BIOSWAY™ PORTABLE BALANCE SYSTEM
(with 4.x software)

OPERATION MANUAL

950-460

BIODEX
Biodex Medical Systems, Inc.
20 Ramsey Road, Shirley, New York, 11967-4704, Tel: 800-224-6339 (*Int'l 631-924-9000*), Fax: 631-924-9338, Email: info@biodex.com, www.biodex.com

FN: 17-308 8/17

BIOSWAY™ PORTABLE BALANCE SYSTEM (with 4.X software)

This manual covers operation procedures for the following products:

950-460 BioSway Portable Balance System w/Case

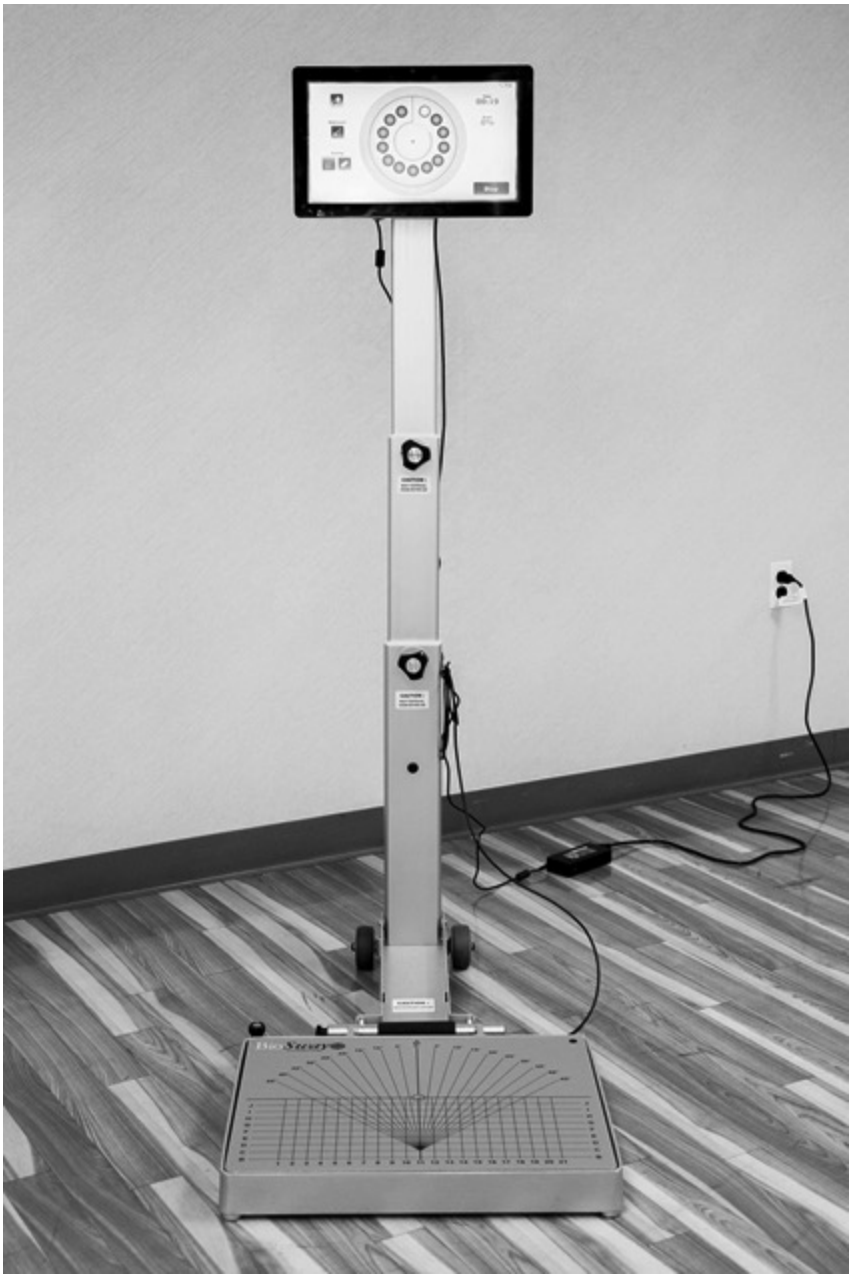

Table of Contents

Definition of Symbols

The following symbols and their associated definitions are used and implied throughout this manual.

Symbol	Definition
	Carefully read these instructions prior to use
	Caution
	General Warning
	General Mandatory Action
	Dangerous Voltage
	“On” Power
	“Off” Power
	Earth (ground)
	Alternating Current
	Fuse
	USB Connector/Cable
	Waste in Electrical Equipment
	Date of Manufacture
	Manufactured By
	Type B Applied Part
	CE Mark
	CE Mark for products with EC Certificate
	Certified for Safety by ETL Intertek

Product Certifications and Classifications

The BioSway Portable Balance System has received the following certifications, and falls within the following classifications:

- ETL and CETL listed to UL 60601-1, CAN/CSA C22.2 No.:601-1-M90 and EN60601-1
- EMC Certified to: EN 60601-1-2
- Class: Type (B) equipment
- CE Conformity to MDD 93/42/EEC

NOTE: *Circuit diagrams for this product are provided in the Schematics section at the back of this manual.*

- Type B Applied Part 
- Weight: 5 lb
- *Hard Case Dimension:* 23.75" w x 22.75" l x 10.75" h
- Total weight in case: 44 lb
- Environmental Operating Conditions:
  - Temperature: 0 to 40˚C
  - Humidity: 0 to 90% rh, non-condensing

Note: For optimum performance, the BioSway should be operated in a normal environment where the temperature and humidity are maintained for normal human comfort.

Before Proceeding

NOTE: *The warnings, cautions and instructions provided in this manual must be read, followed and kept available for consultation at all times. Observing the information, instructions and procedures presented throughout this manual is essential for using this product both properly and safely.*

SPECIFIC CAUTIONS

- Allow only qualified, trained personnel to operate or service this product.
- If the equipment is used in a manner other than specified in this operation manual, the protection provided by the equipment may be impaired and results could be compromised.
- Never leave user unattended on device.

EN GARDE SPÉCIFIQUES

- Permettez au personnel seulement autorisé, entraîné de faire marcher ou assurer l'entretien de ce produit.
- Si l'équipement est utilisé dans une manière autre qu'indiqué dans ce manuel d'opération, la protection fournie par l'équipement peut être diminuée et les résultats pourraient être compromis.
- Ne quittent Jamais le patient sans surveillance.

CAUTION: Unauthorized modifications to this product are not permitted and will void the manufacturer's warranty. Unauthorized modification of the product may result in a hazard to the user and/or patient. Do not modify this equipment without authorization from the manufacturer.

ATTENTION: Les modifications faites sans autorisation à ce produit ne sont pas permises et va faire le vide la garantie du fabricant. La modification faite sans autorisation du produit peut s'ensuivre dans un hasard à l'utilisateur et-ou le patient. Ne modifiez pas cet équipement sans autorisation du fabricant.

Important Safety Information

CAUTION: Federal law restricts this device to sale of or on the order of a medical practitioner. When prescribed for therapeutic purpose, a physician should clearly define the parameters of use (i.e., total work, maximum heart rate) to reduce the risk of patient injury.

ATTENTION: La loi fédérale américaine cet appareil vendu d'ou sur ordonnance d'un médecin. S'il est prescrit pour des fins thérapeutiques, un médecin devrait définir clairement les paramètres d'utilisation (travail total, fréquence cardiaque maximale) pour réduire le risque de blessure du patient.

Follow the unpacking and assembly instructions document.

Before using this equipment, read the entire operation manual carefully. Failure to read the manual may result in user error or injury. Be sure to save all provided documents for future reference.

Make certain to understand all warning and caution labels as explained in the Before Proceeding section of this manual.

This product should be used only as specified in the operation manual.

CAUTION: Biodex devices are designed for use in a client environment.

ATTENTION: Artifices Biodex sont conçus pour une utilisation dans un environnement du client.

For product specifications, refer to the Table of Contents.

Medical electrical equipment requires special precautions regarding EMC and must be assembled and placed into service according to EMC information provided in this manual.

CAUTION: Operation for 950-460: 115 VAC.

ATTENTION: Opération pour 950-460: 115 VAC.

WARNING: Only use approved power supplies.

AVERTISSEMENT: N'utiliser que les alimentations homologuées

CAUTION: To avoid risk of electric shock, this equipment must only be connected to supply mains with protective earth.

ATTENTION: Pour éviter le risque de choc électrique, cet équipement doit uniquement être connecté à un approvisionnement conduites avec la terre protectrice.

CAUTION: The plug is considered the method of disconnecting the product from main power. Do not place the product in a position where the plug is not easily accessible.

ATTENTION: Le bouchon est considérée comme la méthode de déconnexion du produit d'alimentation. Ne placez pas le produit dans une position où le bouchon n'est pas facilement accessible.

CAUTION: This product is intended to remain in one location during operation. It is provided with wheels for relocation that should be used when moving.

ATTENTION: Ce produit est destiné à rester à un endroit pendant le fonctionnement. Il est muni de roues pour la réinstallation qui devraient être utilisés lors du déplacement.

Biodex Warranty

Instrumentation

A. This equipment and its accessories are warranted by BIODEX MEDICAL SYSTEMS, INC. against defects in materials and workmanship for a period of one year from the date of shipment from BIODEX MEDICAL SYSTEMS, INC. During the warranty period, BIODEX MEDICAL SYSTEMS, INC. will in its sole discretion repair or replace the equipment found to have such defects, at no charge to the customer.

   EXCEPT AS STATED ABOVE, THERE ARE NO WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTIES OR MERCHANTABILITY OR FITNESS FOR USE. BIODEX DOES NOT ASSUME LIABILITY FOR INCIDENTAL, CONSEQUENTIAL OR INDIRECT DAMAGES INCLUDING LOSS OF USE, SALES, PROFITS OR BUSINESS INTERRUPTION.

B. This warranty does not apply if the product, as determined by BIODEX MEDICAL SYSTEMS, INC., is defective due to abuse, misuse, modification or service performed by other than a BIODEX MEDICAL SYSTEMS, INC. authorized repair representative. Misuse and abuse include, but are not limited to, subjecting limits and allowing the equipment to become contaminated by fluid materials.

C. In order to obtain warranty repair service and to expedite repair process, please contact BIODEX MEDICAL SYSTEMS, INC. Support Services Dept. at 800-224-6339, and select product support as prompted.

Warranty is non-transferable

Non-Warranty Service

A. Repairs and/or replacements not covered by this warranty may be performed by BIODEX MEDICAL SYSTEMS, INC. authorized service representatives.

B. The cost of transportation to and from the service location will be the responsibility of the customer.

Service Procedure

If there is a service problem, take the following action:

1. Check to see that the problem occurs more than once.
2. Refer to the instruction manual and operations procedure.

If you still think you have a service problem, call BIODEX MEDICAL SYSTEMS, INC., Service Department at (800) 224-6339 and select product service as prompted.

1. Keep yourself and the phone next to the equipment.

2. Service will ask you for a brief description of the problem. We will ask specific questions about the malfunction that occurred. This diagnostic process may take a few minutes, so call us when you can set aside an uninterrupted block of time.
3. After taking the information, we will advise on the action we will take.
4. Sometimes service personnel must consult with engineering and it may take time to get back to you. Be sure to let the service representative know your schedule so that we can call at a convenient time.
5. The return call may be from a person other than whom you first reported the problem to.
6. After analyzing the problem, we will decide if replacement parts will be sent or the unit must be returned.
7. If the unit must be returned, Biodex will provide a return materials authorization number (R.M.A. #.) Pack the table in the carton that it was originally shipped in. It is the customer's responsibility for any damage that occurs during shipping.
8. Non-warranty/non-service contract charges for repair are as follows:

    a. Materials
    +
    b. Time
    +
    c. Travel Zone

Contact information

Manufactured by:

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1. Introduction

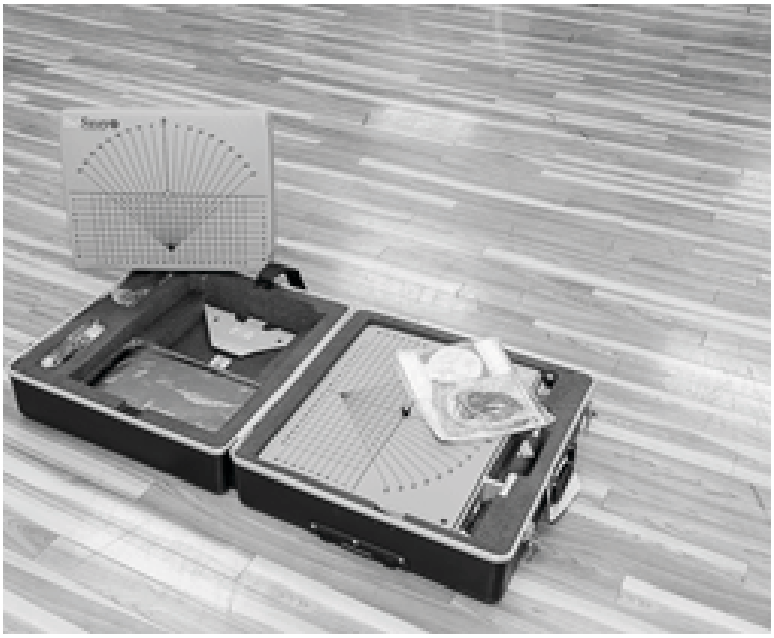

Figure 1.1. The Biodex BioSway is compact, lightweight and easily portable.

Intended Use

The BioSway is a versatile Balance Assessment and Training Device. Lightweight and relatively small, it is easily portable. Set-up only takes minutes to provide the clinician with a choice of six interactive training modes including the Clinical Test of Sensory Integration and Balance protocol.

The easy-to-follow touch screen format makes BioSway simple to learn and operate. All test results and training sessions can be stored and printed. Comparison to normative data helps to communicate need, progress and outcome.

A hard shell "wheelie board" case provides convenience and protection when using the BioSway outside the clinic.

What Does the BioSway Do?

- Provides valid, reliable, and repeatable objectives measures of a patient's neuromuscular control and ability to balance on a firm surface.
- Documents balance rehabilitation and assessment.
- During rehabilitation provides visual feedback of a patient's ability to control their center of gravity (COG).

Indications for Use

The Biodex BioSway can be the cornerstone for the following programs:

- Movement disorders associated with neuromuscular control.
- Amputee prosthetic rehabilitation.
- Orthopedic rehabilitation associated with ligament sprains and poor neuromuscular control.
- Sports medicine and conditioning programs.
- Core and lumbar stabilization strategies.
- Pre- and post-head injury screening.
- Concussion management program.

2. Assembly and Installation

The BioSway is quick and easy to assemble. Simply remove the shipping knob and store it in the handle, connect the components as described on the connection instruction placard, and level the platform as needed. The entire process should take only a few minutes.

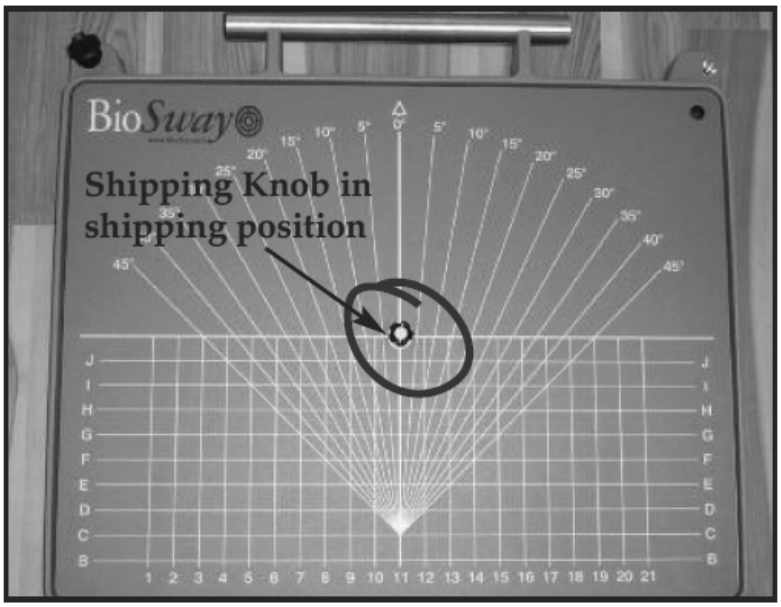

Figure 2.1. Shipping Knob in Shipping Position

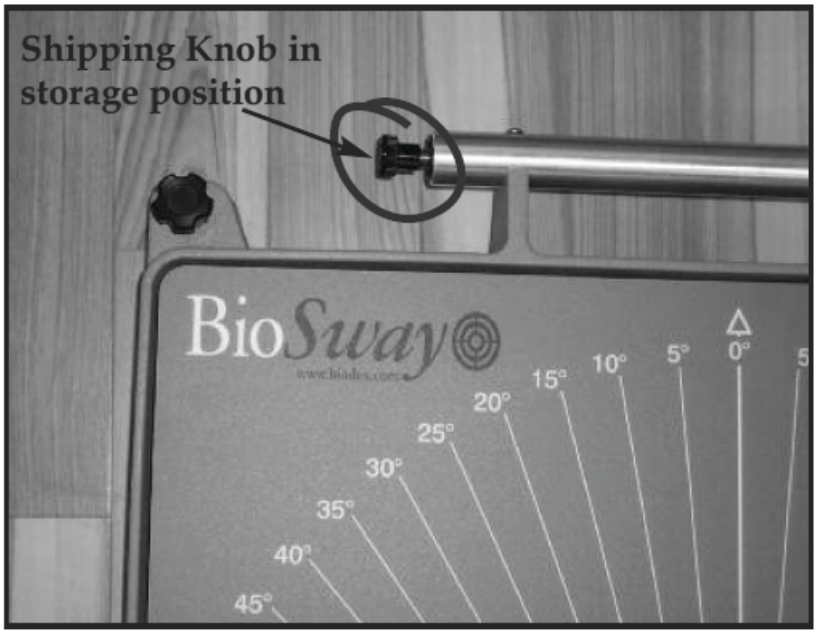

Figure 2.2. Shipping Knob in Storage Position

For Figures 2.1 and 2.2., remove the shipping knob and insert it into the handle for storage. Be sure to replace the knob if transporting the system.

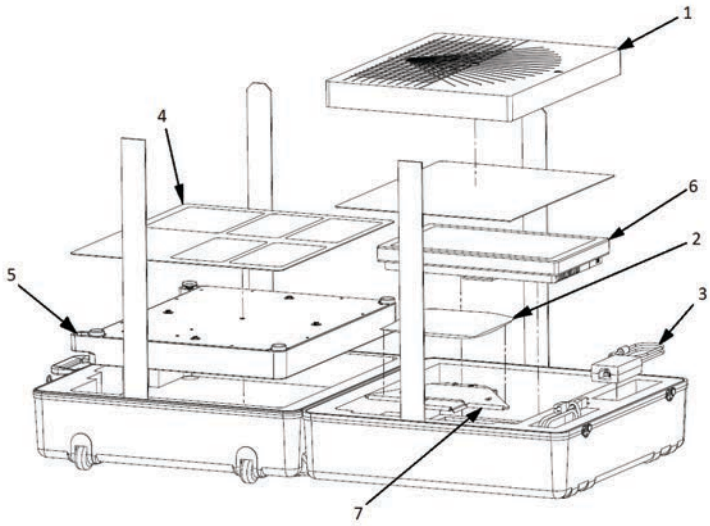

Figure 2.3. BioSway Components Illustrated in the Hard Case.

1. Foam pad
2. Bag (or Pouch) contains a USB cable, two blindfolds, a manual and other miscellaneous items
3. AC power adapter
4. Connection instruction placard
6. Base unit
*7. Display unit (**NOTE:** Store this faced-up in the hard case to protect the screen from case puncture.)*
8. Table Top Stand (included)

Base to Display Connections

1. Remove the back cover panel.
2. Connect the USB cable to the display. Connect the other end of the cable to the base.
3. Connect the power.

Figure 2.4. Base to Display Connections

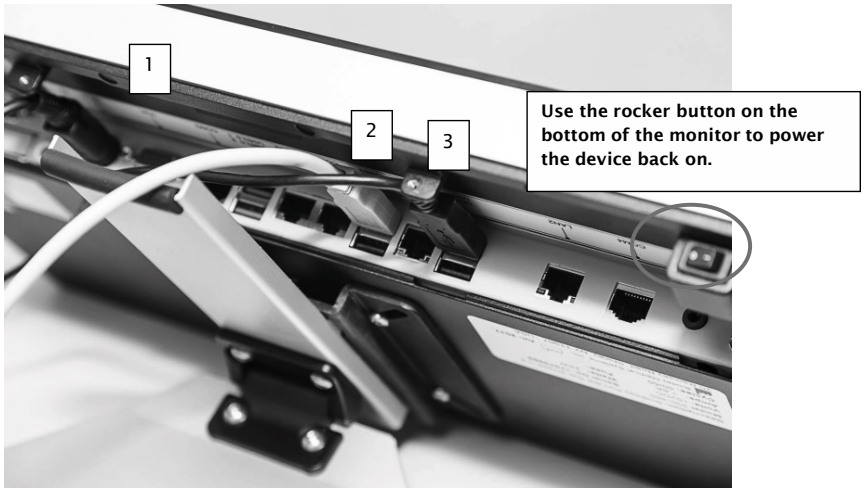

Figure 2.5. Display Connections

1. Plug the power supply into the wall socket. Plug the opposite end of the power supply into the display.
2. Plug the USB cable to the base of the unit.
3. Plug the USB to port on to the cover.

Replace the cover after all of the connections have been made.

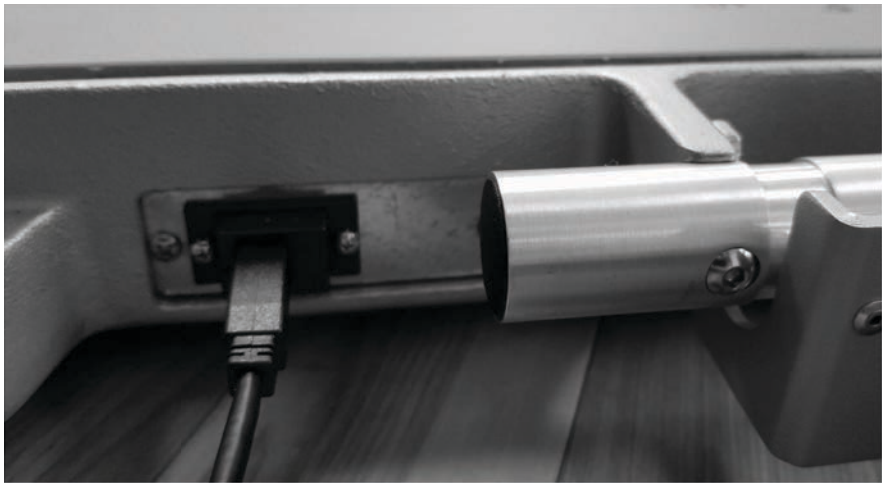

Figure 2.6. Base Connection.

Printer Connection

NOTE: *The printer is sold separately.*

Printers connect directly to the BioSway. Most Windows 7 printers should be compatible with the BioSway, but the drivers for various printers may need to be installed. For help with this, please call Biodex Customer Support at 631-924-9000.

It is possible to connect the device to a printer wirelessly. Please call Customer Support for instructions.

Other devices: Similarly, any Windows 7 keyboard or mouse will also automatically connect using one of the USB connections.

An external monitor can also be connected via the VGA port on the bottom of the display. Once the external monitor's cable is connected, the <Mirror to External Monitor> button in System Utilities must be selected. (This button is accessed by the following navigation steps from the Home screen: Utilities > Configuration > System Configuration > Screen Configuration.)

Platform Setup

This routine ensures the platform is level. The platform is level when the indicator needle is green.

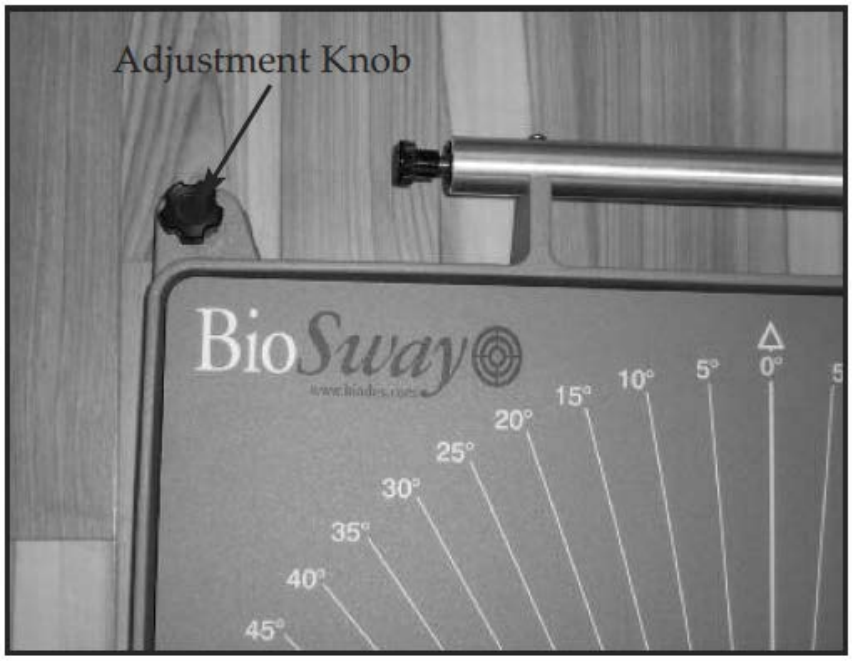

Figure 2.7. Use the Adjustment Knob to compensate for floor irregularities when leveling the platform.

Figure 2.8. When all four boxes on the display are green, the platform is level.

Choice of Display Stands

The BioSway Display connects to either the Table Top Stand (included) or Telescoping Stand with a universal quick-connect mount. Both stands fold for compact transport.

- 950-463 BioSway Display Stand, Table Top (included)
- 950-465 BioSway Display Stand, Telescoping

Table Top Stand for BioSway Display (included)

The Table Top Stand fits into the BioSway case for portability and can also be wall mounted.

BioSway Display on Telescoping Stand (sold separately)

The Telescoping Stand adjusts vertically: 39”to 69” (99 to 175 cm) – measuring from the top of the display. The stand folds at the base to fit into its own travel case.

Figure 2.9. Table Top Stand for BioSway, included.

Connecting the Display to the Telescoping Stand:

Figure 2.10., Figure 2.11., Figure 2.12. Connecting to the Telescoping Stand

Connecting and Disconnecting to/from the Telescoping Stand:

- Position the stand as illustrated above and ensure it clicks into place (See Figure 2.10 and 2.11).
- Press the release tab to remove. (See Figure 2.12).

Connecting the Display to the Table Top Stand:

Figure 2.13. Connecting to the Table Top Stand

Use the Table Top Stand for a Wall Mounted Display:

Figure 2.14. Using Table Top Stand for Wall Mounted Display

Mount the Display to VESA MIS-D:

The BioSway Display mount allows for direct attachment to other 100 mm VESA MIS-D compatible display mounts. It is best to leave the black mounting plate in place. VESA MIS-D is a common interface for a wide variety of monitor products.

Figure 2.15. Mounting the Display to VESA MIS-D.

Designed for Portability with Compact Storage:

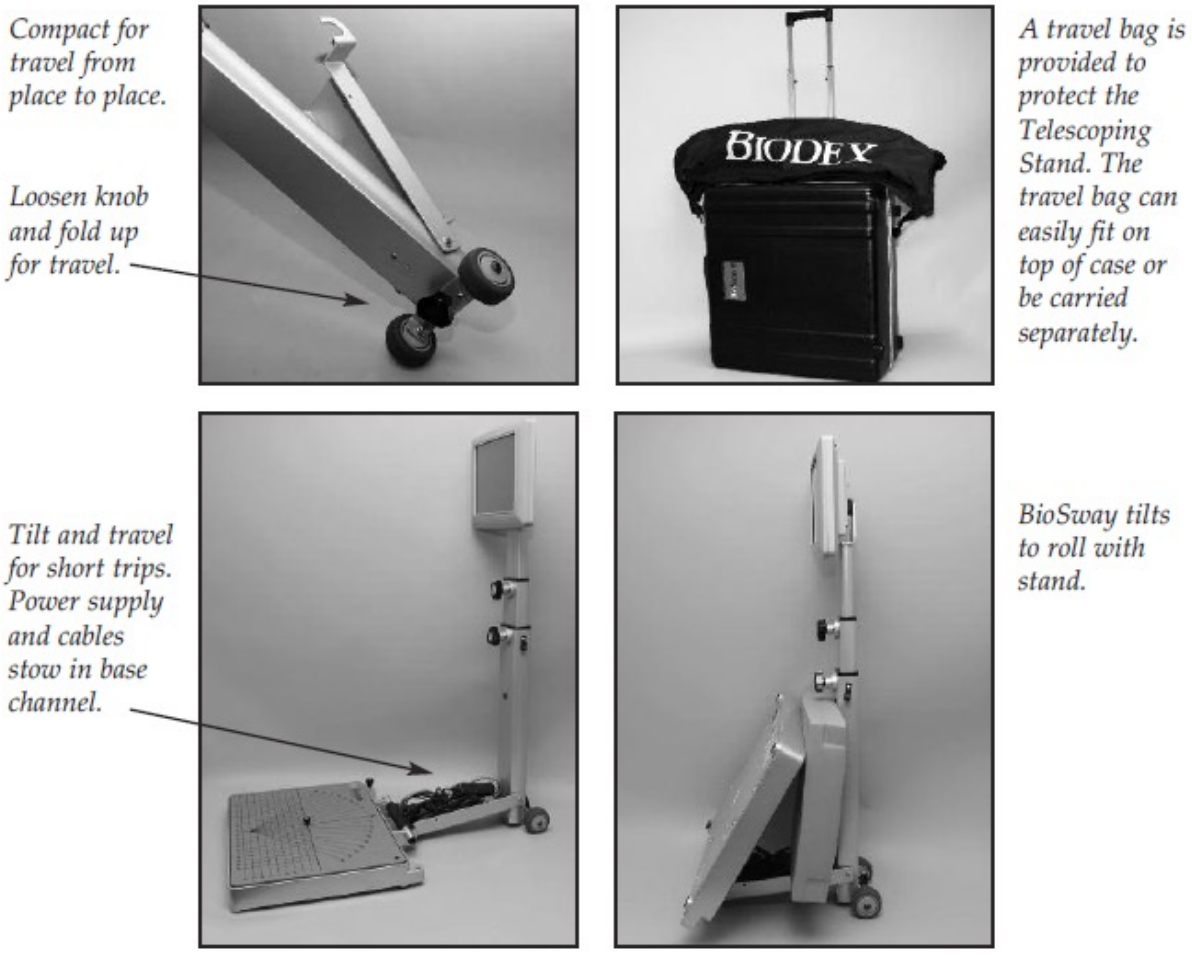

Figure 2.16. Folding Biosway for Storage

3. Clinical Considerations

Prior to using the BioSway with patients, make certain to read and comprehend this entire manual, be completely familiar with all aspects of training and testing, as well as patient history. Be sure to adhere to the following clinical guidelines at all times when using this system. All users should have a verbal understanding of the BioSway prior to stepping on the device. Never allow a patient to use the BioSway while unsupervised.

- A walker can be used as needed for patients that require or feel more comfortable with something to hold onto.
- When patients are working with their eyes closed, ensure that a clinician is ready to assist in case of loss of balance.
- For optimal operation, ensure the patient is standing in the center of the platform.
- Position the display so that the patient can look straight at it. This will help ensure good posture during the test or exercise session.
- There is a learning curve that must be considered when testing with this device. Clinical research suggests practice trials be performed prior to testing.
- It is highly recommended that the clinician remain with the patient during testing or training. An outstretched arm, not touching is reassuring for the patient.

Figure 3.1. Ensure all users have a verbal understanding of the BioSway before using the device. Never allow a patient to use the BioSway without supervision.

4. Getting Started

Power-up

When the unit is plugged in, the display will automatically power up.

Power-down

In order to prevent the device's database from becoming corrupted, it is essential that the correct power-down sequence is performed. Always turn off the display, by touching the X in the upper right corner of the home screen, followed by Shut Down.

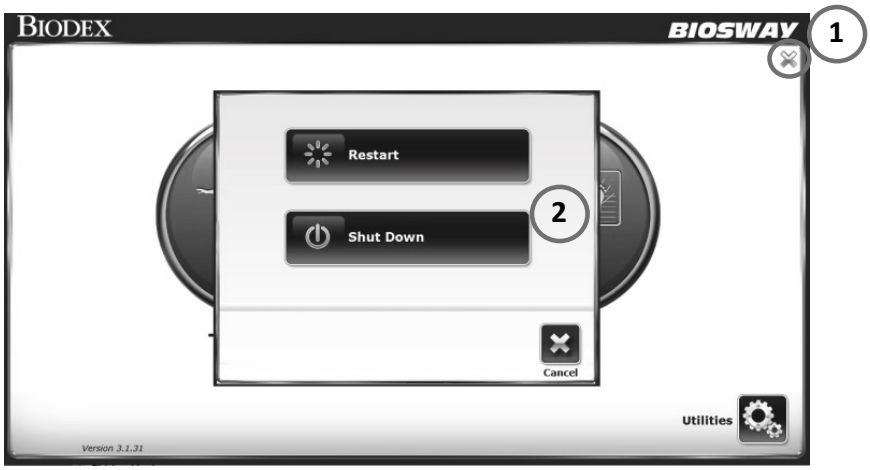

Figure 4.1. Power-down Sequence.

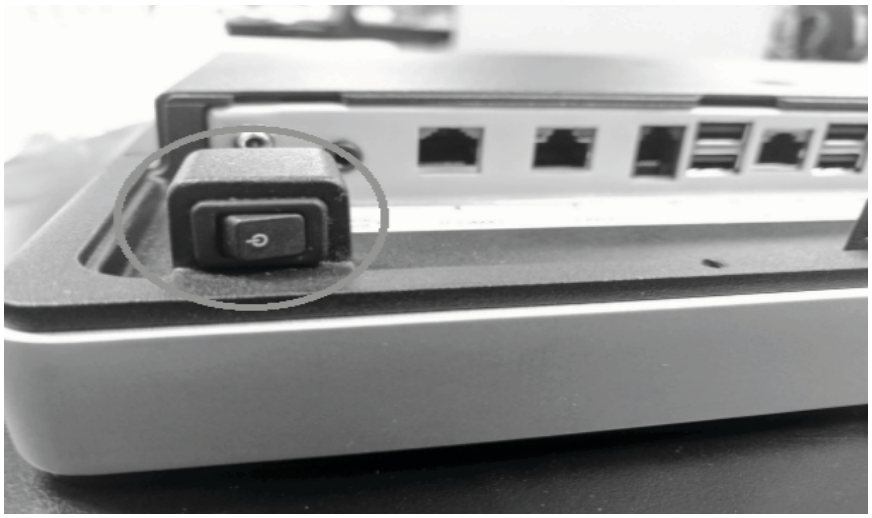

Figure 4.2. Use the rocker button on bottom of the monitor to power the device back on.

Once the display has finished its shut down sequence, power may be removed from the system.

CAUTION: Do not unplug the device before powering down the display!

ATTENTION: Ne débranchez pas l 'appareil avant d' éteindre l 'écran!

Figure 4.3. Do not unplug the device before powering down the display.

The Biodex BioSway System software program is easy to master. Follow the screen prompts as they lead from step-by-step through testing and training protocols or software utility options.

The Main Menu

To Access the BioSway System Main Menu:

1. Press the <ON/STANDBY> button on the display to turn the BioSway ON.
2. There will be brief BIODEX splash screen prior to seeing the Main Menu screen.
3. The Main Menu allows the user to select the Training, Testing, or Utilities menus.
4. If security code was enabled, enter 159. (See Chapter 7, System Utilities, Configuration, for more information on security code access.)

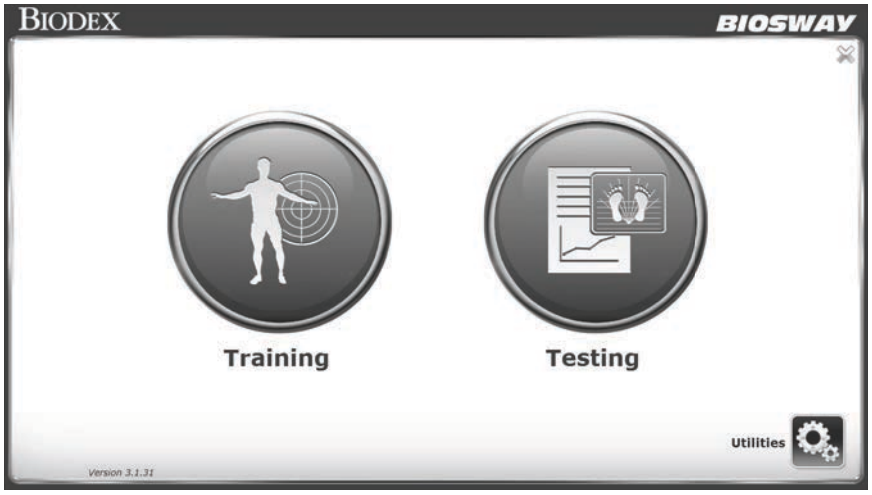

Figure 4.4. Main Menu.

Screen Keys

The following on-screen touch keys are consistent whenever they appear throughout the entire BioSway program.

- <HOME>: Touch this icon to return to the Main Menu.
- <NEXT>: Touch this key to advance to the next screen.
- <BACK>: Touch this key to return to the previous screen.
- <OK>: Touch this key to confirm selections or entries; advances to the next screen.

Patient Setup Information Screen

The Patient Setup information screen will precede all training and testing mode interfaces. Touch the appropriate icon to begin entering information. A pop-up keypad or keyboard is used to enter some parameters such as name and age. Once the desired information is entered/selected, touch <Next> to advance to the Training mode screen. Other adjustments can be made using the icons along the bottom of the screen. The presence of some of these icons is set in the system Utilities section.

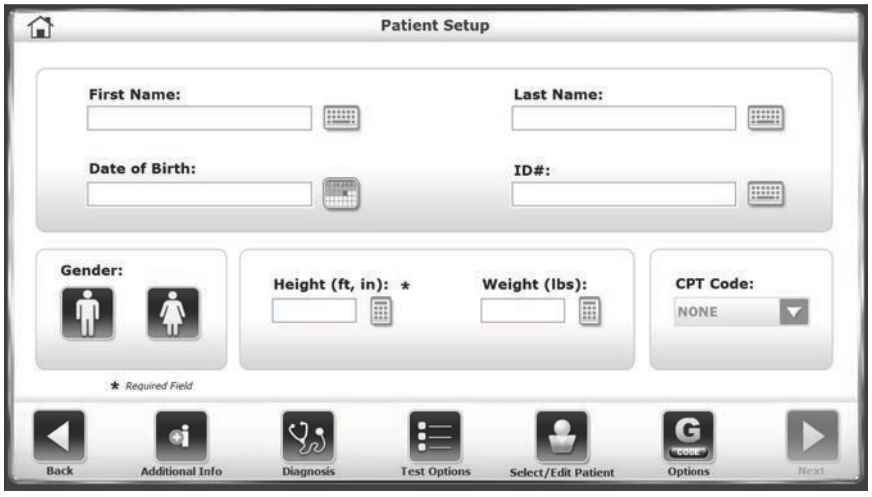

Figure 4.5. The Patient Setup information screen.

Patient Setup Information Screen Parameters

***NOTE**: The parameter for Height is a mandatory field and must be completed before balance training can begin.*

- *First and Last Name*: Optional, touch the pop-up keyboards to enter the first and last name. Touch <OK> to continue.
- *ID#*: Optional or required, depending on Configuration settings. Touch the pop-up <Keypads> to enter an identification number. Touch <OK> to continue.
- *Gender*: Optional, touch the appropriate icon to select <Male> or <Female>.
- *Height*: Required, this setting is used to correlate normative data with training results. Touch the appropriate <Height> icon to select the desired range. This value can be a manual number entry (see Figure 4.5). The manual height entry option can be set within the Configuration option in System Utilities.
- *Weight*: Optional, for new patients, a weight can be entered here in pounds.

NOTE: *If a patient has been selected using the Select a Patient function, the application will display the existing height and weight that was previously recorded. If height or weight has changed, the numbers can be adjusted and new test results will feature the updated information. Once a test is performed, there is no way to edit the height or weight recorded for that test result. Patient height and weight can be changed at any time from the Patient Management screen in System Utilities. The new numbers will be used for any subsequent tests.*

- *Age / Date of Birth*: Range is from 10 to 120 years old. Touch the <Age> keypad and use the pop-up keypad to change the value. This value can be derived from a Date of Birth entry; see Figure 4.5. The Age/DOB option can be set within the Configuration option in system Utilities. Touch <OK> to continue.
- *Test Options*: The Test Options screen will vary with each Training or Testing mode. These settings will be described in more detail in later sections of this document.
- *Select/Edit Patient* (Figure. 4.5): Touch <Select Patient> to designate an existing patient within the device's records for a new training session.

The Select Patient Screen

Figure 4.6. The Select/Edit Patient screen.

In previous versions of the software, a patient with existing data on the device could only be re-tested by either: a) typing in his or her name exactly at it is spelled on an existing record, or b) finding the patient within the set of records in the Patient Management section of System Utilities. Now, with the Select Patient option, users can quickly find an existing patient and get them started on a new training session.

There are two ways to identify specific existing patients from this screen. At the top of the screen, the user can search for a patient's last name or identification number. Select one of the fields and type in either a patient last name or an ID number. Select <OK> to see a listing of search results. To return to the list of all patients, select the circular refresh arrow icon at the top, right of the screen.

Figure 4.7. The Select/Edit Patient Screen Illustrating Search Results. To Reset Listing of all Patients, Select the Circular Refresh Arrow in the Upper Right Corner.

If the number of patient records on the device is relatively small, it may be easier to scroll through the records with the ▲ or ▼ arrows. (The arrows will not scroll through individual records, but rather pages of records—ten per page.)

Patient records can be edited on this screen, or a new patient can be added. Many of the same information fields that are in the Patient Setup screen will need to be entered.

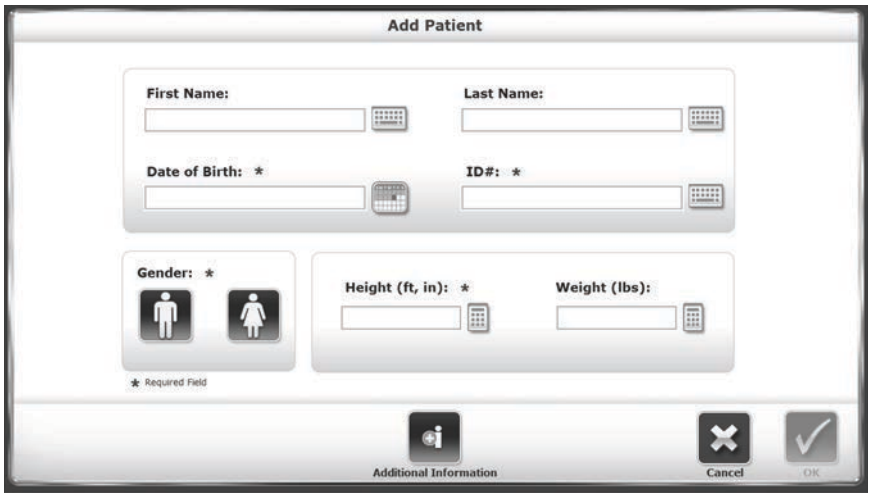

Figure 4.8. The Add Patient Screen.

