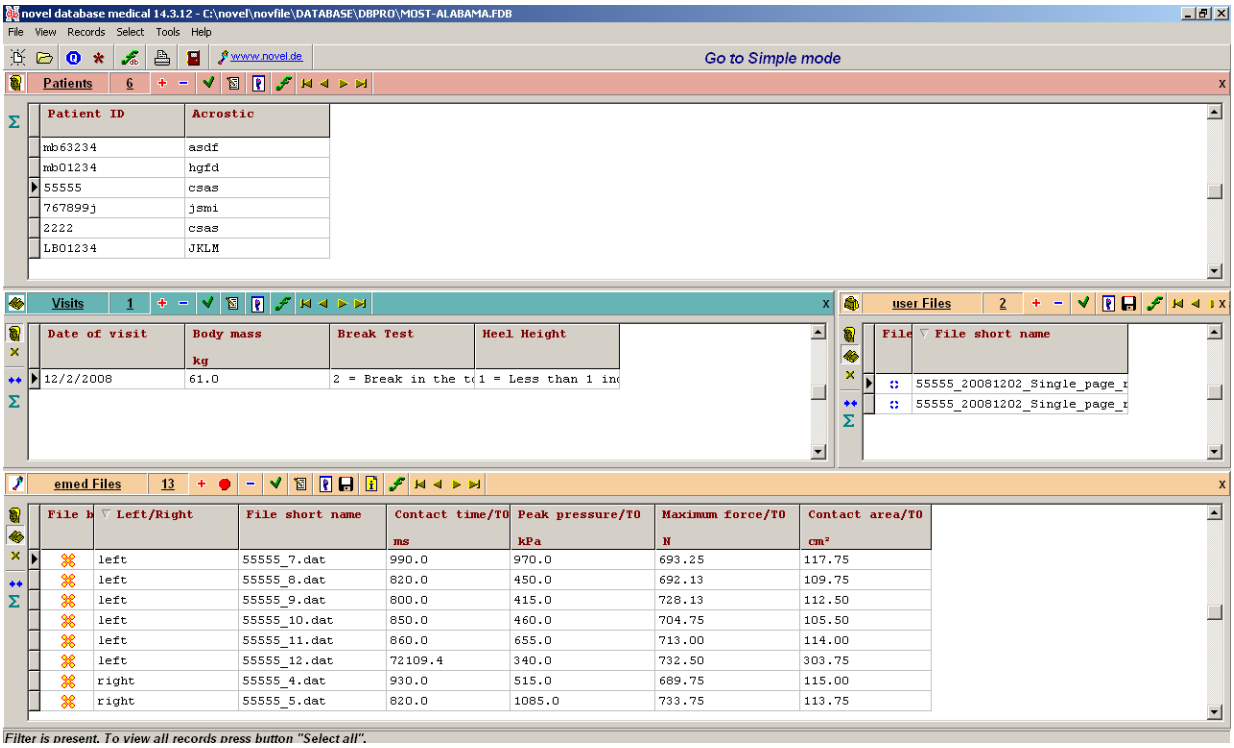
The following screen will welcome you to the Novel database software running in Simple mode.



C. **Click on the** 

button

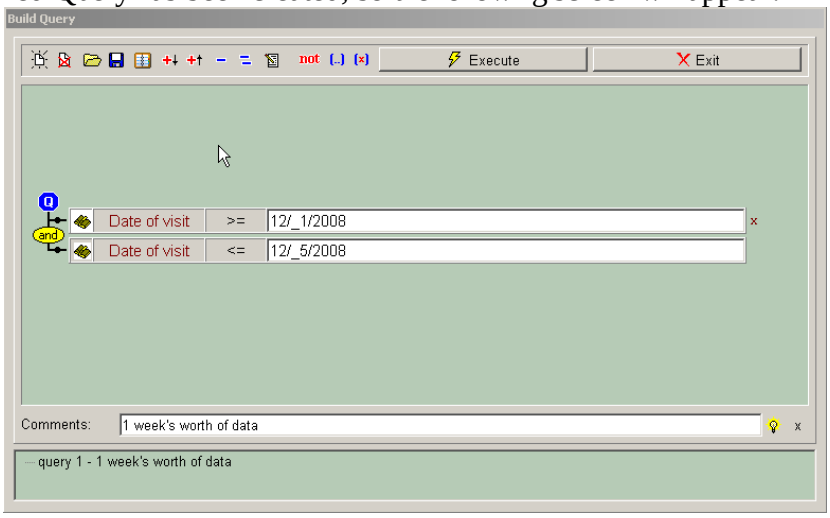
A screen similar the following will appear:



