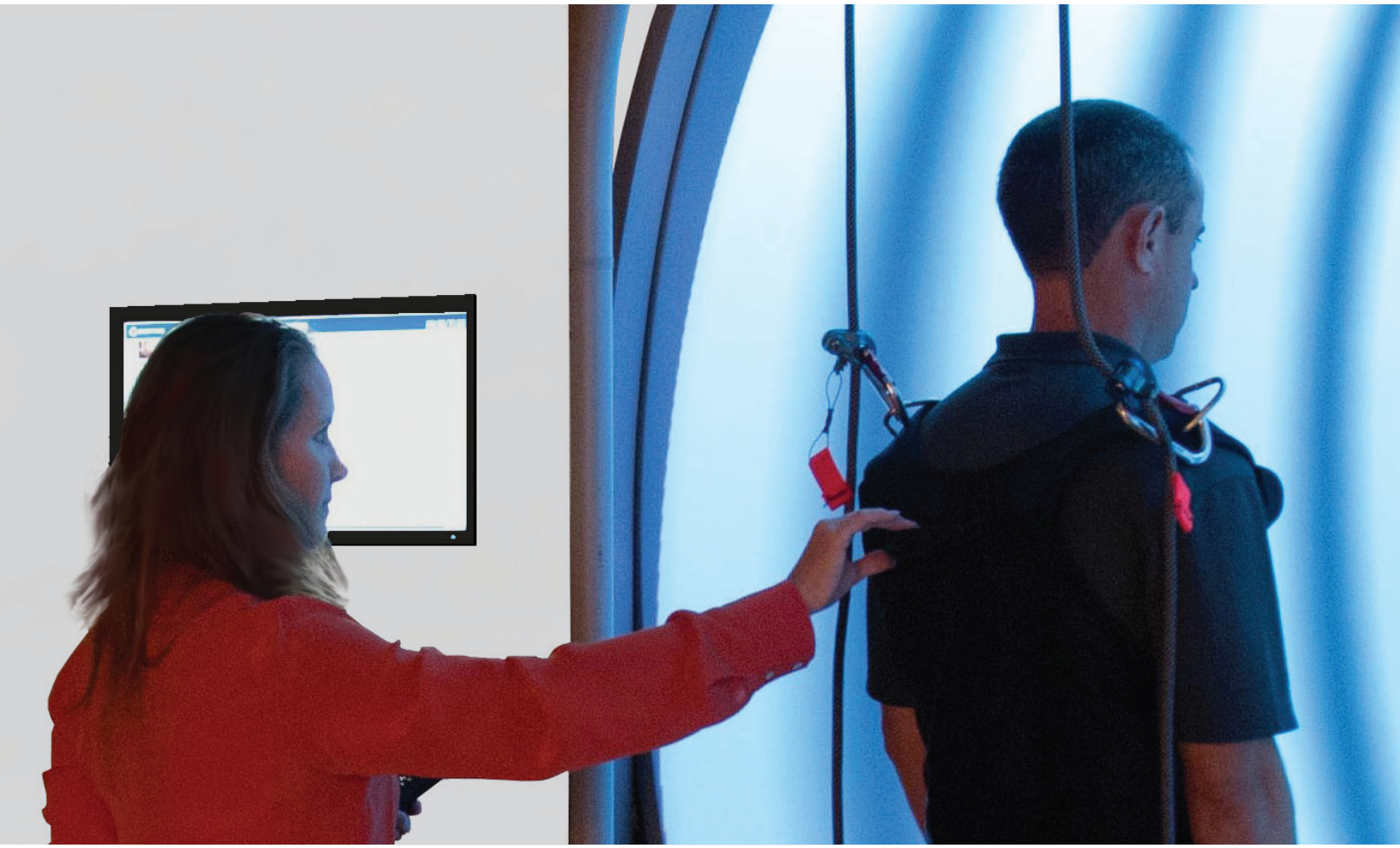
BERTEC

We Bring Balance to Lives®

Bertec® Balance Advantage®
Static System User Manual



www.bertecbalance.com

CE

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Version 1.0.2

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8.1 Extended warranty protection is offered to Licensee pursuant to Licensor's extended warranty terms and conditions set forth in a separate document.