Additional Patient Setup Information Screen Parameters

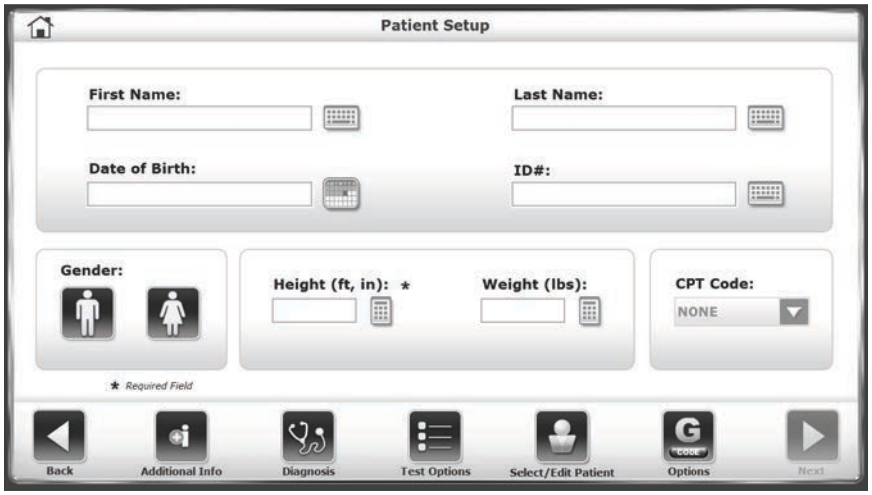

Figure 4.9. Patient Setup Screen.

***NOTE**: The following parameters are only visible when they are activated within the BioSway Configuration settings (i.e., in System Utilities).*

- *Additional Info* (Figure 4.8): Touch <Additional Info> to enter information regarding the patient's health status and the facility where treatment is taking place.
- *Diagnosis* (Figure 4.9): Touch <Diagnosis> to enter diagnostic information for the patient, including an ICD code.
- *CPT Code:* (Figure 4.9): Touch the <CPT Code> drop-down menu to assign a particular CPT (Current Procedural Terminology) code to the patient.
- *G-Code Options* (Figure 4.9): Touch <G-Code> to apply certain G-Code settings to this particular patient.

The Additional Information Screen

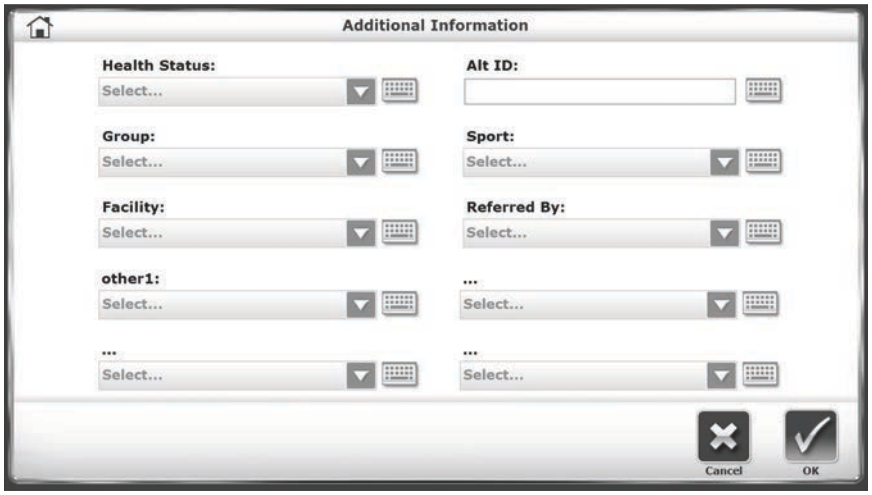

Figure 4.10. The Additional Information Screen.

The Additional Information screen contains a series of drop-down menus and editable fields in which users can enter various types of information about the patient. In each menu, users can enter a new value or item into the drop-down list. Entering Additional Information data is optional.

5. The Training Modes

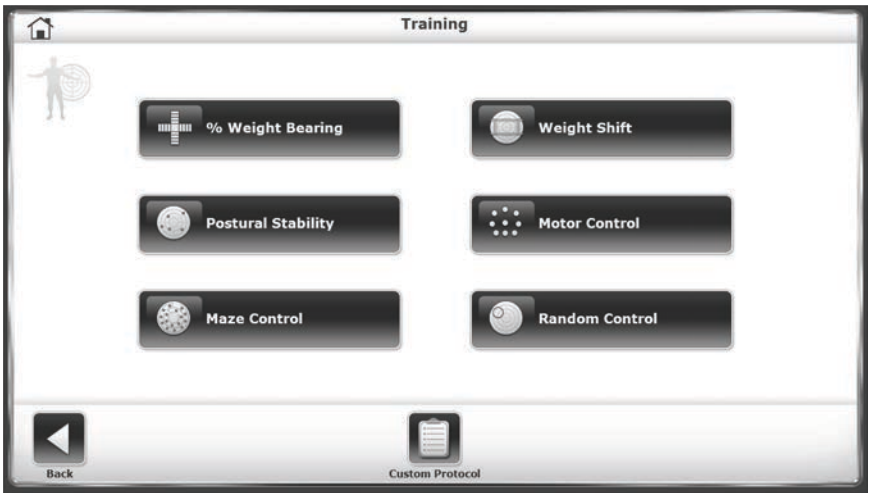

Figure 5.1. The Training Modes Main Menu Screen.

The training modes provide a simple means of setting up training or exercise sessions. Six interactive, game-like training modes are provided. These modes allow for fast patient setups. All six training modes can be customized to provide specific rehab goals and score-keeping functions used to both help motivate users and keep them focused on the task at hand. In addition, custom training protocols that were previously created through the Utilities option can be selected. Typically, a custom protocol is one that a clinician has developed and would like to use with various patients without having to recreate it each time.

In training mode, only the most basic parameters are addressed. If desired, a pre-existing patient can be recalled from the Test/Rehab Results option in Patient Maintenance menu to allow for quick and easy repeat of a training or test session. The print screen function will allow the user to generate a printout of training results.

Training results can also be saved and recalled for later use by touching the <Save> icon on the results screen following any training session. A patient name is required to save the results. If no pre-existing name is available, the name entry screen will be displayed. Fill out the patient information and touch <Save> to record the training result numeric values along with patient foot position on the platform.

To recall a patient and repeat an exercise session, select the desired patient from the Patient Management screen (see Chapter 7, System Utilities) and touch <Repeat>. The Position Patient screen with previous values is presented so the patient can be easily repositioned exactly as in the previous training session.

Training mode formats include: Percent Weight Bearing, Weight Shift, Postural Stability, Motor Control, Maze Control, and Random Control.

Postural Stability Training

The Postural Stability Training mode is designed to emphasize specific movement patterns or strategies by placing targets anywhere on the screen grid. The patient's score is a tally of how many times the patient can touch the targets (i.e., by leaning and shifting their postural stance) during any session. As the patient moves the on-screen cursor during the training session, a tracing feature records the route of the cursor on the grid. This feature can be used to visually illustrate a patient's positioning throughout the routine. Time counts up or down as set.

Figure 5.2. The Postural Stability Training screen.

To Access the Postural Stability Training Mode:

1. At the Main Menu, touch <Training>.
2. Touch <Postural Stability>. The Patient Setup Information screen is displayed. If this is a new patient and for whom the training session is to be saved after its completion, the patient's name and height must be entered. If the training session does not need to be saved, designate a Height value, which will be correlated with normative data for scoring purposes.
3. Touch <Test Options> to advance to the Postural Stability Training Options screen if desired. Here, the total time for the exercise can be set, hold time (i.e., how long a patient has to keep the cursor over the targets) can be set, and the Display Tracing, Display Cursor, and Scoring Tone can be turned on or off.
4. Use the <▲> or <▼> keys to set the total time in ten-second increments (during the routine, the system will count down from the time setting selected). If no time is set, the timer will count up from 00:00.
5. Touch <OK> to confirm the selections or <Cancel> to return to the Patient Setup Information screen without making changes. Touch <NEXT> to advance to the Postural Stability Training screen.
6. At the Postural Stability Training screen, touch the <Place Target> icon (the left-most icon under Targets) and touch the screen location where a target is to be placed. The process can be repeated to place up to nine targets on the screen.

7. To clear any misplaced or unwanted targets, touch the <Clear Target> eraser icon (the right-most icon under Targets). Touch the target(s) to remove.
8. At any time during the training session, the tracing biofeedback can be turned on or off by touching the <Show Tracing> icon (the left-most icon under Tracing). The green biofeedback tracing line can be can be erased by pressing the <Clear Tracing> eraser icon (the right-most icon under Tracing).
9. Explain the training protocol to the patient and press <Start> on the display to begin the training session. The Score number charts the patient's stability performance through the course of the training session. Touch the <Magnifying Glass> icon to enlarge the screen if desired. The elapsed time from the start of the training session is shown at the top right of the display.
10. To stop the training session at any time, press <Stop> on the display. The system will stop gathering data and the platform will return to the locked position.
11. When the training screen has been reviewed, touch <Print Results> to print the results of the session, or <Save Results> to save the training session. If a patient identifier was not entered at the start of the session (i.e., a name or an ID number), it must be entered now in order to save the results of the session.
12. After printing or reviewing the screen, press <Start> to immediately begin another training session using the same parameters, or press <Back> to return to the Patient Setup screen.

Motor Control Training

The Motor Control Training screen is designed to challenge the user to move through a movement pattern consistent with one's "sway envelope". The sway envelope is the area a person can move their Center of Gravity (COG) within their base of support. It is approximated as 8 degrees to one side, 8 degrees to the other (total of 16 degrees of sway,) and 8 degrees forward and 4 degrees back (12 degrees total). Both the Motor Control training and testing modes are based on challenging patients within their sway envelopes.

Scoring is percentage-based and reflects the patient's directional accuracy of his or her movement to the blinking targets. (The more straight-lined the movements, the better it is.)

Figure 5.3. The Motor Control Training Screen.

To Access the Motor Control Training Mode:

1. At the Main Menu, touch <Training>.
2. Touch <Motor Control>. The Patient Setup Information screen is displayed. If this is a new patient and the training session is to be saved after its completion, the patient's name and height must be entered. If the training session does not need to be saved, designate a height value, which will be correlated with normative data for scoring purposes.
3. Touch <Test Options> to advance to the Motor Control Training Options screen if desired. Here, the total time for the exercise can be set, hold time (i.e., how long a patient has to keep the cursor over the targets) can be set, and the Display Tracing, Display Cursor, and Scoring Tone can be turned on or off.
4. Use the <▲> or <▼> keys to set the total time in ten-second increments. During the routine, the system will count down from the time setting selected. If no time is set, the timer will count up from 00:00.
5. Touch <OK> to confirm the selections or <Cancel> to return to the Patient Setup Information screen without making changes. Touch <NEXT> to advance to the Motor Control Training screen.
6. Touch the <Skill Level> icon to tighten or widen the space between targets. Three skill levels are available from which to select, with the easiest target set being the one where the targets are closest together. Touch <Skill Level> until the desired target configuration is displayed.
7. Touch the <Pattern> icon to toggle between a Full, a Left, or a Right target set orientation.
8. At any time during the training session, the tracing biofeedback can be turned on or off by touching the <Show Tracing> icon (the left-most icon under Tracing). The green biofeedback tracing line can be can be erased by pressing the <Clear Tracing> eraser icon (the right-most icon under Tracing). The cursor will still be seen.
9. Explain the training protocol to the patient (i.e., that the patient must move the cursor back and forth from the center target to the perimeter targets). Press <Start> on the display to begin the training session. The Score number charts the patient's stability performance through the course of the training session. Touch the <Magnifying Glass> icon to enlarge the screen if desired. The elapsed time from the start of the training session is shown at the top right of the display and a running patient score is provided in the upper right corner.
10. To stop the training session at any time, press <Stop> on the display. The system will stop gathering data and the platform will return to the locked position.
11. When the training screen has been reviewed, touch <Print Results> to print the results of the session, or <Save Results> to save the training session. If a patient identifier was not entered at the start of the session (i.e., a name or an ID number), it must be entered now in order to save the results of the session.
12. After printing or reviewing the screen, press <Start> to immediately begin another training session using the same parameters, or press <Back> to return to the Patient Setup screen.

Weight Shift Training

This training mode allows for exercises in the most basic of activities; weight shifting. Patients can practice shifting their weight in medial/lateral, anterior/posterior, and diagonal planes. This

can be performed with both static and dynamic settings. During this training routine, the target zone (defined by two parallel blue lines) can be rotated to any of four orientations while the amount of excursion within the target area can be modified to allow for varying levels of difficulty.

Figure 5.4. The Weight Shift Training Screen.

To Access the Weight Shift Training Mode:

1. At the Main Menu, touch <Training>.
2. Touch <Weight Shift>. The Patient Setup Information screen is displayed. If this is a new patient and the training session is to be saved after its completion, the patient's name and height must be entered. If the training session does not need to be saved, designate a height value, which will be correlated with normative data for scoring purposes.
3. Touch <Test Options> to advance to the Weight Shift Training Options screen if desired. Here, the total time for the exercise can be set, hold time (i.e., how long a patient has to keep the cursor over the targets) can be set, and the Display Tracing, Display Cursor, and Scoring Tone can be turned on or off.
4. Use the <▲> or <▼> keys to set the total time in ten-second increments. During the routine, the system will count down from the time setting selected. If no time is set, the timer will count up from 00:00.
5. Touch <OK> to confirm the selections or <Cancel> to return to the Patient Setup Information screen without making changes. Touch <NEXT> to advance to the Weight Shift Training screen.
6. Touch the <Rotate Target > icon to toggle through the four target orientations (i.e., medial/lateral, anterior/posterior, and diagonal planes) until the desired orientation is displayed.
7. On the Weight Shift Training screen, touch the <Skill Level> icon to tighten or widen the target box area. Three skill levels are available, with the easiest being the one where the target box area is the widest. Touch <Skill Level> until the desired target box area configuration is displayed.

8. At any time during the training session, the tracing biofeedback can be turned on or off by touching the <Show Tracing> icon (the left-most icon under Tracing). The tracing line can be erased by pressing the <Clear Tracing> eraser icon (the right-most icon under Tracing). The cursor will still be seen.
9. Explain the training protocol to the patient (i.e., that the patient must move the cursor back and forth from the two blue perimeter target bars). Press <Start> to begin the training session. The Elapsed Time from the start of the training session is shown at the top right of the display, and a running patient score is provided in the upper right corner.
10. To reposition the target zone hit lines, touch the desired line (it will temporarily change from blue to green) and re-touch the screen where the line is to be relocated.
11. Scoring is percentage-based and equals net good hits divided by the total target hits. If a red boundary line is crossed, that counts against the good hit total. All outside boundary hits are subtracted from the total amount of target hits. This value equals the net good hits.

    For example: if a patient achieved ten target hits, but there were four times the cursor went outside the boundary, 10-4 = 6 good hits. The score = 6/10 or 60%.
12. To stop the training session at any time, press <Stop> on the display. The system will stop gathering data and the platform will return to the locked position.
13. When the training screen has been reviewed, touch <Print Results> to print the results of the session, or <Save Results> to save the training session. If a patient identifier was not entered at the start of the session (i.e., a name or an ID number), it must be entered now in order to save the results of the session.
14. After printing or reviewing the screen, press <Start> to immediately begin another training session using the same parameters, or press <Back> to return to the Patient Setup screen.

Percent Weight Bearing Training

Percent Weight-Bearing Training provides real-time feedback of the percentage of weight-bearing on a patient's foot, ankle, knee, hip, body side, and such. In this mode, targets can be set that encourage patients to focus on weight-bearing goals in anterior, posterior, medial, and lateral movements. Therapists and patients should find weight-bearing training to be an effective mode for communicating what, where, and how a patient's body weight is located.

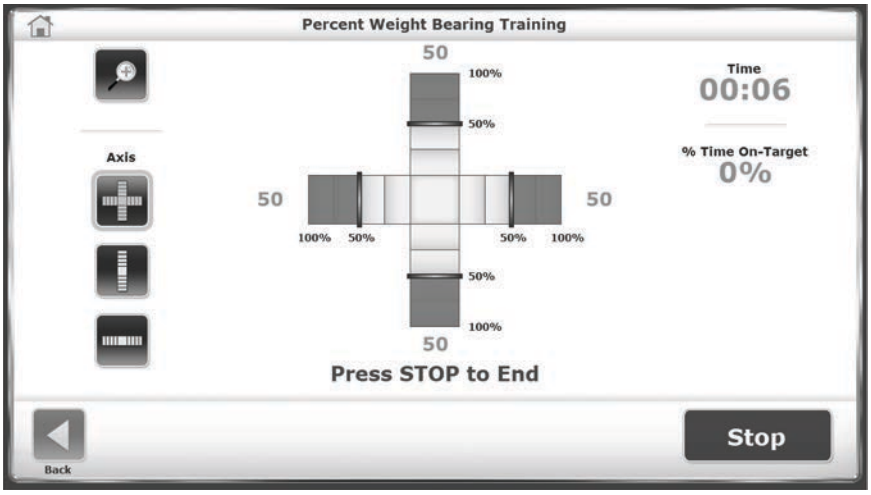

Figure 5.5. The Percent Weight Bearing Training Screen.

Figure 5.6. If Desired, the Exercise Orientation can be set to Medial/Lateral Only.

To Access the Percent Weight Bearing Training Mode:

***NOTE**: Percent Weight Bearing training mode is used with the platform in static mode only.*

1. At the Main Menu, touch <Training>.
2. Touch <% Weight Bearing>. The Patient Setup Information screen is displayed. If this is a new patient and the training session is to be saved after its completion, the patient's name and height must be entered. If the training session does not need to be saved, designate a height value, which will be correlated with normative data for scoring purposes.
3. Touch <Test Options> to advance to the Percent Weight Bearing Training Options screen if desired. Here, the total time for the exercise can be set, hold time (i.e., how long a patient has to keep the cursor over the targets) can be set, and the Display Tracing, Display Cursor, and Scoring Tone can be turned on or off.
4. Use the <▲> or <▼> keys to set the total time in ten-second increments. During the routine, the system will count down from the time setting selected. If no time is set, the timer will count up from 00:00.
5. Use the <▲> or <▼> keys to set the scoring forgiveness range, which is used to make it easier or harder for patients to perform the weight shifting tasks they will be asked to perform.
6. Touch <OK> to confirm the selections or <Cancel> to return to the Patient Setup Information screen without making changes. Touch <NEXT> to advance to the Position Patient screen.

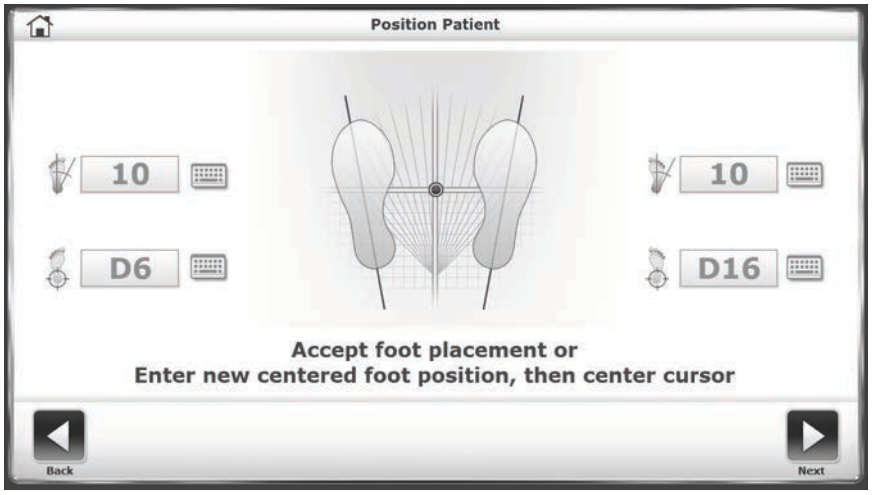

Figure 5.7. Position Patient Screen.

The dot on the Position Patient screen represents the patient's Center of Gravity. Have the patient stand in a natural stance, slightly adjusting foot placement until the dot is on or close to the center axis. Using the four keypads, enter the patient's left foot, left heel, right foot and right heel positions using the midline of the foot and the platform grid as reference points. As a reference, use the table below for foot positioning based on patient height:[1]

Table 5.1. Patient Foot Placement

Height Default:	Foot Angle:	Heel Position:
< 53"	10/10	F7/F15
53 – 59"	10/10	E7/E15
59 – 65"and 65 – 73"	10/10	D67/D16
73" +	10/10	C5/C17

7. Touch <Next> to advance to the Percent Weight Bearing Training screen (see Figure 5.7).
8. On the Percent Weight Bearing Training screen, touch one of the three <Axis> icons to select an exercise orientation.
9. Explain the training protocol to the patient (i.e., that the patient should shift or maintain the moving zone back and forth from the two blue perimeter target bars). Press <Start> to begin the training session. The elapsed time from the start of the training session is shown

[1] McIlroy WE, Maki BE. Preferred placement of feet during quiet stance: development of a standardized foot placement for balance testing. Clinical Biomechanics Vol 17, No. 1 66-70 1997.

at the top right of the display and a running patient score (i.e., the percentage of time spent on target) is provided in the upper right corner.

10. To reposition the target zone hit lines, touch the desired line (it will temporarily change from blue to green) and re-touch the screen where the line is to be relocated.
11. Scoring is the percentage of time spent within the target range. The axis will show green when weight bearing is within target settings.
12. To stop the training session at any time, press <Stop> on the display. The system will stop gathering data.
13. When the training screen has been reviewed, touch <Print Results> to print the results of the session, or <Save Results> to save the training session. If a patient identifier was not entered at the start of the session (i.e., a name or an ID number), it must be entered now in order to save the results of the session.

Maze Control Training

This mode allows the patient to follow a set pattern of movement throughout a maze in both static and dynamic environments. Three skill levels allow the maze to be modified to create a simple or more difficult environment through which the patient must navigate. Change the platform from static mode to dynamic mode to facilitate progression.

To Access the Maze Control Training Mode:

1. At the Main Menu, touch <Training>.
2. Touch <Maze Control>. The Patient Setup Information screen is displayed. If this is a new patient and the training session is to be saved after its completion, the patient's name and height must be entered. If the training session does not need to be saved, designate a height value, which will be correlated with normative data for scoring purposes.
3. Touch <Test Options> to advance to the Maze Control Training Options screen if desired. Here, the total time for the exercise can be set and the Display Tracing, Display Cursor, and Scoring Tone can be turned on or off.

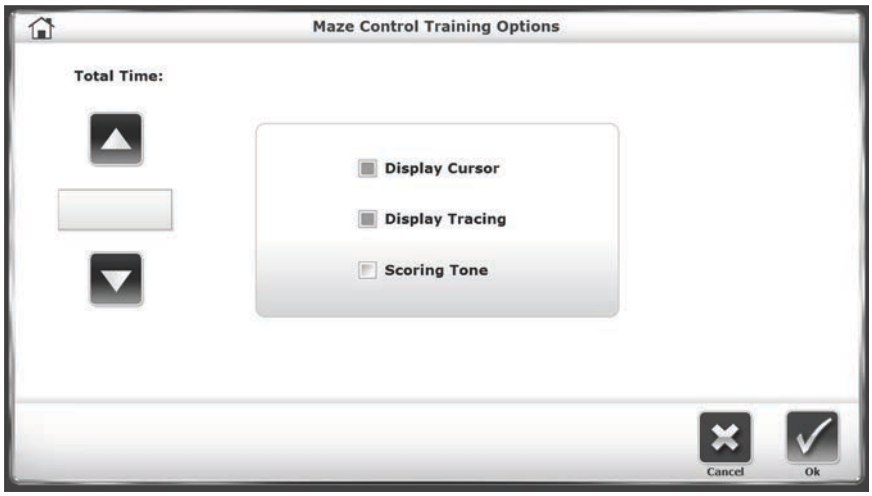

Figure 5.8. The Maze Control Training Options Screen.

4. Use the <▲> or <▼> keys to set the total time in ten-second increments. During the routine, the system will count down from the time setting selected. If no time is set, the timer will count up from 00:00.
5. Touch <OK> to confirm the selections or <Cancel> to return to the Patient Setup Information screen without making changes. Touch <NEXT> to advance to the Maze Control Training screen.
6. On the Maze Control Training screen, touch the <Skill Level> button to increase or decrease the difficulty level for the patient to move the cursor through the maze. Three skill levels are available:
    - Easiest maze has 26 total targets or 13 in each direction.
    - Moderate has 52 targets or 26 in each direction.
    - Most difficult has 74 targets or 37 in each direction.

Figure 5.9. The Maze Control Training Screen.

7. At any time during the training session, the tracing biofeedback can be turned on or off by touching the <Show Tracing> icon (the left-most icon under Tracing). Press the <Clear Tracing> eraser icon (the right-most icon under Tracing) to remove any tracing that is left from a previous training session. The cursor will still be seen.
8. Explain the training protocol to the patient (i.e., that the patient should move the cursor through the maze clearing each blue ball target while not touching the maze wall boundaries). Touch the <Magnifying Glass> icon to enlarge the screen if desired. Press <Start> to begin the training session. The elapsed time from the start of the training session is shown at the top right of the display and a running patient score is provided in the upper right corner.
9. Scoring is percentage-based and equals net good hits divided by the total target hits. If a red boundary line is crossed, that counts against the good hit total. All outside boundary hits are subtracted from the total amount of target hits.

    This value equals the net good hits. In the case of the easiest maze: if all the blue ball targets are cleared, but the maze wall is hit 6 times, the resulting score will be 22/26, or 85%.

10. To stop the training session at any time, press <Stop> on the display. The system will stop gathering data and the platform will return to the locked position.
11. When the training screen has been reviewed, touch <Print Results> to print the results of the session, or <Save Results> to save the training session. If a patient identifier was not entered at the start of the session (i.e., a name or an ID number), it must be entered now in order to save the results of the session.
12. After printing or reviewing the screen, press <Start> to immediately begin another training session using the same parameters, or press <Back> to return to the Patient Setup screen.

Random Control Training

This training mode allows the patient to perform neuromuscular control activities in response to random patterns generated by the display. The size and speed of the target can be modified for progressions ranging from easy to difficult. While in static mode the patient can work within their sway envelope to move the cursor and attempt to keep it within the moving target. In dynamic mode the patient must utilize various hip, knee, and ankle strategies to keep the cursor within the random moving target.

To Access the Random Control Training Mode:

1. At the Main Menu, touch <Training>.
2. Touch <Random Control>. The Patient Setup Information screen is displayed. If this is a new patient and the training session is to be saved after its completion, the patient's name and height must be entered. If the training session does not need to be saved, designate a height value, which will be correlated with normative data for scoring purposes.
3. Touch <Test Options> to advance to the Random Control Training Options screen if desired. Here, the total time for the exercise can be set, hold time (i.e., how long a patient has to keep the cursor over the targets) can be set, and the Display Tracing, Display Cursor, and Scoring Tone can be turned on or off.

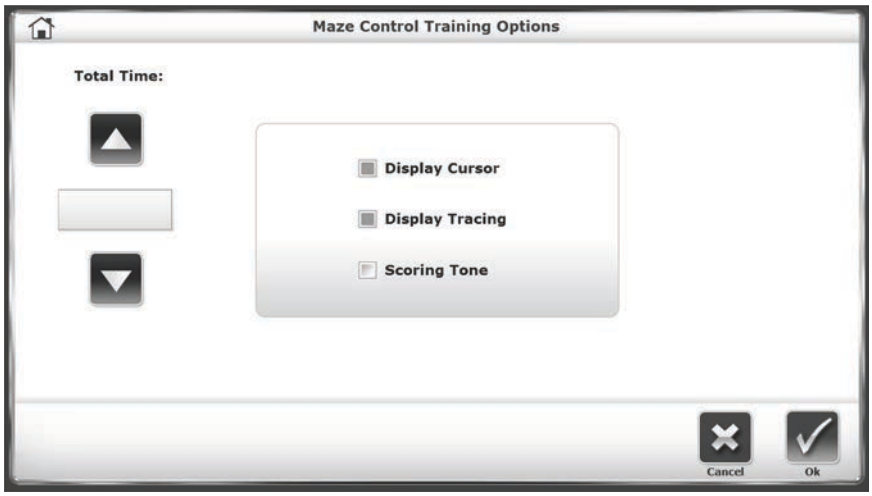

Figure 5.10. The Maze Control Training Options Screen.

4. Use the <▲> or <▼> keys to set the total time in ten-second increments. During the routine, the system will count down from the time setting selected. If no time is set, the timer will count up from 00:00.

5. Touch <OK> to confirm the selections or <Cancel> to return to the Patient Setup Information screen without making changes. Touch <NEXT> to advance to the Random Control Training screen.

6. On the Random Control Training screen, there are two settings that can be adjusted to challenge the patient. The <Circle Speed> button allows the user to toggle between three different speeds for the target to move about the circular grid. For example, the single green circle setting denotes the slowest or least challenging setting. Touch the <Skill Level> button to increase or decrease the target size. The target is the red circle that will start off in the center of the grid. The larger the target, the easier it will be for the patient to keep the cursor inside its boundary as it randomly moves about the grid.

Figure 5.11. The Random Control Training Screen.

7. At any time during the training session, the tracing biofeedback can be turned on or off by touching the <Show Tracing> icon (the left-most icon under Tracing). Press the <Clear Tracing> eraser icon (the right-most icon under Tracing) to remove any tracing that is left from a previous exercise session. The cursor will still be seen.

8. Explain the training protocol to the patient (i.e., that the patient should move the cursor along with the randomly moving red target circle, keeping it inside the circle as much as possible.). Touch the <Magnifying Glass> icon to enlarge the screen if desired. Press <Start> to begin the training session. The elapsed time from the start of the training session is shown at the top right of the display and a running patient score is provided in the upper right corner.

9. Scoring is percentage-based and equals the total time the patient is able to keep the cursor inside the target circle.

10. To stop the training session at any time, press <Stop> on the display. The system will stop gathering data and the platform will return to the locked position.

11. When the training screen has been reviewed, touch <Print Results> to print the results of the session, or <Save Results> to save the training session. If a patient identifier was not entered at the start of the session (i.e., a name or an ID number), it must be entered now in order to save the results of the session.

12. After printing or reviewing the screen, press <Start> to immediately begin another training session using the same parameters, or press <Back> to return to the Patient Setup screen.

6. Testing

Static testing measures the angular excursion of the patient's Center of Gravity (COG). Body height is a factor for static measures. A person's COG is approximately 55% of their height. Based on a selected height, an appropriate static measure scaling is applied. Testing in this mode is ideal for baseline testing for movement disorder, vestibular dysfunction, and orthopedic patients. Good static testing scores can lead to a progression into dynamic testing and training.

Test formats include Sensory Integration (m-CTSIB, BESS), Postural Stability, Bilateral Comparison (i.e., comparison of postural stability performance of standing on one leg versus standing on the other), Limits of Stability, and Motor Control. There is an option for selecting a customized protocol.

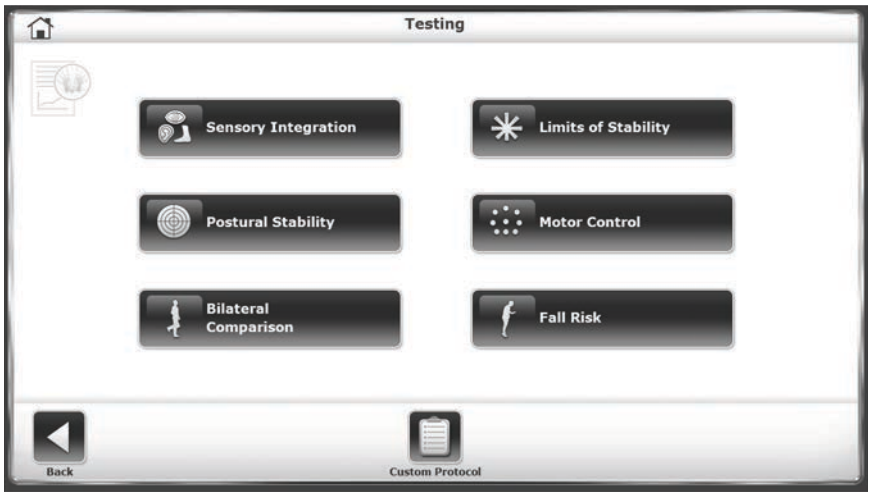

Figure 6.1. The Testing Menu Screen.

Sensory Integration Tests

Touching the Sensory Integration button displays a submenu where the user can select either a m-CTSIB or BESS test. If one or more Customized Sensory Integration tests have been created, a button (or buttons) for those tests are displayed on the Sensory Integration submenu. Custom Sensory protocols are based on either the m-CTSIB or BESS test.

The process of creating Custom Sensory integration tests are covered in the System Utilities section of this manual.

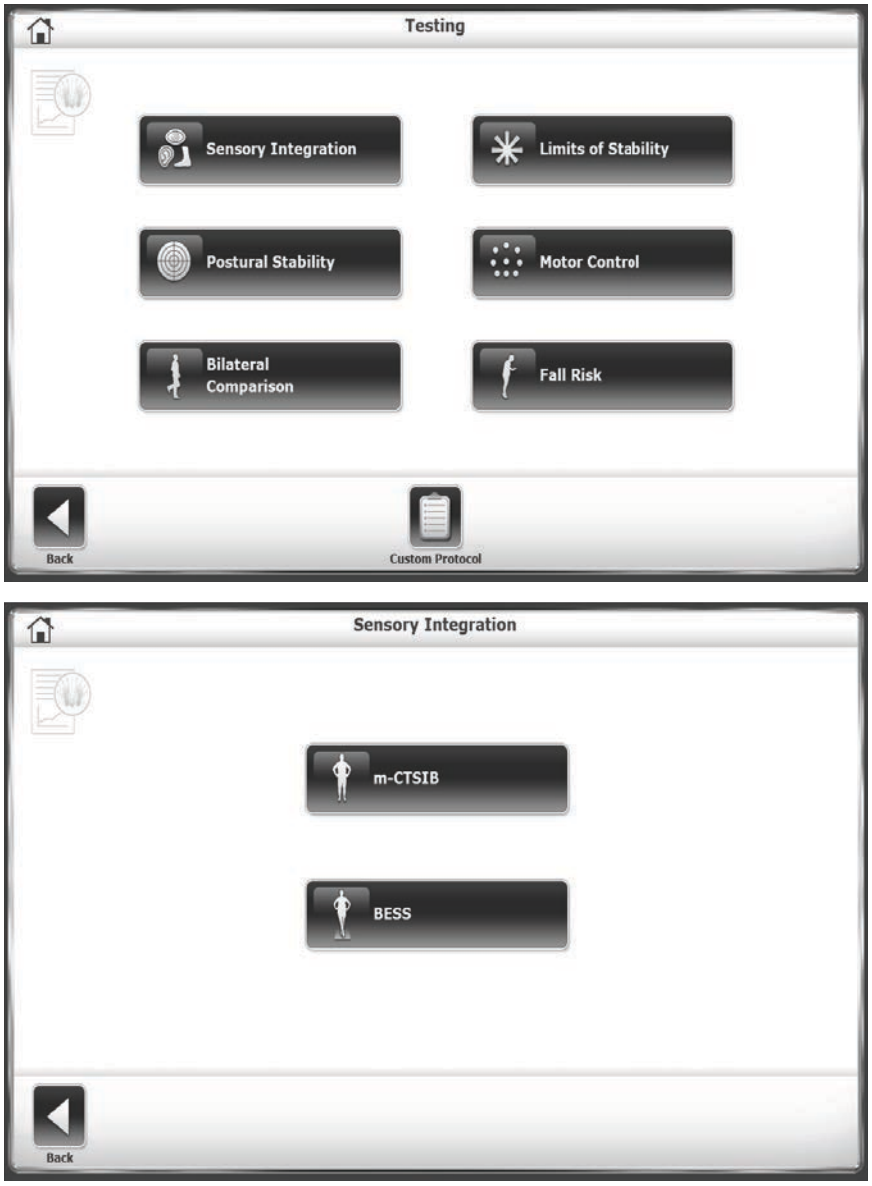

Figure 6.2. Sensory Integration Submenu Screen.

Clinical Test of Sensory Integration and Balance – CTSIB or m-CTSIB (Modified CTSIB)

The Clinical Test of Sensory Interaction and Balance (CTSIB) is a standardized test for balance assessment on a static surface. The CTSIB test protocol is well documented as an effective test for identifying individuals with mild to severe balance problems. The test provides a generalized assessment of how well a patient can integrate various sensory conditions during a balance test. The test accounts for how well the patient compensates when one or more of those sensory conditions are compromised. The CTSIB consists of six conditions:

Table 6.1. Clinical Test of Sensory Interaction and Balance (CTSIB)

Condition:	Sensory Condition:	Input:
1	Eyes open/firm surface	Incorporates visual, vestibular and somatosensory inputs. This is considered the baseline condition.
2	Eyes closed/firm surface	Eliminates visual input to evaluate vestibular and somatosensory inputs.
3	Visual conflict/firm surface	Some vision input present but information conflicts with vestibular information. This condition relies on more vestibular and somatosensory inputs.
4	Eyes open/dynamic surface	Used to evaluate somatosensory interaction with visual input.
5	Eyes closed/dynamic surface	Used to evaluate somatosensory interaction with vestibular input.
6	Visual conflict/dynamic surface	Used to evaluate the mediation of visual with and vestibular and somatosensory inputs.

Another version of this test, called the modified CTSIB, or m-CTSIB, is often used. The m-CTSIB eliminates conditions 3 and 6. Biodex balance products use the m-CTSIB format of four conditions (#'s 1, 2, 4, and 5) as the default with the option to include the other two if desired.

A Note Concerning Eye Glasses for the Visual Conflict Condition:

Clinicians who want to perform the Visual Conflict conditions will require some type of glasses that provide a distorted yet transparent image. Commercially available prism type glasses are commonly used. Other improvised glasses are: 3D glasses, or clear safety glasses in which the lenses have been marred or covered with Scotch™ type tape.

What is being measured during the CTSIB test?

- Sway Index
- Stability Index

The Sway Index is really the standard deviation of the Stability Index. The higher the Sway Index the more unsteady the person was during the test. The Sway Index is an objective quantification of what commonly is performed with a time-based pass/fail for completing the CTSIB stage in 30 seconds without falling or assigning a value of 1 to 4 to characterize the sway; 1= minimal sway, 4 = a fall.

The Stability Index is the average position from the center. The Stability index does not indicate how much the patient swayed; only their position. Consider the following example:

If a patient is positioned in a manner that biases placement from the center, the Stability Index will be a large value. However, if the patient swayed very little, the standard deviation would be low. This is evident when viewing the COG plots. A patient could have a score of 6.5, yet the standard deviation would only be .8. The printout tracing will show the patient did not sway very much. However, if the patient were positioned off-center, or even on center, and swayed a lot, the standard deviation would be higher. Thus the standard deviation is indicative of sway.

If a patient cannot complete a condition, it is noted as DNC (Did Not Complete) on results screen and report. Specific information on the Stability Index can be found in the Appendices.

***NOTE**: A standardized indexed foam pad that matches the size of the BioSway platform is provided. The foam pad should be used for the dynamic (foam) surface conditions in the CTSIB test.*

Performing an m-CTSIB Test

Prior to conducting an m-CTSIB test, check to ensure that the most desirable normative data set currently associated with the test is in place. For instance, if testing a high school athlete, the "M & F (male and female), Age 13-18, 20 sec trial" normative data may be wanted. For instructions on configuring normative data, see the System Utilities section of this document. In summary, the steps are to (starting at the main screen) select the following options from the screens as they are displayed:

- Utilities
- Configuration
- BioSway Configuration
- Sensory Integration Defaults
- m-CSTIB Defaults

At the m-CTSIB Defaults screen, use the drop-down menu to select the desired normative data set, or begin populating the fields with the facility's normative data. If adding the facility's own data, be sure to save the normative data set with a name that will be easy for others to recognize.

1. At the Main Menu, touch <Testing>.
2. Touch<Sensory Integration>.
3. Touch <m-CTSIB>. The Patient Setup information screen is displayed. If this is a new patient and the training session is to be saved after its completion, the patient's name and height must be entered. If the training session does not need to be saved, designate a height value, which will be correlated with normative data for scoring purposes.
4. Touch <Test Options> to advance to the m-CTSIB Testing Options screen if desired.
5. Here the test trial time can be set, the sensory conditions to be tested can be selected, the number of trials can be entered, and the rest countdown time (i.e., the time between trials) can be entered.
6. Use the <▲> or <▼> keys to set the total Test Trial Time in five-second increments down to a minimum of ten seconds (during the test the system will count down from the time setting selected).
7. To select the sensory conditions to be included in the test, touch the checkboxes next to the desired conditions. The four conditions in an m-CTSIB will be selected by default.
8. To set the Number of Trials or Rest Countdown, touch the appropriate key and enter the setting from the keypad displayed.
9. To have either the cursor or tracing biofeedback displayed during the test, touch the checkboxes next to the options.
10. To have the patient record a foot position for the test, touch the checkbox next to Record Foot Position.

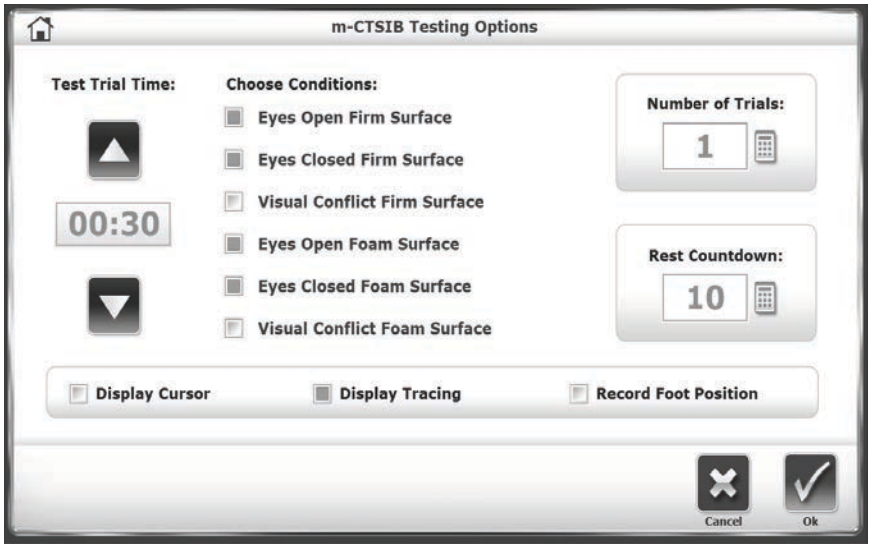

Figure 6.3. m-CTSIB Testing Options Screen.