D. Choose the Query button .

Query the database for the past week's data. This will allow you to export only the data which was collected in the past week and therefore decrease the file transfer size, as well as ease the process of data analysis.

a. A predefined Query has been created, so the following screen will appear:



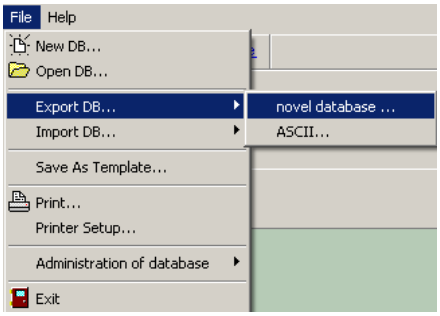
b. Change the Date of visit >= value to the beginning of the week and the Date of visit <= value to the end of the week.

c. Click the Execute button to execute the Query.

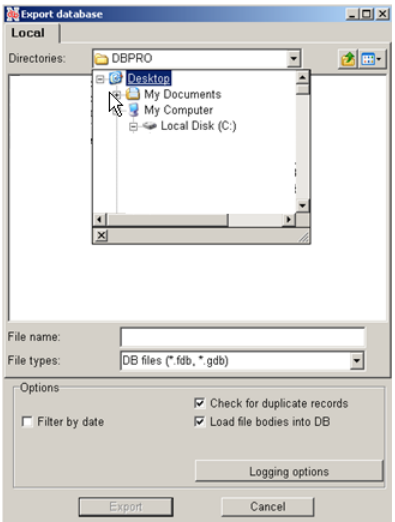
E. Export the Queried data

After the query has run you will again now be viewing the advanced mode of the database.

a. Click on File | Export | novel database...:



b. Choose a predefined location which is easy to navigate to, such as a folder on the desktop, to export the database to:



c. Name the database in the format: "M" for MOST; "I" or "B" for respective study site ("I" for University of Iowa and "B" for University of Alabama, Birmingham); "P" for plantar pressure; date of transfer YYYYMMDD format; i.e. "MB_P20090126" for UAB where date of transfer was January 26, 2009 or "MI_P20090126" for University of Iowa where date of transfer was January 26, 2009 and click the Export button.

F. Reset and exit the Novel Database Software

Once the data export is complete, click on the Go to Simple mode button to return the database to the examiner's simple mode view. Then exit the software by clicking the  button from the toolbar, or click the File Menu | Exit

G. Transferring data to the SF Coordinating Center:

See "Secure Data Gateway" Operations Manual.

Appendix 2 The Printed Report

art and science
quality in pressure distribution measurement
novel

MOST

Patient ID:

Patient ID: mb01234

Anamnesis

Diagnosis

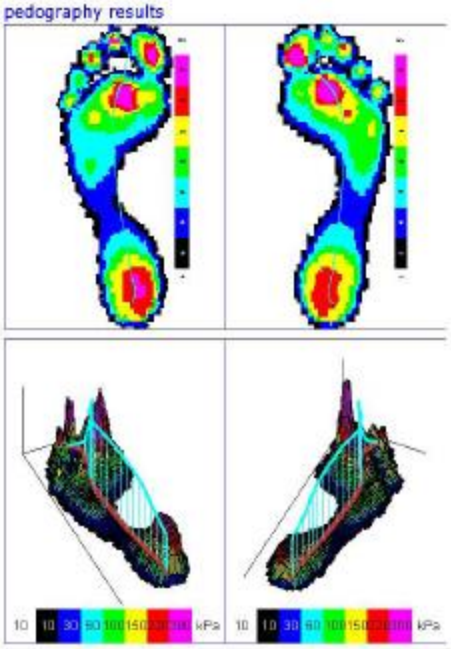
Conclusion/ Therapy/ Comments

The colorful footprints that you see in this report depict the pressure under your feet when you walk. The areas that appear in red or violet are areas of higher pressure, while the areas that appear in black or blue are areas of lower pressure. Areas that appear in yellow or green are areas of your foot that experience moderate pressure when you walk.