CLAUSE 9 Maintenance

9.1 If requested by Licensee, Licensor shall provide the maintenance which may be necessary for proper operation of the Products.

CLAUSE 10 Indemnification

10.1 Licensee shall indemnify and hold Licensor harmless from and against any and all claims, actions, suits, liabilities, judgments, losses, damages, attorneys' fees, and other expenses of every nature and character arising out of the use of the Products by Licensee and/or its agents.

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14.1 The validity, performance, construction, and interpretation of this Agreement shall be governed by the laws of the State of Ohio and the United States of America, excluding conflicts of laws, rules, and regulations.

Instructions for Use

This manual covers standard operating procedures for the following products:

- Bertec® Balance Advantage® Prime IVR
- Bertec® Balance Advantage® Functional
- Bertec® Balance Advantage® Essential
- Bertec® Balance Advantage® Portable Systems



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

Read Carefully Before Proceeding

Intended Use:
Balance Evaluation and Rehabilitation

The Bertec® Balance Advantage® (BBA) family of products is intended as an objective platform used for gathering and characterizing movement of subjects with balance disorders or instability.

BBA systems should only be operated by qualified personnel.



WARNING: To avoid risk of electrical shock, BBA systems must only be connected to properly grounded power sources that are routed through the patient isolation transformer of Prime IVR, Functional, or Essential systems. Portable systems should not be connected to wall power while testing a patient.

- The successful use of the Bertec® technology requires an appropriate level of professional expertise to develop proper treatment programs that are specific to the patient and their individual cases. The user should be confident they understand the operation of the system, can properly administer test protocols, and interpret results.

- The BBA Prime IVR system is intended to remain in place after installation. Bertec® Corporation must be contacted if, for any reason, the BBA Dynamic system must be moved. BBA Static units (Functional and Essential) may be moved as necessary.

NOTE: Bertec® equipment must only be serviced by qualified personnel. Please do not attempt to service equipment yourself. Please contact Bertec® first for any service or support requests.



WARNING: Do not modify Bertec® systems in any way. Modifications will void the warranty.



For additional product service or support, please contact: Bertec® Corporation 2500 Citygate Drive, Columbus, OH 43219 phone: 614-450-0331 or support@bertec.com

-For additional product safety information, please see page 100

General Maintenance

Bertec® balance systems require only basic maintenance, performed on an as-needed basis.

CLEANING INSTRUCTIONS (See Maintenance Manual)

Prime IVR™ Systems

- Wipe down the inner surface of dome with damp cloth or Windex-like solution.
- Gently dust the fisheye lens with supplied brush or microfiber cloth. Lens cleaner solution (also supplied with each system) may also be sprayed on the fisheye lens and then wiped away. NEVER clean the fisheye lens with something other than a microfiber cloth or supplied brush.
- Periodically clean air vents on the projector.
- Wipe down the balance plate with a damp cloth or standard cleaning solution.
- Lamp replacement - When a lamp is approaching its end of life, the projector will notify the user a new lamp needs to be installed. Contact Bertec® Corporation when this occurs.

Static Portable Systems (Essential and Functional)

- Wipe down the top surface of the balance plate with any standard cleaner.
- The foam block may be wiped down with any standard cleaner.
- For good hygiene, patients should wear footies.

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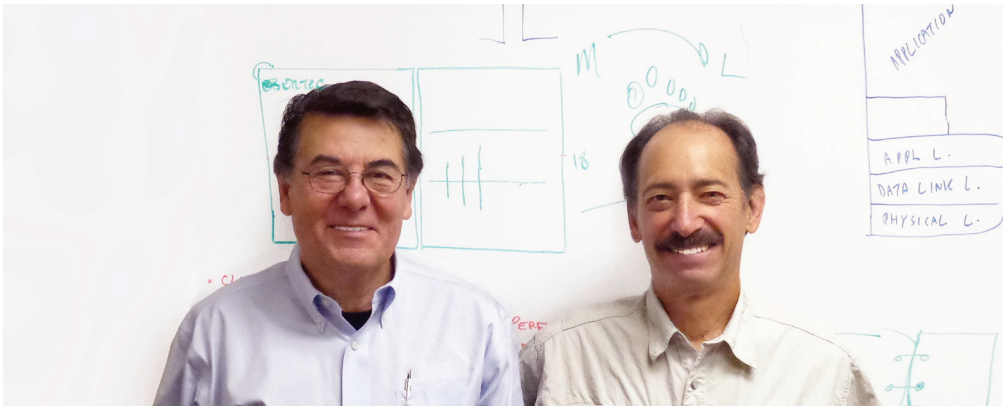
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Company Overview