11. Touch <OK> to confirm the selections and return to the Patient Setup screen.
12. Press <Next> to advance to the m-CTSIB Testing screen. Or, if the Record Foot Position checkbox was checked, it will advance to the Position Patient screen (see Figure 6.7).
13. On Position Patient screen, the dot on the Position Patient screen represents the patient's Center of Gravity. Have the patient stand in a natural stance, slightly adjusting foot placement until the dot is on or close to the center axis. Using the four keypads, enter the patient's left foot, left heel, right foot, and right heel positions using the midline of the foot and the platform grid as reference points. As a reference, use the table below for foot positioning based on patient height:[2]

Table 6.2. Patient Foot Placement

Height Default:	Foot Angle:	Heel Position:
< 53"	10/10	F7/F15
53 – 59"	10/10	E7/E15
59 – 65"and 65 – 73"	10/10	D67/D16
73" +	10/10	C5/C17

14. Touch <Next> to advance to the m-CTSIB Testing screen.

[2] IBID.

Figure 6.4. m-CTSIB Testing Screen.

15. With the patient ready to begin the test, touch <Start> and <Collect Data>. The screen will provide a three-second countdown before beginning each test trial. The display screen will include Test Trial Time, the Score, what number Trial is occurring, and the Condition that is being tested. If desired, at this point, touch the <Magnifying Glass> icon to enlarge the grid circle.
16. If desired, touch the <Show Tracing> icon (the left-most icon under Tracing). Press the <Clear Tracing> eraser icon (the right-most icon under Tracing) to remove any tracing that is left from a previous training session.

    ***NOTE**: To stop a test in progress at any time, touch <Stop>.*
17. When the first condition is finished, the screen will display "Trial 1 Complete / Prepare for Condition 2" and a rest countdown will begin for the second condition. Touch <Collect Data> to begin the second condition and continue in the same manner to complete subsequent conditions.
18. When the first trial is finished, the screen will display "Trial 1 Complete," and a rest countdown will begin for the second trial. Touch <Collect Data> to begin the first condition of the second test trial and continue in the same manner to complete subsequent trials.
19. After completing all trials, a "Test Complete" message is displayed. Touch <Results> to advance to the m-CTSIB Test Results screen.
20. At the m-CTSIB Test Results screen, touch <Print> to automatically generate a printed report if desired.
21. To save the test data, touch <Save Results> and touch <OK> in response to the "Save Results for later reporting or export?" prompt. The system will display "Save Results Completed" after the results are saved. If a patient identifier was not entered at the start of the session (i.e., a name or an ID number), it will need to be entered now in order to save the results of the session.
22. To return to the Opening Menu from the Test Results screen touch the <Home> icon in the upper left corner.

BESS Test

During a BESS test, balance tasks are performed on both a level surface and a foam pad. The BioSway BESS test is an enhanced version of the more traditional BESS test. In a traditional BESS test, scoring is time and error based. With the BioSway's force platform technology, time and error counting is replaced with an objective quantification of sway. Errors can be noted but do not count in scoring.

NOTE: *Typically, the conditions of the BESS test are conducted with eyes closed. Practitioners should never leave the patient unattended during testing.*

Performing a BESS Test

1. At the Main Menu, touch <Testing> and <Sensory Integration>.
2. Touch <BESS>. The Patient Setup information screen is displayed. If this is a new patient and the training session is to be saved after its completion, the patient's name and height must be entered. If the training session does not need to be saved, designate a height value, which will be correlated with normative data for scoring purposes.
3. Touch <Test Options> to advance to the BESS Testing Options screen if desired.
4. Here the test trial time can be set, the sensory conditions to be tested can be selected, the number of trials can be entered, and the rest countdown time (i.e., the time between trials) can be entered.
5. Use the <▲> or <▼> keys to set the total Test Trial Time in five-second increments down to a minimum of ten seconds. During the test the system will count down from the time setting selected.
6. To select what sensory conditions should be included in the test, touch the checkboxes next to the desired conditions. All six conditions will be selected by default.
7. To set the Number of Trials or Rest Countdown, touch the appropriate key and enter the setting from the displayed keypad.
8. To display either the cursor or tracing biofeedback during the test, touch the checkboxes next to the options.
9. To have the patient record their foot position for the test, touch the checkbox next to Record Foot Position.
10. To manually note errors during each session (e.g., the patient grabs hold of the device handrails), touch the checkbox next to Error Scoring.

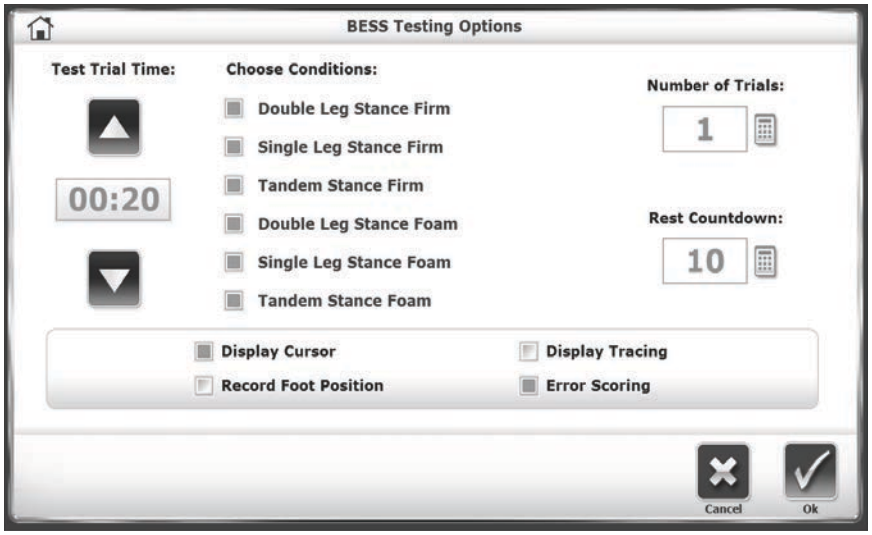

Figure 6.5. BESS Testing Options Screen.

11. Touch <OK> to confirm the selections and return to the Patient Setup screen.
12. Press <Next> to advance to the BESS Testing screen. Or, if Record Foot Position was checked, it will advance to the Position Patient screen (see Figure 6.7).
13. The dot on the Position Patient screen represents the patient's Center of Gravity. Have the patient stand in a natural stance, slightly adjusting foot placement until the dot is on or close to the center axis. Using the four keypads, enter the patient's left foot, left heel, right foot and right heel positions using the midline of the foot and the platform grid as reference points. As a reference, use the table below for foot positioning based on patient height: [3]

Table 6.3. Patient Foot Placement Table

Height Default:	Foot Angle:	Heel Position:
< 53"	10/10	F7/F15
53 – 59"	10/10	E7/E15
59 – 65"and 65 – 73"	10/10	D67/D16
73" +	10/10	C5/C17

[3] IBID.

14. Touch <Next> to advance to the BESS Testing screen.

Figure 6.6. BESS Test Screen.

15. With the patient ready to begin the test, touch <Start> and <Collect Data>. The screen will provide a three-second countdown before beginning each test trial. The display screen will include Test Trial Time, the Score, what number Trial is occurring, and the Condition that is being tested. If desired, touch the <Magnifying Glass> icon to enlarge the grid circle.

    If desired, touch the <Show Tracing> icon (the left-most icon under Tracing). Press the <Clear Tracing> eraser icon (the right-most icon under Tracing) to remove any tracing that is left from a previous training session.

    ***NOTE**: To stop a test in progress at any time, touch <Stop>.*

16. When the first condition is finished, the screen will display "Trial 1 Complete / Prepare for Condition 2" and a rest countdown will begin for the second condition. Touch <Collect Data> to begin the second condition and continue in the same manner to complete subsequent conditions.

17. When the first trial is finished, the screen will display "Trial 1 Complete," and a rest countdown will begin for the second trial. Touch <Collect Data> to begin the first condition of the second test trial and continue in the same manner to complete subsequent trials.

18. After completing all trials, a "Test Complete" message is displayed. Touch <Results> to advance to the BESS Test Results screen.

19. At the BESS Test Results screen, touch <Print> to automatically generate a printed report if desired.

20. To save the test data, touch <Save Results> and touch <OK> in response to the "Save Results for later reporting or export?" prompt. The system will display "Save Results Completed" after the results are saved. If a patient identifier was not entered at the start of the session (i.e., a name or an ID number), it will need to be entered now in order to save the results of the session.

21. To return to the Opening Menu from the Test Results screen touch the <Home> icon in the upper left corner.

Postural Stability Test

The Postural Stability test emphasizes a patient's ability to maintain a center of balance. The patient's score on this test assesses deviations from center, thus a lower score is more desirable than a higher score.

Platform stability can be varied during a test by selecting <More Options> from the Postural Stability Testing screen. Clinicians can set trial time, number of trials, and rest countdown times.

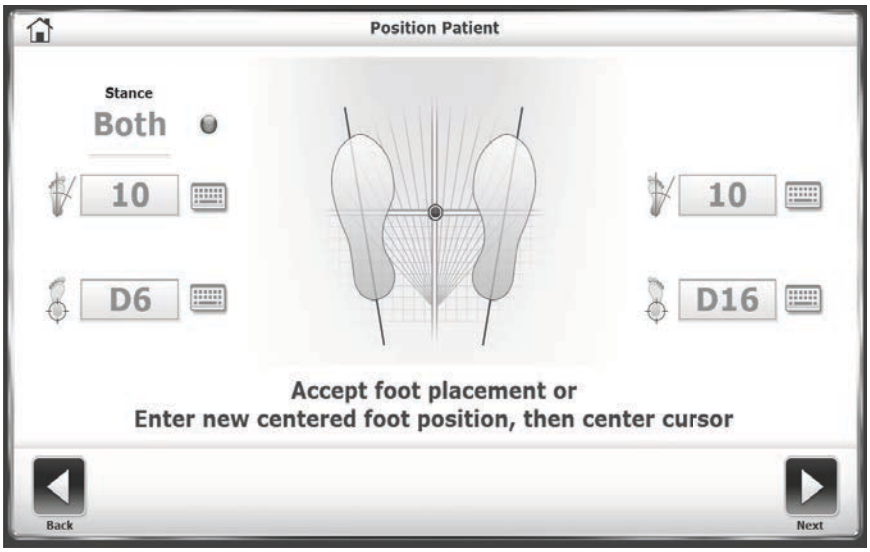

Figure 6.7. The Patient Position Screen with Patient Positions Entered.

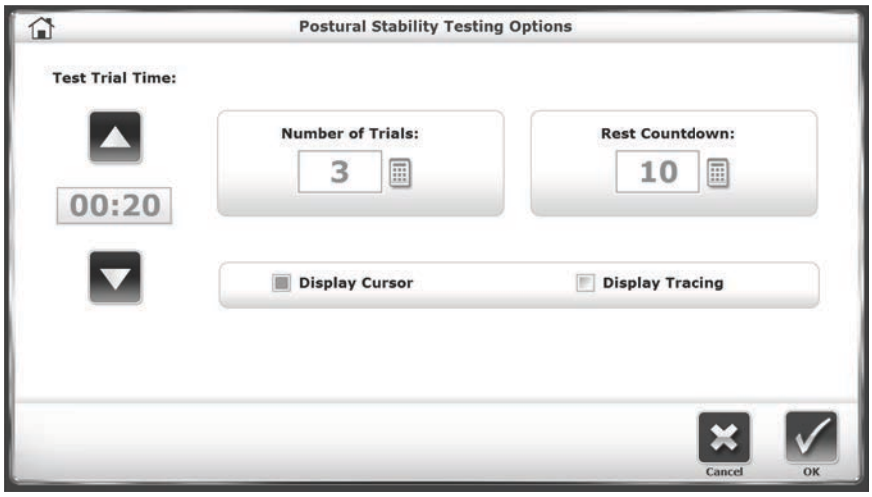

Figure 6.8. The Postural Stability Testing Options Screen.

Figure 6.9. The Postural Stability Testing Screen.

Performing a Postural Stability Test

1. At the Main Menu, touch <Testing>.
2. Touch <Postural Stability>. The Patient Setup information screen is displayed. If this is a new patient and the training session is to be saved after its completion, the patient's name and height must be entered. If the training session does not need to be saved, designate a height value, which will be correlated with normative data for scoring purposes.
3. Touch <Test Options> to advance to the Postural Stability Testing Options screen if desired.
4. Here the test trial time can be set, the sensory conditions to be tested can be selected, the number of trials can be entered, and the rest countdown time (i.e., the time between trials) can be entered.
5. Use the <▲> or <▼> keys to set the total Test Trial Time in five-second increments down to a minimum of ten seconds. During the test the system will count down from the time setting selected.
6. To set the Number of Trials or Rest Countdown, touch the appropriate key and enter the setting from the keypad displayed.
7. To have either the cursor or tracing biofeedback displayed during the test, touch the checkboxes next to the options.
8. Touch <OK> to confirm the selections and return to the Postural Stability Testing screen.
9. Touch <Next> to display the Position Patient screen.
10. The dot on the Position Patient screen represents the patient's Center of Gravity. Have the patient stand in a natural stance, slightly adjusting foot placement until the dot is on or close to the center axis. Using the four keypads, enter the patient's left foot, left heel, right foot and right heel positions using the midline of the foot and the platform grid as

reference points. As a reference, use the table below for foot positioning based on patient height:[4]

Table 6.4. Patient Foot Placement Table

Height Default:	Foot Angle:	Heel Position:
< 53”	10/10	F7/F15
53 – 59”	10/10	E7/E15
59 – 65”and 65 – 73”	10/10	D67/D16
73” +	10/10	C5/C17

11. Touch <Next> to advance to the Postural Stability Testing screen.
12. If desired, touch the <Show Tracing> icon (the left-most icon under Tracing). Press the <Clear Tracing> eraser icon (the right-most icon under Tracing) to remove any tracing that is left from a previous training session.
13. Press <Start> to activate the Postural Stability Test screen.
14. With the patient ready to begin the test, touch <Collect Data>. The screen will provide a three-second countdown before beginning the first of three test trials. (The number of trials can be set on the Test Options screen, but the default is three.) The display screen will include the Trial Time and Platform Setting. Trial Number and score are displayed. If desired, touch the <Magnifying Glass> icon to enlarge the grid circle.

    ***NOTE**: To stop a test in progress at any time and return to the Postural Stability Testing screen with the platform locked, touch <Stop>.*
15. When the first trial is finished, the screen will display "Trial 1 Complete," the platform will return to the locked position, and a rest countdown will begin for the second trial. Touch <Collect Data> to begin the second test trial and continue in the same manner to complete subsequent trials.
16. After completing the test, a "Test Complete" message is displayed. Touch <Results> to advance to the Postural Stability Test Results screen.
17. At the Postural Stability Test Results screen, touch <Print> to automatically generate a printed report if desired.
18. To save the test data, touch <Save Results> and touch <OK> in response to the "Save Results for later reporting or export?" prompt. The system will display "Save Results Completed” after the results are saved. If a patient identifier was not entered at the start of the session (i.e., a name or an ID number), it will need to be entered now in order to save the results of the session.

[4] IBID.

19. To return to the Opening Menu from the Postural Stability Test Results screen touch the <Home> icon in the upper left corner.

Suggested Protocol for General Postural Stability Balance Testing

Test Protocol Commonly Used in Postural Stability Testing:

- Test Duration: 20 seconds
- Stance: Two Leg

Reliability studies and other significant research have been performed for this protocol. Three or four trial repetitions should be performed prior to testing.

The patient's performance is noted as a stability index. The stability index represents the variance of platform displacement in degrees from level. A high number is indicative of a lot of motion, which is indicative of the patient having trouble balancing. Differences between right and left limbs can be noted.

Orthopedic problems often present as neuromuscular control problems. This can be seen in single leg testing (involved versus uninvolved.) Balance training can improve patient control.

Geriatric patients can be tested for excessive sway. The direction of the sway is important with regards to the predisposition of a fall direction. Falling to either side significantly increases the chances of a hip fracture[5].

Limits of Stability (LOS) Test

This test challenges patients to move and control their center of gravity within the base of support. During each test trial, patients must shift their weight to move the cursor from the center along a target path and back as quickly and with as little deviation as possible. The same process is repeated for each of the targets. Target paths activate in a random order.

This test is a good indicator of dynamic control within a normalized sway envelope. Poor control, inconsistent, or increased times suggests further assessment for lower extremity strength, proprioception, vestibular, or visual deficiencies.

The patient's Limits of Stability is measured as how far from the center the patient can sway. This (sway) Angle (°) is displayed on the screen. The Angle (°) is derived from the position of the patient's center of gravity (COG) taken from a center position of zero and the estimated height of the patient's COG taken as .55 times the patient height (see Appendix A for more details on the scoring formula).

[5] See References 1, 2, and 3 in Chapter 11.

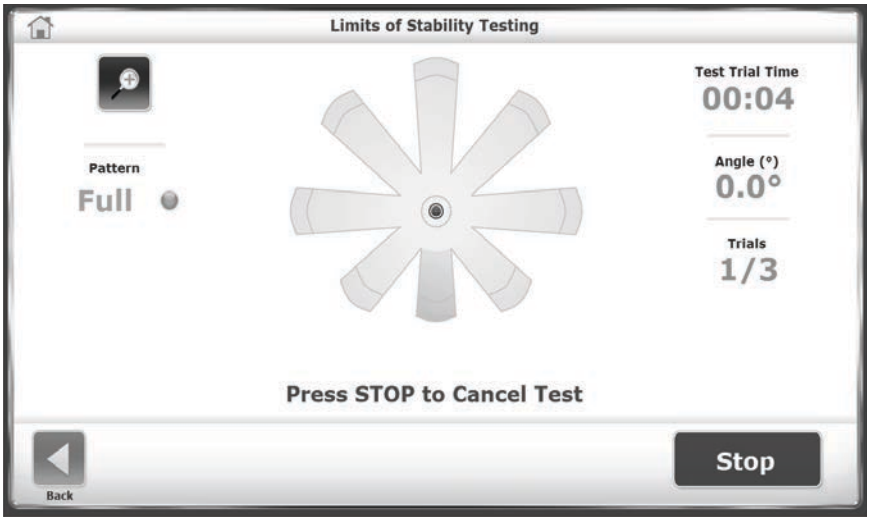

Figure 6.10. The Limits of Stability Testing Screen.

Performing a Limits of Stability Test

1. At the Main Menu, touch <Testing>.
2. Touch <Limits of Stability>. The Patient Setup Information screen is displayed. If this is a new patient and the training session is to be saved after its completion, the patient's name and height must be entered. If the training session does not need to be saved, designate a height value, which will be correlated with normative data for scoring purposes.
3. Touch <Test Options> to advance to the Limits of Stability Testing Options screen if desired. Here the test trial time can be set, the sensory conditions to be tested can be selected, the number of trials can be entered, and the rest countdown time (i.e., the time between trials) can be entered.

Figure 6.11. The Limits of Stability Testing Options Screen.

4. To set the Number of Trials or Rest Countdown, touch the appropriate key and enter the setting from the keypad displayed.

5. Touch <OK> to confirm the selections and return to the Patient Setup screen.
6. Touch <Next> to display the Position Patient screen. The dot on the Position Patient screen represents the patient's Center of Gravity. Have the patient stand in a natural stance, slightly adjusting his or her foot placement until the dot is on or close to the center axis. Using the four keypads, enter the patient's left foot, left heel, right foot and right heel positions using the midline of the foot and the platform grid as reference points.[6]

Table 6.5. Patient Foot Placement Table

Height Default:	Foot Angle:	Heel Position:
< 53"	10/10	F7/F15
53 – 59"	10/10	E7/E15
59 – 65"and 65 – 73"	10/10	D67/D16
73" +	10/10	C5/C17

7. Touch <Next> to advance to the Limits of Stability Testing screen.
8. At the Limits of Stability Testing screen, touch the blue <Pattern> button to toggle between Full, Left, or Right target orientations.
9. Press <Start> to activate the Limits of Stability Test screen.
10. With the patient ready to begin the test, touch <Collect Data>. The screen will provide a three-second countdown before beginning each test trial. The display screen will include Test Trial Time (counts up), Angle, and Number of Trials. If desired, touch the <Magnifying Glass> icon to enlarge the grid circle. If desired, touch the <Magnifying Glass> icon to enlarge the grid circle. During each test trial, patients must shift their weight to move the cursor from the center along a target path and back as quickly and with as little deviation as possible. The same process is repeated for each of the targets. After completing each target path, return to center and hold for three seconds before the next target path appears. Target paths activate in a random order.

    ***NOTE**: To stop a test in progress at any time and return to the Limits of Stability Testing screen with the platform locked, touch <Stop>.*

11. Each trial is finished when the patient has completed all of the paths-or the time set in the Test Options screen has elapsed. When the first trial is finished, the screen will display "Trial 1 Complete," and a ten-second rest countdown will begin for the second trial. Touch <Collect Data> to begin the second test trial and continue in the same manner to complete subsequent trials.
12. After completing all trials, a "Test Complete" message is displayed. Touch <Results> to advance to the Limits of Stability Test Results screen.

[6] IBID.

13. At the Limits of Stability Test Results screen, touch <Print> to automatically generate a printed report if desired.

14. To save the test data, touch <Save Results> and touch <OK> in response to the "Save Results for later reporting or export?" prompt. The system will display "Save Results Completed" after the results are saved. If a patient identifier was not entered at the start of the session (i.e., a name or an ID number), it will need to be entered now in order to save the results of the session.

15. To return to the Opening Menu from the Limits of Stability Test Results screen, touch the <Home> icon in the upper left corner.

Motor Control Test

Similar to the Limits of Stability test, this test challenges patients to move and control their center of gravity within a base of support. During each test trial, patients must shift their weight to move the cursor from the center target to a blinking target and back as quickly and with as little deviation as possible. The same process is repeated for each of the targets. Targets on the screen blink in random order. Three skill levels allow the targets to be grouped closer together or spread further apart, and the platform setting can be static or dynamic.

This test is a good indicator of dynamic control within a normalized sway envelope. Poor control, inconsistent or increased times suggests further assessment for lower extremity strength, proprioception, vestibular or visual deficiencies. The default setting for the Motor Control test is the moderate still level.

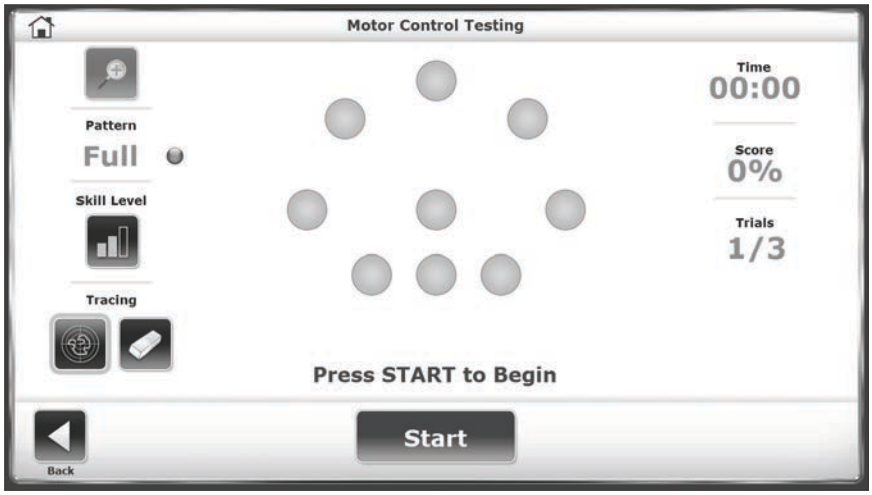

Figure 6.12. The Motor Control Testing Screen.

Performing a Motor Control Test

1. At the Main Menu, touch < Testing>.
2. Touch <Motor Control>. The Patient Setup Information screen is displayed. If this is a new patient and the training session is to be saved after its completion, the patient's name and height must be entered. If the training session does not need to be saved, designate a height value, which will be correlated with normative data for scoring purposes.

3. Touch <Test Options> to advance to the Motor Control Testing Options screen if desired. Here the test trial time can be set, the sensory conditions to be tested can be selected, the number of trials can be entered, and the rest countdown time (i.e., the time between trials) can be entered.
   - To set the Number of Trials or Rest Countdown, touch the appropriate key and enter the setting from the keypad displayed.
   - To set the Motor Control Hold Time, use the <▲> or <▼> keys to select a time, ranging from .25 to 5 full seconds.
4. Touch <OK> to confirm the selections and return to the Patient Setup screen.

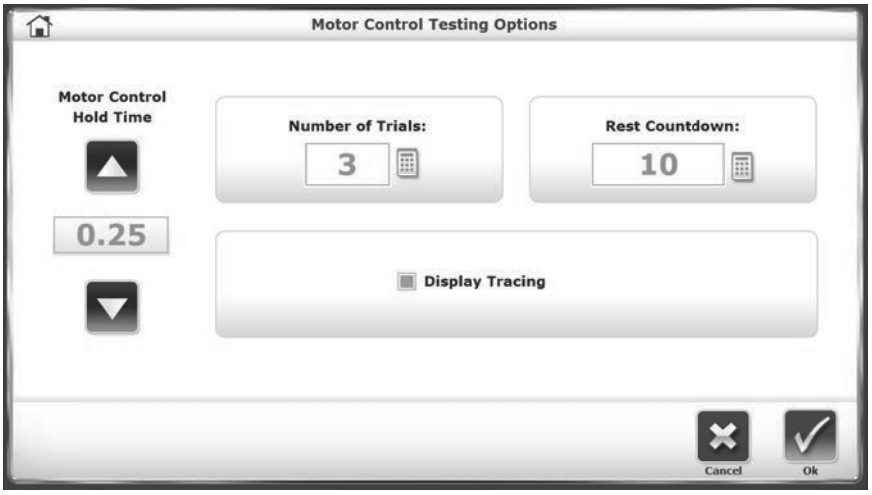

Figure 6.13. The Motor Control Testing Options Screen.

5. Touch <Next> to display the Position Patient screen. The dot on the Position Patient screen represents the patient's Center of Gravity. Have the patient stand in a natural stance, slightly adjusting his or her foot placement until the dot is on or close to the center axis. Using the four keypads, enter the patient's left foot, left heel, right foot and right heel positions using the midline of the foot and the platform grid as reference points. [7]

Table 6.6. Patient Foot Placement Table

Height Default:	Foot Angle:	Heel Position:
< 53"	10/10	F7/F15
53 – 59"	10/10	E7/E15
59 – 65"and 65 – 73"	10/10	D67/D16
73" +	10/10	C5/C17

[7] IBID.

6. Touch <Next> to advance to the Motor Control Testing screen.
7. At the Motor Control Testing screen, touch the blue <Pattern> button to toggle between Full, Left, or Right target orientations.
8. Touch the <Skill Level> icon to toggle between Easy, Moderate, or Difficult target orientations (with the most-spread-out targets being the most difficult).
9. If desired, touch the <Show Tracing> icon (the left-most icon under Tracing). Press the <Clear Tracing> eraser icon (the right-most icon under Tracing) to remove any tracing that is left from a previous training session.
10. Press <Start> to activate the Motor Control Test screen.
11. With the patient ready to begin the test, touch <Collect Data>. The screen will display a three-second countdown before beginning each test trial. The display screen will include Test Trial Time, the Score, what number Trial is occurring, and the Platform Setting. If desired, touch the <Magnifying Glass> icon to enlarge the grid circle.

    ***NOTE**: The Score in a Motor Control test is derived from how straight a path the patient moves the cursor between the targets. For more information on this calculation, refer to Appendix A.*

    ***NOTE**: To stop a test in progress at any time and return the platform to a locked position, touch <Stop>.*
12. When the first trial is finished, the screen will display "Trial 1 Complete," and a ten-second rest countdown will begin for the second trial (ten seconds is the default time; this can be adjusted in the Test Options function). Touch <Collect Data> to begin the second test trial and continue in the same manner to complete subsequent trials.
13. After completing all trials, a "Test Complete" message is displayed. Touch <Results> to advance to the Motor Control Test Results screen.
14. At the Motor Control Test Results screen, touch <Print> to automatically generate a printed report if desired.
15. To save the test data, touch <Save Results> and touch <OK> in response to the "Save Results for later reporting or export?" prompt. The system will display "Save Results Completed" after the results are saved. If a patient identifier was not entered at the start of the session (i.e., a name or an ID number), it will need to be entered now in order to save the results of the session.
16. To return to the Opening Menu from the Motor Control Test Results screen touch the
17. <Home> icon in the upper left corner.

Bilateral Comparison Test

Like the m-CTSIB test, this test measures patients' sway index. However, in a Bilateral Comparison test, the patient is standing on one leg in the middle of the platform for a predetermined time after which the patient performs the same test standing on the other leg. Clinicians can use the comparative data to draw conclusions about possible treatments for the injured limb.

Performing a Bilateral Comparison Test

1. At the Main Menu, touch <Testing>.
2. Touch <Bilateral Comparison>. The Patient Setup Information screen is displayed. If this is a new patient and the training session is to be saved after its completion, the patient's name and height must be entered. If the training session does not need to be saved, designate a height value, which will be correlated with normative data for scoring purposes.
3. Touch <Test Options> to advance to the Bilateral Comparison Testing Options screen if desired. Here the test trial time can be set, the sensory conditions to be tested can be selected, the number of trials can be entered, and the rest countdown time (i.e., the time between trials) can be entered.
4. Use the <▲> or <▼> keys to set the total Test Trial Time in five-second increments down to a minimum of ten seconds. During the test, the system will count down from the time setting selected.
5. To set Initial or Ending Platform Stability (static, 1 is the next most stable, 12 is least stable,) touch the appropriate key and enter the setting from the keypad displayed. Touch <OK> to return to the Bilateral Comparison Testing Options screen and set the Ending Platform Stability in the same manner.
6. To set the Number of Trials or Rest Countdown, touch the appropriate key and enter the setting from the displayed keypad.
7. To have either the cursor or tracing biofeedback displayed during the test, touch the checkboxes next to the choices.
8. Touch <OK> to confirm the selections and return to the Patient Setup screen.

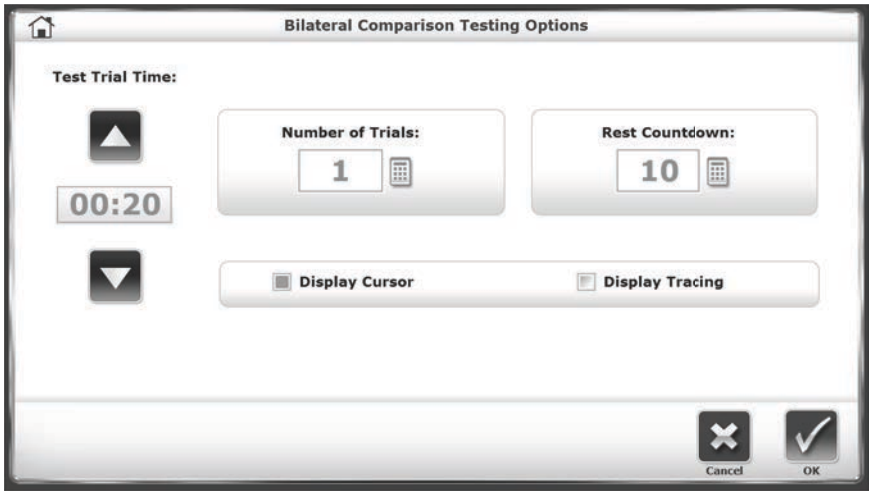

Figure 6.14. The Bilateral Comparison Testing Options Screen.

9. Touch <Next> to advance to the Bilateral Comparison Testing screen.
10. If desired, touch the <Show Tracing> icon (the left-most icon under Tracing). Press the <Clear Tracing> eraser icon (the right-most icon under Tracing) to remove any tracing that is left from a previous training session.
11. Press <Start> to activate the Bilateral Comparison Test screen.
12. With the patient ready to begin the test, touch <Collect Data>. The screen will provide a three-second countdown before beginning each test trial. The display screen will include

Test Trial Time, the Sway Index, what number Trial is occurring, and the Platform Setting. If desired, touch the <Magnifying Glass> icon to enlarge the grid circle.

13. Please note, directly under the grid circle is an indicator of which leg is being tested. There are two tests in each trial; one for each leg.

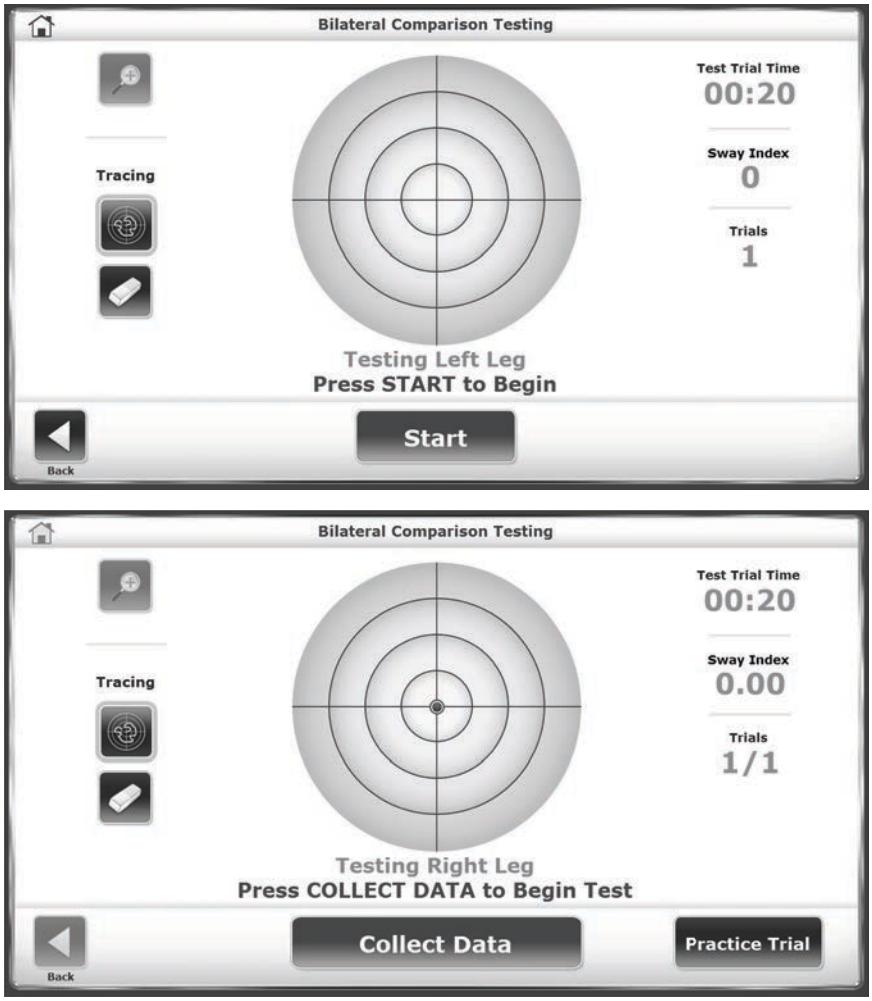

Figure 6.15. The Bilateral Comparison Testing Screens--One for Each Leg.

***NOTE**: To stop a test in progress at any time and return the platform to a locked position, touch <Stop>.*

14. When the first trial is finished, the screen will display "Trial 1 Complete," and a ten-second rest countdown will begin for the second trial. (Note: ten seconds is the default time; this can be adjusted in the Test Options.) Touch <Collect Data> to begin the second test trial and continue in the same manner to complete subsequent trials.
15. After completing all trials, a "Test Complete" message is displayed. Touch <Results> to advance to the Bilateral Comparison Test Results screen.
16. At the Bilateral Comparison Test Results screen, touch <Print> to automatically generate a printed report if desired.

17. To save the test data, touch <Save Results> and touch <OK> in response to the "Save Results for later reporting or export?" prompt. The system will display "Save Results Completed" after the results are saved. If a patient identifier was not entered at the start of the session (i.e., a name or an ID number), it will need to be entered now in order to save the results of the session.
18. To return to the Opening Menu from the Bilateral Comparison Test Results screen, touch the Home> icon in the upper left corner.

Fall Risk Test

Falls are a common occurrence among older people, even for those in good health and with no apparent balance problems[8,9]. The BioSway System Fall Risk test allows identification of potential fall candidates. Test results are compared to age-dependent normative data. Scores higher than normative values suggest further assessment for lower extremity strength, proprioception, and vestibular or visual deficiencies.

With force platform technology, an objective quantification of the patient's postural sway velocity can be used to predict risk.[10,11,12] Velocity can be described as the *speed* of an individual's sway as balance is maintained. Higher velocities, when cues are given to specifically stand as motionless as possible, are suggestive of postural control deficits.

The Fall Risk test protocol is based on research from the University of Dayton (Bigelow, et al[13]) and the University of Jyväskylä in Finland (Pajala, et al[14]). Once adopted into the Biodex Balance products as a test, a reliability study of this protocol was conducted by Bryan Riemann, PhD, and Kelsey Piersol, MSSM, of Armstrong State University[15]. With a reliable test and protocol, normative data was established. Please see the Normative Data section of this document for more details on this research.

NOTE: *Typically, one of the conditions of the Fall Risk test is conducted with the patient's eyes closed and another one is conducted with the patient in a narrow stance. Practitioners should never leave the patient unattended during testing.*

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[8] Stel VS, Smit JH, Pluijm SM, Lips P. Balance and mobility performance as treatable risk factors for recurrent falling in older persons. *J Clin Epidemiol*. 2003;56:659–668.

[9] Hill K, Schwarz J, Flicker L, Carroll S. Falls among healthy, community-dwelling, older women: a prospective study of frequency, circumstances, consequences and prediction accuracy. *Aust N Z J Public Health*. 1999;23:41–58.

[10] Thapa PB, Gideon P, Brockman KG, Fought RL, Ray WA. Clinical and biomechanical measures of balance as fall predictors in ambulatory nursing home residents. J Gerontol Med Sci. 1996;51A:M239–M246.

[11] Bergland A, Wyller TB. Risk factors for serious fall related injury in elderly women living at home. *Inj Prev.* 2004;10:308–313. 5 - Stel VS, Smit JH, Pluijm SM, Lips P.

[12] Kannus P, Sievanen H, Palvanen M, Parkkari J. Prevention of falls and consequent injuries in elderly people. Lancet. 2005;366:1885-1893.

[13] Bigelow KE, Berme N. Development of a protocol for improving the clinical utility of posturography as a fall-risk screening tool. *J Gerontol A Biol Sci Med Sci*. 2011;66A: 228–233.

[14] Pajala, S., Era, P., Koskenvuo, M., Kaprio, J., Törmäkangas, T., Rantanen, T. Force platform balance measures as predictors of indoor and outdoor falls in community-dwelling women aged 63-76 years. J Gerontol A Biol Sci Med Sci. 2008;63A:171–178.

[15] Riemann, B.L., Piersol, K. Intersession reliability of self-selected and narrow stance balance testing in older adults. *Aging Clinical and Experimental Research* 2016 DOI: 10.1007/s40520-016-0687-2.

Performing a Fall Risk Test:

1. Position the support handles and the display height and tilt for patient comfort.
2. At the Main Menu, touch <Testing>, and <Fall Risk>.
3. The Patient Setup information screen is displayed. If this is a new patient and the training session is to be saved after its completion, the patient's name and height must be entered. If the training session does not need to be saved, designate a height value, which is correlated to the software's scoring algorithm based on the calculated Center of Gravity.
4. Touch <Test Options> to advance to the Fall Risk Testing Options screen if desired.
5. For a valid comparison to normative data, the test must include the default conditions displayed in Figure 6.16 below, including Test Trial Time (45 seconds), Number of Trials (1), Rest Countdown (30 seconds), and the Display Cursor/Tracing and Record Foot Position options (disabled).

   NOTE: *All four of the conditions can be tested on this screen instead of just the two pictured below.*

   - For tests in a narrow stance, patients should be positioned with a 7.5cm separation between feet. On the platform grid, each foot was placed two blocks away from the AP midline with the navicular tubercle over the ML midline.

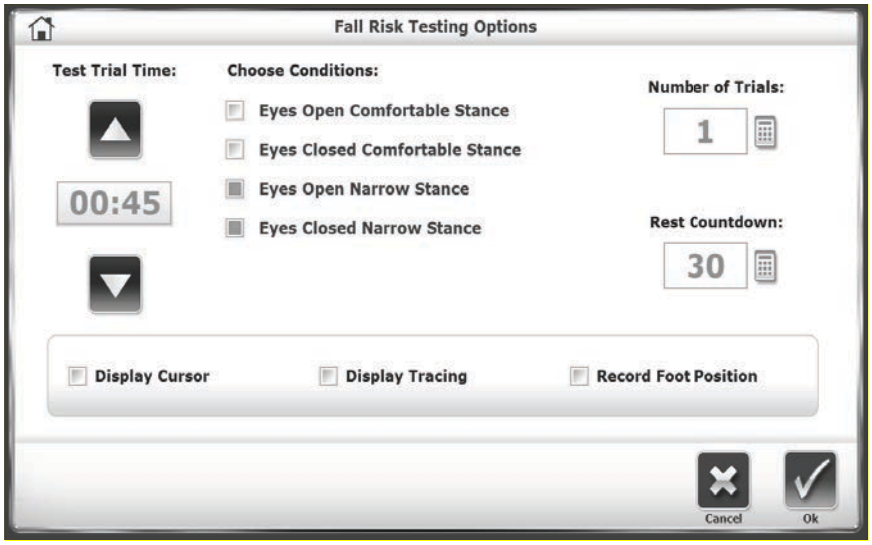


Figure 6.16. Fall Risk Testing Options Screen.

6. Touch <OK> to confirm the selections and return to the Patient Setup screen.
7. Press <Next> to display the Fall Risk Testing screen.
8. Once standing comfortably on the platform, the patient is informed what to expect during the test. Explain that one's hands should be placed on one's hips and to stand as motionless as possible. (These instructions were given to the group of patients whose scores serve as normative data. Therefore, the testing instructions and conditions should mirror that group as much as possible in order to ensure comparisons made to normative data from that group are valid.) With the patient ready to begin the test, touch <Start> and <Collect Data>. The screen will provide a three-second countdown before beginning each test trial. The display screen will include Test Trial Time, the Velocity (the speed of an individual's sway as they maintain their balance), what number Trial is occurring, and the

Condition that is being tested. If desired, touch the <Magnifying Glass> icon to enlarge the grid circle.

Figure 6.17. Fall Risk Testing Screen.

9. For tests in a narrow stance, patients should be positioned with a 7.5cm separation between feet. Each foot should be placed two blocks away from the AP midline with the navicular tubercle over the ML midline.

***NOTE**: To stop a test in progress at any time, touch <Stop>.*

10. When the first condition is finished, the screen will display 'Trial 1 Complete / Prepare for Condition 2' and a rest countdown will begin for the second condition. Touch <Collect Data> to begin the second condition and continue in the same manner to complete subsequent conditions.
11. When the first trial is finished, the screen will display 'Trial 1 Complete.'
12. After completing all trials, a 'Test Complete' message is displayed. Touch <Results> to advance to the Fall Risk Test Results screen.
13. At the Fall Risk Test Results screen, touch <Print> to automatically generate a printed report if desired.
14. To save the test data from the Results screen, touch <Save Results> and touch <OK> in response to the 'Save Results for later reporting or export?' prompt. The system will display 'Save Results Completed' after the results are saved. If a patient identifier was not entered at the start of the session (i.e., a name or an ID number), it will need to be entered now in order to save the results of the session. If the test result is not saved and <Back> or <Home> is touched, the system will prompt the user for confirmation because of the possible loss of data for the test just performed.
15. Touching <Codes/Comments> allows the user to add additional information pertaining to the test. CPT, ICD, G-Codes or comments regarding the test can be added at the conclusion of the test or at a future time.
16. To return to the Opening Menu from the Fall Risk Test Results screen touch the <Home> icon in the upper left corner.