You should not be at all alarmed if you see a few areas of red or violet where high pressure is being exerted on your foot. It is entirely normal for some areas of the foot to experience higher pressures and other areas of the foot to experience lower pressures. In most people, the foot is very well-adapted to absorb the pressures to which it is exposed. On the other hand, if you are diabetic, your foot may have lost some of its ability to respond ideally to the high pressure that may be exerted on it.

If you are diabetic, and you notice some areas of your footprint that appear brightly colored in red or violet, you should bring this printed report with you to your next doctor's visit. Your doctor may be able use the information to make recommendations about how best to care for your feet and minimize your risk of pressure-related foot problems.

pedography results

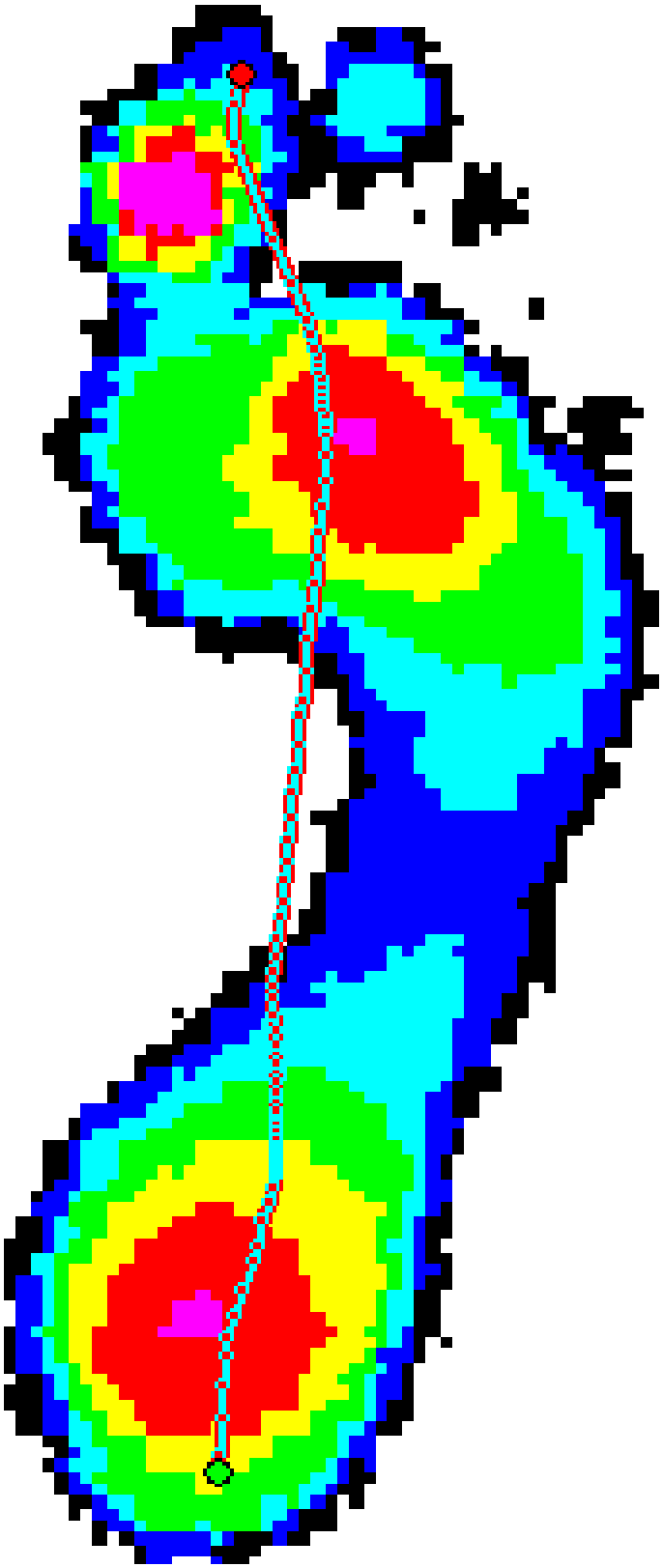


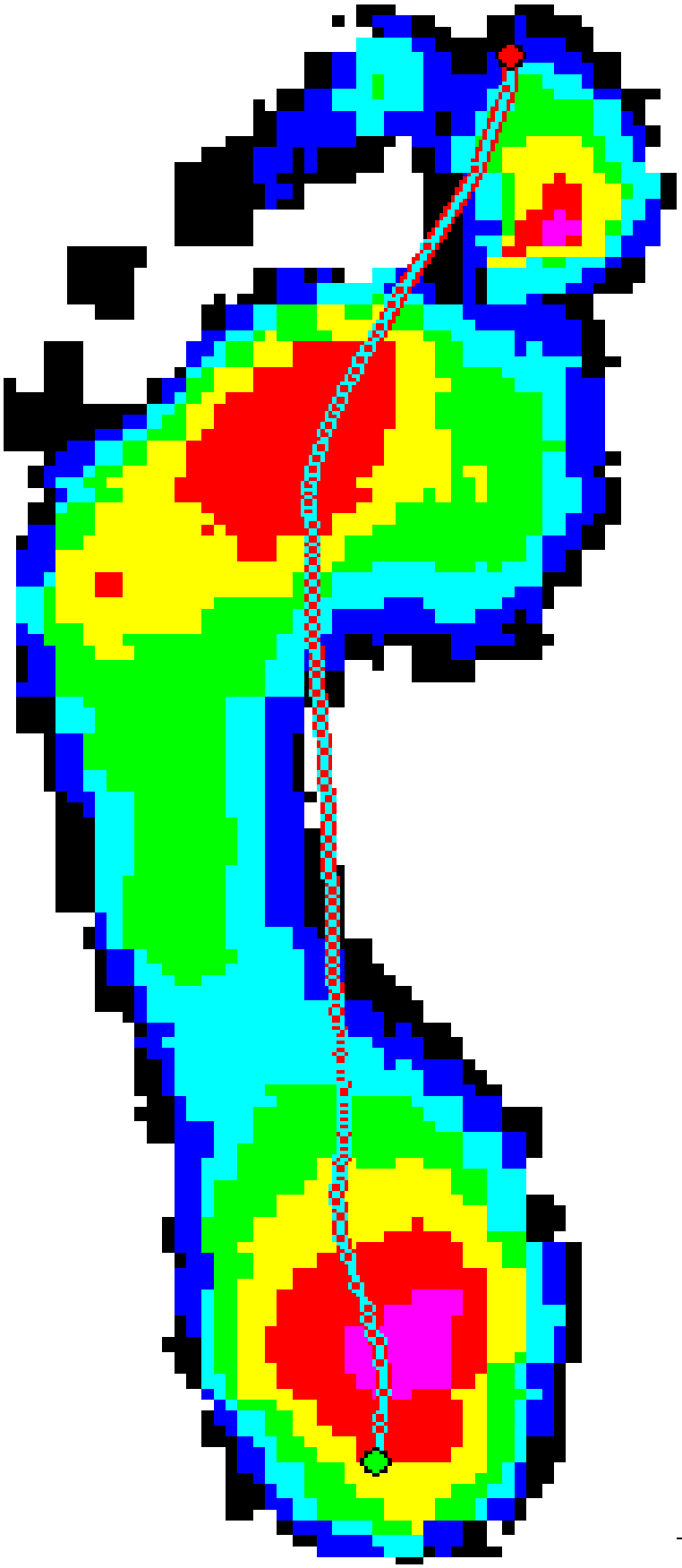
Generated on: 12/5/2008	Generated by:	Date of visit: 12/2/2008	Patient ID: mb01234	

- 1 -

Appendix 3 Footprint Markers

(appearing on separate pages so that they can be color printed, laminated, and put to use)