Dr. Necip Berme (left) and Dr. Lewis Nashner (right)

Bertec is an internationally recognized designer, manufacturer, and marketer of research-grade and clinical biomechanical equipment and software. Used by athletic trainers, physical therapists, and other professionals working to understand the movement of the human body, Bertec's tools help athletes and patients to meet their performance and rehabilitation goals.

Institutions as varied as Nike, the US Olympic Swimming Team, Toyota Robotics, the NIH, Cleveland Clinic, Mayo Clinic, Harvard University, and hundreds of others around the world rely on Bertec, a 40-person technology firm based in Columbus, Ohio. Founded in 1987, Bertec continues to tackle some of the most ambitious engineering projects in multiple disciplines including biomechanics, mechatronics, immersive virtual reality, eye tracking, and computer vision to bring industry leading solutions to practitioners, researchers, and clinicians.

Welcome

Welcome to the Bertec® Balance Advantage® Static Systems User Manual. This is a concise, easy-to-use guide for both implementing and utilizing a Bertec® Balance Advantage® Package, along with its related components. Not every section within this manual is applicable to every package, as packages differ in functionality and available features to suit a variety of different clinical and research needs. Sections which are only applicable to certain packages are marked as such. Below is a brief overview of the six Bertec® Balance Advantage® Static System Packages, along with their main differences in functionality and available features.

About Bertec® Balance Advantage® Static Packages



Bertec®'s Balance Advantage® Static line includes Essential and Functional packages; all six products are designed to assist clinicians in rehabilitating patients. These packages are illustrated and described in respective order in Figure 1, Figure 2, Figure 3, and Figure 4 on the following pages, along with their corresponding features and technical details. For a brief overview of each package's functionality, refer to Table 1.

Table 1: Bertec® Balance Advantage® Packages and their Corresponding Features.

Package	Static Plate Assessments	Portable Option	COBALT Protocol Option	IVR Training Modules	Balance & Mobility Training Modules
Dynamic CDP/IVR™*	X	X	X	✓	✓
Prime IVR™*	✓	X	X	✓	✓
Static Essential	✓	✓	✓	X	✓
Static Functional	✓	✓	✓	X	✓
Portable Essential	✓	N/A	✓	X	✓
Portable Functional	✓	N/A	✓	X	✓
Tender Essential	✓	N/A	✓	X	✓

*Not Covered in this manual.



This manual covers the features offered by all six Bertec® Balance Advantage® Static Packages; as mentioned before, not every section is applicable to every package—clinicians only need to read the features which apply to their package.

As depicted in Table 1, all packages are capable of static plate assessments, although not all training protocols are available on all packages. More information about static plate assessments, analysis, and training is located on pages 38-74.

Bertec® Balance Advantage® Static Packages

Bertec® Prime IVR™

Standard Package

Bertec® Balance Advantage® software

Visual surround dome (74"W x 42"D x 105"H) with LCD projector

Dual-balance force plate (18" x 20")

Cart-mounted, dedicated computer

Touchscreen monitor

Color Printer

Foam balance pad (18" x 20" x 4")

Wooden rocker board



Specifications

Features

Standardized assessment protocols with normative data

Low 1.5" profile in an 18" x 20" dual-balance force plate

High-sensitivity dual-balance force plate

Immersive virtual environment visual surround

Set of training scenes for projection into dome

Training

Quick Training

Mobility

Closed Chain Weight

Shifting Seated

Training

Assessments

mCTSIB

Limits of Stability

Weight Bearing Squat

Rhythmic Weight Shift

Unilateral Stance

Immersive Visual Stimuli

Rock wall

Checkerboard Room

Optokinetic stripes (horizonal and vertical, adjustable width and speed)