7. System Utilities

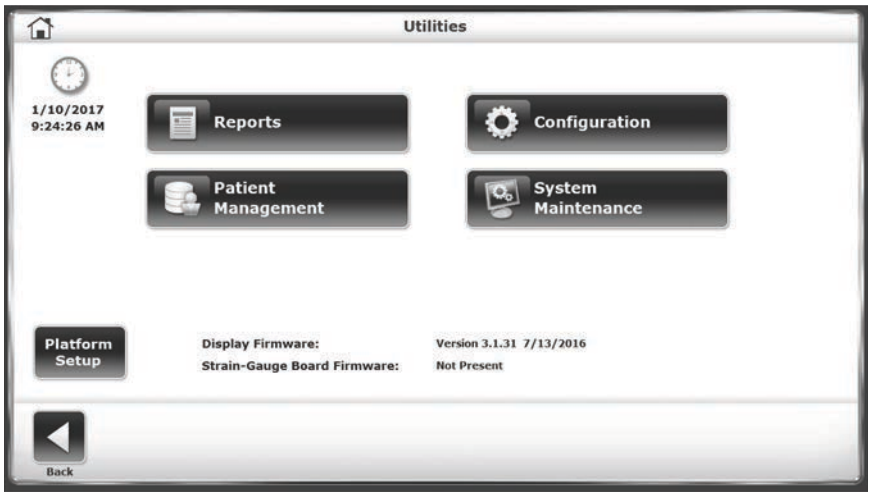


Figure 7.1. The Utilities Screen

The Utilities Menu allows access to the Reports, Configuration, Patient Management, and System Maintenance screens. The System Maintenance screen (not displayed) is accessed through the Utilities menu. To access the system Utilities menu, touch <Utilities> on the Main screen.

***NOTE**: The Advanced System Maintenance is an icon that is normally hidden; instructions on accessing it are discussed in separate documentation.*

The Utilities menu displays technical information about the BioSway firmware version. To access any of these configurations, enter 159 at the "Access ID Code" screen and touch <OK>.

Reports

The Reports function is another way to navigate to the Test Results screens detailed in the Patient Management section, the main difference being that Codes/Comments or G-Code data cannot be edited in Reports section screens.

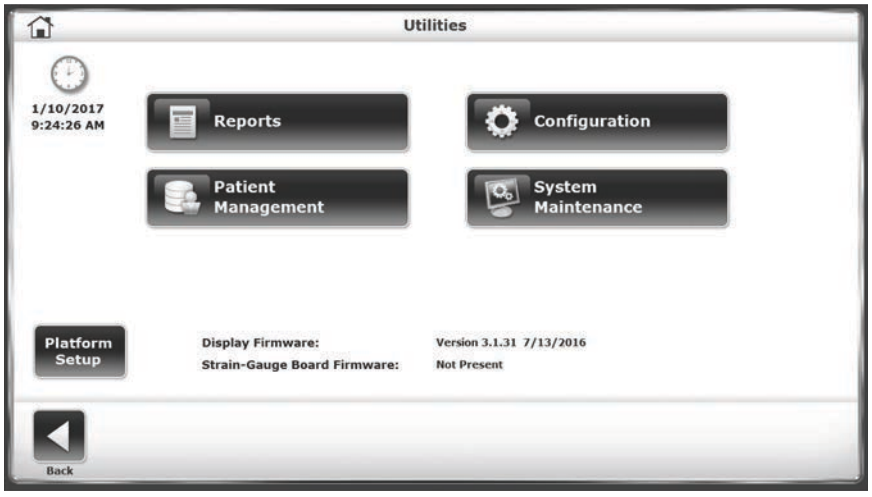


Figure 7.2. Utilities Menu.

View Test Results and Print Report

1. To view a list of patient result reports, touch <Reports>, select any Report row, and press the <Next> button.

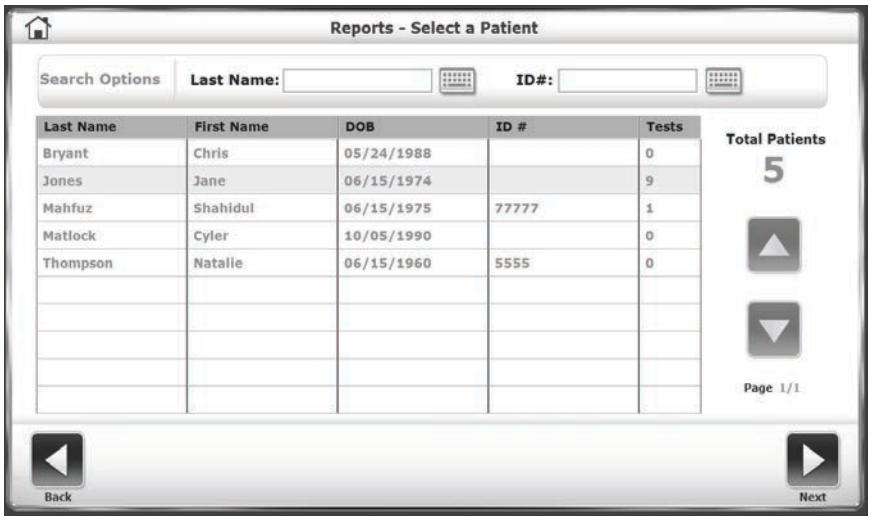


Figure 7.3. Reports – Select a Patient Screen.

2. On the Reports – Test Results screen, the user can view individual test results, or, if there is more than one particular report, view or print a Progress Report.

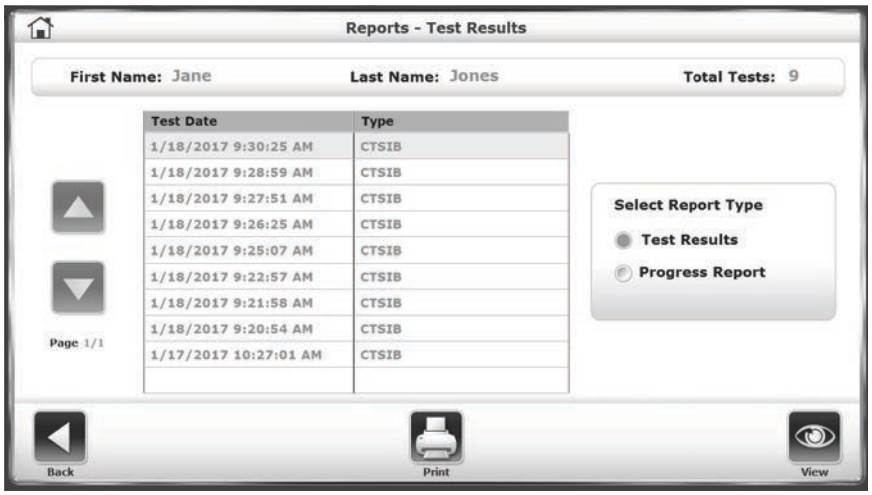


Figure 7.4. Reports – Test Results Screens.

3. Click on a particular Test Date row and click on <View> to see the Stored Test Results for that particular test.

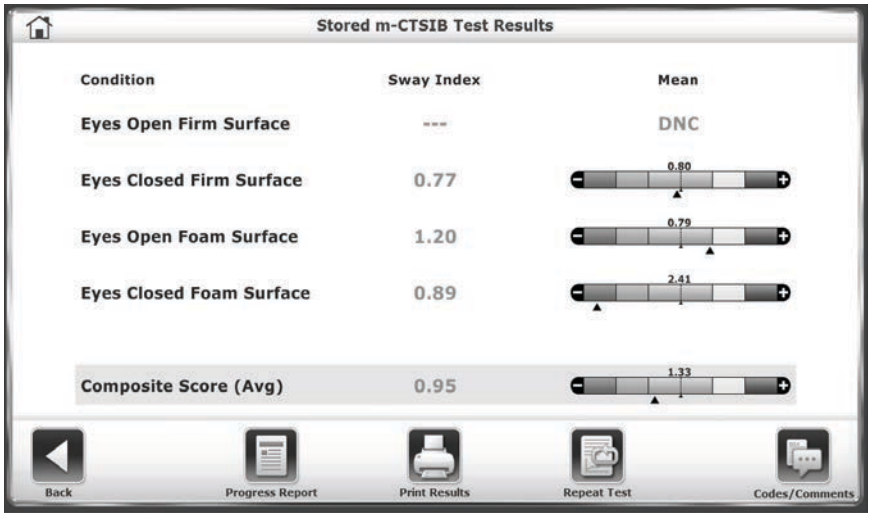


Figure 7.5. Sample Stored Test Results Screen for an m-CTSIB Test. In this Example, the DNC Designation Means that the Patient did not Complete the Eyes Open Firm Surface Test Condition.

4. Clicking on <Print Results> on the Stored Test Results screen will display a print preview for the report.
   - On this screen, the user can select the printer to be used in the drop-down menu on the left. Under <Copies>, the user enters the number of copies to be printed.
   - Touch <Export PDF> to export a PDF version of the report to a flash drive inserted in one of the display's USB ports.
   - Touch one of the <Magnifying Glass> buttons to zoom in (+) or zoom out (-) increasing or decreasing the size of the print preview.
   - If the report contains more than one page, use the <▲> or <▼> keys to navigate through the pages.
   - Touch <Advanced> to display a Windows print dialog screen. From this Windows screen, the user can select options to further refine the printed report.

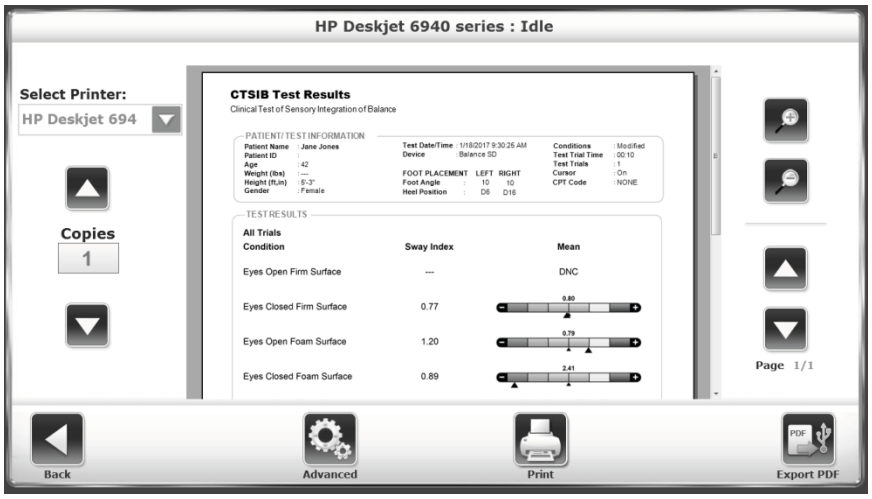


Figure 7.6. Print options Screen.

5. When <Export PDF> is touched, the report will automatically be exported as a PDF file to a generated folder titled BioReports on a USB flash drive. An error message is displayed if a USB flash drive is not inserted in one of the USB ports on the device's display.
6. From the Stored Test Results screen, the user has the option of viewing a Progress Report, initiating a repeat of the same test, or editing the various codes and comments (e.g., CPT, ICD, G-Code) associated with the patient.

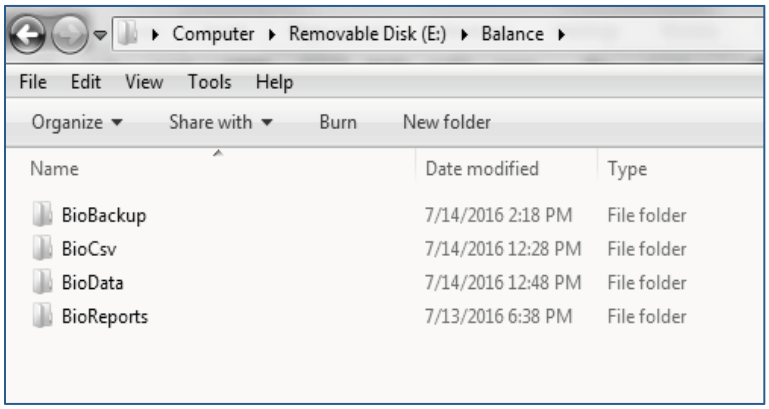


Figure 7.7. Location on Hard Drive in which the <Export PDF> File is Saved.

As illustrated in Figure 7.7, the BioReports folder is just one of several subfolders that are automatically generated in the main directory. The following is a list of the subfolders, along with the types of files contained:

- *BioBackup*: The backup of system settings with database.
- *BioCsv*: Both individual CSV file and multi data CSV files.
- *BioData*: The patient test results as a Binary file.
- *BioReports*: The reports in PDF format.

Sample reports:

The Biodex BioSway System offers reports for each of the test modes. The data presented from balance testing is common on different reports. Reports can be generated to reflect single leg, both legs and bilateral comparison testing protocols. Report formats include Postural Stability, Bilateral comparison, Limits of Stability, Motor Control, Fall Risk, Sensory Integration, which includes the CTSIB and BESS Test.

Sample reports are illustrated below. For detailed information on the various reports refer to Appendix B.

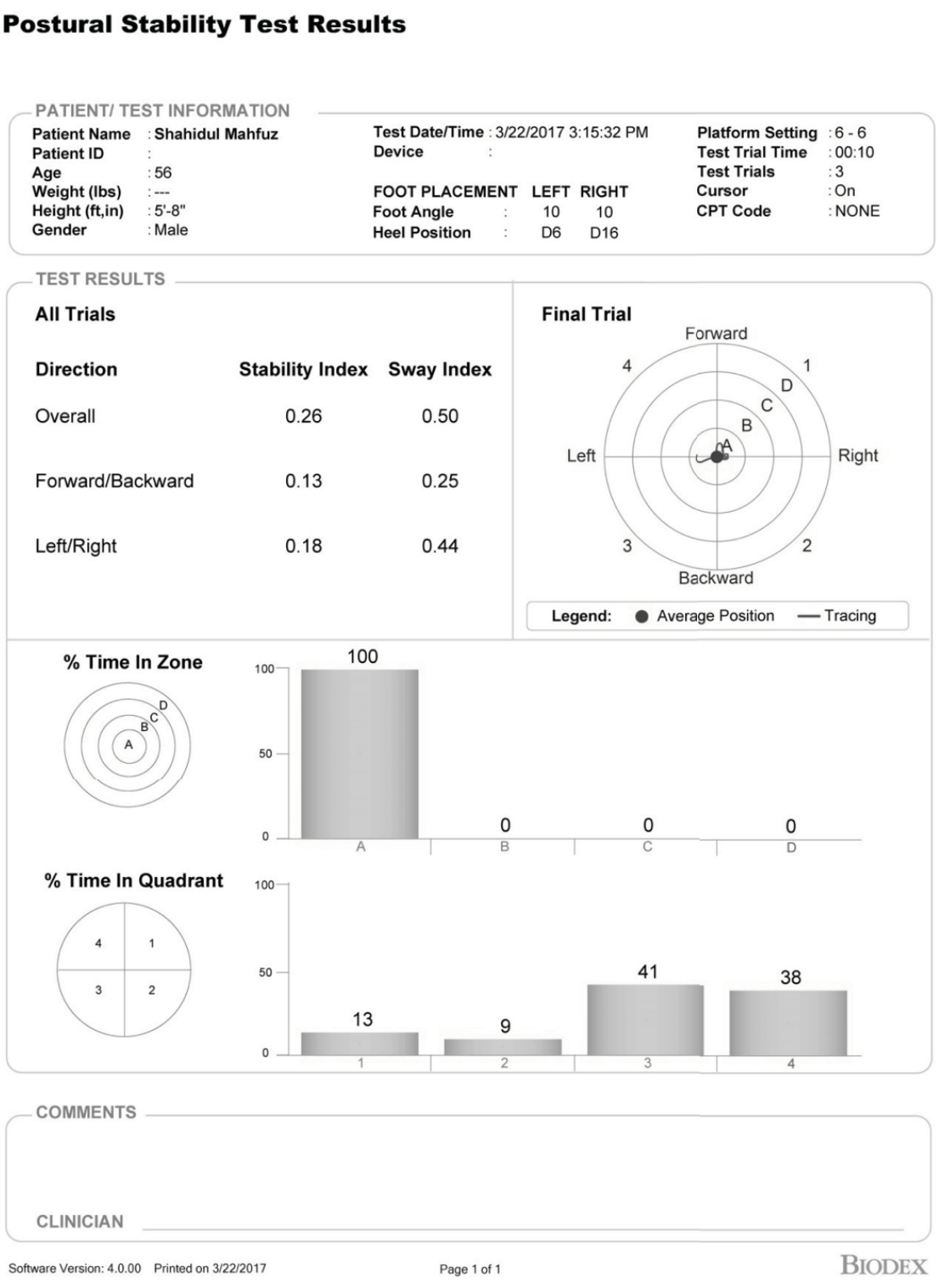


Figure 7.8. Example of a Postural Stability Test.

Bilateral Comparison
Test Results

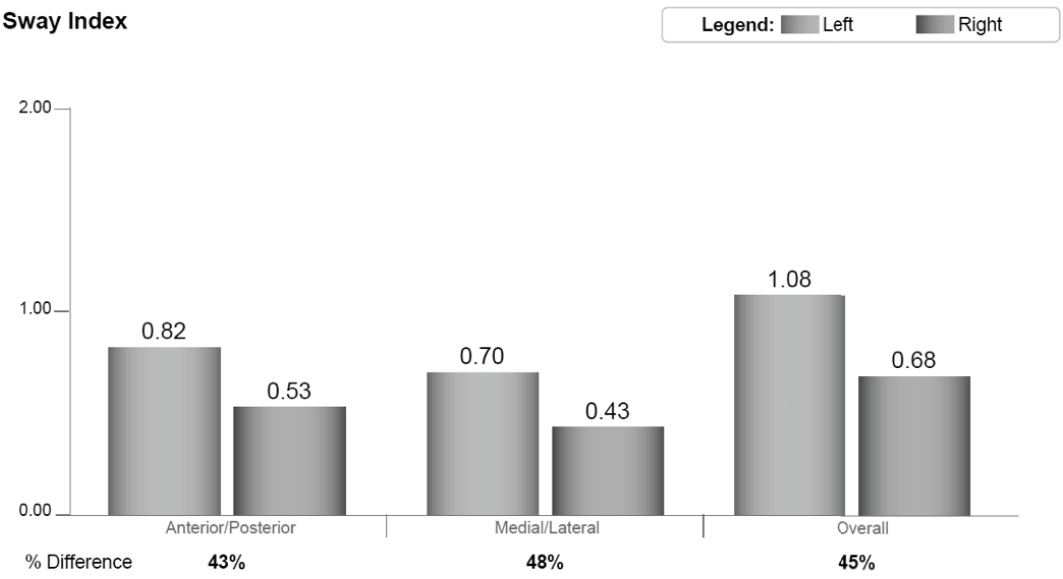
PATIENT/ TEST INFORMATION

Patient Name	: **Shahidul Mahfuz**	**Test Date/Time**	: 5/3/2017 10:31:02 AM	**Platform Setting**	: Static
Patient ID	: 77777	**Device**	: Balance SD	**Test Trial Time**	: 00:20
Age	: 41			**Test Trials**	: 1
Weight (lbs)	: ---			**Cursor**	: On
Height (ft,in)	: 5'-8"			**CPT Code**	: NONE
Gender	: Male			**ICD Code**	:

TEST RESULTS

Direction	Left Sway Index	Right Sway Index	% Difference
Anterior/Posterior	0.82	0.53	43%
Medial/Lateral	0.70	0.43	48%
Overall	1.08	0.68	45%

Sway Index



COMMENTS

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Figure 7.9. Example of a Bilateral Comparison Test.

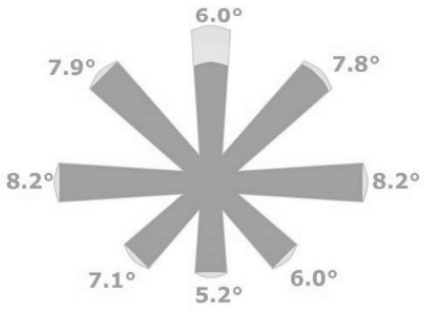
Limit of Stability Test Results

PATIENT/ TEST INFORMATION

Patient Name	: **Shahidul Mahfuz**	**Test Date/Time**	: 3/22/2017 3:37:10 PM	**Platform Setting**	: Static
Patient ID	:	**Device**	:	**Test Trials**	: 1
Age	: 56			**Cursor**	: On
Weight (lbs)	: ---	**FOOT PLACEMENT**	**LEFT RIGHT**	**Pattern**	: Full
Height (ft,in)	: 5'-8"	**Foot Angle**	: 10 10	**CPT Code**	: NONE
Gender	: Male	**Heel Position**	: D6 D16		

TEST RESULTS

Direction	Angle (°)	% of Standard
Forward	6.0°	76
Forward/Right	7.8°	97
Right	8.2°	102
Backward/Right	6.0°	100
Backward	5.2°	130
Backward Left	7.1°	118
Left	8.2°	102
Forward Left	7.9°	99
Composite Score (Avg.)	**7.0°**	**88**



COMMENTS

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Figure 7.10. Example of a Limit of Stability Test.

Motor Control Test Results

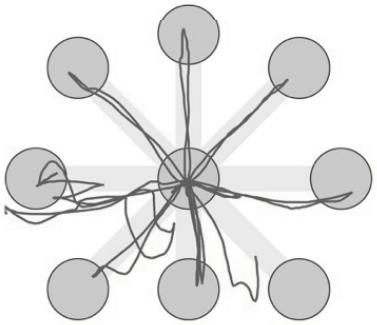
PATIENT/ TEST INFORMATION

Patient Name	: **Shahidul Mahfuz**	**Test Date/Time**	: 3/22/2017 3:43:28 PM	**Platform Setting**	: 6 - 6
Patient ID	:	**Device**	: Balance SD	**Level**	: Medium
Age	: 56			**Test Trials**	: 1
Weight (lbs)	: ---	**FOOT PLACEMENT**	**LEFT RIGHT**	**Cursor**	: On
Height (ft,in)	: 5'-8"	**Foot Angle**	: 10 10	**CPT Code**	: NONE
Gender	: Male	**Heel Position**	: D6 D16		

TEST RESULTS

Direction	Efficiency %	Time
Forward	1.00	00:02
Forward/Right	1.41	00:02
Right	0.89	00:03
Backward/Right	1.62	00:02
Backward	10.9	00:01
Backward Left	3.53	00:02
Left	0.49	00:05
Forward Left	1.66	00:02
Composite Score (Avg.)	**2.69**	**00:19**

0 50 100



COMMENTS

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Figure 7.11. Example of a Motor Control Test.

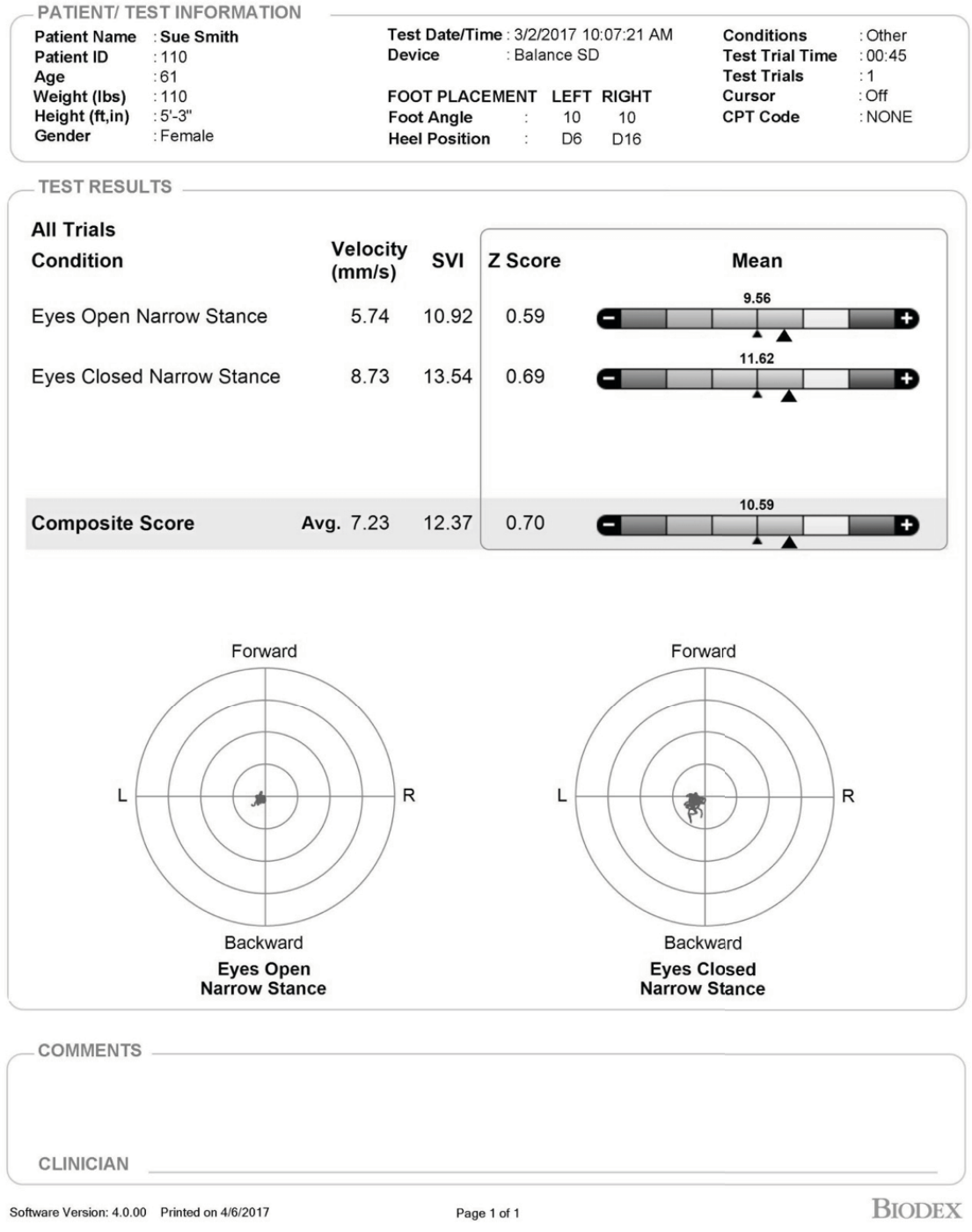


Figure 7.12. Example of a Fall Risk Test.

BESS Test Results

Balance Error Scoring System

PATIENT/ TEST INFORMATION

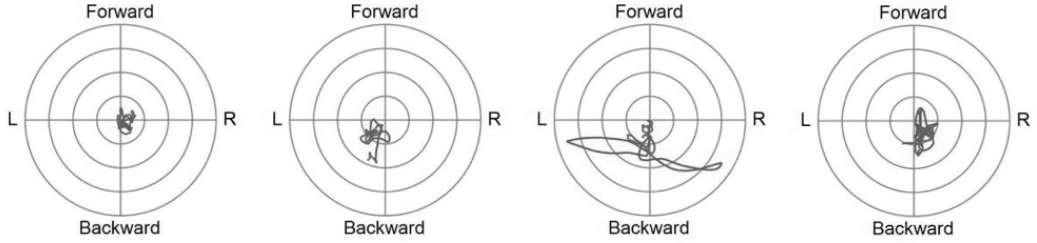
Patient Name	: Robert Jones	**Test Date/Time**	: 4/6/2017 11:36:44 AM	**Conditions**	: Other
Patient ID	: 2457	**Device**	: Balance SD	**Test Trial Time**	: 00:10
Age	: 0			**Test Trials**	: 1
Weight (lbs)	: 180	**FOOT PLACEMENT**	**LEFT RIGHT**	**Cursor**	: On
Height (ft,in)	: 6'-0"	**Foot Angle**	: 10 10	**CPT Code**	: NONE
Gender	: Male	**Heel Position**	: D6 D16		

TEST RESULTS

All Trials

Condition	Sway Index	Errors
Single Leg Stance Firm	1.50	0
Tandem Stance Firm	2.21	0
Double Leg Stance Foam	4.56	1
Single Leg Stance Foam	2.18	2
Composite Score	**Avg.** 2.61	**Total** 3

Final Trial



COMMENTS

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Figure 7.13. Example of a BESS Test.

View and Print Progress Report

1. If the patient has multiple tests, a progress report can be viewed. Select the <Progress Report> radio button under Select Report Type, and select <View>.

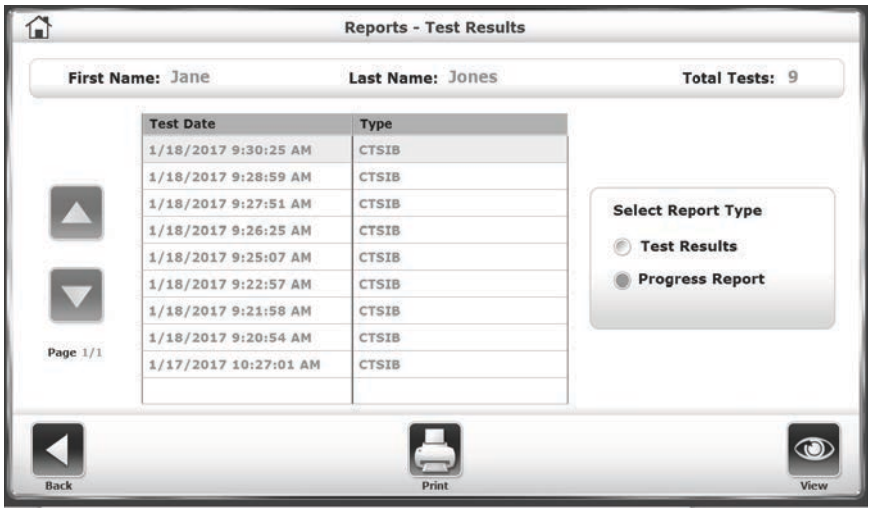


Figure 7.14. The Reports – Test Results screen with the Progress Report Radio Button Selected.

2. On the CTSIB Progress Report Selection screen, you can select what Conditions should be displayed in the report.

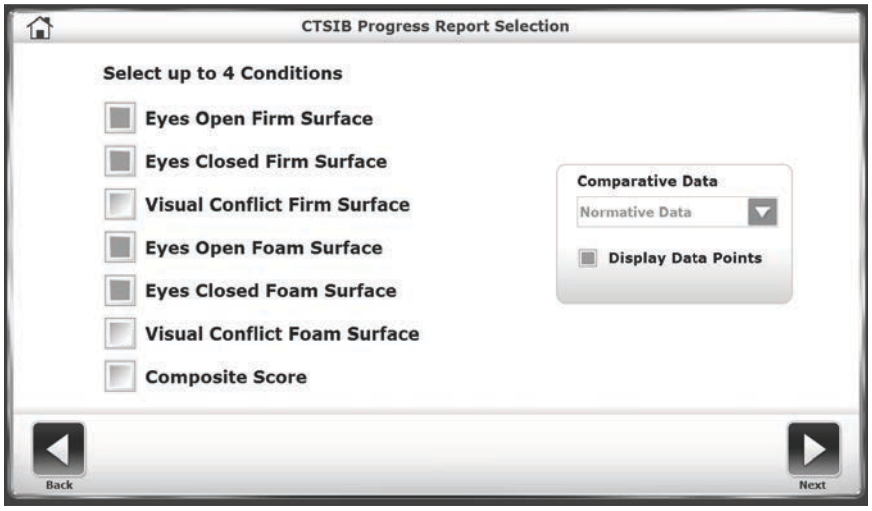


Figure 7.15. The CTSIB Progress Report Selection Screen.

The user also set the Comparative Data in the report to be based on normative data or a certain percentage over the patient's original baseline score if it is available/applicable for the particular test.

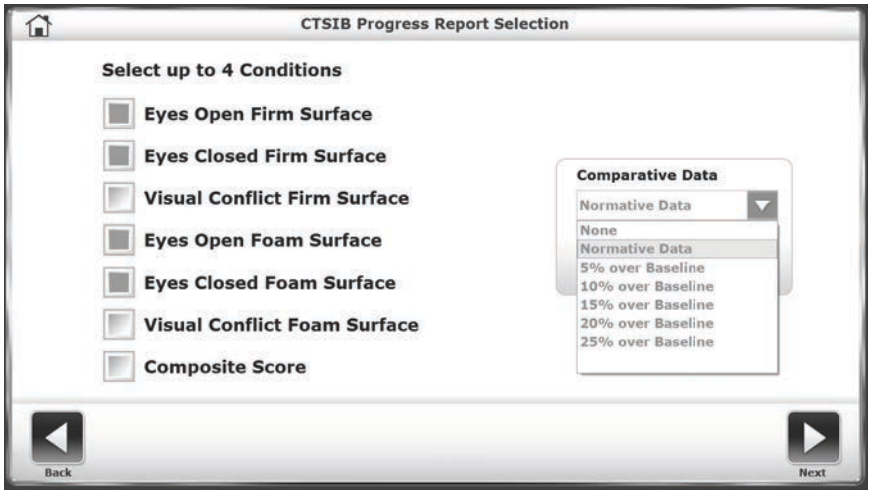


Figure 7.16. Selecting the type of comparative data in the Progress Report Selection Screen.

3. If the user selects Normative Data as the comparative data type, a specific normative data set must be designated before touching <Next>.

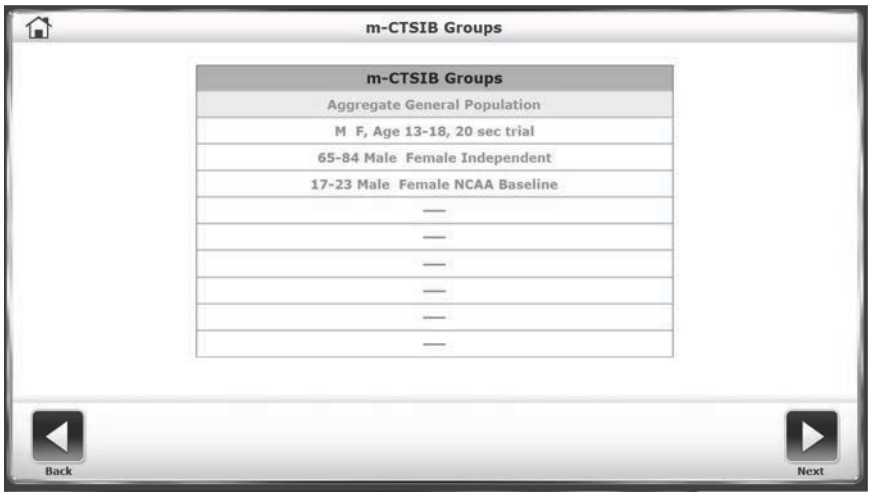


Figure 7.17. Selecting a Specific Set of Normative Data to be used in the Progress Report.

4. The resulting Progress Report screen illustrates the data points of the tests over time.

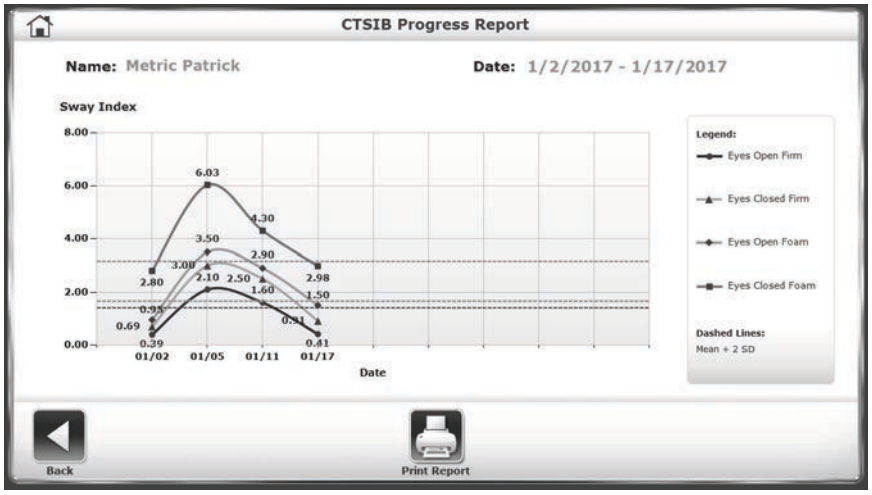


Figure 7.18. A Sample Progress Report for a Series of CTSIB Tests.

5. The user can touch <Print Report> on this screen to bring up the print options screen. The Progress Report print options screen can also be accessed at the Reports – Test Results screen (Figure 7.27) by touching <Print> on that screen.

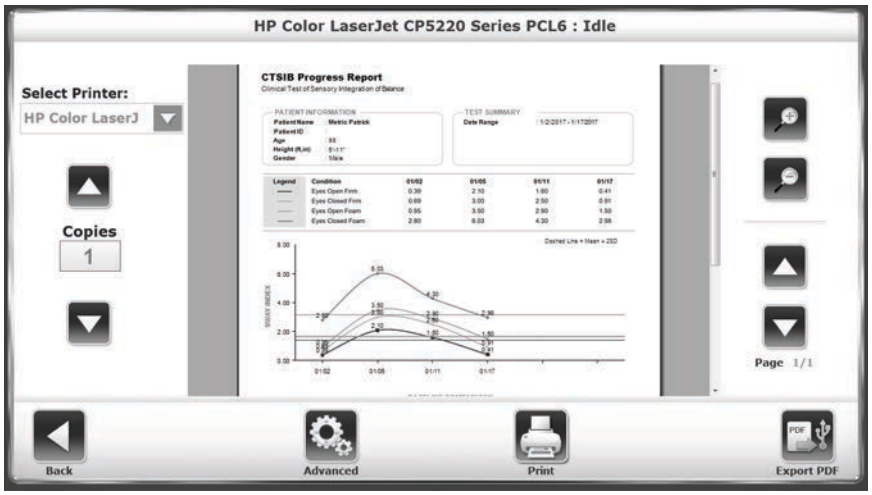
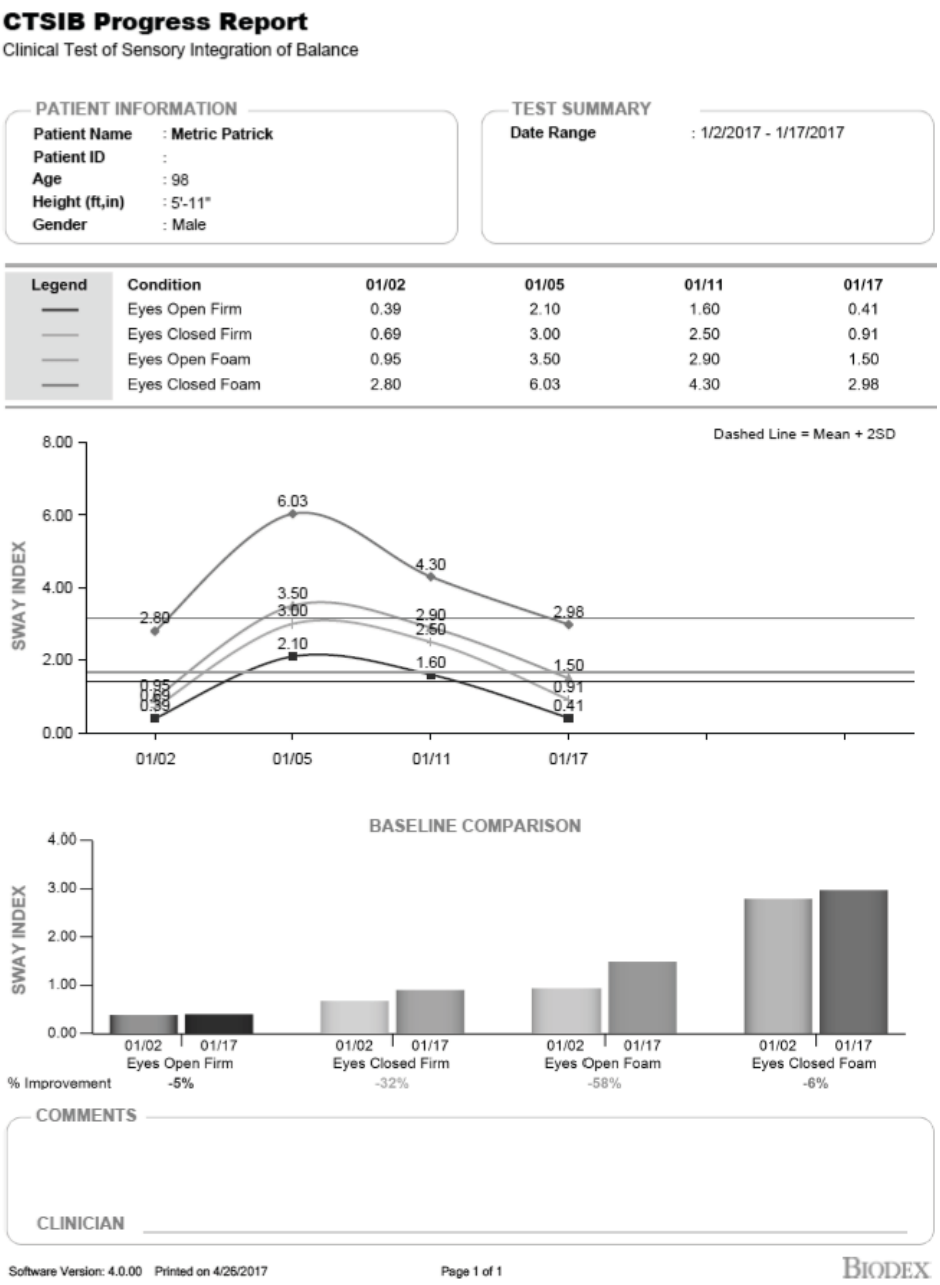


Figure 7.19. Print Options Screen for a Progress Report.

- Touch one of the <Magnifying Glass> buttons to zoom in (+) or zoom out (-) increasing or decreasing the size of the print preview.
- If the report contains more than one page, use the <▲> or <▼> keys to navigate through the pages.
- Touch <Advanced> to display a Windows print dialog screen. From this Windows screen, the user can select options to further refine the printed report.

A sample of a printed Progress Report is shown on the following page.



CTSIB Progress Report

Clinical Test of Sensory Integration of Balance

PATIENT INFORMATION

Patient Name : Metric Patrick
Patient ID :
Age : 98
Height (ft,in) : 5'-11"
Gender : Male

TEST SUMMARY

Date Range : 1/2/2017 - 1/17/2017

Legend	Condition	01/02	01/05	01/11	01/17
	Eyes Open Firm	0.39	2.10	1.60	0.41
	Eyes Closed Firm	0.69	3.00	2.50	0.91
	Eyes Open Foam	0.95	3.50	2.90	1.50
	Eyes Closed Foam	2.80	6.03	4.30	2.98

BASELINE COMPARISON

% Improvement -5% -32% -58% -6%

COMMENTS

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Figure 7.20. A Sample Printed Progress Report.