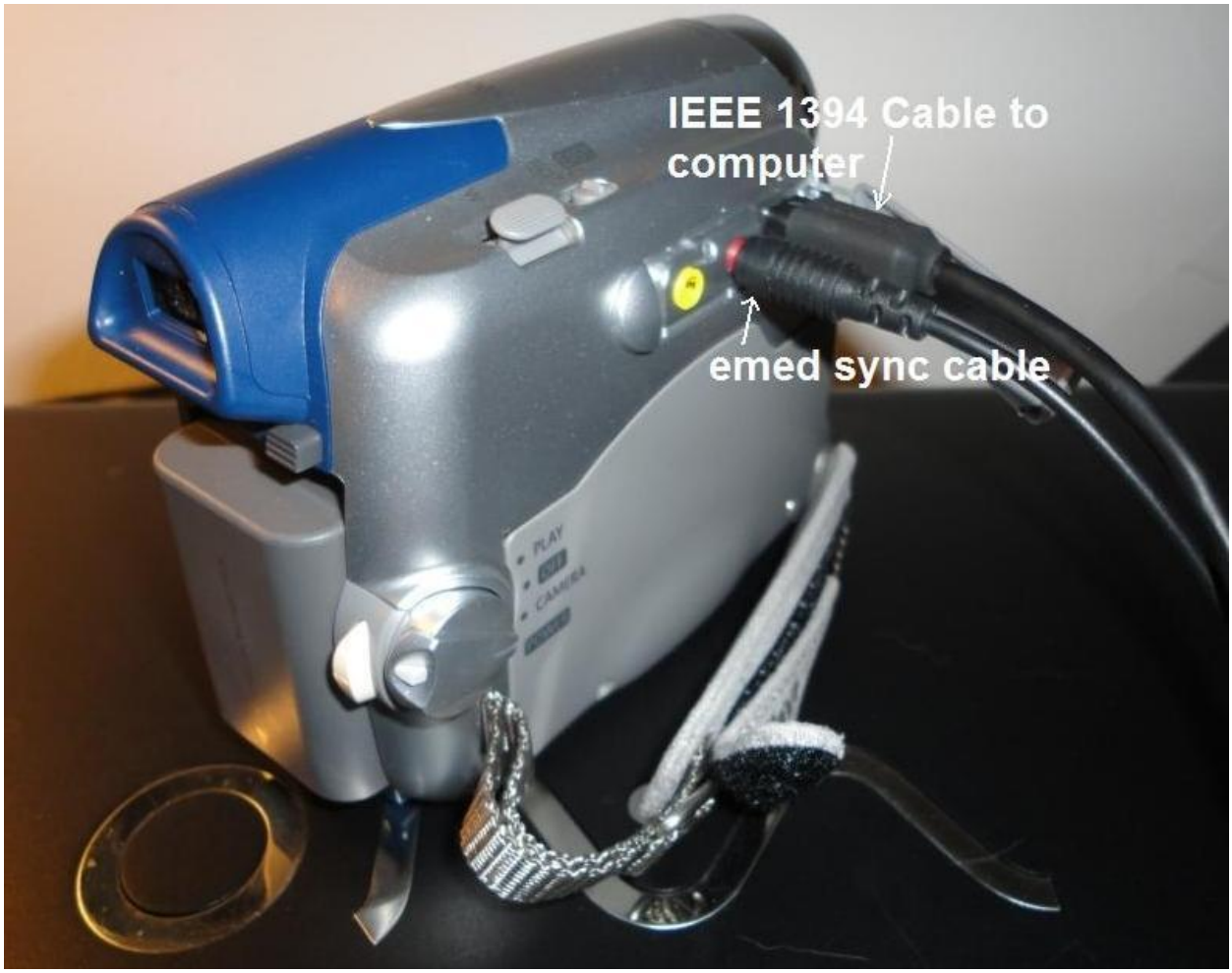




Appendix 4 Correct Connection of Cables from Video Camera to Emed Platform

The photo above shows correct connection of cables from Emed platform to video camera.*

***Please note that the cable colors shown in this photo may vary from the cable colors at the clinic site.**



The photo above shows correct connection of cables from Emed platform to video camera.*

***Please note that the cable colors shown in this photo may vary from the cable colors at the clinic site.**