Grocery aisle (real-time adjustable parameters)

Flight simulator

Castle Corridor

Max Load = 500 Lbs

Bertec® Balance Advantage® Essential

Standard Package

Bertec® Balance Advantage® Software

Dual-balance force plate

Height adjustable workstations (2)

Touchscreen display for clinician

Color screen display for patient

Dedicated computer

Wireless pointing device/mouse

Uninterruptable Power Supply

Patient Isolation Transformer

Biocompatible Foot Covers

Wooden rocker board

Foam balance pad

Optional Components

Foam balance pad (18" x 20" x 5")

Carrying case
(custom to fit all components)

Extended Warranty

COBALT™ powered by Bertec®



SPECIFICATIONS

Features

Standardized protocols with normative data

Low 1.5" profile in an 18" x 20" configuration

High-sensitivity dual-balance force plate

Assessments

Limits of Stability

mCTSIB

Weight Bearing Squat

Rhythmic Weight Shift

Unilateral Stance

Solution

Intuitive software

Ongoing support

500 lb load capacity

One year parts and labor warranty

Training

Quick Training

Mobility

Closed Chain

Weight Shifting

Seated Training

Bertec® Balance Advantage® Functional

Standard Package

Bertec® Balance Advantage® Software

Dual-balance force plate

Height adjustable workstations (2)

Touchscreen display for clinician

Color screen display for patient

Dedicated computer

Wireless pointing device/mouse

Uninterruptable Power Supply

Patient Isolation Transformer

Biocompatible Foot Covers

Wooden rocker board

Optional Components

Bertec® Vision Advantage®

Extended Warranty

COBALT™ powered by Bertec®



SPECIFICATIONS

Features

Standardized protocols with normative data

Low 1.5" profile in a 20" x 60" configuration

High-sensitivity dual-balance force plate

Training

Quick Training

Mobility

Closed Chain

Weight Shifting

Seated Training

Assessments

Limits of Stability

mCTSIB

Weight Bearing Squat

Rhythmic Weight Shift

Unilateral Stance

Sit to Stand

Step Up and Over

Step Quick Turn

Tandem Walk

Walk Across

Forward Lunge

Solution

Intuitive software

Ongoing support

500 lb load capacity

One year parts and labor warranty

Bertec® Balance Advantage® Portable Essential

Bertec® Balance Advantage® Tender Essential

Standard Package

Bertec® Balance Advantage® software

Dual-balance force plate

Laptop computer

Power cable and USB cable

Wireless pointing device/mouse

Foam balance pad (18" x 20" x 4")

Database merge and sync

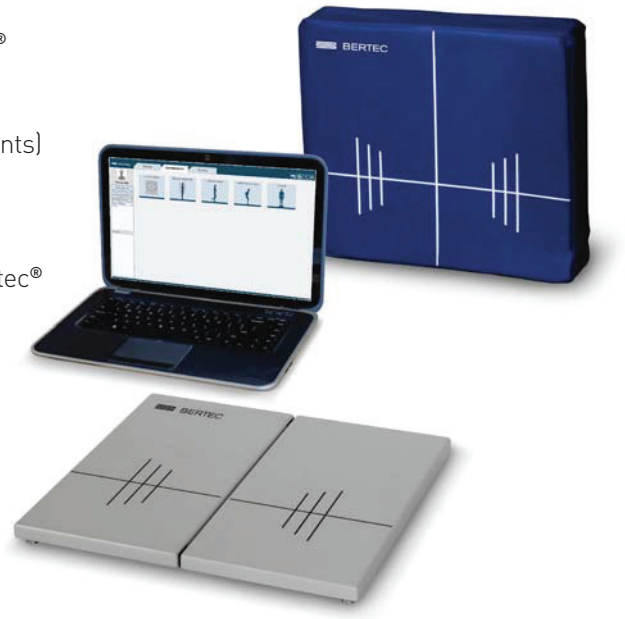
Optional Components

Bertec® Vision Advantage®

Carrying case
(custom to fit all components)