The report can be interpreted as:

- Baseline started on 01/02/2017.
- There was an injury on 01/05/2017.
- Gradual the improvements can be seen on both the 01/11/2017 and 01/17/2017 dates.

Figure 7.21. System Configuration Screen.

To advance to the Configuration screen from the Utilities Menu, touch <Configuration>. A submenu is displayed featuring two icons; one for System Configuration and one for BioSway Configuration.

System Configuration

The System Configuration screen allows the user to select between various display options and to set specific parameters for a variety of functions.

The following is a description of System Configuration screen options. Once all parameters and values are set, touch <Back> to exit and return to the Utilities Menu. Touch <Back> a second time to return to the Main Menu.

System Configuration Screen Parameters

Test Completion Screen TimeOut: This setting determines how long the Test Results screen will be displayed before the screen saver activates following completion of the exercise session. The default is one minute, but the range can be adjusted from 0:00 to 30:00 minutes. Touch the <□>or <□> icons to increase or decrease the value.

Screen Saver: The Screen Saver setting determines how long the display screen remains ON when the system is no longer in use. Once the selected time expires, the screen fades to black even if the BioSway printer remains ON. Use the < □> or < □> arrows to increase or decrease the value displayed in 1 minute increments. The Time Out range is from 00:00. Touch <OK> to confirm the changes and return to the Configuration screen. Touch <Cancel> to return to the Configuration screen without making any changes.

Set Date/Time: Touch <Set Date/Time> to change the system time or date. Touch to highlight the value to change, use the <□>or <□> icons to increase or decrease the value as desired. Touch <OK> to return continue and return to the Configuration screen.

Tone Volume: Touch any section of the horizontal bar to select a new tone volume setting. Selecting low numbers along the bar will result in lower volume while selecting high numbers makes the louder. Tone volume settings range from 0 to 10.

Measure Units: The device can be configured to display either U.S. or metric measurements. To change units, touch the displayed units and touch the desired setting to select.

Change Access ID Code: At the Default Settings screen, users can change the Access Code used to access the Default Settings screen, as well as other secure settings in the device software. To change the access ID code, select a New Access ID Code by entering the value using the displayed keypad. Press <OK> to save the New Access ID Code and return to the Default Settings screen.

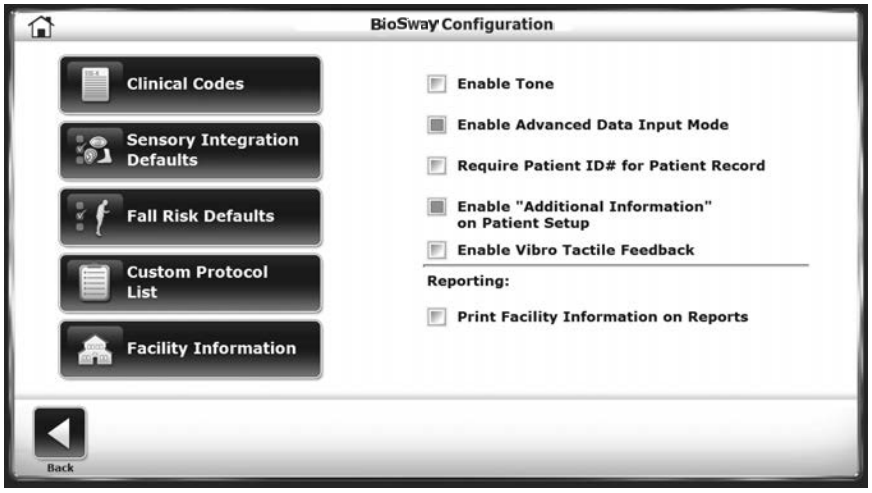


Figure 7.22. BioSway Configuration Screen.

BioSway Configuration

The BioSway Configuration screen allows the user to further configure the BioSway user settings for Clinical Codes, Facility Information, etc. Descriptions of the BioSway Configuration screen options are detailed below. Once all parameters and values are set as desired, touch <Back> to exit and return to the Configuration submenu. Touch <Back> again to return to the main Utilities menu.

BioSway Configuration Screen Parameters

Clinical Codes: The Clinical Codes screen allows the user to activate the CPT Codes, G-Codes, and Diagnostic/ICD Codes options on the Patient Information Setup screen. It allows a default CPT Code to be set.

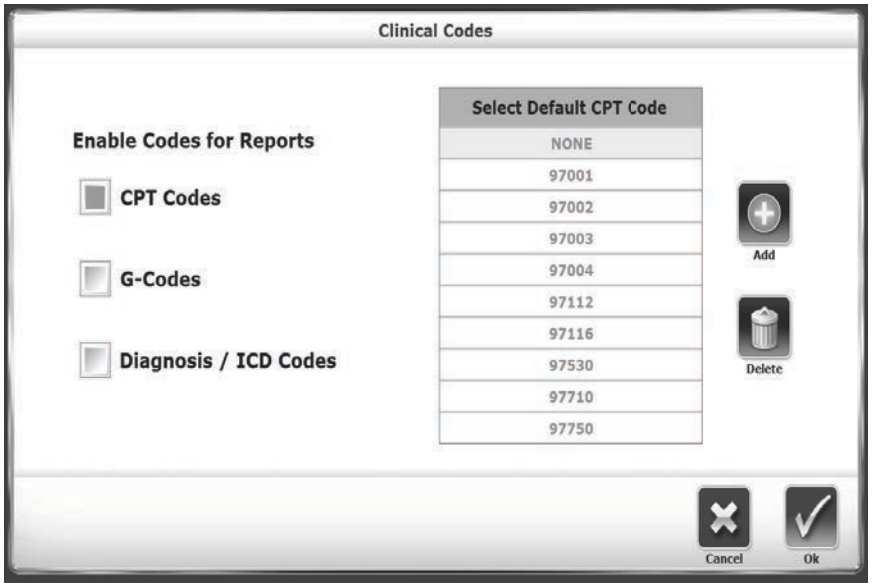


Figure 7.23. Clinical Codes Screen.

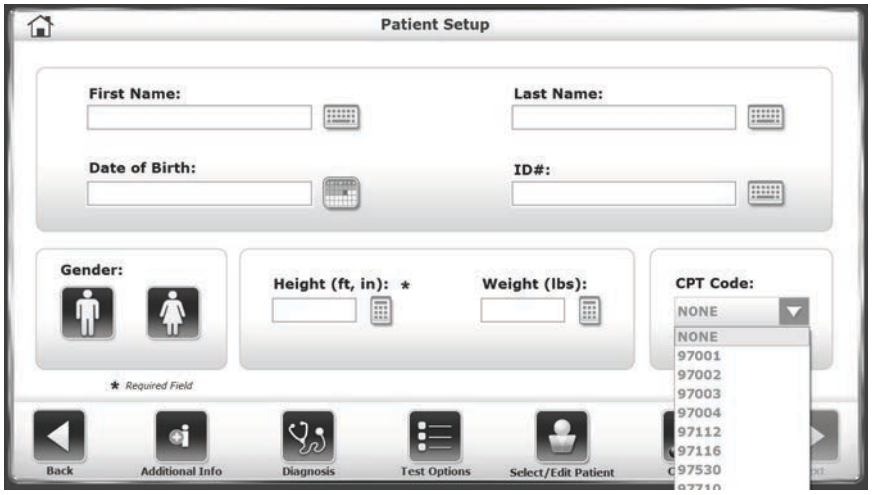
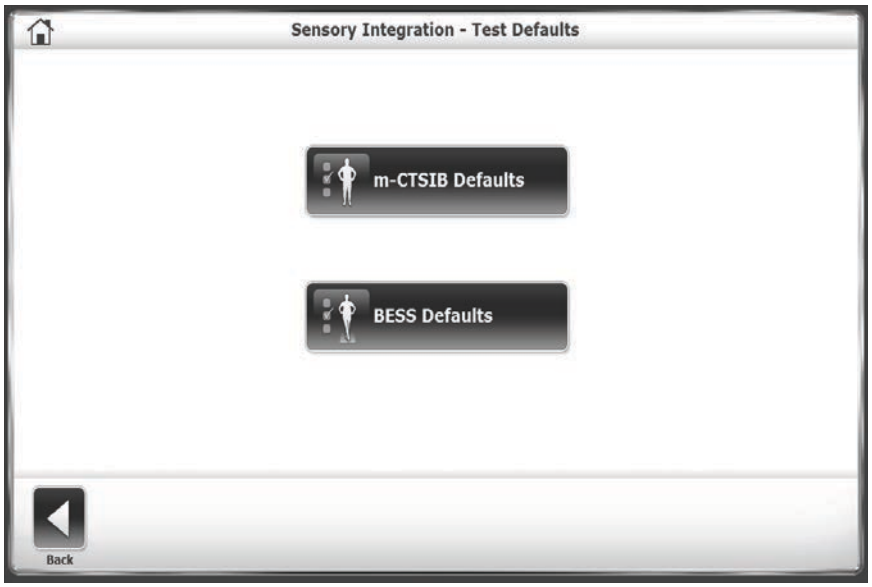


Figure 7.24. Patient Setup Screen with Clinical Codes (CPT) Option Activated.

Sensory Integration Defaults: The normative data in both sensory integration tests (m-CTSIB and BESS) can be specified to each facility's needs, although only m-CTISB default data is provided; users must enter their own default BESS normative data.



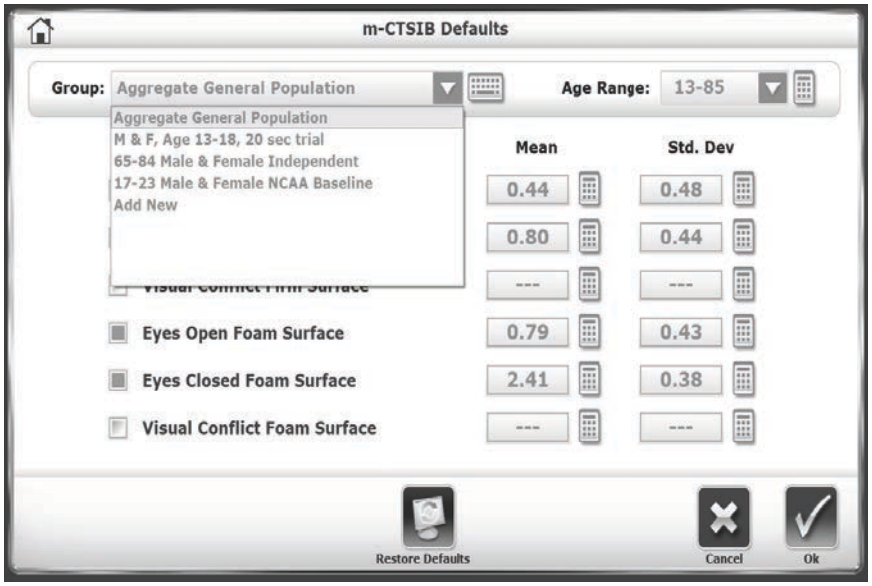


Figure 7.25. m-CTSIB Defaults Screen.

For each type of test, select the Group and Age Range drop-down menu to make changes or add a new group, and select the keypad icons beside each row to edit the normative data for that group. Selecting the <Restore Defaults> icon reverts the normative data back to the factory setting.

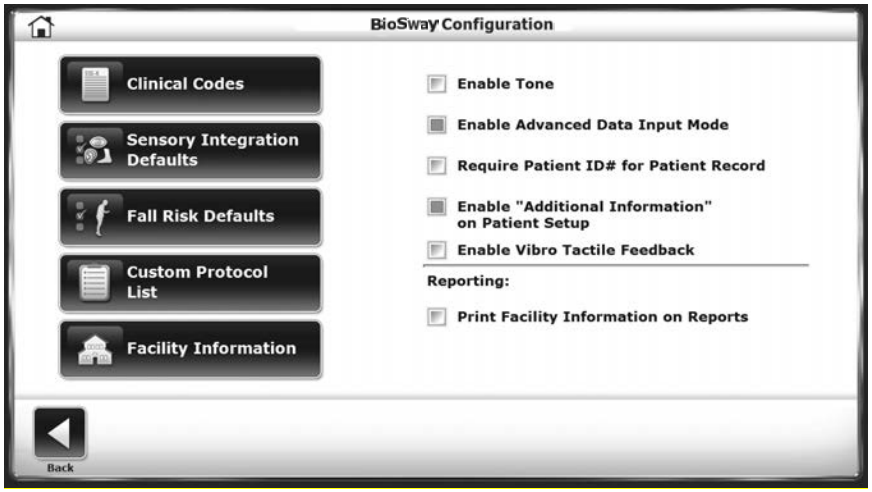


Figure 7.26. BioSway Configuration Screen.

Fall Risk Defaults: For the Fall Risk Test, users can change the default settings and associated normative data.

NOTE: Changing the default conditions will make comparisons to the default normative invalid.

Custom Protocol List: Users can add, edit, or delete customized testing or training protocols from this screen. (More detail is presented later in this section.)

Facility Information: Use this screen to enter information about the facility; reports can be configured to show facility details.

Enable Tone: Touch this checkbox to be able to hear audio biofeedback when testing or training with the device.

Enable Advanced Data Input Mode: Touch this checkbox to input a patient's exact date of birth and height numbers in the Patient Setup screen (as opposed to designating an Age number and Height range; see Figure 7.24)

Require Patient ID# for Patient Record: Touch this checkbox to require users to input a specific Patient ID# for each new patient that in training or testing sessions.

Enable "Additional Information" on Patient Setup: Touch this checkbox to enable the Additional Info icon at the bottom of the Patient Setup screen.

Enable Vibro Tactile feedback: If the Biodex VibroTactile™ System was purchased to use with the BioSway, check this box.

Enable Impairment %: Touch this checkbox to input a G-code impairment percentage number for patients with Stored Test Results.

Print Facility Information on Reports: Touch this checkbox to input information about the particular facility that will be displayed on printed reports.

Create, Save, and Recall Custom Protocols

Custom training and testing protocols can be created and edited in the system Utilities. Once created, the protocols can be accessed from the main Training and Testing menus. (In both cases, the <Custom Protocol> button is in the bottom center of the menu.)

To Create a New Protocol:

1. At the main screen, touch <Utilities>.
2. At the system Utilities screen, touch <Configuration>.
3. Select <BioSway Configuration> from the Configuration screen submenu.
4. Select <Custom Protocol List> from the BioSway Configuration submenu.
5. The Custom Protocol list is displayed.
6. Select <Add Protocol>.

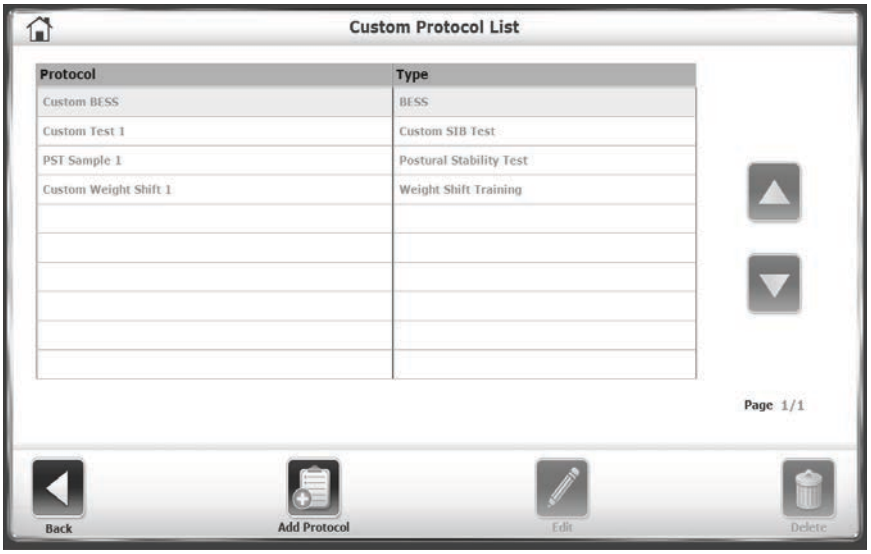


Figure 7.27. Custom Protocol List Screen.

7. Depending on whether a training protocol or testing protocol is to be added, select either the <Training> or <Testing> button on the resulting screen. Protocol creation is same for both.
8. Proceed with configuring the training or testing session for the normal Training or Testing mode selected. One of the differences that will be noticed is that Protocol Setup mode is displayed at the top of the screen. Likewise, at the bottom of the screen, the <Test Options> button is displayed where the <Start> button would be displayed in the actual training or testing mode.

Figure 7.28. Protocol Setup Screen for Postural Stability Training.

9. When finished configuring the test or training session, touch <Save Protocol>. At this point the protocol can be saved with a specific name that will be displayed in the Custom Protocol List.

To Select a Custom Protocol From the Training or Testing Menus:

1. To select a previously created custom protocol touch <Custom Protocol> from either the Training or Testing menu screens.
2. A listing of either training or testing protocols is displayed. Select the desired custom protocol from the list and proceed with the training or testing.

To Delete a Protocol:

1. At the main screen, touch <Utilities>.
2. At the system Utilities screen, touch <Configuration>.
3. Select <BioSway Configuration> from the Configuration screen submenu.
4. Select <Custom Protocol List> from the BioSway Configuration submenu.
5. The Custom Protocol list is displayed.
6. Select the Custom Protocol row to delete.
7. Select <Delete>.
8. A confirmation screen is displayed, confirming that the protocol is to be deleted. Touch <OK> confirm or <Cancel> to return to the Custom Protocol List screen.

   ***NOTE**: The <Edit> button is only applicable to Custom Sensory Tests.*

Create, Save, and Recall Custom Sensory Tests

With the option to create a custom protocol specifically for sensory testing, clinicians have an added versatility if they feel the m-CTSIB and BESS tests cannot be adequately customized to their needs. A Custom Sensory Test differs slightly from other Custom Protocols in that it is not accessed from the <Custom Protocols> button on the main Testing screen.

Instead, Custom Sensory Tests are displayed as their own button on the Sensory Testing submenu, alongside the <m-CTSIB> and <BESS> Test buttons.

To Create a Custom Sensory Integration Test:

1. At the main screen, touch <Utilities>.
2. At the system Utilities screen, touch <Configuration>.
3. Select <BioSway Configuration> from the Configuration screen submenu.
4. Select <Custom Protocol List> from the BioSway Configuration submenu.
5. The Custom Protocol list is displayed.
6. Select <Add Protocol>.
7. Touch the <Testing> button on the resulting Protocol Setup screen.
8. Touch the <Sensory Integration> button.
9. Touch the <Custom Sensory Integration> button.
10. Touch the Protocol Name field and use the keypad to name the protocol.

11. Touch the Condition Name fields and use the keypad to add conditions.

12. Touch the <Foot Position> icon next to each condition name to customize a foot position, regular stance, narrow base of support, single leg (left or right), or tandem straight.

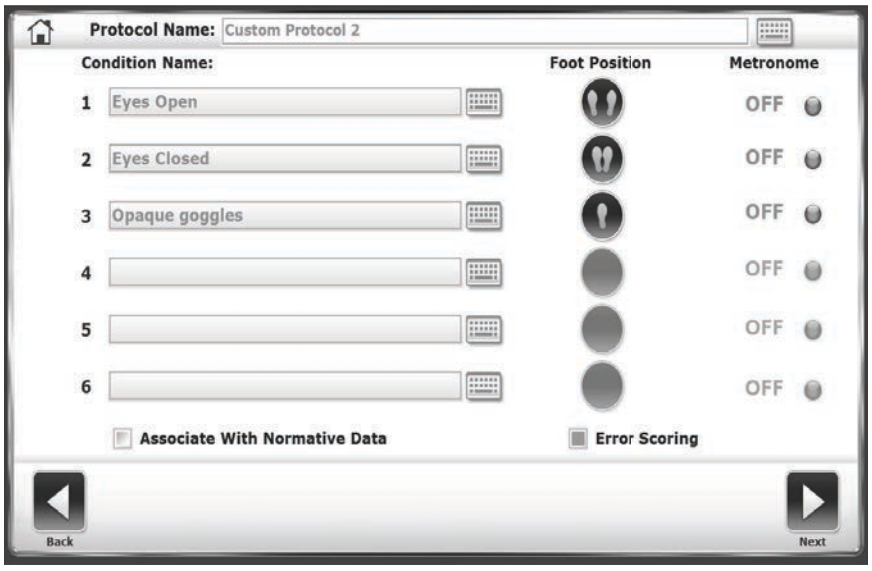


Figure 7.29. Custom Sensory Test Setup Screen.

NOTE: *On the BioSway, due to the platform size and rectangular shape, the diagonal foot position requires patients with larger feet to position feet corner to corner.*

13. Touch the <Metronome> field to select a metronome time if using a vestibular ocular reflex (head shake). The frequency can be 1, 2, or 3 Hertz per second for a 30-degree rotation from facing forward in both directions (60 degrees total).

14. Touch the Associate with normative data square to denote that this protocol will be connected to a set of normative values. Note that the square will turn green when selected. Practitioners can select from one of the normative data sets that come with the device or they can add their own to be associated with this protocol.

15. Touch the Error Scoring square if conducting a BESS test and errors need to be reported.

16. Touch the <Next> button to access the Custom Protocol Overview screen.

17. The Custom Protocol Overview screen features the options that have been selected for the new Custom Sensory Integration test. From this screen, the tracing function can be turned on or off.

18. Touch the <More Options> button to access the Options screen for the Custom Sensory newly created Integration test. From this screen, the Test Trial Time, Number of Trials, Rest Countdown can be changed. Note that one or more of the conditions can be deselected.

19. Touch <OK> to return to Protocol Overview screen. Touch the <Save Protocol> button to save the new protocol.

20. Touch the <Home> button from the Custom Protocol Overview screen to return to the main menu.

21. Touch on the <Testing> button.

22. Touch the <Custom Sensory Integration> button to access the Custom Sensory Integration screen featuring the newly created protocol.

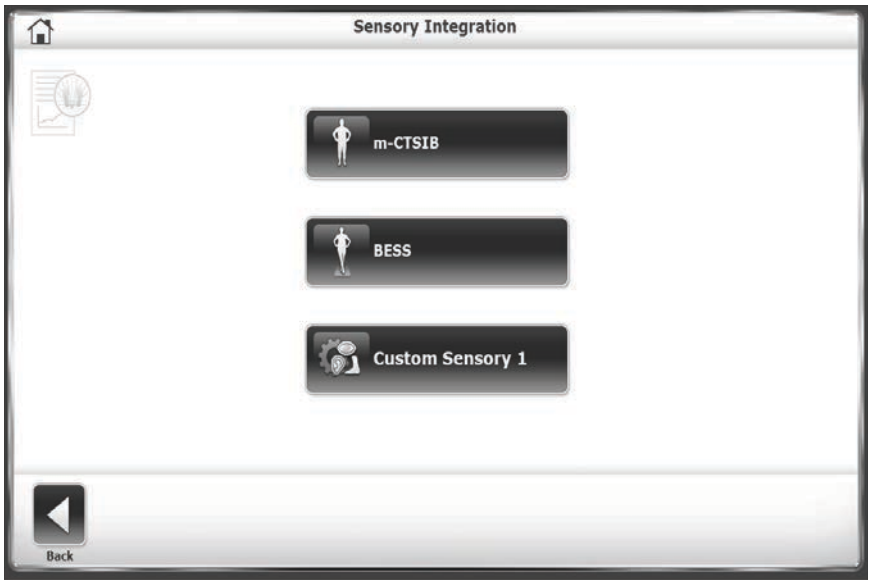


Figure 7.30. The Sensory Integration Screen Featuring the Newly Created Custom Sensory Test.

The Custom Sensory Integration test is a specialized CTSIB test protocol that allows practitioners to customize their sensory integration tests with the following features for up to six named conditions:

- Specified foot placement (normal, narrow, tandem, single)
- Vestibular Ocular Reflex challenges (1, 2, or 3 hertz frequency)
- Error counting (for BESS tests)

A Custom Sensory Integration test can be configured in the manner that CTSIB tests have been customized in past versions of the software. Practitioners can set the:

- Number of trials
- Time length of each trial
- Rest countdown time between each trial
- Whether or not the screen tracing (cursor) is visible during the trials

The ability to create a custom protocol was added in this software update in order to provide more versatility for custom sensory integration protocols and the BESS test protocol. Note that the Custom Sensory Integration button will not be displayed on the Testing menu until a Custom Sensory Integration test has been created.

System Utilities: Patient Management

Figure 7.31. The Patient Management – Select a Patient Screen.

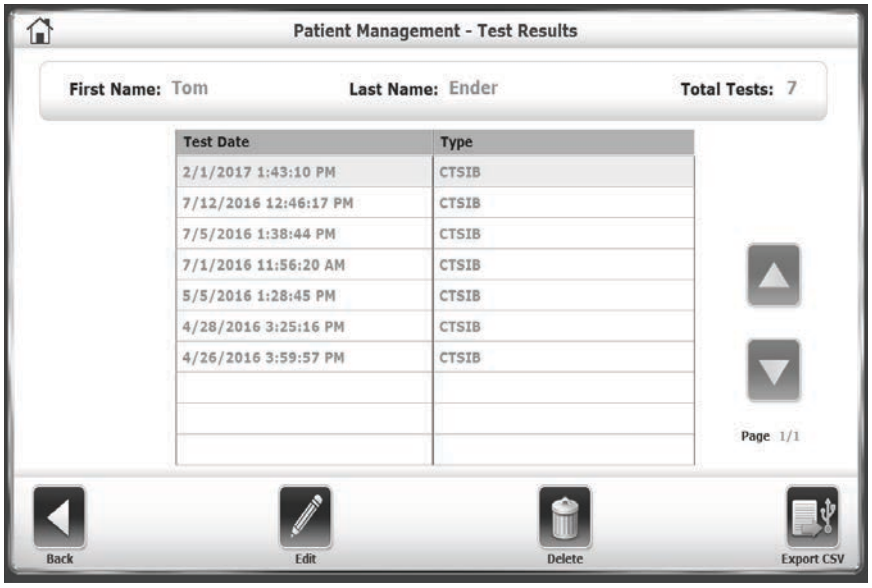


Figure 7.32. The Patient Management – Test Results Screen.

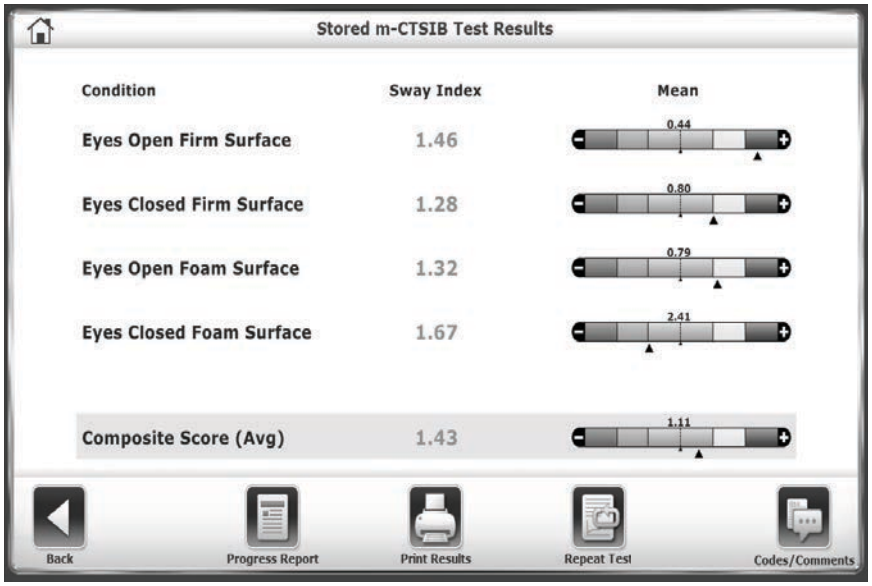


Figure 7.33. The stored Test Results Screen for an m-CTSIB Test.

To advance to the Patient Management screen, select a Patient screen from the Utilities Menu, touch <Patient Management>. Enter 159 at the Access ID Code prompt and touch <OK>. The Patient Management screen is displayed.

From this screen, new patients can be added with the <Add Patient> button. Touching this button displays screens similar to the Patient Setup screens that are available prior to any Training or Testing session.

To view an individual's records or an individual's test results from the main Patient Management screen, (Figure 7.31), select the row containing the patient information to be viewed and touch <Next>. From the Patient Management – Test Results screen (Figure 7.32), select <Edit>. The stored test results screen for that particular test are displayed (Figure 7.33).

To edit a patient's profile information, select a row on the Patient Management - Select a Patient screen and touch <Edit>. The patient's information can be edited and saved from the resulting screen.

Patient Management functions include the ability to delete an individual patient file, delete multiple patient files, and import or export patient data. A description of each feature follows.

Deleting Patient Files

To Delete A Single Patient File:

1. Touch to highlight the patient file to delete.
2. Touch <Delete> to delete the selected patient file. The system prompts to ensure that the selected file is to be deleted. The function will delete all test results associated with the patient.
3. Touch <OK>. The selected file is deleted and the system returns to the Patient Management screen.

To Delete an Entire Range of Patient Files:

1. Touch the <Delete Range> icon. A screen is displayed on which the user has the option to select a range of patient records to delete: All records, Records From a certain date to present time, records Prior To a certain date, or all records between certain dates (From/To). The system prompts to ensure the selected files are to be deleted.
2. Touch <OK>. The selected files are deleted and the system returns to the Patient Management screen.
3. The option of deleting a certain type of test; only Fall Risk Tests, for example is available.

Printing and Editing Stored Results

To Print a Stored Test Result:

1. Select a particular row at the Patient Management. Select a Patient screen and touch <Next>. At the Patient Management – Test Results screen, touch <Edit>. The system displays the Stored Test Results screen for the selected patient.
2. Touch <Print Results> to print out the patient file. At the Print screen, the user has the option to send the record to a connected printer (by selecting it in the Select Printer drop-down menu), or to export the document to a PDF without printing it.
3. When <Export PDF> is selected, the PDF will be exported to an automatically generated folder titled BioReports on a USB flash drive. An error message is displayed if a USB drive is not inserted in one of the USB ports on the device's display at this point.

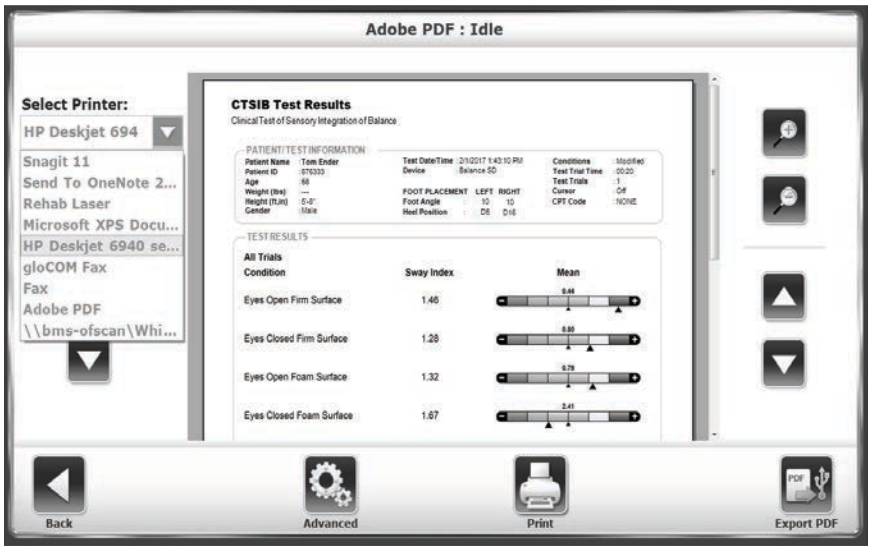


Figure 7.34. Print Screen.

4. From the Stored Test Results screen, the user has the option of viewing a Progress Report, initiating a repeat of the same test, or editing the various codes and comments (e.g., CPT, ICD, G-Code) associated with the patient.

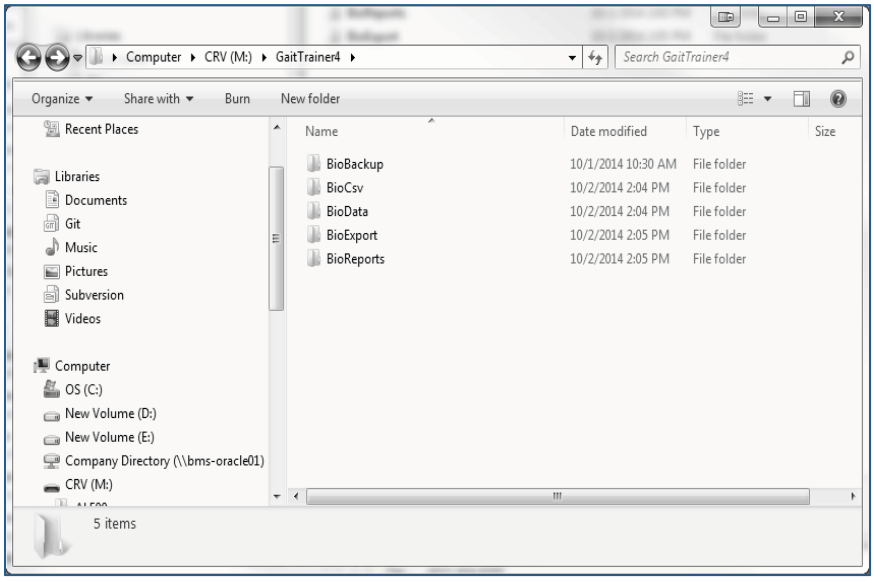


Figure 7.35. The Hard Drive Saving Location for the <Export PDF> Function.

As illustrated in Figure 7.35, the BioReports folder is just one of several subfolders that are automatically generated in the main directory. The following is a list of the subfolders, along with the types of files they contain:

- *BioBackup*: The backup of system settings with database.
- *BioCsv*: Both individual CSV file and multi data CSV files.
- *BioData*: The patient test results as a Binary file.
- *BioExport*: The event log file.
- *BioReports*: The reports in PDF format.

Exporting Patient Data

The Export Patient Data function allows patient data from a stored test to be exported in a binary (.bio) file format or a CSV format.

To Export a Specific Patient Data File:

1. Select a particular row at the Patient Management. Select a Patient screen and touch <Next>. At the Patient Management – Test Results screen, <Export CSV>. The file is automatically saved to a folder named BioCsv on an inserted USB flash drive.
2. The user can export multiple files from the Patient Management – Select a Patient screen. Touch <Export Multiple>. The following screen is displayed:

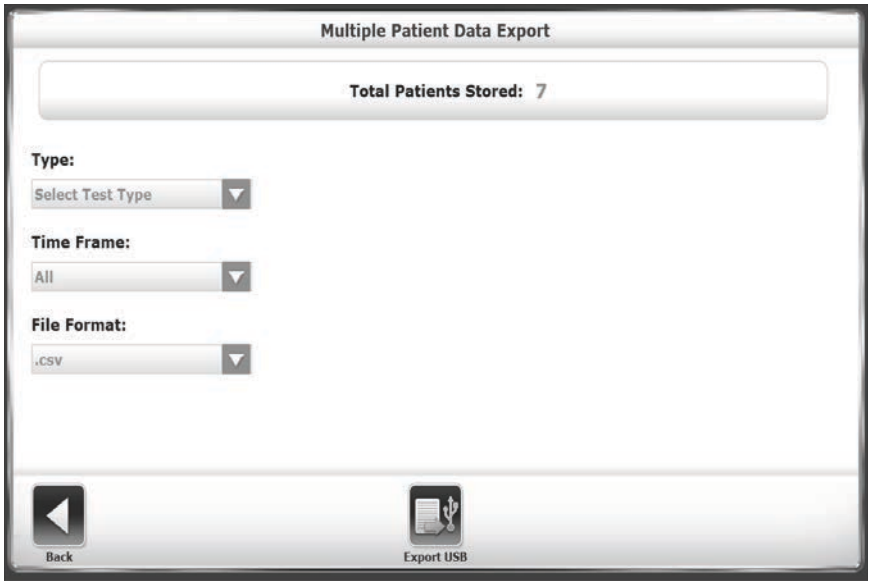


Figure 7.36. The Multiple Patient Data Export Screen.

3. On the Multiple Data Export screen, the user has the option to filter results by Type (whole patient records or particular test types), Time Frame (From, Prior To, From/To) and File Format (.csv or .biodata).
4. When the desired filters are set, touch <Export USB> and a file is saved to an automatically created folder named “BioCsv” or “BioData” on an inserted USB flash drive.

To Export a Multi Record Data Export as a CSV File:

This option is used to export all the patient test results in a single CSV file matching the selected test type for the export option. It can be opened using a CSV compatible program such as Excel.

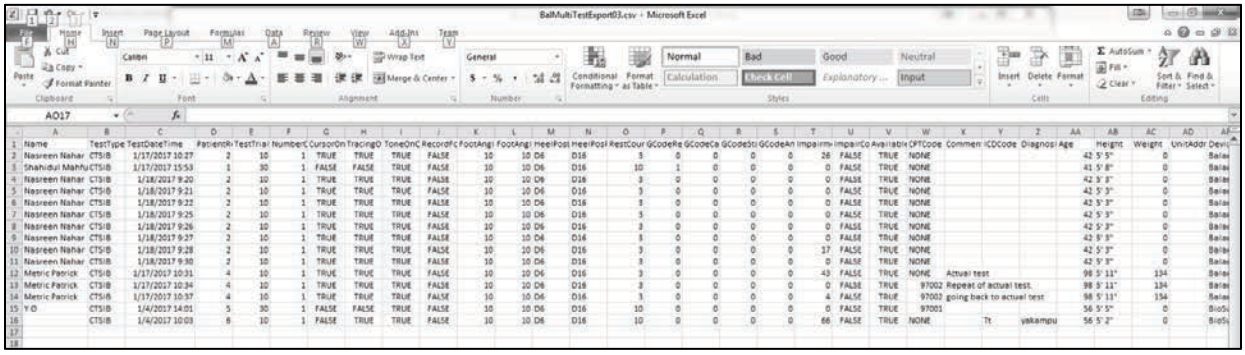


Figure 7.37. Example of File Export to a CVS File Format.

Importing Patient Data

The Import Patient Data function allows patient data from a stored test to be imported in a .biodata file format.

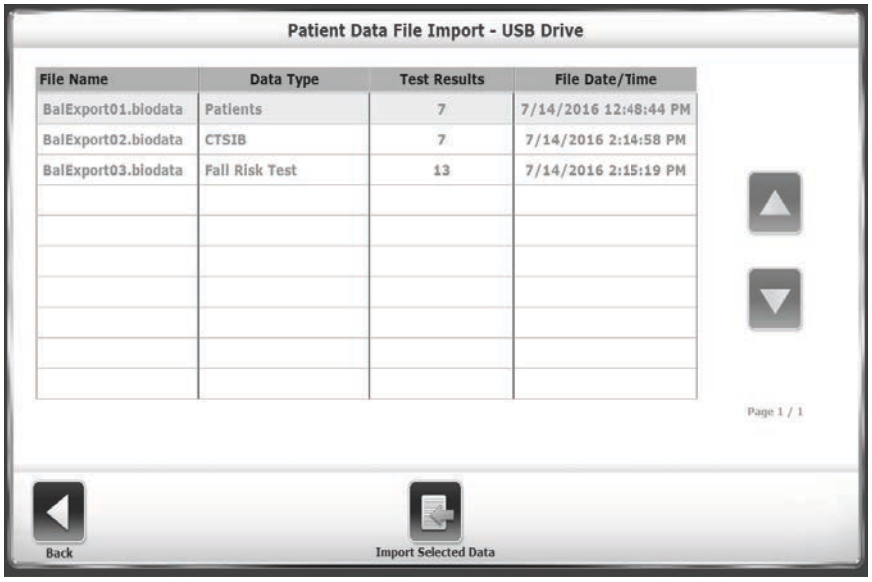


Figure 7.38. The Patient Data File Import Screen.

From the Patient Management - Select a Patient screen, select <Import>. On the resulting Patient Data File Import - USB Drive screen, the user can select the file to import from an inserted USB flash drive directory.

Depending on how the files were exported, different options for the types of files to be imported (whole patient files as opposed to only certain types of tests) are presented.

System Utilities: System Maintenance

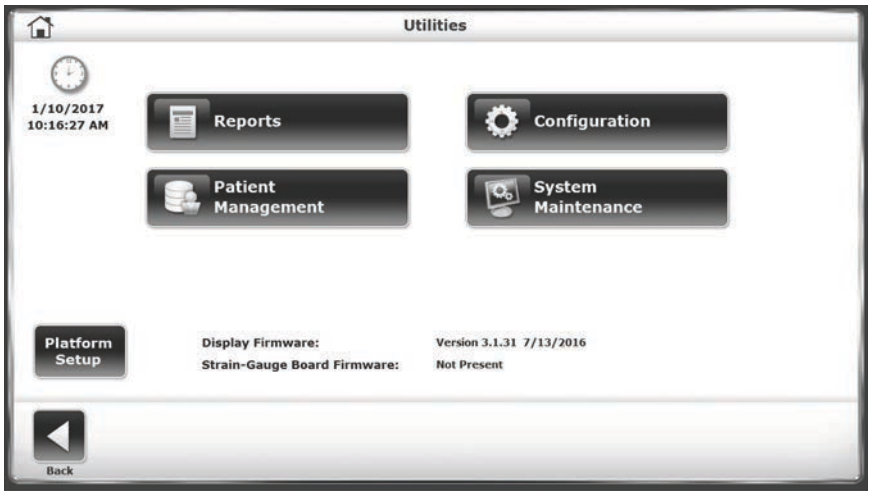


Figure 7.39. Utilities Screen

The System Maintenance main menu contains icons for three configurations related to database maintenance:

- Backup to USB
- Restore from USB
- Database Cleanup

Figure 7.40. Database Maintenance Main Screen.

Backup to USB

The Backup to USB function creates a backup database of current patient records on a removable USB flash drive. After inserting a flash drive into one of the device's USB ports, selecting the <Backup to USB> icon generates this screen:

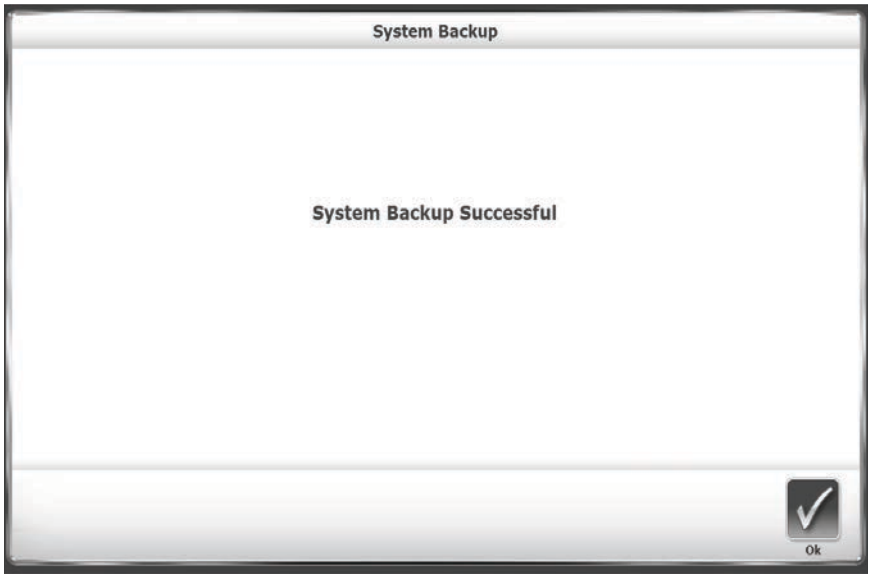


Figure 7.41. Backup to USB Screen.

Restore from USB

The Restore from USB function allows users to restore a previously backed up database to be the device's current data set. The restoration is made from a removable flash drive used in the Backup to USB function. Select the <Restore from USB> icon to perform the restoration.

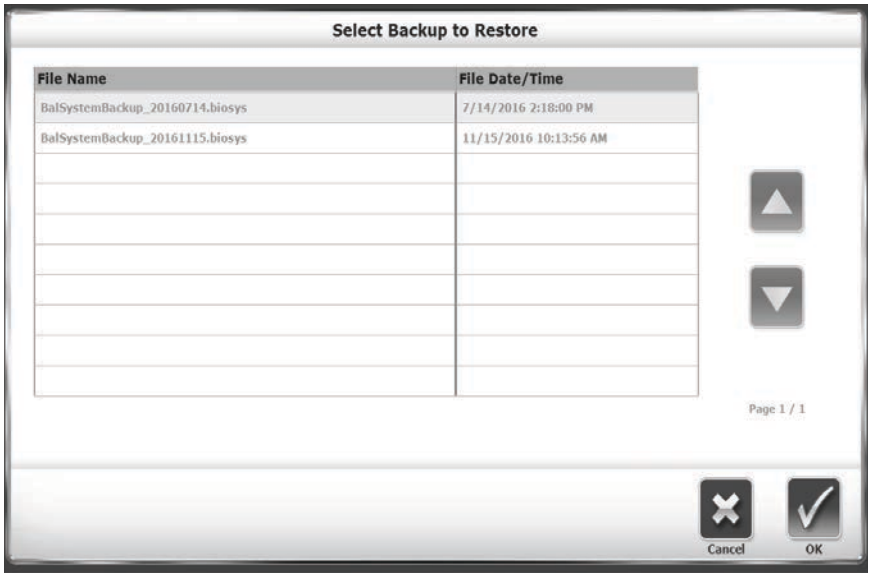


Figure 7.42. Restore from USB Screen.

A list of backed up databases is displayed (see Figure 7.42). The most recently backed up database is the bottom row of the list. Select the database to be restored as the device's current data set, and select <OK>. The confirmation screen is displayed:

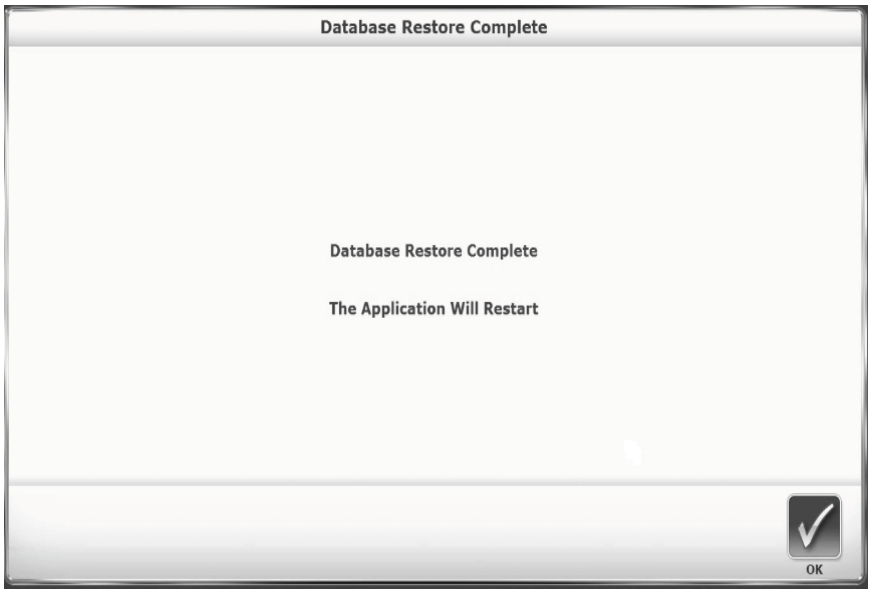


Figure 7.43. Restore from USB Confirmation Screen.

The time it takes to reach the Database Restore Complete screen depends on the size of the database. The BioSway application restarts once <OK> is touched. The Backup operation makes a backup of the entire system—not just the database. All system selections and settings are backed up and the Restore operation restores all of these settings, in addition to the patient data. This includes the backup and restoration of the facility name. , for added safety/security, all backup data is encrypted.

Database Cleanup

Database Cleanup is an administrative, maintenance function that reduces the system's overall file size.

Software Updates

From time to time, it may be necessary to update the device's software.

Updating the Software:

1. Download the updated software from www.biodex.com to a portable flash drive. Be sure to save the file in the root directory of the drive.
2. While the device monitor is displaying the main screen (with the <Testing> and <Training> icons), insert the flash drive into one of the USB ports. The Software Update screen is displayed.
3. Follow the directions on the screen to complete the update.

Figure 7.44. Software Update Screen.

8. Clinical Codes and Normative Data

ICD-10 (ICD-10-CM)

On October 1, 2015, ICD-10-CM code sets replaced ICD-9-CM to report diagnoses and inpatient procedures. The transition affected all entities and providers covered by the Health Insurance Portability Accountability Act (HIPAA).

Read more on the APTA website including:

- Answers to FAQs.
- Downloadable PDFs with common codes for physical therapy
- An ICD-10 discussion forumhttps://www.apta.org/AptaLogin.aspx?SSORedirect=1&RedirectTo=http://communities.apta.org/l/li/&redir=cC9mby9zYy9jYXRpZD0xOTc.b64

CPT Codes

The following codes may apply to treatments using Biodex products:

97110	Therapeutic procedure, one or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion, and flexibility.
97112	Neuromuscular re-education of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities.
97116	Gait Training (includes stair climbing).
97530	Therapeutic activities, direct (one-on-one) patient contact by the provider (use of dynamic activities to improve functional performance), each 15 minutes.
97535	Self-care/home management training (e.g., activities of daily living [ADL] and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-one-one contact by provider), each 15 minutes.
97750	Physical performance test or measurement (e.g., musculoskeletal, functional capacity with written report), each 15 minutes.

***NOTE**: Reimbursement amounts vary among plans and states.*

G-Codes

G-Codes are a method of recording and tracking a patient's functional limitation at the outset of therapy, during the course of therapy, and at the time of discharge. G-Codes are now required by Medicare for outpatient therapy services billed under Medicare Part B in order to collect data on beneficiaries' functional outcomes from therapy services.

Functional tests are used to report a functional limitation category (G-Code) and a percentage of impairment (Severity Code Modifier). The G-Codes will be used by those who provide outpatient therapy services such as physical therapists, occupational therapists, speech language pathologists, physicians, physician assistants, nurse practitioners, and clinical nurse specialists. G-Codes can be assigned in the Percent Weight Bearing Training mode as well as for the m-CTSIB test.

To Use the G-Code Functionality With the Percent Weight Bearing Mode:

1. Touch the <Training> button on the Home screen.
2. Touch the <% Weight Bearing> button.
3. On the Patient Setup screen, touch the <G-CODE> button.

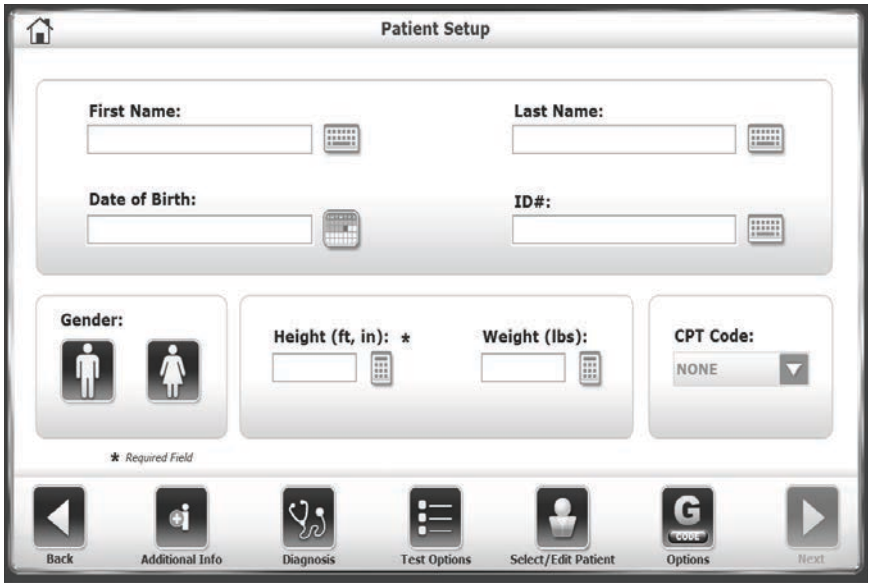


Figure 8.1. Patient Setup screen. The G-CODE Button is Present, but Red in Color, Meaning it has not yet been Configured.

***NOTE:** The <G-CODE> button is only visible if the G-Code functionality is activated in the System Utilities. (Utilities > Configuration > BioSway Configuration > Clinical Codes).*

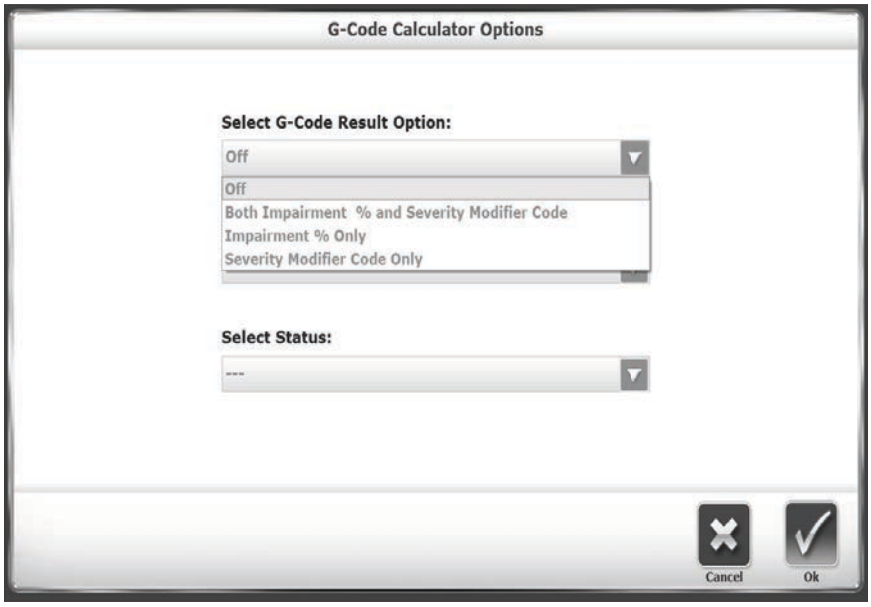


Figure 8.2. The G-Code Calculator Options Screen--G-Code Result Option.

4. On this screen, G-Code data can be associated with the patient by making selections in the drop-down menus. The top drop-down menu allows selection of a G-Code Result Option. This means that the Report will feature the Impairment %, the Severity Modifier Code, or both. If the drop-down menu is set to Off, the Report will show neither column and the <G-Code> button on the Set-Up screen has a red (as opposed to green) dot on it.

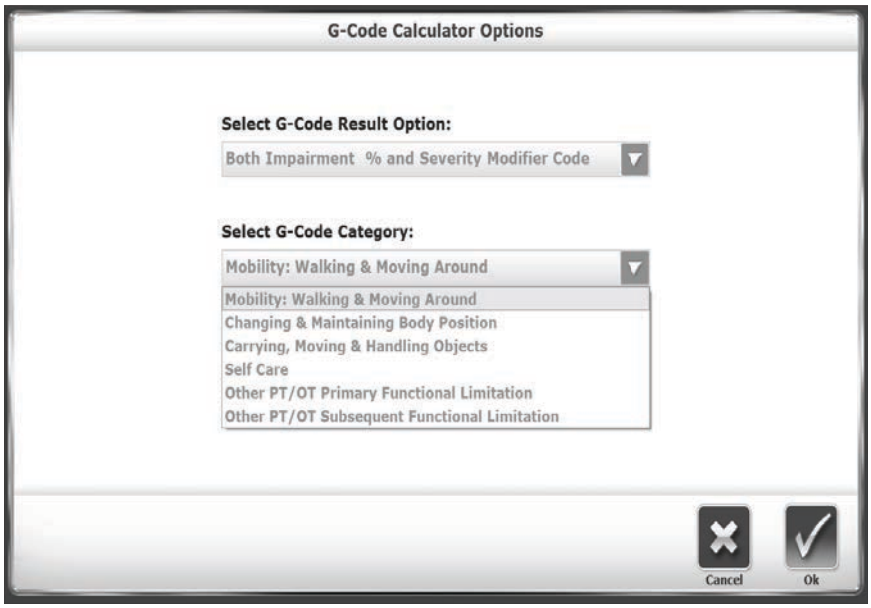


Figure 8.3. The G-Code Calculator Options Screen--G-Code Category.

5. The G-Code category drop-down menu features a list of commonly used rehabilitation categories. The category most likely to be associated when using the BioSway is the Changing and Maintaining Body Position.

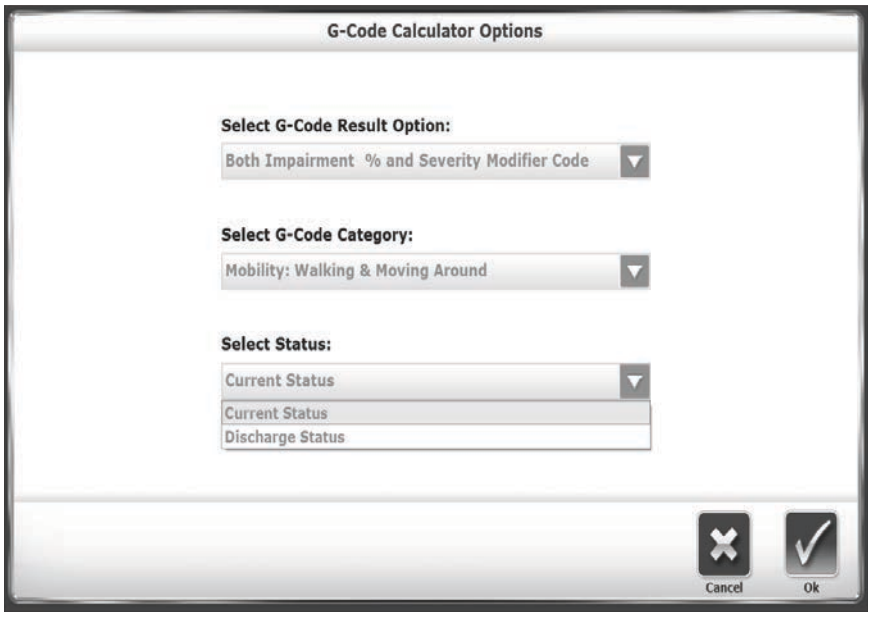


Figure 8.4. The G-Code Calculator Options Screen--Status.

6. The Status drop-down menu relates to the patient's treatment timeline. If this is the patient's first treatment, or one in a series of treatments, the status is set to Current Status. If it is the last treatment, the Discharge Status is selected.
7. When a selection has been made from all three drop-down menus, touch <OK> to return to the Patient Setup screen. The <G-CODE> button is green instead of red.

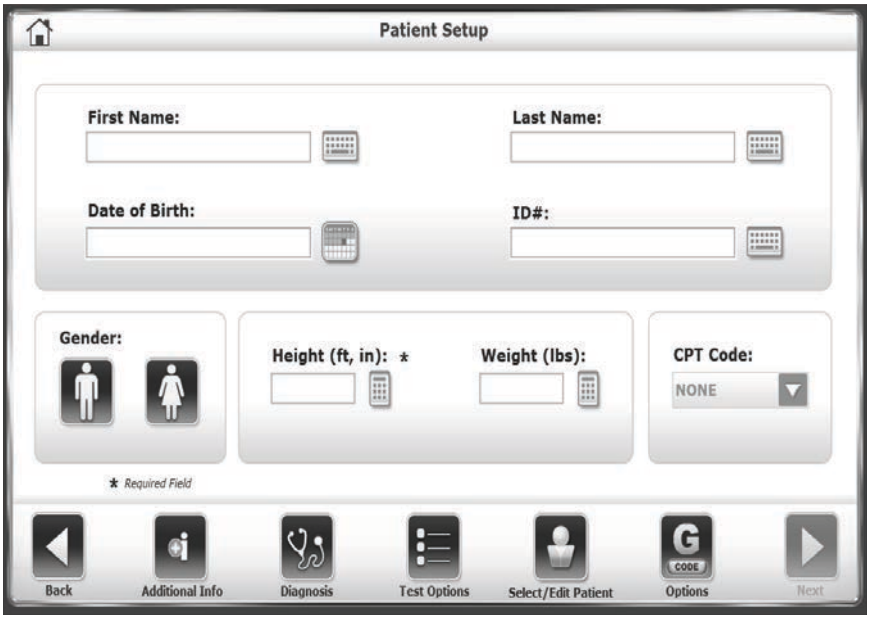


Figure 8.5. Patient Setup Screen. The G-CODE Button is Green in Color Meaning it has been Configured.

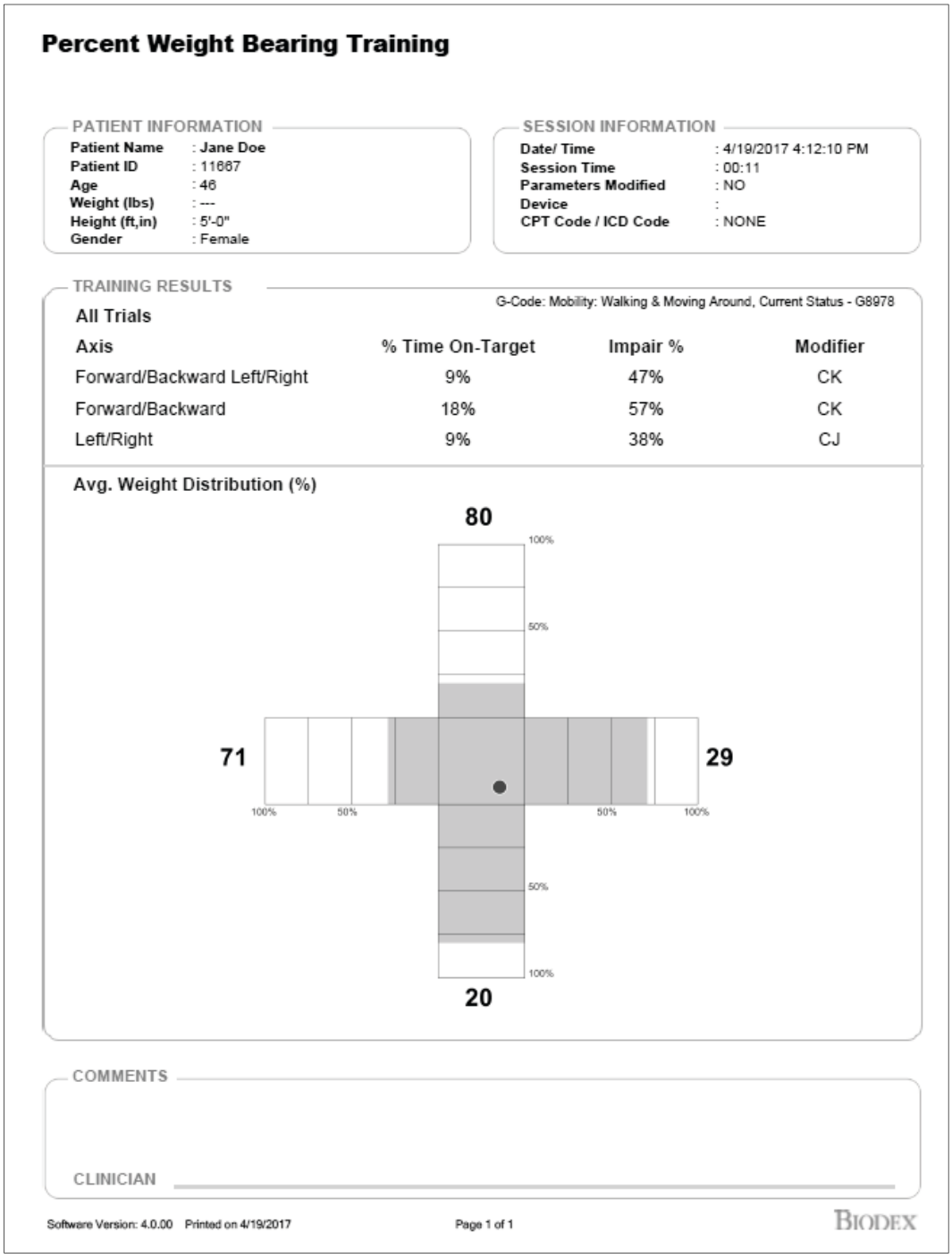
G-Codes can be associated for the m-CTSIB test. The process is the same as for the Percent Weight Bearing Training described above.

The Impairment Percentage numbers refer to the degree to which the patient is considered impaired; with 100% meaning the patient is completely impaired and unable to do the associated task without help. The Severity Code Modifiers are a series of impairment level ranges made up of about 20 percentage points each, where "CI", for example, would represent a status of 1-19% impairment.

Modifier Impairment / Limitation / Restriction	Modifier Code
0%	CH
1-19%	CI
20-39%	CJ
40-59%	CK
60-79%	CL
80-99%	CM
100%	CN

Figure 8.6. The Scale of Seven Modifiers is Intended to Denote the Patient's Degree of Impairment/Limitation/Restriction.

When selected and associated, the G-Code, Impair %, and the Modifier Code are displayed on the right side of the test report.



Percent Weight Bearing Training

PATIENT INFORMATION

Patient Name	: **Jane Doe**
Patient ID	: 11667
Age	: 46
Weight (lbs)	: ---
Height (ft,in)	: 5'-0"
Gender	: Female

SESSION INFORMATION

Date/ Time	: 4/19/2017 4:12:10 PM
Session Time	: 00:11
Parameters Modified	: NO
Device	:
CPT Code / ICD Code	: NONE

TRAINING RESULTS

G-Code: Mobility: Walking & Moving Around, Current Status - G8978

All Trials

Axis	% Time On-Target	Impair %	Modifier
Forward/Backward Left/Right	9%	47%	CK
Forward/Backward	18%	57%	CK
Left/Right	9%	38%	CJ

Avg. Weight Distribution (%)

COMMENTS

CLINICIAN

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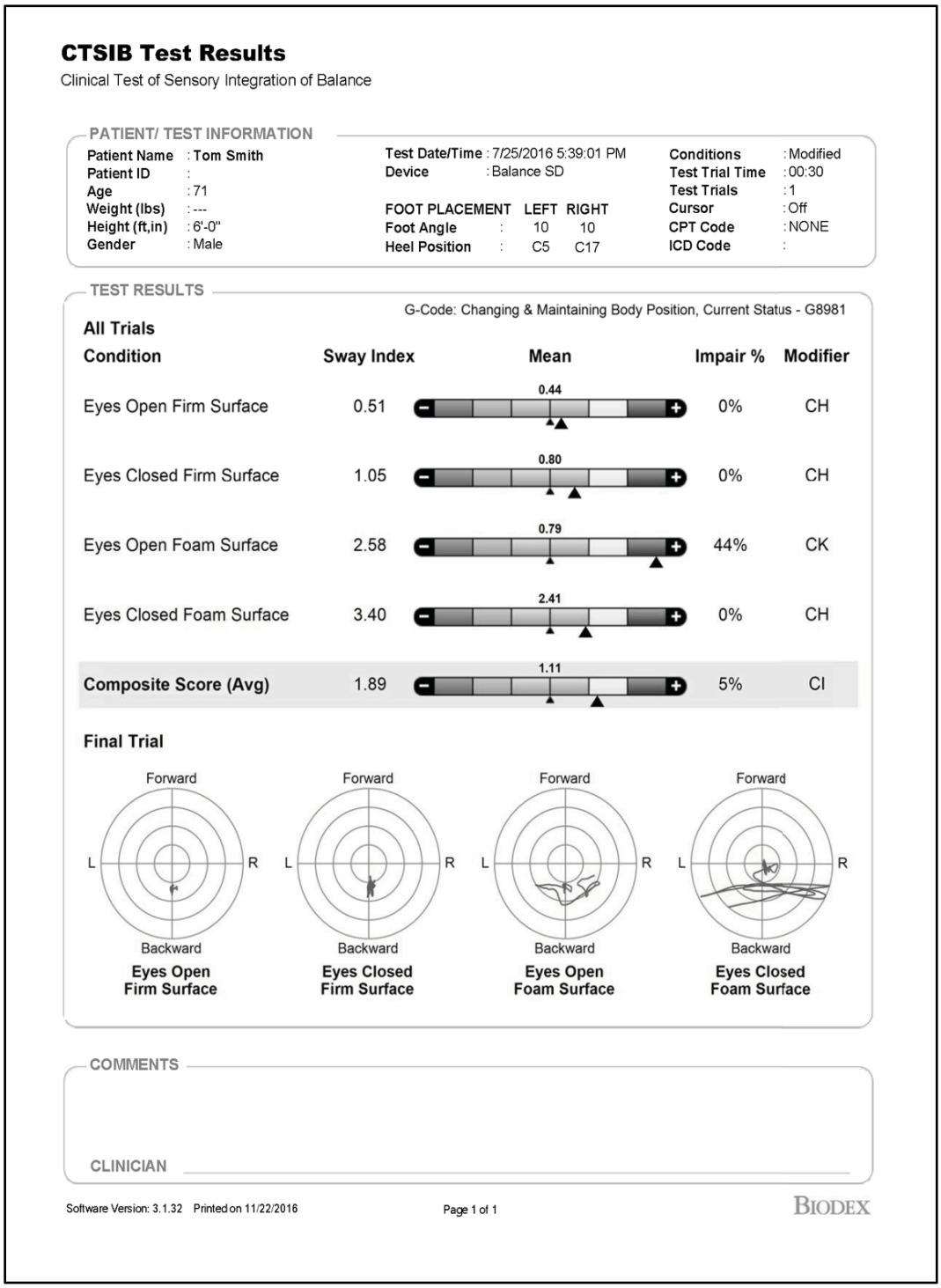
Figure 8.7. Percent Weight Bearing Training Report.



CTSIB Test Results

Clinical Test of Sensory Integration of Balance

PATIENT/ TEST INFORMATION

Patient Name	: Tom Smith	Test Date/Time	: 7/25/2016 5:39:01 PM	Conditions	: Modified
Patient ID	:	Device	: Balance SD	Test Trial Time	: 00:30
Age	: 71			Test Trials	: 1
Weight (lbs)	: ---	FOOT PLACEMENT	LEFT RIGHT	Cursor	: Off
Height (ft,in)	: 6'-0"	Foot Angle	: 10 10	CPT Code	: NONE
Gender	: Male	Heel Position	: C5 C17	ICD Code	:

TEST RESULTS

G-Code: Changing & Maintaining Body Position, Current Status - G8981

All Trials

Condition	Sway Index	Mean	Impair %	Modifier
Eyes Open Firm Surface	0.51	0.44	0%	CH
Eyes Closed Firm Surface	1.05	0.80	0%	CH
Eyes Open Foam Surface	2.58	0.79	44%	CK
Eyes Closed Foam Surface	3.40	2.41	0%	CH
Composite Score (Avg)	1.89	1.11	5%	CI

Final Trial

Forward / L / R / Backward

Eyes Open Firm Surface | Eyes Closed Firm Surface | Eyes Open Foam Surface | Eyes Closed Foam Surface

COMMENTS

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Figure 8.8. The G-Code Impair % and the Modifier Code on the Clinical Test of Sensory Integration of Balance Patient Record.

To Alter the Impairment Percentage Numbers Manually:

1. Select the patient's name (row) on the Patient Management - Select a Patient screen in system Utilities and touch <Next>.

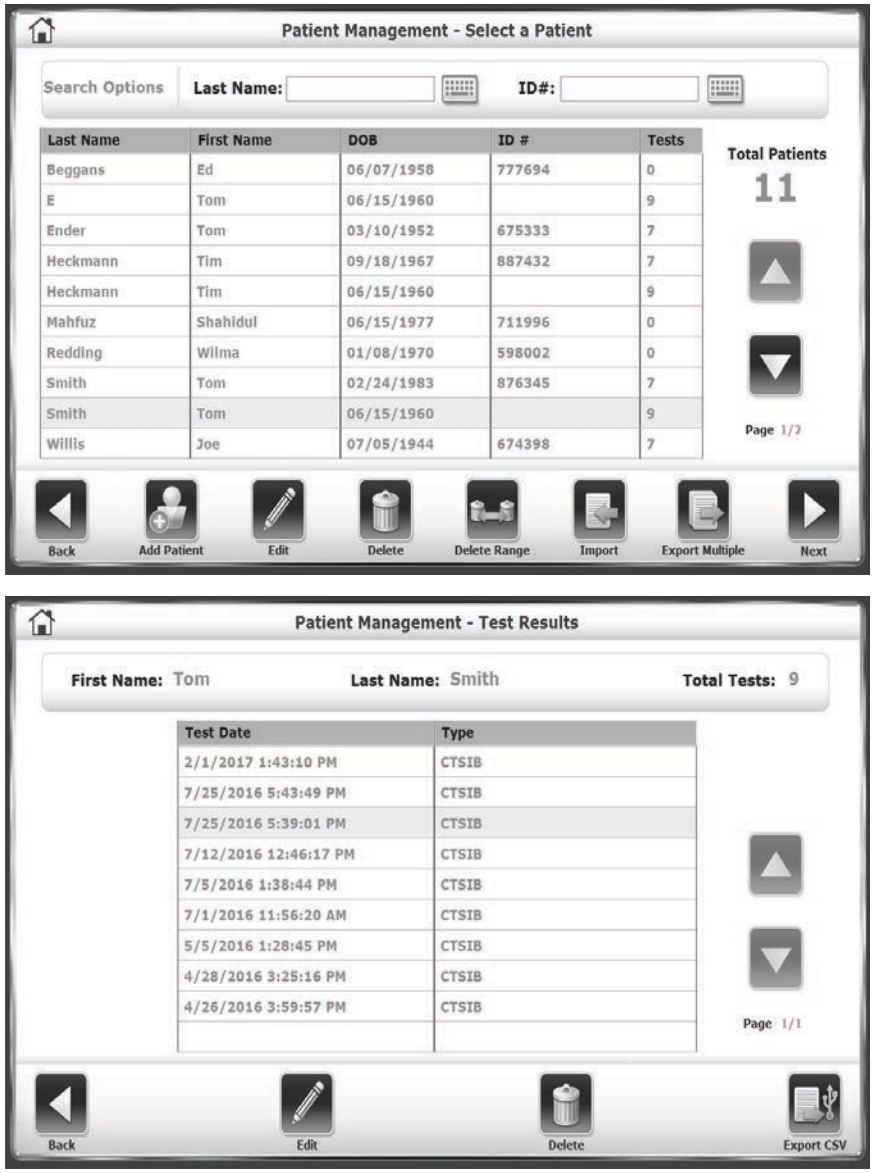


Figure 8.9. The first Steps for Adjusting a Patient's G-Code Information is Locating The Test in the Patient Management Section of the System Utilities.

2. Select the test (row) for which the G-Code information is to be adjusted and touch the <Edit> button.
3. On the resulting screen, touch the <Impair %> field to be adjusted. In this example, the Impairment percentage to be adjusted is for the third condition, 'Eyes Open Foam Surface', which is currently at 44%.

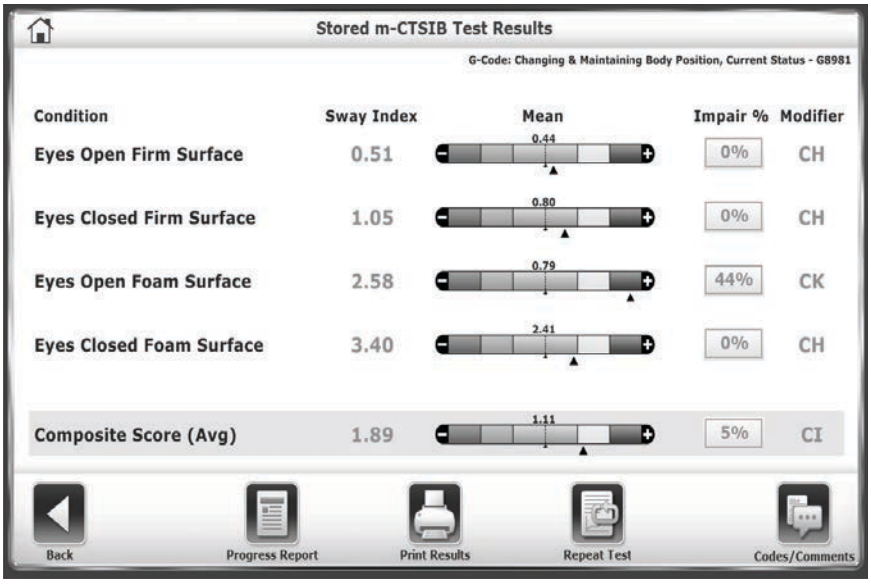
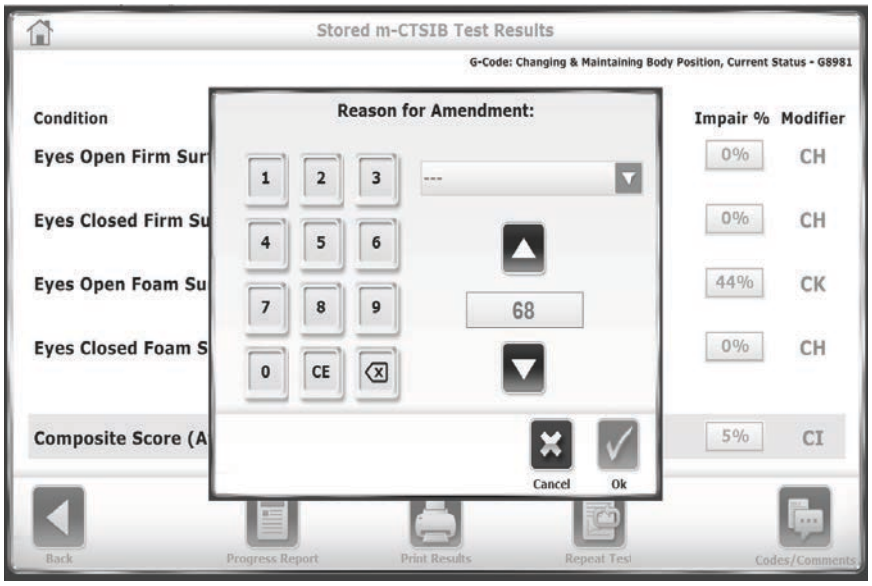


Figure 8.10. The Stored Test Results Screen. The Impairment Percentages can be Adjusted by Touching the boxes with the Numbers.

4. When the box is touched, an external window is displayed, allowing the percentage number to be changed using either the arrows or the keypad. Use the drop-down menu to select a reason for making the change (e.g., Clinical Judgment).



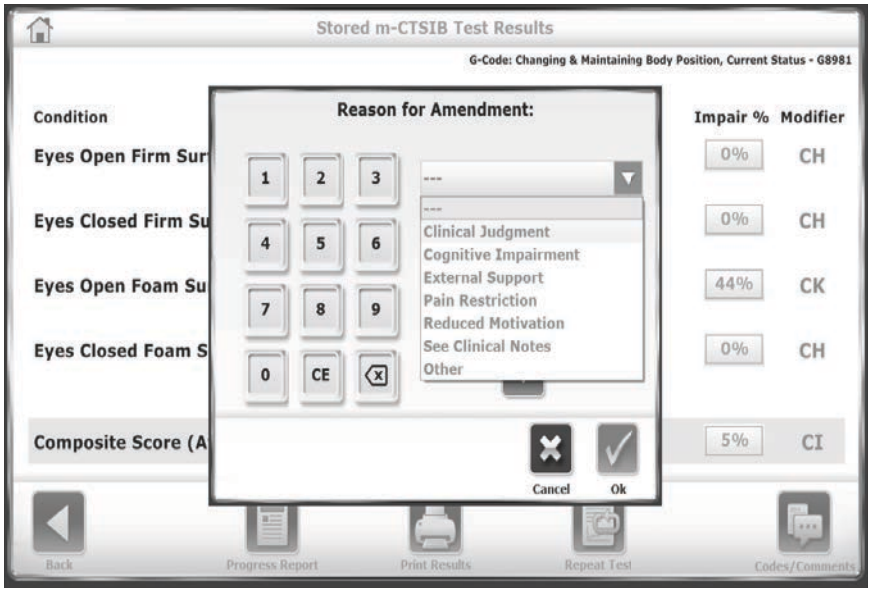


Figure 8.11. Reason for Amendment External Screen. Use this Screen to Set a New Impairment %, as well as Giving a Reason for Making the Change.

5. Once a new Impairment % number and a reason for the change have been entered/selected, touch <OK>. The new Impairment percent as well as a new modifier code (since in this case the change in percentage [44 to 68] was significant enough to warrant a change in Modifier Code category; from CK to CL) is displayed on the resultant screen. A red asterisk is displayed next to the data that has been changed.

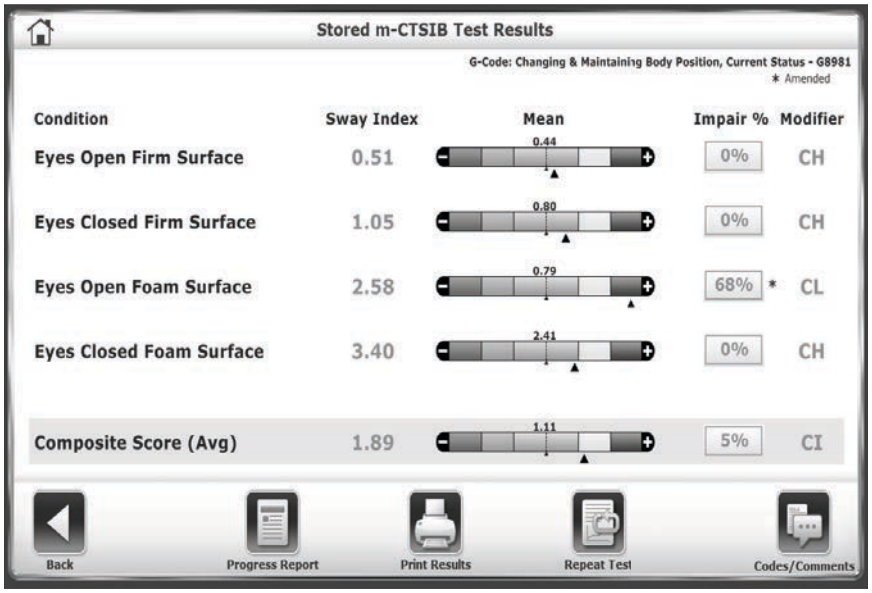


Figure 8.12. Stored Test Results, with Updated Impair % Number, Modifier Code, and Red 'Amended' Asterisk.

Normative Data

The new Biodex BioSway Balance device comes equipped with several sets of normative data. Normative data for balance are typically noted as the average and standard deviation numbers derived from various scores in previous controlled studies. These data sets are separated into different population groups in order to give relevant norms for the population being tested.

It is highly recommended that when tests are conducted the correct normative data set associated with the population and protocol is used. Having the relevant normative data enables the vetting of baseline testing. Additionally, if a patient does not have a baseline test, the normative data becomes the baseline for that patient.

m-CTSIB Test

For the m-CTSIB test, there are four normative data sets available:

- For the Aggregate General Population, ages 13 – 85, data on CTSIB reliability and predictive score is the combined data of the three other data sets listed below.
- The Male and Female, ages 13 – 18, 20 second trial normative data was collected from a population of student athletes, male and female, ages 13 – 18. The data was collected by Carolinas Medical Center, Charlotte, NC, Department of Sports Medicine & Special Events, at four special events during the 2011 summer. Data analysis was provided by Raymond F. McKenna, PT, PhD, Clinical Associate Professor, Stony Brook University School of Health Technology and Management, Department of Physical Therapy State University of New York.
- The 65 – 84 Male and Female Independent normative data was collected from two populations of older adults, male and female, ages 65 – 84. The data was collected by Georgia Southern University in Statesboro, GA, and Adelphi University in Garden City, NY.
- The 17 – 23 Male and Female NCAA Baseline normative data was collected from a population of athletes, male and female, ages 17 – 23. The data was collected by David Bica, DO and Anthony S. Kulas PhD, ATC, LAT, Department of Sports Medicine, the Brody School of Medicine, East Carolina University, Greenville, NC.

Table 8.1. Data Table for the m-CTSIB Normative Data Set.

Population	Sample Size	Eyes Open Firm Surface Sway Index Mean	Std Dev.	Eyes Closed Firm Surface Sway Index Mean	Std Dev.	Eyes Open Foam Surface Sway Index Mean	Std Dev.	Eyes Closed Foam Surface Sway Index Mean	Std Dev.
M F, Age 13-18, 20 sec trial	1500	0.48	0.39	0.66	0.38	0.75	0.31	1.87	0.27
17-23 Male Female NCAA Baseline	480	0.32	0.4	0.67	0.35	0.6	0.33	2.08	0.26
65-84 Male Female Independent	215	0.66	0.4	1.17	0.38	1.13	0.38	3.5	0.32
Aggregate Population, ages 13 – 84	2195	0.44	0.48	0.8	0.44	0.79	0.43	2.41	0.38

The following is a snapshot of BioSway m-CTSIB defaults, which is an implementation of the above table.

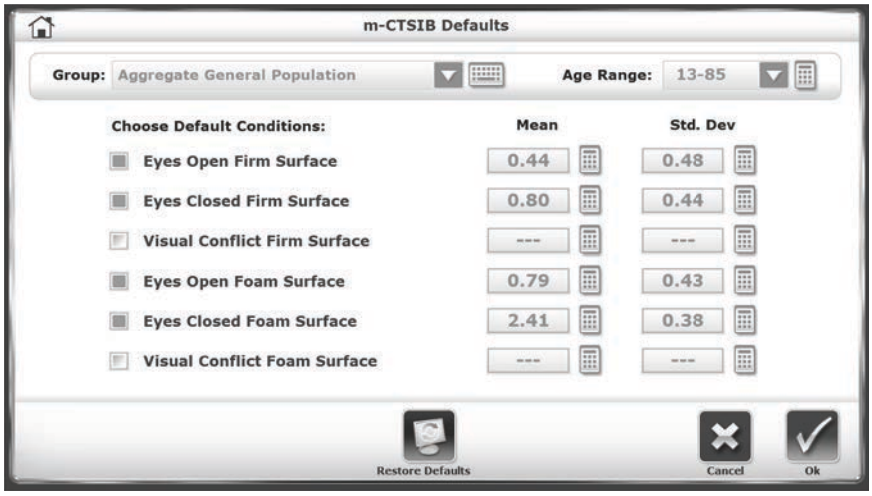


Figure 8.13. m-CTSIB Defaults Screen.