Extended Warranty

COBALT™ powered by Bertec®



SPECIFICATIONS

Features

Standardized protocols with normative data

Low 1.5" profile in an 18" x 20" configuration

High-sensitivity dual-balance force plate

Assessments

mCTSIB

Limits of Stability

Weight Bearing Squat

Rhythmic Weight Shift

Unilateral Stance

Solution

Intuitive software

Ongoing support

500 lb load capacity

One year parts and labor warranty

Training

Quick Training

Mobility

Closed Chain

Weight Shifting

Seated Training

Bertec® Portable Functional

Standard Package

Bertec® Balance Advantage® Software

Dual-balance force plate

Laptop computer

Power cable and USB cable

Wireless pointing device/mouse

Foam balance pad (18" x 20" x 4")

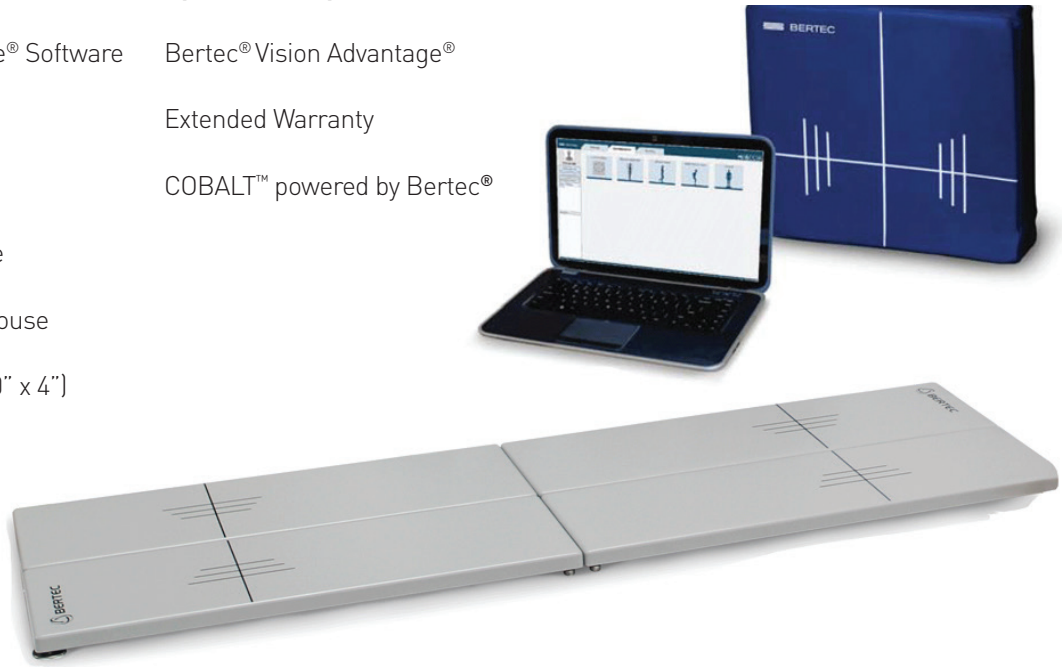
Database merge and sync

Optional Components

Bertec® Vision Advantage®

Extended Warranty

COBALT™ powered by Bertec®



SPECIFICATIONS

Features

Standardized protocols with normative data

Low 1.5" profile in a 20" x 60" configuration

High-sensitivity dual-balance force plate

Training

Quick Training

Mobility

Closed Chain

Weight Shifting

Seated Training

Assessments

Limits of Stability

mCTSIB

Weight Bearing Squat

Rhythmic Weight Shift

Unilateral Stance

Sit to Stand

Step Up and Over

Step Quick Turn

Tandem Walk

Walk Across

Forward Lunge

Solution

Intuitive software

Ongoing support

500 lb load capacity

One year parts and labor warranty

Turning on the Prime IVR

Note: Only for Prime systems. Other system users should refer to the following page for starting their system(s).

To Initialize the Projector:

1. Point the projector's remote control in the approximate direction of the projector (doing so on the side of the machine works best, so that the dome does not stop the remote's signal).
2. Press its (green) power button once, and wait 10-15 seconds for the bulb to illuminate.

Note: The remote's power button is highlighted in Figure 7. If an extended period of time passes and the projector has not turned on, press the power button again and make sure the remote is pointed at the projector.

To turn off the projector, point the remote at the projector, press the power button twice and wait 10-15 seconds before trying again.