Fall Risk Test Normative Data

To determine the reliability, 30 older adults (15 men, 15 women) completed the test on two separate days. The intraclass correlation coefficient results ranged from 0.74 to 0.86 with no significant (P<.05) differences between the testing sessions. The standard error of measurement ranged from 15.9% to 23.6%.

Table 8.2. Descriptive statistics and reliability results between the two testing sessions (1.9 ±.7 day separation) in thirty older adults.

	Session 1	Session 2	ICC	Systematic bias		SEM (%)
	$\bar{X}$ ± SD (mm/s)	$\bar{X}$ ± SD (mm/s)		$\bar{X}$ change (%)	*P* value	
Self-selected eyes open	4.9 ± 1.8	5.1 ± 2.1	.86	3.1	.427	15.9
Self-selected eyes closed	6.9 ± 3.7	6.5 ± 3.4	.82	−4.4	.414	23.6
Narrow-eyes open	6.2 ± 2.7	6.7 ± 2.6	.74	7.6	.192	23.3
Narrow-eyes closed	9.1 ± 3.9	10.0 ± 5.1	.81	6.8	.200	21.2

$\bar{X}$ mean, *SD* standard deviation, *ICC* intraclass correlation coefficient, *SEM* standard error of measurement

In Table 9.3, note that the mean postural sway velocity of 338 subjects are broken into four Age Groups. The standard deviations from the mean are separated by three separate boundary ranges for 1, 2, and 3 SDs. LB refers to the lower boundary in the range and UB refers to the upper boundary. For the Z-Score in a patient's Fall Risk Test report, the 1, 2, and 3 SD ranges are represented by colors green, yellow, and orange, respectively.

Table 8.3 Z-Score boundaries data table for the Fall Risk Test report.

						Score Boundaries					
						1 SD		2 SD		3 SD	
		Age Group	n	Mean	SD	LB	UB	LB	UB	LB	UB
Self-Selected	Eyes Open	50-59	108	6.43	2.07	-9.82	9.82	-10.49	10.49	-11.76	11.76
		60-69	108	7.98	2.10	-11.42	11.42	-12.09	12.09	-13.38	13.38
		70-79	81	9.03	2.27	-12.76	12.76	-13.48	13.48	-14.88	14.88
		>80	41	9.76	2.45	-13.78	13.78	-14.57	14.57	-16.08	16.08
Self-Selected	Eyes Closed	50-59	108	7.88	2.53	-12.02	12.02	-12.83	12.83	-14.39	14.39
		60-69	108	9.63	2.53	-13.77	13.77	-14.58	14.58	-16.13	16.13
		70-79	81	10.89	2.92	-15.67	15.67	-16.61	16.61	-18.40	18.40
		>80	41	11.68	3.24	-16.99	16.99	-18.03	18.03	-20.02	20.02
Narrow	Eyes Open	50-59	108	8.45	1.92	-11.60	11.60	-12.21	12.21	-13.40	13.40
		60-69	108	9.56	2.32	-13.37	13.37	-14.12	14.12	-15.55	15.55
		70-79	81	10.37	2.50	-14.47	14.47	-15.27	15.27	-16.80	16.80
		>80	41	11.43	2.67	-15.81	15.81	-16.67	16.67	-18.31	18.31
Narrow	Eyes Closed	50-59	108	10.06	2.38	-13.97	13.97	-14.74	14.74	-16.20	16.20
		60-69	108	11.62	2.78	-16.18	16.18	-17.07	17.07	-18.78	18.78
		70-79	81	12.58	3.05	-17.57	17.57	-18.55	18.55	-20.42	20.42
		>80	41	14.29	3.51	-20.04	20.04	-21.17	21.17	-23.32	23.32

The following is an illustration of the BioSway Fall Risk defaults, which is an implementation of above table.

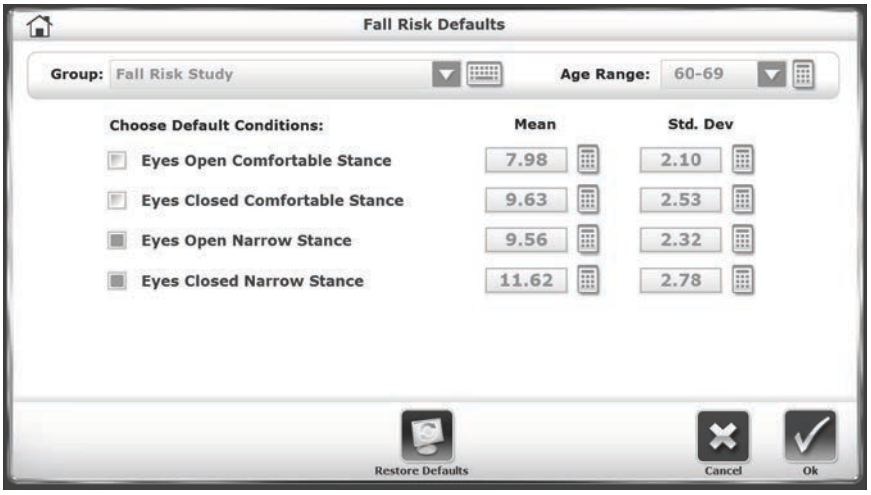


Figure 8.14. Fall Risk Defaults Screen

9. System Specifications

Dimensions:

Platform Dimension: 21.25" w x 19" l x 2.5" h (54 x 48 x 7 cm)

Weight: 19 lb (8.6 kg)

Display Angle: Adjustable from vertical back to approximately 45°

Display Specifications:

Display Size and Type: 15.6 inch AIO resistive touch screen computer.
Display resolution: 1366x768

Operating System: Windows 7 Intel Celeron Proc, 32 G SSD

Printing: PCL printing via USB port

Memory: 2 G RAM

Audio out with standard stereo line jack

Video Out Display: supports simultaneous analog up to 1366x768 resolution User Interface and Device Capabilities:

USB ports: Four 1.1 host ports to support

Mass Storage Device: USB Thumb drive Keyboard

Mouse wired and wireless to allow for remote control operation.
Plus:

(1) Remote CRT connector

(1) Serial communication port Printer: HP DeskJet

Hard Case Dimension: 23.75" w x 22.75" l x 10.75" h(60 x 58 x 27 cm)

Total Weight (including case): 44 lb (20 kg)

User Capacity: 500 lb (227 kg)

Power: 115V/230VAC, 50/60 HZ, 15 amp line

Certification: ETL listed to UL 60601-1 and CAN/CSA C22.2 No.:601.1-M90. CE conformity to EN 60601-1, EMC compliance to EN 60601-1-2.

Warranty: one year parts and labor.

10. Maintenance

The Biodex BioSway System requires only the most basic general maintenance, performed on an as-needed basis at least every three to four months.

Cleaning Instructions

With the system turned OFF, wipe down all surfaces except for the monitor/display with a damp cloth. Mild soap and water can be used to remove stains and scuff marks. As needed, inspect all locking and adjustment mechanisms for signs of wear or damage.

If there are any questions or further assistance is required, contact the Biodex Customer Service Department.

11. References and Bibliography

References

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12. Electromagnetic Compatibility

Conformance to Standards

This equipment conforms to the following safety standards:

Table 12.1. Safety Standards Conformance Table

Standard	***Edition and/or date***
IEC60601-1-2	First Edition, 2007

Accompanying EMC Documents

This medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

- Portable and mobile RF communications equipment can affect medical electrical equipment.
- Use of accessories, transducers, and cables other than those specified, with the exception of accessories, transducers, and cables sold by the manufacturer of this equipment, as replacement parts for internal and external components, may result in increased emissions or decreased immunity of the equipment.
- The BioSway System should not be used adjacent to or stacked with other equipment. If the BioSway System is used while positioned adjacent to other equipment, it should be observed to verify normal operation in the configuration in which it will be used.

List of Cable Accessories

The list in Table includes all accessory cables supplied with the BioSway System for which the manufacturer of this equipment claims compliance to EN 60601-1-2 when used with the BioSway System.

Table 12.2 BioSway System Cables

Cable Description	***Part No.***	***Cable Length***
USB Cable	Biodex # C14397	10ft

Declaration of Conformity

Table 12.3. Emission Test Table

Manufacturer's declaration electromagnetic emissions		
The BioSway System is intended for use in the electromagnetic environment specified below. The customer or the user of the BioSway System should assure that it is used in such an environment.		
Emission test	***Compliance***	***Electromagnetic environment***
RF emissions CISPR 11	Group 1	The BioSway System generates RF energy only for its internal functions. Therefore, its RF emission is very low and is not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class A	The BioSway System is suitable for use in all establishments including domestic establishments and those directly connected to the public low voltage power supply network supplying buildings used for domestic purposes.
Harmonic distortion EN 61000-3-2	Class A	
Voltage fluctuations and flicker EN 61000-3-3	Complies	

Table 12.4. Immunity Test Tables

Manufacturer's declaration electromagnetic immunity			
The BioSway System is intended for use in the electromagnetic environment specified below. The customer or the user of the BioSway System should assure that it is used in such an environment.			
Immunity test	***IEC 60601-1-2 Test level***	***IEC 60601-1-2 Compliance level***	***Electromagnetic environment – guidance***
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact	Contact ± 6	Floor should be wood, concrete or ceramic tiles. If floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients/burst IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input/output lines	Power ± 2 kV Signal ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV diff. mode ± 2 kV com. mode	Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	*IEC 60601 Test level*	*IEC 60601-1-2 Compliance level*	*Electromagnetic environment – guidance*
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5% UT (> 95% of dip in UT) for 1/2 cycle 40% UT (60% of dip in UT) for 5 cycle 70% UT (30% of dip in UT) for 25 cycle < 5% UT (> 95% of dip in UT) for 5 sec	< 5% UT (> 95% of dip in UT) for 1/2 cycle 40% UT (60% of dip in UT) for 5 cycle 70% UT (30% of dip in UT) for 25 cycle < 5% UT (> 95% of dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If a better mains power quality is required, it is recommended that the BioSway System is powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	If image distortion occurs, it may be necessary to position the BioSway System display further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
Conducted RF IEC 61000-4-6	3 Vrms, 150 KHz to 80 MHz	3 Vrms, 150 KHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the BioSway System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = 1.2√ P 150 KHz to 80 MHz d = 1.2√ P 80 MHz to 800 MHz d = 2.3√ P 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watt (W) according to the transmitter manufacturer, and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 Vrms, 80 MHz to 2.5 GHz	3 V/m, 80 MHz to 2.5 GHz	

Immunity test	*IEC 60601-1-2 Test level*	*IEC 60601-1-2 Compliance level*	*Electromagnetic environment – guidance*
Note 1. UT is the a.c. mains voltage prior to application of the test level. **Note 2**. At 80 MHz and 800 MHz, the higher frequency range applies. **Note 3**. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people.			
[a] Field strength from mixed transmitters, such as base stations for radio telephones and land mobile radios, amateur radio, AM or FM broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BioSway System is used exceeds the applicable RF compliance levels above, the BioSway System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BioSway System. [b] Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended Separation Distances

Table 12.5. Immunity Test Tables

Recommended separation distances between portable and mobile RF communications equipment and the BioSway System.			
The BioSway System is intended for use in the electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the BioSway System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the BioSway System as recommended below, according to the maximum output power of the communication equipment.			
Rated maximum output power of transmitter [W]	***Separation distance according to frequency of transmitter [m]***		
	150 KHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **Note 1**. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. **Note 2**. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Operating Temperature

Do not expose the equipment to a temperature change of more than 5˚ F (3˚ C) per hour. Limits of low and high operating temperature ranges are 59˚ to 86˚ F (15˚ C to 30˚ C).

Appendix A: Data Definitions and Interpretation

Calculation of Limits of Stability Direction Control

In this Appendix, the terms and metrics used in both training and testing protocols are defined.

Different tests within the BioSway Balance System use different scoring methods. It can be summarized as follows:

1. *Sway Index* – CTSIB, BESS, Postural Stability, Bilateral Test.
2. *Stability Index* - Postural Stability Test.
3. *Angle* – Limit of Stability Test.
4. *Direction Efficiency %* - Motor Control Test.
5. *Sway Velocity Index/ Z Score* – Fall Risk Test.

Sway Index: Sway Index calculation is from a static measure, when information is collected by positioning the patient on a static force plate and then sampling and recording patient movement. The system employs a series of strain gauges to determine variation in the subject's resultant center of pressure (COP). The center of pressure is the patient's center of gravity projection on the platform resulting from sway angle and the patient height. Data is sampled at the rate of 20Hz. Each recorded sample consists of a (X, Y) coordinates. What is displayed is the sway angle derived from the position of the COG from zero and the height of the patients COG taken as .55 times the patient height.

This data is recorded for later analysis and also displayed, in real time on, an LCD display observable by the patient. The resultant movement results in a 'spaghetti plot' as shown below. This plot indicates patient movement from one sample to the next.

Essentially, the database consists of an array of (X, Y) coordinates defining the calculated COP. The data can be interpreted as an ordered series of sequential vectors from point to point.

The Score, or Sway Index, is the Root Mean Squared distance (RMS distance) of the X,Y coordinates.

For a 2D position represented by X,Y, the calculation would be:
For the mean position X:

$$\sigma_x = \frac{1}{n}\sum_{i=1}^{n} x_i$$

For the mean position Y:

$$\sigma_y = \frac{1}{n}\sum_{i=1}^{n} y_i$$

Resulting in:

$$\emptyset = \sqrt{\frac{1}{n}\left(\sum_{i=1}^{n}(x_i - \sigma_x)^2 + \left(y_i - \sigma_y\right)^2\right)}$$

Where:

Ø = resulting Sway Index (score).

n = number of samples.

Stability Index (SI): The Stability Index is the average position from center, in degrees. It is important the patient has a COG (Center Of Gravity) centered before starting. The score ranges from 0.0 to 20.0, where each ring on the screen represents 5.0 degrees.

Stability Index with dynamic platform motion represents the variance of platform displacement in degrees, from level, in all motions during a test. A high number is indicative of a lot of movement during a dynamic test. With static measures, it is the angular excursion of the patient's Center Of Gravity.

Use as a starting point for a perfectly balanced state.

$$SI = \frac{1}{n}\sum_{i=1}^{n}\sqrt{X_i^2 + Y_i^2}$$

Where n = number of samples.

Forward/Backward (Anterior/Posterior) Stability Index: Represents the variance of platform displacement in degrees, from level, for motion in the sagittal plane.

$$SI_y = \frac{1}{n}\sum_{i=1}^{n}\sqrt{Y_i^2}$$

Left/Right (Medial/Lateral) Stability Index: Represents the variance of foot platform displacement in degrees, from level, for motion in the frontal plane.

$$SI_x = \frac{1}{n}\sum_{i=1}^{n}\sqrt{X_i^2}$$

Angle: The sway angle, Angle (°), is derived from the position of the patient's center of gravity (COG) from a center position of zero and the estimated height of the patient's COG.

Direction Efficiency %:

$$Direction\ Efficiency\% = \frac{Straight\ Line\ Distance\ x\ 2}{Actual\ distance\ to\ and\ from}\ X\ 100$$

Sway Velocity Index: A value based on Velocity (mm/s), which is the total distance the COP traveled in the medial lateral path/time.

It is referred to an index because each patient's score is first normalized by a natural log function (Ln) of the medial-lateral center of pressure velocity (CPV_{ML}), divided by the patient's body height (BH). To make the scoring similar to other types of sway indexes calculated by the system software, it is multiplied by 1000.

$$Sway\ Velocity\ Index = \frac{\mathrm{Ln}(\ CPV_{ML}\ )}{BH}\ X\ 1000$$

Where:

CPV_{ML} = Mean medial-lateral center of pressure velocity (mm/s).
BH=Patient's body height in cm.

Velocity (mm/s) is the total distance the COP traveled in the medial lateral path/time.

$$SVI\ as\ Standardized\ Score = Z\ Score = \frac{\mathrm{SVI} - \mu_{SVI-AG}}{\sigma_{SVI-AG}}$$

Where:

SVI= Sway Velocity Index from patient.
μ_{SVI-AG}= Mean Sway Velocity Index for respective Age Group.
σ_{SVI-AG}= Standard Deviation Sway Velocity Index for respective Age Group.

This value is compared to normative data as a Z score. A Z score indicates how many standard deviations SVI is from the mean.

Platform setting: Indicates the stability (stiffness) of the foot platform. When locked, the platform is fully stable (static). A setting of 1 is the most stable released setting. A setting of 12 is the least stable foot platform setting. Stability settings of 1 through 12 allow the platform a full 20 degrees of deflection from level in any direction. For patient centering prior to testing, the platform deflection is limited to less than five degrees.

Appendix B: Interpretation of Reports

Clinical Test of Sensory Integration and Balance – CTSIB or m-CTSIB (Modified CTSIB) Data Interpretation

The Clinical Test of Sensory Interaction and Balance (CTSIB) is standardized test for balance assessment on a static surface. The CTSIB test protocol is well documented in the literature as an effective test for identifying individuals with mild to severe balance problems. Typically, the modified CTSIB test is performed. The m-CTSIB consists of four conditions. The test provides a generalized assessment of how well a patient can integrate various senses with respect to balance and compensate when one or more of those senses are compromised. See the table below for more description of each condition.

Table B.1. Clinical Test of Sensory Interaction and Balance (CTSIB)

	Condition Name	Understanding of the condition
Condition 1	Eyes open firm surface	Accurate information is available to all three sensory systems: visual, vestibular and somatosensory. Normal individuals are very stable in this condition.
Condition 2	Eyes closed firm surface	No visual input is available. The Patient must rely on somatosensory and vestibular inputs. Somatosensory is the primary sensory input. Vestibular inputs are secondary. High sway scores are indicative of problems with somatosensory. In normal individuals there is no significant difference in sway with eyes open or closed on a firm surface.
Condition 3*	Visual conflict on firm surface	Some vision present but information conflicts with vestibular information. This condition brings in more vestibular and somatosensory inputs
Condition 4	Eyes open on a dynamic surface	The unstable surface confounds the somatosensory information as it imposes additional challenges to the musculoskeletal system. Primary inputs are visual with vestibular as secondary. Normal individuals will sway more on the unstable surface, but will not fall.
Condition 5	Eyes closed on dynamic surface	This condition focuses on the vestibular sensory input as visual is not available and somatosensory is challenged by the unstable surface. Again normal individuals will sway more on the unstable surface, but will not fall.
Condition 6*	Visual conflict on dynamic surface	Used to evaluate the mediation of visual with and vestibular and somatosensory inputs

** Visual conflict conditions are not performed in m-CTSIB. The m-CTSIB eliminates conditions 3 and 6. Biodex Balance products use the m-CTSIB format of four conditions as the default with the ability to include the other two if desired.*

What is being measured during the CTSIB test? The Sway Index (See Appendix A for a definition). The higher the Sway Index the more unsteady the person was during the test. The Sway Index is an objective quantification of what commonly is done with a time-based pass/fail for completing the CTSIB stage in 30 seconds without falling, or assigning a value of 1 to 4 to characterize the sway; 1= minimal sway, 4 = a fall. The score is indicated as on the graph relative to the mean. Each color segment represents one standard deviation from the mean. The circled example is within one standard deviation.

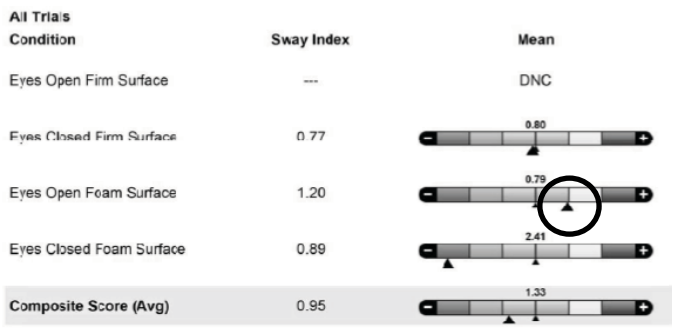


Figure B.1. Sample Stored Test Results for a CTSIB Test.

To interpret or apply the test results, consider the condition under which the sway was the greatest. Normal balance includes the ability to hold still in various situations depending on the activity or circumstance demands. The COG sway scores indicate how well the patient accomplished this. Lower scores reflect little movement that are considered better than higher scores that reflect more movement.

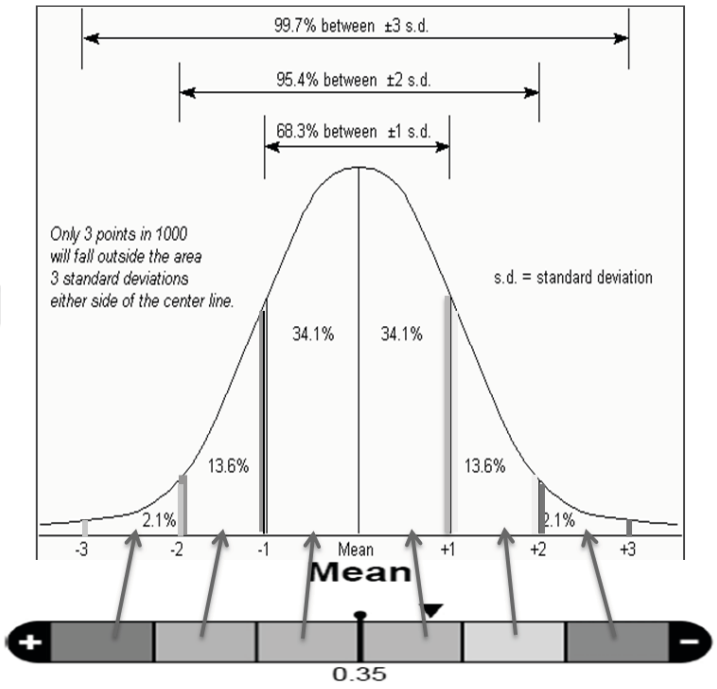


Figure B.2. Standard Deviation Chart for CTSIB Test Results.

Firm Surface: Eyes open vs. Eyes closed:

Normal individuals standing on a firm surface have similar amounts of sway with eyes open or closed. On a firm surface, when significantly more sway is present with the eyes closed than the patient having difficulty using somatosensory inputs (this is the input up from the feet). An ankle strategy should be used for primary balance control on a firm surface.

Unstable (Foam) surface: Eyes open vs Eyes closed:

With eyes open on an unstable surface, normal individuals have significantly more sway than when standing on a firm surface. And, even more sway on the unstable surface with their eyes closed. However; they do not become overly unstable or fall. Patients that do become unstable or fall when standing on foam with eyes open may have difficultly using visual information for balance control and/or may have lower extremity musculoskeletal problems. A hip strategy should be used on unstable surfaces.

Note: *These tests are targeting sensory integration deficits. Standing on an unstable surface presents biomechanical and musculoskeletal challenges. Patient with ankle or foot problems, joint weakness, or pain will have high scores. As such in these patients, it cannot be assumed*

that sensory abnormalities are the underlying cause as they cannot be distinguished from motor (musculoskeletal) issues. Ideally, the patient should be screened for motor problems prior to the CTSIB test. Only patients without motor problems should be tested with the CTSIB. The Limits of Stability test is an effective test to ease out this question.

***Note:** Log transformation is applied to the patient score as well as to the normative data (see the section on Log Transformation for more information).*

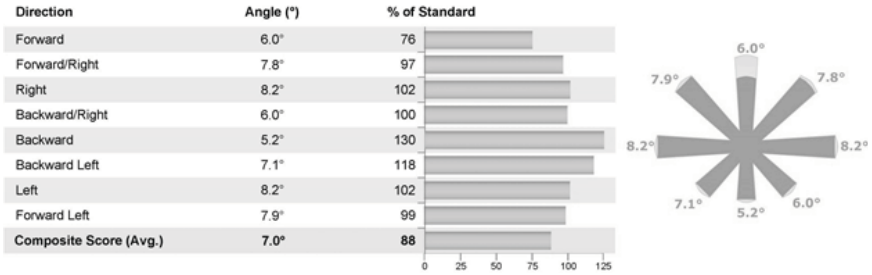
BESS test data interpretation

Sway index and conditions are the same as CSTIB. The inclusion of error scoring is additional.

Limit of Stability Test Data Interpretation

This test is a good indicator of dynamic control within a normalized sway envelope. Poor control, inconsistent, or increased times suggests further assessment for lower extremity strength, proprioception, vestibular, or visual deficiencies.

The patient's Limits of Stability is measured as the 'how far from the center' the patient can sway. This sway Angle (˚) is illustrated on the display screen.



Direction	Angle (°)	% of Standard
Forward	6.0°	76
Forward/Right	7.8°	97
Right	8.2°	102
Backward/Right	6.0°	100
Backward	5.2°	130
Backward Left	7.1°	118
Left	8.2°	102
Forward Left	7.9°	99
Composite Score (Avg.)	**7.0°**	**88**

Figure B.3. Limit of Stability Test Data from Report.

***Note:** Refer to Appendix A for the definition of Sway Angle listed as Angle (˚).*

% of Standard: The score relative to the standardize sway envelope; 8 degrees to side, 8 degrees forward, and 4 degree backwards.

Composite Score: The average of all the eight targets for a Full pattern. For a Left or Right pattern, it will be five targets.

$$Composite\ Score = \frac{1}{n}\sum_{i=1}^{n}(DEff)$$

Where: n = Number of Targets.

Postural Stability Test Data Interpretation

The Postural Stability test emphasizes a patient's ability to maintain a center of balance. The patient's score or Stability Index on this test assesses deviations from the center; thus a lower score is more desirable than a higher score. The stability index does not indicate how much the patient swayed; only the position.

All Trials

Direction	Stability Index	Sway Index
Overall	0.26	0.50
Forward/Backward	0.13	0.25
Left/Right	0.18	0.44

Figure B.4. Sample Postural Stability Test Data.

Where:

Stability Index: is the average position from center.
Sway Index: is the Root Mean Square distance for the X, Y coordinates over the course of the test.

Note: *Refer to for Appendix A for the equation for Stability and Sway Index.*

Percent Time In Zone/Quadrant: These values represent the percentage of test time the patient spends in each zone/quadrant during the test.

The target zones, A, B, C, and D, are equal to specific ranges of deflection and radiate in concentric circles from the center of the foot platform as follows:

- Zone A = zero to five degrees platform deflection from level.
- Zone B = six to ten degrees platform deflection from level.
- Zone C = 11 - 15 degrees platform deflection from level.
- Zone D = 16 - 20 degrees platform deflection from level.

Quadrants represent the four quarters of the Test Grid in the X and Y axis as follows:

- Quadrant 1 = right forward (anterior).
- Quadrant 2 = right backward (posterior).
- Quadrant 3 = left backward (posterior).
- Quadrant 4 = left forward (anterior).

Figure B.5. Target Zone/Quadrant Diagram.

Motor Control Test Data Interpretation

This test is a good indicator of dynamic control within a normalized sway envelope. Poor control, inconsistent, or increased times suggests further assessment for lower extremity strength, proprioception, vestibular, or visual deficiencies.

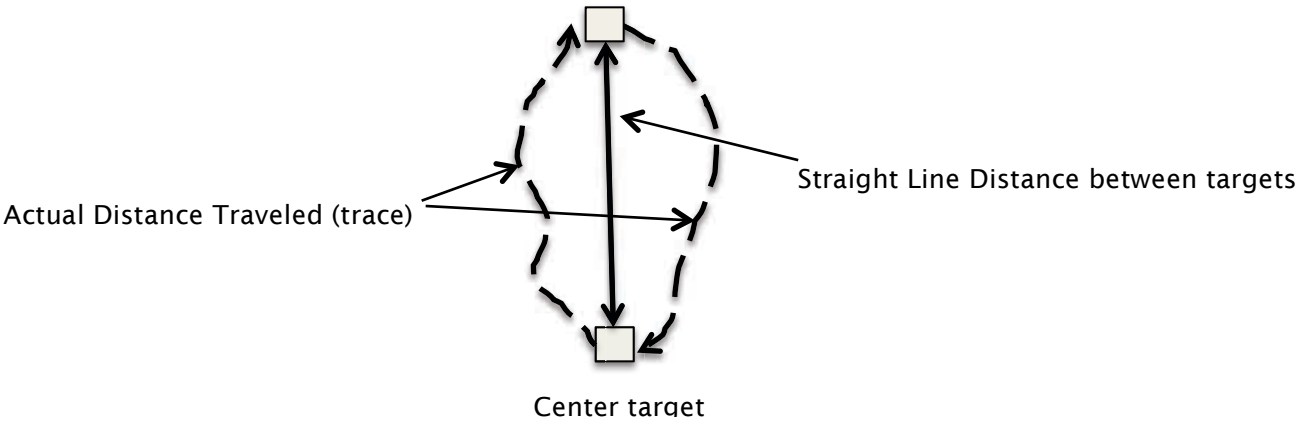


Figure B.6. Limits of Stability Direction Control Diagram.

Direction	Efficiency %	Time
Forward	1.00	00:02
Forward/Right	1.41	00:02
Right	0.89	00:03
Backward/Right	1.62	00:02
Backward	10.9	00:01
Backward Left	3.53	00:02
Left	0.49	00:05
Forward Left	1.66	00:02
Composite Score (Avg.)	**2.69**	**00:19**

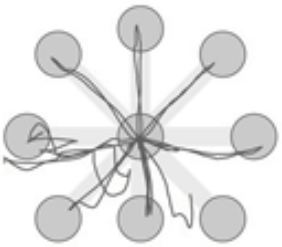


Figure B.7. Sample of Data Taken from a Motor Control Report.

As noted in Appendix A, the Calculation of Direction Efficiency %:

$$Direction\ Efficiency\% = \frac{Straight\ Line\ Distance\ x\ 2}{Actual\ distance\ to\ and\ from}\ X\ 100$$

Composite Score: The average of all the eight targets for a Full pattern. For a Left or Right pattern, it is the average of five targets.

$$Composite\ Score = \frac{1}{n}\sum_{i=1}^{n}(DEff)$$

Where n = Number of Targets.

Fall Risk Test Data Interpretation

With force platform technology, an objective quantification of the patient's postural sway velocity can be used to predict risk. Velocity can be described as the speed of an individual's sway as balance is maintained. Higher velocities, when cues are given to specifically stand 'as motionless as possible', are suggestive of postural control deficits.

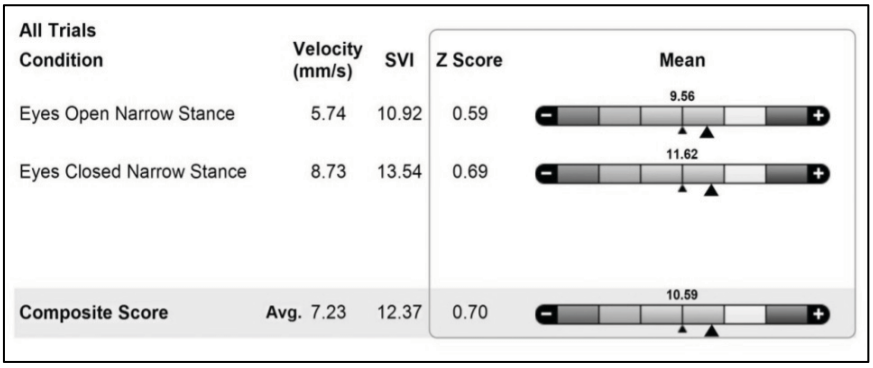


Figure B.8. Sample Data Taken from a Fall Risk Test.

For details of Sway Velocity Index, see the Appendix A.

This value is compared to normative data as a Z score. A Z score indicates how many standard deviations SVI is from the mean.

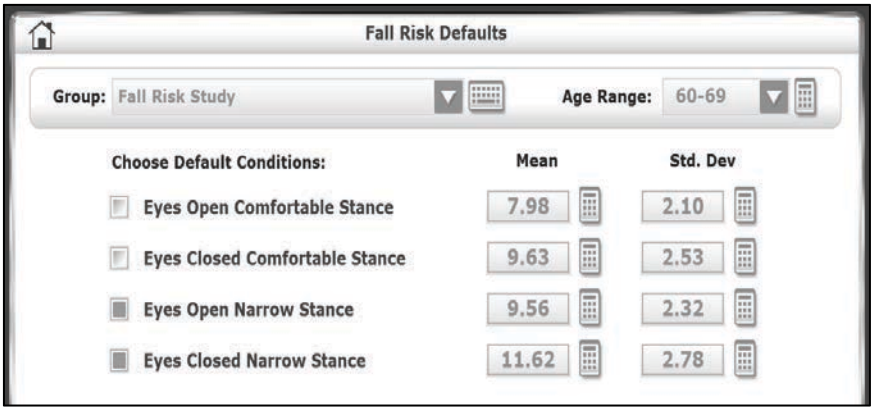


Figure B.9. Fall Risk Defaults Screen.

In this example (taken from the Normative data for this test), each box (green, yellow, red, purple) on the normative bar represents one standard deviation that can be found on the Fall Risk Default of that Age group (e.g., 60-69 for this example), which has a standard deviation value of 2.32.

Therefore, using the above formula:

$$\text{Z Score} = (10.92\text{-}9.56) / 2.32 = 0.5862.$$

Appendix C: CSV File Export (Balance SD and BioSway)

	A	B	C	D	E
1	Name	Shahidul Mahfuz			
2	DOB	6/15/1960 0:00			
3	GenderID	1			
4	TestID	5			
5	TestType	3			
6	TestDateTime	4/20/2017 11:37			
7	PatientRecordID	1			
8	TestTrialTime	20			
9	NumberOfTrials	1			
10	CursorOnOff	OFF			
11	TracingOnOff	OFF			
12	ToneOnOff	ON			
13	RecordFootPositions	TRUE			
14	FootAngleLt	10			
15	FootAngleRt	10			
16	HeelPosLt	D6			
17	HeelPosRt	D16			
18	RestCountDownTime	10			
19	GCodeResultsOption	0			
20	GCodeCategory	0			
21	GCodeStatus	0			
22	GCodeAmendReason	0			
23	ImpairmentComposite	34			
24	ImpairCompAmended	FALSE			
25	AvailableForMyNorms	TRUE			
26	CPTCode	NONE			
27	Comments				
28	ICDCode				
29	Diagnosis				
30	Age	56			
31	Height	5' 8"			
32	Weight	0			
33	UnitAddress				
34	DeviceName	BioSway			
35	FacilityID	0			

36	SwayIndex_1	2.292760457			
37	Goal_1	0.8			
38	ImpairmentValue_1	34			
39	ImpairmentAmended_1	FALSE			
40	Data start				
41	Number of Conditions	1			
42	Condition: 1	Trial: 1			
43	2632	5000			
44	2632	5000			
45	2719	4912			
…					
…					
848	3246	6930			
849	3158	6842			
850	Data end				

Figure C.1. Sample CSV File Export Format.

CSV File Format Explanation – Balance Test File Format Description

The Balance CTSIB Test results are used as an example to explain the CSV file format. Similar formats apply to other Balance Test types. Please note that row headings may vary.

The example CTSIB test result presented below is for the patient: Shahidul Mahfuz performed on April 20th, and was a 20-second trial of the Single Condition – 'Eyes Open Firm Surface' single trial test.

The CSV file is divided into two different segments:

1. Device, Patient, Test/ Exercise results segment.
2. X, Y Coordinate Data points segment.

Segment A – Device, Patient, Test/Exercise results

Starting from the top of the file, it displays the device information, patient information, and different test results. The left column contains the heading/label and the right column(s) displays the corresponding values.

	A	B	C	D
1	Name	Shahidul Mahfuz		
2	DOB	6/15/1960 0:00		
3	GenderID	1		
4	TestID	5		
5	TestType	3		
6	TestDateTime	4/20/2017 11:37		
7	PatientRecordID	1		
8	TestTrialTime	20		
9	NumberOfTrials	1		
10	CursorOnOff	OFF		
11	TracingOnOff	OFF		
12	ToneOnOff	ON		
13	RecordFootPositions	TRUE		
14	FootAngleLt	10		
15	FootAngleRt	10		
16	HeelPosLt	D6		
17	HeelPosRt	D16		
18	RestCountDownTime	10		
19	GCodeResultsOption	0		
20	GCodeCategory	0		
21	GCodeStatus	0		
22	GCodeAmendReason	0		
23	ImpairmentComposite	34		
24	ImpairCompAmended	FALSE		
25	AvailableForMyNorms	TRUE		
26	CPTCode	NONE		
27	Comments			
28	ICDCode			
29	Diagnosis			
30	Age	56		
31	Height	5' 8"		
32	Weight	0		
33	UnitAddress			
34	DeviceName	BioSway		
35	FacilityID	0		
36	SwayIndex_1	2.292760457		
37	Goal_1	0.8		
38	ImpairmentValue_1	34		
39	ImpairmentAmended_1	FALSE		
40	Data start			
41	Number of Conditions	1		
42	Condition: 1	Trial: 1		
43	2632	5000		

Figure C.2. Sample CSV File for Patient Shahidul Mahfuz.

The file rows and columns are defined in Table C.1 below.

Table C.1. Sample CSV File for Patient Shahidul Mahfuz.

Field Heading	Description
Username	The patient's name. This field is only present in USB exported records, not serial exported records (example above is from a serial export).
DOB	Date of Birth of the Patient.
GenderID	Male = 1, Female = 2.
TestID	Used to identify the unique Test ID in database.
TestType	3=CTSIB.
TestDateTime	The date/time the test or training exercise was performed.
PatientRecordID	Used to identify the unique Patient ID in database.
TestTrialTime	Time in seconds used for the test for each condition.
NumberOfTrials	Number of Trials.
CursorOnOff	Cursor was used or not – ON/OFF.
TracingOnOff	Tracing is ON or OFF.
ToneOnOff	Tone is ON or OFF.
RecordFootPositions	Foot position recorded or not – True/False.
FootAngleLt	Foot Angle Left.
FootAngleRt	Foot Angle Right.
HeelPosLt	Heel Position Left.
HeelPosRt	Heel Position Right.
RestCountDownTime	Rest count down in seconds.
GCodeResultsOption	G-Code tuned on or off.
GCodeCategory	Category of G-Code.
GCodeStatus	Status of G-Code, 0= Current or 1= Discharge.
GCodeAmendReason	Amendment reason (if any).
ImpairmentComposite	Impairment Value for Composite Score.
ImpairCompAmended	Impairment Value for Composite Score amended or not – True/False.
AvailableForMyNorms	Available for use in MyNorms.
CPTCode	ON or OFF (if CPT Codes were used/saved wit this result).
Comments	Comments entered with test results (optional).
ICDCode	ICD Codes, if used/saved with this result.
Diagnosis	Diagnosis commentary entered with test results (optional).
Age	Calculated age of Patient.
Height	Height information of the Patient.
Weight	Weight information of the Patient.
UnitAddress	Unique identifier for the Balance unit used for the test (i.e., MAC address).

Field Heading	Description
DeviceName	Device name of the unit on which the test was performed (i.e., Balance SD/ BioSway).
FacilityID	Facility Information.
SwayIndex_1	Sway Index of the Condition. In this example, condition number 1, Eyes Open Firm Surface, was used. However, the Sway Index is used in a similar manner for: • SwayIndex_1- Eyes Open Firm Surface • SwayIndex_2- Eyes Closed Firm Surface • SwayIndex_3- Visual Conflict Firm Surface • SwayIndex_4- Eyes Open Foam Surface • SwayIndex_5- Eyes Closed Foam Surface • SwayIndex_6- Visual Conflict Foam Surface.
Goal_1	Goal/ Normative data of that Condition. In this example, condition number 1was used. Therefore, the heading is displayed as Goals_1.
ImpairmentValue_1	Impaired value for Condition 1.
ImpairmentAmended_1	Impaired Amended reason for Condition 1.

Postural Stability Test

Note: *The fields contained in the following table are specific to test types other than CTBIS.*

Table C.2. Sample CSV File for the Postural Stability Test.

Field Heading	Description
Type	Set to PST for a Postural Stability Test.
Leg Tested	0=Left foot, 1=Right foot, 2=Both feet.
StabilityOverall	Overall Stability Index and Standard Deviation scores (Left or Both Stance).
StabilityAntPost	Anterior/Posterior Stability Index and Standard Deviation scores (Left or Both Stance).
StabilityMedialLat	Medial Lateral Stability Index and Standard Deviation (Left or Both Stances).
PercentTimeinZoneA **…** **PercentTimeinZoneD**	% Time in zones (A through D).
PercentTimeinQuad1 **…** **PercentTimeinQuad4**	% Time in Quadrant (I through IV).
PlatformInitial **PlatformEnding**	Initial and Ending platform.
SwayOverall **SwayAntPost** **SwayMedialLat**	Sway Index for Overall, Anterior/Posterior and Medial Lateral.

Segment B – X,Y Coordinate Data Points

This segment describes the X,Y coordinate data points. It starts within the record containing the words 'Data start' (as illustrated in the left column of the following table) and ends with the record containing the words 'Data end'. All test/exercise results have a Data Start and a Data end point. In this example, the data point values displayed as -61,36 represent the X coordinate value as -61 and the Y coordinate as 36.

	A	B	C	D	E	F
40	Data start					
41	Number of Conditions	1				
42	Condition: 1	Trial: 1				
43	2632	5000				
44	2632	5000				
45	2719	4912				
46	2719	5000				
47	2719	5088				
48	2719	5000				
49	2807	5088				
841	2982	7368				
842	3070	7193				
843	3158	7193				
844	3246	7018				
845	3246	7018				
846	3246	7018				
847	3246	6930				
848	3246	6930				
849	3158	6842				
850	Data end					

Figure C.3. CSV File Format Explanation – Data Points.

Each point is an X,Y rectangular coordinate, where 0, 0 is the center of the graph, to the left is negative X, and to the bottom is negative Y. The data points are generated at a sample rate of 40 per second.

X, Y Scaling

For all tests and exercises performed in Dynamic mode (available in Balance SD only), the X,Y coordinate data is scaled to 1/100th degrees for a range of 20 degrees (up to a maximum value of 2,000) of platform tilt. For tests with the yellow-ringed background, each ring represents approximately 5 degrees of platform tilt. For LOS, the farthest targets (center of target) at the most difficult level represent 8 degrees of platform tilt (value of approximate 800).

For all tests and exercises performed in Static mode, the X,Y coordinate data is scaled to 1/100th for a range of 20 (up to a maximum value of 2,000), mapped to 8 degrees of body tilt angle. For example, 8 degrees of body tilt is a value of 2,000, and 2 degrees of body tilt is a value of 500. For tests with the yellow-ringed background, each ring represents approximately 2 degrees of body tilt. For LOS, the farthest targets (center of target) at the most difficult level represent 8 degrees of body tilt (value of 2,000).

Calculation of Sway Index from the CSV File Data

The sample CTSIB test result below was a 20-second trial of a single condition 'Eyes Open Firm Surface' only.

From the file, it is easy to see that the displayed Sway Index is 2.292.

34	DeviceName	BioSway			
35	FacilityID	0			
36	SwayIndex_1	2.292760457			
37	Goal_1	0.8			
38	ImpairmentValue_1	34			
39	ImpairmentAmended_1	FALSE			

Figure C.4. CSV File Format Explanation – Data Points.

The following section describes the Sway Index and how to verify/obtain the same data using the Excel spreadsheet.

Calculation Using the Formula on an Excel Sheet – CTSIB Test – Single Trial:

Figure C.5 is the Data segment of the sample CSV file. In order to calculate the Sway Index, it is necessary to include a few formulas. On the Excel spreadsheet, cell A and cell B represent original data. In Excel, columns are often referred as cells.

	A	B	C	D	E	F
40	Data start					
41	Number of Conditions	1				
42	Condition: 1	Trial: 1				
43	2632	5000				
44	2632	5000				
45	2719	4912				
46	2719	5000				
47	2719	5088				
48	2719	5000				
49	2807	5088				
841	2982	7368				
842	3070	7193				
843	3158	7193				
844	3246	7018				
845	3246	7018				
846	3246	7018				
847	3246	6930				
848	3246	6930				
849	3158	6842				
850	Data end					
851						

Figure C.5. CSV File Format Calculation – Data Point Segment of the Original Exported CSV File

In Figure C.5, the data starts from the 43rd row and ends in the 849th row. Therefore, the total number of records/rows of data is: [(849-43) + 1] = 807. This will vary with each test since the 40Hz sample rate is an approximation. 807 is used as the total number of data points in this example, but that number is different in each test.

Please note that some of the rows in following figures have been hidden for better representation. For an original calculation, it is not required to hide any of the rows.

How to Determine the Total Number of Data Points within a CSV File:

Using row 851 of the Excel spreadsheet as the repository, determine the total of the individual data points starting from row 43 and ending with row 849 for cells A and B as follows:

1. In cell A, row 851 enter the following formula:
   =SUM(A43:A849)

	A	B	C	D
40	Data start			
41	Number of Conditions	1		
42	Condition: 1	Trial: 1		
43	2632	5000		
44	2632	5000		
45	2719	4912		
46	2719	5000		
47	2719	5088		
48	2719	5000		
49	2807	5088		
841	2982	7368		
842	3070	7193		
843	3158	7193		
844	3246	7018		
845	3246	7018		
846	3246	7018		
847	3246	6930		
848	3246	6930		
849	3158	6842		
850	Data end			
851	=SUM(A43:A849)			
852				

Figure C.6. CSV File Format Calculation – Data Point Calculation for Condition 1

2. In cell B, row 425 enter the following formula:

   =SUM(B43:B849)

	A	B	C	D
40	Data start			
41	Number of Conditions	1		
42	Condition: 1	Trial: 1		
43	2632	5000		
44	2632	5000		
45	2719	4912		
46	2719	5000		
47	2719	5088		
48	2719	5000		
49	2807	5088		
841	2982	7368		
842	3070	7193		
843	3158	7193		
844	3246	7018		
845	3246	7018		
846	3246	7018		
847	3246	6930		
848	3246	6930		
849	3158	6842		
850	Data end			
851	2951065	=SUM(B43:B849)		
852				

Figure C.7. CSV File Format Calculation – Data Point Calculation for Trial 1

3. To determine the Sway Index for each data point within the spreadsheet, enter the following formula in cell C of every row starting with the first data point in row 43 and ending with the last data point in row 849:

   =((A43-$A$851/807)*(A43-$A$851/807))+((B43-$B$851/807)*(B43-$B$851/807))

	A	B	C	D	E	F	G	H	I
40	Data start								
41	Number of Conditions	1							
42	Condition: 1	Trial: 1							
43	2632	5000	=((A43-$A$851/807)*(A43-$A$851/807))+((B43-$B$851/807)*(B43-$B$851/807))						
44	2632	5000	5232877.284						
45	2719	4912	5429813.602						
46	2719	5000	5062125.176						
47	2719	5088	4709924.749						
48	2719	5000	5062125.176						
49	2807	5088	4552609.974						
841	2982	7368	559640.2278						
842	3070	7193	366237.027						
843	3158	7193	270698.2513						
844	3246	7018	169521.0506						
845	3246	7018	169521.0506						
846	3246	7018	169521.0506						
847	3246	6930	182041.4768						
848	3246	6930	182041.4768						
849	3158	6842	290100.6788						
850	Data end								
851	2951065	5685427							
852									

Figure C.8. CSV File Format Calculation – Calculate Sway Index for Every Data Point.

4. To find the Sway Index value, enter the following formula taking the sum of all the data points and placing it into cell C:

   =SQRT(SUM(C43:C849)/807)/1000.

   Using this formula, the resultant Sway Index value is equal to: 2.295.

	A	B	C	D	E
40	Data start				
41	Number of Conditions	1			
42	Condition: 1	Trial: 1			
43	2632	5000	5232877.284		
44	2632	5000	5232877.284		
45	2719	4912	5429813.602		
46	2719	5000	5062125.176		
47	2719	5088	4709924.749		
48	2719	5000	5062125.176		
49	2807	5088	4552609.974		
841	2982	7368	559640.2278		
842	3070	7193	366237.027		
843	3158	7193	270698.2513		
844	3246	7018	169521.0506		
845	3246	7018	169521.0506		
846	3246	7018	169521.0506		
847	3246	6930	182041.4768		
848	3246	6930	182041.4768		
849	3158	6842	290100.6788		
850	Data end				
851	2951065	5685427	=SQRT(SUM(C43:C849)/807)/1000		
852					

Figure C.9. CSV File Format Calculation – Calculate the Sum of all Sway Indices

Where: 807 = the number of samples for this example.
1000 = the scale factor.

5. The value of the Sway Index contained in the exported CSV file matches the value calculated in the Excel spreadsheet after all of the formulas have been entered and applied (see Figure C.10 below).

	A	B	C	D	E
40	Data start				
41	Number of Conditions	1			
42	Condition: 1	Trial: 1			
43	2632	5000	5232877.284		
44	2632	5000	5232877.284		
45	2719	4912	5429813.602		
46	2719	5000	5062125.176		
47	2719	5088	4709924.749		
48	2719	5000	5062125.176		
49	2807	5088	4552609.974		
841	2982	7368	559640.2278		
842	3070	7193	366237.027		
843	3158	7193	270698.2513		
844	3246	7018	169521.0506		
845	3246	7018	169521.0506		
846	3246	7018	169521.0506		
847	3246	6930	182041.4768		
848	3246	6930	182041.4768		
849	3158	6842	290100.6788		
850	Data end				
851	2951065	5685427	**2.295034593**		
852					
853			Sway Index		

Figure C.10. CSV File Format Calculation – Final Results.

Calculation Using Formula on Excel Sheet – CTSIB Test – Multi-Trial:

This example is presented using a single condition and single trial for ease of understanding. In the field, the CTSIB (/m-CTSIB) test can be performed using multiple conditions and multiple trials. For multiple trials, the data will be displayed as Condition 1, Trial 1, Condition 2 Trial 2, or as Condition 1 Trial 1, Condition 1 Trial 2, Condition 2 Trial 1, Condition 2 Trial 2, etc.

For the following example, the Sway index is displayed as 7.405 with one condition and two trials.

	A	B	C	D	E	F
36	SwayIndex_1	7.405026527				
37	Goal_1	0.44				
40	Data start					
41	Number of Conditions	1				
42	Condition: 1	Trial: 1				

Figure C.11. Excel Spreadsheet Illustrating the Sway Index.

The sway index for trial 1 is 10.44 and 0.71 for trial 2. Overall, the averaged sway index is 7.405. The data points calculation in this case is: (807+807) = 1614.

	A	B	C
40	Data start		
41	Number of Conditions	1	
42	Condition: 1	Trial: 1	
43	-2105	-10351	
44	-2018	-10351	
45	-2018	-10351	
46	-2018	-10351	
846	-2368	-9561	
847	-2368	-9561	
848	-2368	-9561	
849	-2368	-9561	
850	Condition: 1	Trial: 2	
851	-2719	-7982	
852	-2719	-7982	
853	-2807	-7982	
854	-2807	-7982	
1654	-2456	-9825	
1655	-2456	-9825	
1656	-2456	-9737	
1657	-2456	-9737	
1658	Data end		

Figure C.12. Excel Spreadsheet Illustrating the Conditions and Trials

1. Remove the text in between the data points (e.g., Condition 1 Trail 2) to avoid any error while calculating each individual data point.
2. Determine the total of the individual data points starting from row 43 and ending with row 850 for cells C and D as follows:
   a. In cell C, row 850, enter the following formula:

=SUM(A43:A849)

	A	B	C
36	SwayIndex_1	7.405026527	
37	Goal_1	0.44	
40	Data start		
41	Number of Conditions	1	
42	Condition: 1	Trial: 1	
43	-702	-3333	
44	-877	-3158	
45	-965	-2982	
46	-1140	-2807	
845	14912	-4737	
846	15263	-4737	
847	15439	-4649	
848	15439	-4474	
849	15526	-4386	
850	0	0	=SUM(A43:A849)
851	-4211	-3333	
852	-4123	-3158	
853	-4035	-3070	
854	-4035	-2982	
1653	-3772	-4737	
1654	-3772	-4737	
1655	-3772	-4737	
1656	-3772	-4737	
1657	-3684	-4737	
1658	Data end		

Figure C.13. Data Point Calculation

b. In cell D, row 850, use the following formula:

=SUM(B43:B849)

	A	B	C	D
36	SwayIndex_1	7.405026527		
37	Goal_1	0.44		
40	Data start			
41	Number of Conditions	1		
42	Condition: 1	Trial: 1		
43	-702	-3333		
44	-877	-3158		
45	-965	-2982		
46	-1140	-2807		
845	14912	-4737		
846	15263	-4737		
847	15439	-4649		
848	15439	-4474		
849	15526	-4386		
850	0	0	-101196	=SUM(B43:B849)
851	-4211	-3333		
852	-4123	-3158		
853	-4035	-3070		
854	-4035	-2982		
1653	-3772	-4737		
1654	-3772	-4737		
1655	-3772	-4737		
1656	-3772	-4737		
1657	-3684	-4737		
1658	Data end			

Figure C.14. Data Point Calculation

3. Determine the total of the individual data points starting from row 851 and ending with row 1659 for cells C and D as follows:

a. In Cell C, row 1659, enter the following formula:

=SUM(A851:A1657)

	A	B	C
36	SwayIndex_1	7.405026527	
37	Goal_1	0.44	
40	Data start		
41	Number of Conditions	1	
42	Condition: 1	Trial: 1	
43	-702	-3333	
44	-877	-3158	
45	-965	-2982	
46	-1140	-2807	
845	14912	-4737	
846	15263	-4737	
847	15439	-4649	
848	15439	-4474	
849	15526	-4386	
850	0	0	-101196
851	-4211	-3333	
852	-4123	-3158	
853	-4035	-3070	
854	-4035	-2982	
1653	-3772	-4737	
1654	-3772	-4737	
1655	-3772	-4737	
1656	-3772	-4737	
1657	-3684	-4737	
1658	Data end		
1659			=SUM(A851:A1657)
1660			

Figure C.15. Data Point Calculation

b. In Cell D, row 1659, enter the following formula:

=SUM(B851:B1657)

	A	B	C	D
36	SwayIndex_1	7.405026527		
37	Goal_1	0.44		
40	Data start			
41	Number of Conditions	1		
42	Condition: 1	Trial: 1		
43	-702	-3333		
44	-877	-3158		
45	-965	-2982		
46	-1140	-2807		
845	14912	-4737		
846	15263	-4737		
847	15439	-4649		
848	15439	-4474		
849	15526	-4386		
850	0	0	-101196	-2470354
851	-4211	-3333		
852	-4123	-3158		
853	-4035	-3070		
854	-4035	-2982		
1653	-3772	-4737		
1654	-3772	-4737		
1655	-3772	-4737		
1656	-3772	-4737		
1657	-3684	-4737		
1658	Data end			
1659			-2952898	=SUM(B851:B1657)

Figure C.16. Data Point Calculation.

4. To find the Sway Index value, enter the following formula taking the sum of all the data points on each row from 43 to 850 and placing it into cell E:

=((A43-$C$850/807)*(A43-$C$850/807))+((B43-$D$850/807)*(B43-$D$850/807))

	A	B	C	D	E	G	H	I	J	K	L
36	SwayIndex_1	7.405026527									
37	Goal_1	0.44									
40	Data start										
41	Number of Conditions	1									
42	Condition: 1	Trial: 1									
43	-702	-3333			=((A43-$C$850/807)*(A43-$C$850/807))+((B43-$D$850/807)*(B43-$D$850/807))						
44	-877	-3158			574284.4073						
45	-965	-2982			711197.7951						
46	-1140	-2807			1094013.656						
845	14912	-4737			228931780.2						
846	15263	-4737			239611234.4						
847	15439	-4649			244771722.1						
848	15439	-4474			244246602.2						
849	15526	-4386			246721460.1						
850	0	0	-101196	-2470354							

Figure C.17. Sway Index Value for Condition 1, Trial 1

5. Repeat step 4 to determine the Sway Index value for each row from 851 to 1659:
=((A851-$C$1659/807)*(A851-$C$1659/807))+((B851-$D$1659/807)*(B851-$D$1659/807))

	A	B	C	D	E	G	H	I	J	K	L	M
36	SwayIndex_1	7.405026527										
37	Goal_1	0.44										
40	Data start											
41	Number of Conditions	1										
42	Condition: 1	Trial: 1										
43	-702	-3333			406368.5461							
44	-877	-3158			574284.4073							
45	-965	-2982			711197.7951							
46	-1140	-2807			1094013.656							
845	14912	-4737			228931780.2							
846	15263	-4737			239611234.4							
847	15439	-4649			244771722.1							
848	15439	-4474			244246602.2							
849	15526	-4386			246721460.1							
850	0	0	-101196	-2470354								
851	-4211	-3333			=((A851-$C$1659/807)*(A851-$C$1659/807))+((B851-$D$1659/807)*(B851-$D$1659/807))							
852	-4123	-3158			1814670.938							
853	-4035	-3070			1971101.134							
854	-4035	-2982			2216920.792							
1653	-3772	-4737			111528.0611							
1654	-3772	-4737			111528.0611							
1655	-3772	-4737			111528.0611							
1656	-3772	-4737			111528.0611							
1657	-3684	-4737			99402.59892							
1658	Data end											
1659			-2952898	-3569121								

Figure C.18. Sway Index Value for Condition 1, Trial 2

6. To find the Sway Index value, enter the following formula taking the sum of all the data points on cell C and placing it into cell E:

   =SQRT(SUM(C43:C849)/807)/1000, using this formula output is 7.4092

	A	B	C	D	E	G	H
36	SwayIndex_1	7.405026527					
37	Goal_1	0.44					
40	Data start						
41	Number of Conditions	1					
42	Condition: 1	Trial: 1					
43	-702	-3333			406368.5461		
44	-877	-3158			574284.4073		
45	-965	-2982			711197.7951		
46	-1140	-2807			1094013.656		
845	14912	-4737			228931780.2		
846	15263	-4737			239611234.4		
847	15439	-4649			244771722.1		
848	15439	-4474			244246602.2		
849	15526	-4386			246721460.1		
850	0	0	-101196	-2470354			
851	-4211	-3333			1492039.49		
852	-4123	-3158			1814670.938		
853	-4035	-3070			1971101.134		
854	-4035	-2982			2216920.792		
1653	-3772	-4737			111528.0611		
1654	-3772	-4737			111528.0611		
1655	-3772	-4737			111528.0611		
1656	-3772	-4737			111528.0611		
1657	-3684	-4737			99402.59892		
1658	Data end						
1659			-2952898	-3569121	=SQRT(SUM(E43:E1657)/1614)/1000		

Figure C.19. Using Formula to Calculate the Sum of all Sway Indexes

Where:

1614 = the number of samples for this example.

1000 = the scale factor.

7. After all of the formulas have been entered and applied, the final output matches the value of the Sway Index displayed in the exported CSV file as illustrated in Figure C.19 below.

	A	B	C	D	E	G
36	SwayIndex_1	7.405026527				
37	Goal_1	0.44				
40	Data start					
41	Number of Conditions	1				
42	Condition: 1	Trial: 1				
43	-702	-3333			406368.5461	
44	-877	-3158			574284.4073	
45	-965	-2982			711197.7951	
46	-1140	-2807			1094013.656	
845	14912	-4737			228931780.2	
846	15263	-4737			239611234.4	
847	15439	-4649			244771722.1	
848	15439	-4474			244246602.2	
849	15526	-4386			246721460.1	
850	0	0	-101196	-2470354		
851	-4211	-3333			1492039.49	
852	-4123	-3158			1814670.938	
853	-4035	-3070			1971101.134	
854	-4035	-2982			2216920.792	
1653	-3772	-4737			111528.0611	
1654	-3772	-4737			111528.0611	
1655	-3772	-4737			111528.0611	
1656	-3772	-4737			111528.0611	
1657	-3684	-4737			99402.59892	
1658	Data end					
1659			-2952898	-3569121	7.409299925	
1660						
1661					Sway Index	

Figure C.20. Excel File Format Calculation- Final Results

Calculation of Stability Index from the CSV File Data

The following section will describe the Stability Index and how to verify/ obtain that same data using an Excel spreadsheet.

The displayed Overall Stability Index for the exported Postural Stability Test file is 10.030.

18	TracingOnOff	ON				
19	ToneOnOff	OFF				
20	RestCountDownTime	10				
21	StabilityOverall	10.03069618				
22	StabilityAntPost	6.310578426				
23	StabilityMedialLat	6.495353483				
24	SwayOverall	9.975201913				
25	SwayAntPost	6.801880444				
26	SwayMedialLat	7.296511196				

Figure C.21. CSV File Format Calculation – Snippet From Original Exported CSV File.

Calculation Using the Formula on the Excel Sheet – Postural Stability Test

The process to calculate the Stability Index from the sample Postural Stability Test exported csv file is similar to that used to calculate the CTSIB (/m-CTSIB) test.

	A	B	C	D
46	Data start			
47	Trial: 1			
48	4298	9035		
49	4211	9123		
50	4123	9035		
51	4035	9035		
52	3947	9035		
53	3772	9035		
445	-2632	-8509		
446	-2018	-8509		
447	-1491	-8509		
448	-1140	-8509		
449	-877	-8421		
450	-702	-8421		
451	-614	-8421		
452	Data end			
453				

Figure C.22. CSV file format calculation – Data point segment of the original exported csv file

In the file displayed in C.21, it is evident that the data starts in the 48th row and ends in the 451th row. Therefore, the total number of records/rows of data is calculated as: [(451-48) + 1] = 404. This will vary with each test since the 40Hz sample rate is only an approximation. 404 is used in this example alone as the total number of data points.

Please note that some of the rows in following figures have been hidden for better representation. For an original calculation, it is not required to hide any of the rows.

How to Determine the Total Number of Data Points within a CSV File:

Using row 453 of the Excel spreadsheet as the repository, determine the total of the individual data points starting from row 48 and ending with row 451 for cell A:

1. In cell A, row 851 enter the following formula:

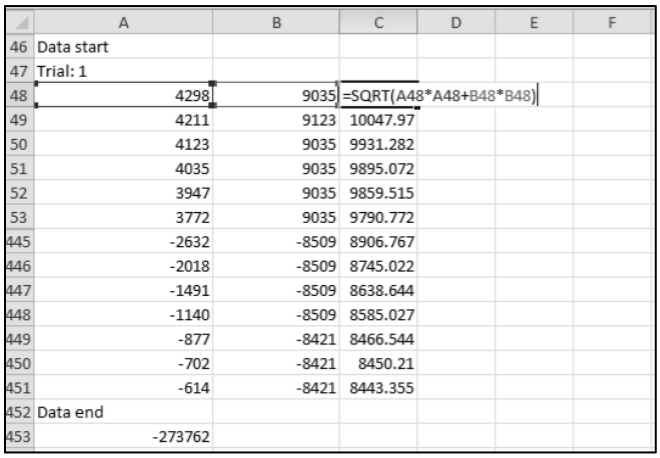
   =SUM(A48:A451)

	A	B	C	D	E
46	Data start				
47	Trial: 1				
48	4298	9035			
49	4211	9123			
50	4123	9035			
51	4035	9035			
52	3947	9035			
53	3772	9035			
445	-2632	-8509			
446	-2018	-8509			
447	-1491	-8509			
448	-1140	-8509			
449	-877	-8421			
450	-702	-8421			
451	-614	-8421			
452	Data end				
453	=SUM(A48:A451)				

Figure C.23. CSV File Format Calculation – Finding the Total of Individual Data Points

2. To determine the Stability Index for each data point within the spreadsheet, enter the following formula in cell C of every row starting with the first data point in row 48 and ending with the last data point in row 451:

=SQRT(A48*A48+B48*B48)

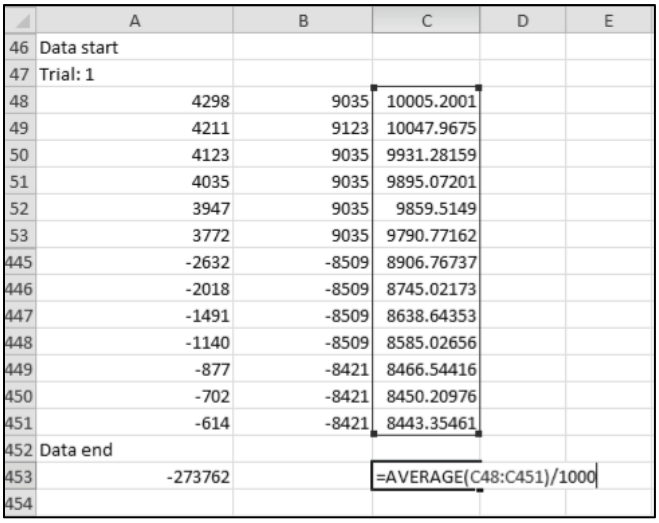


	A	B	C	D	E	F
46	Data start					
47	Trial: 1					
48	4298	9035	=SQRT(A48*A48+B48*B48)			
49	4211	9123	10047.97			
50	4123	9035	9931.282			
51	4035	9035	9895.072			
52	3947	9035	9859.515			
53	3772	9035	9790.772			
445	-2632	-8509	8906.767			
446	-2018	-8509	8745.022			
447	-1491	-8509	8638.644			
448	-1140	-8509	8585.027			
449	-877	-8421	8466.544			
450	-702	-8421	8450.21			
451	-614	-8421	8443.355			
452	Data end					
453	-273762					

Figure C.24. CSV File Format Calculation- Using Formula to Calculate Stability Index for Each Data Point.

3. To find the Stability Index value, enter the following formula to take the sum of all the data points in cell C.

   =AVERAGE(C48:C451)/1000, using this formula output is 10.030



	A	B	C	D	E
46	Data start				
47	Trial: 1				
48	4298	9035	10005.2001		
49	4211	9123	10047.9675		
50	4123	9035	9931.28159		
51	4035	9035	9895.07201		
52	3947	9035	9859.5149		
53	3772	9035	9790.77162		
445	-2632	-8509	8906.76737		
446	-2018	-8509	8745.02173		
447	-1491	-8509	8638.64353		
448	-1140	-8509	8585.02656		
449	-877	-8421	8466.54416		
450	-702	-8421	8450.20976		
451	-614	-8421	8443.35461		
452	Data end				
453	-273762		=AVERAGE(C48:C451)/1000		
454					

Figure C.25. CSV File Format Calculation- Using Formula to Calculate the Sum of all Stability Indexes.

   Where: 1000 = the scale factor

4. After all of the formulas have been entered and applied, the final output matches the value of the Stability Index displayed in the exported CSV file as illustrated in Figure C.25 below.

	A	B	C	D
46	Data start			
47	Trial: 1			
48	4298	9035	10005.2001	
49	4211	9123	10047.96746	
50	4123	9035	9931.281589	
51	4035	9035	9895.072006	
52	3947	9035	9859.514897	
53	3772	9035	9790.771624	
445	-2632	-8509	8906.767371	
446	-2018	-8509	8745.021727	
447	-1491	-8509	8638.643528	
448	-1140	-8509	8585.026558	
449	-877	-8421	8466.544159	
450	-702	-8421	8450.209761	
451	-614	-8421	8443.354606	
452	Data end			
453	-273762		**10.03070344**	
454				
455			Overall Stability Index	
456				

Figure C.26. CSV file format calculation- final results

Multi Record Data Export for Creating Custom Normative Data

The Balance SD system allows the user to export multiple records of any type of test in to a single CSV file. This exported file can be used to create normative data. The example in Figure C.26 is a snapshot of a previously exported CTSIB test-type CSV file.

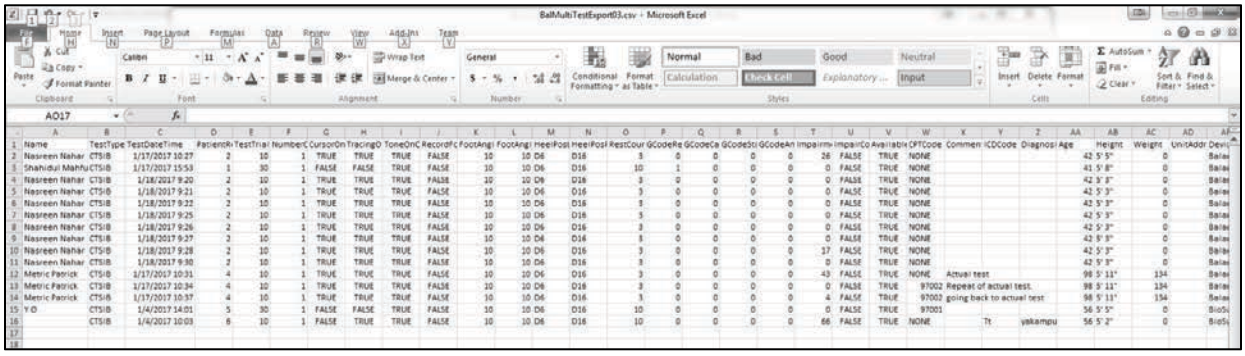


Figure C.27. Display of csv file data opened in Microsoft Excel.

Each row represents an individual test record. There will be more columns for each row than displayed on the sample report. It is suggested that the unnecessary data columns be deleted or hidden. The statistical analysis can easily be performed on this data.

***Note:** The data used in the following example may not necessarily represent real data. It is presented to demonstrate how to obtain normative data.*

1. First, remove or hide all unnecessary columns. For the example displayed in this manual, the following columns are displayed: Name, TestDateTime, Age, Height, SwayIndex_1, SwayIndex_2, SwayIndex_3, SwayIndex_4. There are 100 rows of data.

2. Next, insert a blank column after each SwayIndex column for calculation purposes. In this case, columns F, H, J, and L were inserted.

3. Enter the following formula for each row in column F from cell E2 to E100:

   =IF(E2,LN(E2),"")

   Note: *Any erroneous sample that has a value of 0 will be discarded by the use of the IF in the formula.*

4. Repeat step 3 for the other columns: H, J, and L from cell 2 to 100.
   Note: *Remember to change the column name in the formula for each column.*

5. At the end of the Data (row 101 for our example), enter the following formula for each of the following columns: E, G, I, and K:

   =AVERAGE(E2:E100)

   Note: *Remember to change the value in the parentheses (e.g., E2: E100) with the appropriate value for each column.*

6. Enter the following formula on row 102 for each of the following columns F, H, J, and L.

   =STDEV(F2:F100)

   Note: *Remember to change the value in the parentheses (e.g., F2: F100) with the appropriate value for each column.*

	A	B	C	D	E	F	G	H	I	J	K	L
1	Name	TestDateTime	Age	Height	SwayIndex_1	ln(column E)	SwayIndex_2	ln(column G)	SwayIndex_4	ln(column I)	SwayIndex_5	ln(column K)
2	######	5/4/2011 14:39	15	59"-65"	1.82	0.598836501	0.49	-0.713349888	0.51	-0.673344553	0.55	-0.597837001
3	######	5/5/2011 12:04	15	59"-65"	0.78	-0.248461359	0.68	-0.385662481	0.63	-0.46203546	2.43	0.887891257
4	######	5/5/2011 12:08	15	65"-73"	0.28	-1.272965676	0.62	-0.478035801	0.26	-1.347073648	1.45	0.371563556
5	######	5/5/2011 12:15	15	59"-65"	0.44	-0.820980552	0.64	-0.446287103	0.35	-1.049822124	1.33	0.285178942
6	######	5/7/2011 11:39	15	65"-73"	0.49	-0.713349888	0.65	-0.430782916	0.84	-0.174353387	2.19	0.783901544
7	######	5/7/2011 11:42	15	59"-65"	0.47	-0.755022584	0.81	-0.210721031	0.76	-0.274436846	2.47	0.904218151
8	######	5/7/2011 13:08	15	59"-65"	0.8	-0.223143551	1.12	0.113328685	1.68	0.518793793	0.93	-0.072570693
9	######	5/7/2011 12:42	15	59"-65"	0.48	-0.733969175	1.52	0.418710335	0.48	-0.733969175	1.12	0.113328685
10	######	5/7/2011 12:46	15	59"-65"	0.3	-1.203972804	0.74	-0.301105093	0.94	-0.061875404	2.22	0.797507196
90	######	6/4/2011 13:47	16	65"-73"	0.79	-0.235722334	0.8	-0.223143551	0.85	-0.162518929	1.77	0.570979547
91	######	6/4/2011 13:52	14	65"-73"	0.4	-0.916290732	0.55	-0.597837001	0.76	-0.274436846	1.65	0.500775288
92	######	6/4/2011 13:56	15	65"-73"	0.49	-0.713349888	0.55	-0.597837001	0.7	-0.356674944	1.86	0.620576488
93	######	6/4/2011 14:01	16	65"-73"	0.39	-0.94160854	0.52	-0.653926467	0.61	-0.494296322	1.46	0.378436436
94	######	6/4/2011 14:05	15	59"-65"	0.46	-0.776528789	0.55	-0.597837001	0.75	-0.287682072	1.69	0.524728529
95	######	6/4/2011 14:09	18	65"-73"	0.33	-1.108662625	0.38	-0.967584026	0.47	-0.755022584	1.77	0.570979547
96	######	6/4/2011 14:14	16	65"-73"	0.28	-1.272965676	0.74	-0.301105093	0.44	-0.820980552	1.86	0.620576488
97	######	6/4/2011 14:18	16	59"-65"	0.44	-0.820980552	0.46	-0.776528789	0.58	-0.544727175	1.94	0.662687973
98	######	6/4/2011 14:22	15	65"-73"	0.5	-0.693147181	0.8	-0.223143551	0.75	-0.287682072	1.87	0.625938431
99	######	6/4/2011 14:27	15	73+"	0.22	-1.514127733	0.42	-0.867500568	0.42	-0.867500568	1.46	0.378436436
100	######	6/4/2011 14:31	16	59"-65"	0.46	-0.776528789	0.56	-0.579818495	0.66	-0.415515444	2.59	0.951657876
101		Average			**0.578989899**		**0.769191919**		**0.791919192**		**1.809494949**	
102		SD				**0.463771078**		**0.423821469**		**0.385981772**		**0.346537331**
103												

Figure C.28. Display of CTSIB Data Columns with those that are not of Interest Deleted.

7. The example in Figure C.27 illustrates the final format after the necessary modification has been made to the original CSV file. The Average and the Standard Deviation was calculated from Sway indexes (with Natural Logarithm applied on each score). This can be used as the normative value and can be entered into the Balance product software (BioSway and/or SD).

   Tips for Excel users: A .CSV file that has been opened using Excel and modified using cell formatting will not retain any of the original formatting when saved. If it is necessary to retain the original formatting, the file can be saved as an Excel file (.xls file).

Appendix D: Log Transformation

REPORT ENHANCEMENTS TO THE CLINICAL TEST OF SENSORY INTEGRATION AND BALANCE

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Professor and Director,
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The purpose of this section is to present the methods used to interpret and display an individual's score on the Clinical Test of Sensory Integration and Balance (CTSIB) performed on the Biodex Balance Systems relative to a selected normative database. The Biodex Balance Systems provide line graphs and a mark (i.e., black triangle) depicting the location of an individual's CTSIB scores relative to the selected reference database. The middle vertical lines provide an indication of the reference database mean and the colored bars represent one, two, and three standard deviation units from the reference database mean. Thus, if the triangle is located to the right of the black vertical line, the individual scored higher than the reference database mean, which suggests poorer balance performance. Further, if the triangle appears in the yellow zone, the patient is between one and two standard deviations units worse than the mean, and if the triangle appears in the orange zone, the individual scored between two and three standard deviation units worse than the mean. Thus, practitioners can not only interpret whether an individual scores better or worse than the reference database mean, but also have an indication regarding the magnitude of the distance.

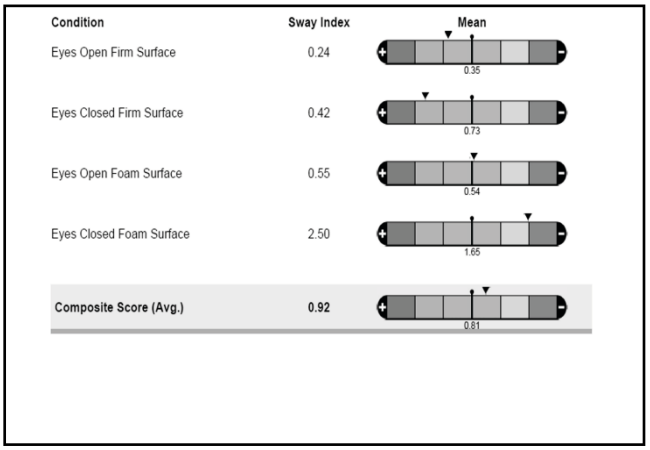

Figure D.1. On screen and report output of CTSIB testing with line graphs in original (raw) units. The color boxes represent one, two and three standard deviations from the reference database mean. The triangle represents the individual score

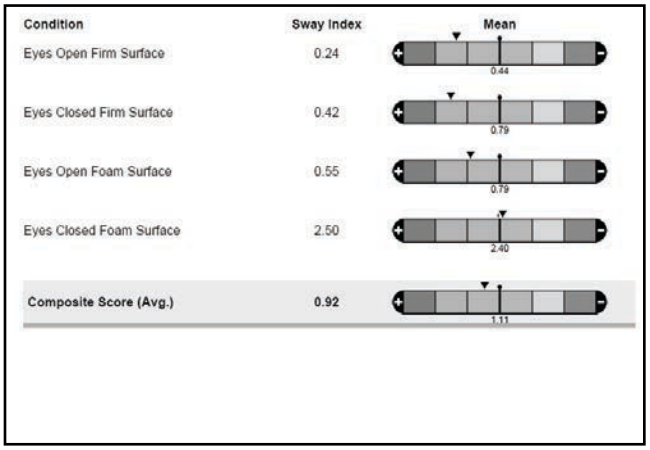

Figure D.2. On screen and report output of CTSIB testing with line graphs in natural log transformed units. The color boxes represent one, two and three standard deviations from the reference database transformed mean. The triangle represents

Figure D.1 is consistent with how units have always been traditionally provided by previous Biodex Balance Systems. On Figure D.2, the line graphs are drawn using the selected reference database that has undergone natural log transformation. The natural log transformation provides a more accurate method of interpreting the individual's performance relative to the

selected reference database by adjusting the reference database to more closely resemble a normal (i.e., bell shaped curve) distribution of scores. By using this transformation, the usual distribution of scores relative to the mean apply. Specifically, it can be expected that 68% of healthy individuals will score within one standard deviation of the mean (green boxes), 95% of healthy individuals will score within two standard deviations of the mean (blue and yellow boxes), and 99% of healthy individuals will score within three standard deviations of the mean (purple and orange boxes).

BACKGROUND

Interpretation of an individual's score with respect to reference (i.e., normative) data is a common challenge faced by many practitioners. One approach to interpreting an individual's score is to consider the distance of the scores from the mean in standard deviation units. A prerequisite to using this approach is that the reference database must be normally distributed (i.e., bell shaped curve). When the reference database is normally distributed, it is possible to take advantage of certain probability ranges within the distribution of the reference database. 68% of the scores will be within one standard deviation, 95% of the scores will be within two standard deviations, and 99% of the scores will be within three standard deviations. If practitioners consider individuals scoring beyond (i.e., outside) 95% of the reference database as reflective of pathology, they would seek individuals demonstrating scores that exceed two standard deviations from the reference database mean for intervention or more extensive evaluation. In the case of balance testing, higher scores of center of pressure movement (i.e., Sway Index) are considered to reflect a deficiency in balance ability. Thus, the practitioner would be prudent to consider an individual with a Sway Index greater than two standard deviations from the mean as indicative of postural instability.

Many metrics of human performance used by practitioners have minimum or maximum scores. Center of pressure movement is one such measure. Maintaining balance with very little corrective action and body sway would produce Sway Indices that would approach zero. In contrast, individuals demonstrating postural instability would demonstrate sway indices that could become extremely large. The effect of this characteristic on reference databases is to produce reference distributions that deviate from being normally distributed. Specifically in the case of Sway Indices, the reference distributions become positively skewed. Because of the skewness, the probability ranges of the normal distribution cannot be immediately applied. In these circumstances, a data transformation becomes necessary prior to standardizing the scores. Common transformations to improve normality include square root or logarithmic (e.g., base 10, natural log). Specific to logarithm transformations, is the useful feature that it moves large values closer together while moving small values farther apart. As a result, positively skewed distributions become closer to a normal distribution.

METHODOLOGY AND RESULTS

A review of several large databases of Clinical Test of Sensory Integration and Balance (CTSIB) testing conducted on the Biodex Balance Systems revealed, similar to other human performance measures that have a minimum value, the existence of slight to moderate positive skewness. The purpose of this section is to describe the process of deciding upon the natural logarithm transformation and standardization method that is used to interpret an individual's performance on each of the CTSIB conditions.

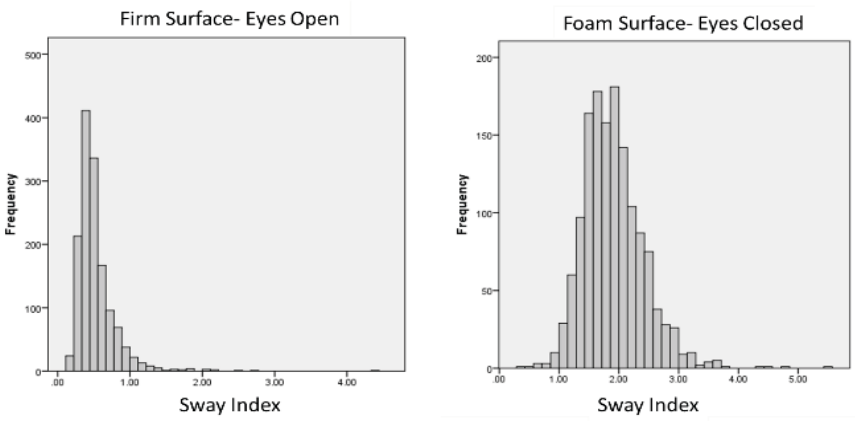

Figure D.3. Positive skewness was more evident in the less challenging (left) than the more challenging (right) CTSIB conditions.

Exploratory analysis of the five commonly used reference databases with CTSIB testing on the Biodex Balance Systems yielded varying degrees of positive skewness (range: 0.5 to 6.3), particularly for the less challenging CTSIB conditions (Figure D.3). Additionally, the exploratory analyses revealed the lower boundaries of two standard deviations from the mean to cross zero for two of the conditions (Table D.1).

Table D.1. Results of the exploratory analysis conducted on the five most commonly used reference databases for CTSIB testing on the Biodex Balance Systems.

Database	N	Clinical Test of Sensory Integration and Balance Conditions							
		Firm Surface- Eyes Open		Firm Surface- Eyes Closed		Foam Surface- Eyes Open		Foam Surface- Eyes Closed	
		$\overline{X}$±SD	Skew	$\overline{X}$±SD	Skew	$\overline{X}$±SD	Skew	$\overline{X}$±SD	Skew
EC1	487	.39±.26	6.3	.80±.29	1.6	.68±.28	2.9	2.30±.56	.5
CT1	135	.57±.22	1.3	.66±.25	1.4	.94±.35	1.2	1.44±.48	2.1
CD1	536	.49±.20	2.1	.71±.30	2.0	.86±.35	4.5	2.01±.58	.9
BD1	100	.26±.09	1.9	.53±.20	1.2	.38±.11	.6	1.05±.35	.9
CD2	1507	.52±.27	4.1	.71±.34	4.6	.77±.26	2.1	1.90±.49	.9

Thus, to improve using the multiples of the standard deviation to interpret scores, further analyses were conducted to identify the optimal data transformation. Specifically, Box-Cox Transformational Analyses were conducted to determine the optimal data transformation. This procedure examines a variety of transformations, followed by plotting of the skewness value against each transformation. By examining the plots (Figure 4), the optimal transformation that

best reduced the skewness (closest to zero) across the four CTSIB conditions could be identified.

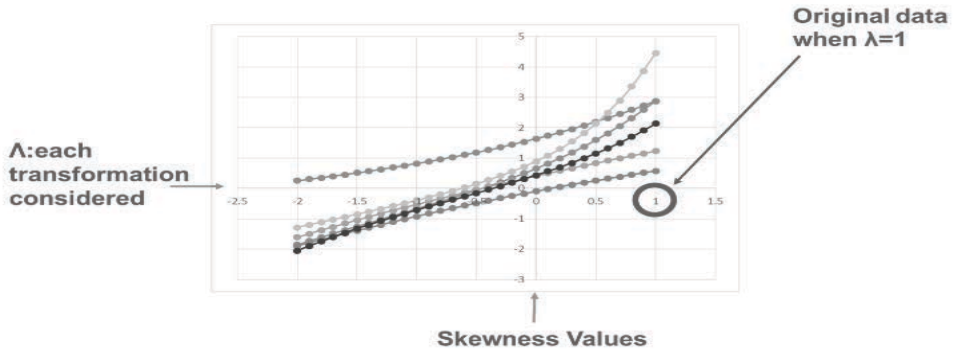

Figure D.4. Example plot (Firm surface-eyes closed) following the Box-Cox transformational analyses on each of the reference databases (lines graphed). By examining the plot, the transformation (horizontal axes) that produces the minimal skewness value (vertical axes) could be identified. On the horizontal axes (λ) zero corresponds to a natural logarithm transformation and one corresponds to the original data (no transformation).

Across the four CTSIB conditions, examination of the plots revealed that a natural logarithm transformation would best minimize skewness (Figure 5).

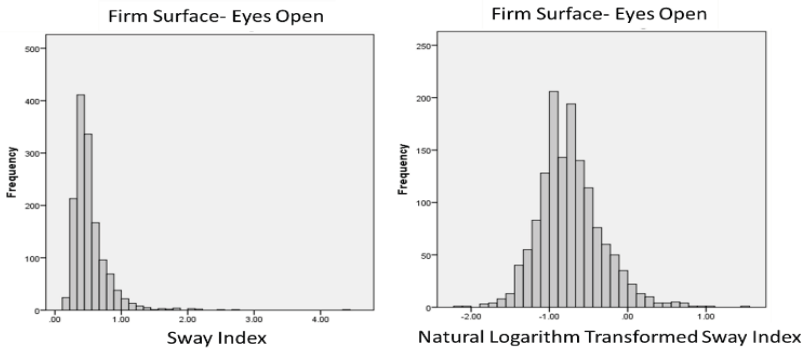

Figure D.5. Distribution of Firm Surface-Eyes Open prior to natural logarithm transformation (left) and following transformation (right).

In summary, by providing the option to have an individual's score and reference database natural logarithm transformed, users can more accurately interpret an individual's CTSIB performance proportionally relative to the distribution of the selected reference database.

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