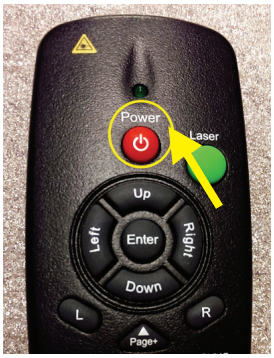
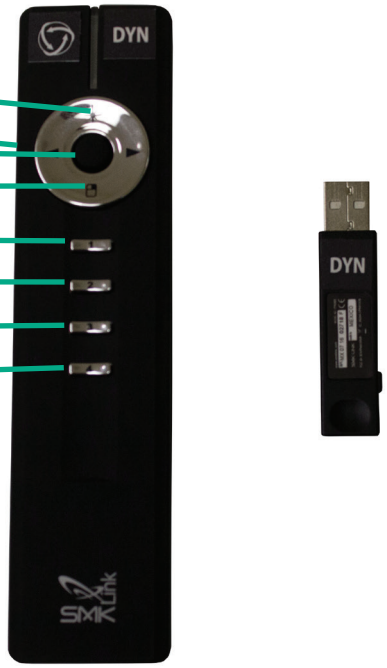


Figure 7: Power Button.

A wireless remote is included with every package to assist clinicians in managing the Balance Advantage® program while they assist patients. The remote generally serves the functions below; however, these functions may change for some specific tests. Refer to protocol sections for more information regarding modified functions.

- Green Laser Pointer
- Mouse (Back Button, Left Click)
- Mouse Scroller
- Right Click
- Next Condition
- Previous Condition
- Start/End Trial
- Switch between Patient and Clinician Screen



Note: The USB Dongle is shown to the right of the remote in Figure E1. It needs to be plugged into the computer's USB for the remote to function with the system.

Figure E1: Remote and Dongle.

Initial Startup and Login

All Bertec® Balance Advantage® systems include either a dedicated tower computer attached to a cart or a laptop. Instructions are included below for each system – be cognizant of the system's wires when testing a patient.

To Turn on and log in to a Dedicated Tower System for the First Time:

1. Press the power button on the top of the computer tower.
2. The power button will illuminate once the system is turned on.
3. Log in to the desktop.
4. On the desktop, click on the Bertec® Balance Advantage® logo to load the software.
5. If prompted for a password, enter "password" in all lower-case letters, then press the Enter key on the keyboard (or click the "Login" button).
6. Refer to page 12 for help navigating the clinician home screen. Refer to page 13 to setup/configure the system.

To Turn on and log in to a Portable (Laptop) System for the First Time:

1. Press the power button on the side of the laptop (circled in Figure 9).
2. Log in to the desktop.
3. On the desktop, double click the Bertec® Balance Advantage® logo to load the software.
4. If prompted for a password, enter "password" in all lower-case letters. Afterwards, press the Enter key on the keyboard (or click the "Login" button).
5. Refer to page 12 for navigating the clinician home screen. Refer to pages 14-19 to setup/configure the system.



Figure 9: Laptop Power Button.

It is crucial that the plate remains clear of any objects during system start-up until the operator has completely turned on the system and logged into the Balance Advantage® software. The purpose of this step is to allow the system to tare the plate upon start-up of the software. If the plate is interrupted during this self-zeroing process, refer to Appendix F. Alternatively, logout and restart the program (instructions shown below).

To log out of Balance Advantage:

1. Click on the log out button, located in the upper right corner of the screen (shown in Figure 10).
2. Click on the exit button (shown in Figure 11).



Figure 10: Software Log out Button.



Figure 11: Exit Button.

Once the system has been setup, the system administrator (admin operator) can create operator accounts for other staff members/clinicians. Refer to page 16 for more information regarding operators and how to add operator accounts.

Routine Startup and Login

After the initial startup and login, refer to the following instructions for subsequent logins.

To Start the System:

1. Push the computer's power button.
2. Log in to the desktop.
3. On the desktop, click on the Bertec® Balance Advantage® logo to load the software.
4. Keep the plate clear of objects until the operator is successfully logged in to the system.
5. If the plate is disturbed during this process, refer to Appendix F or logout of the program. Refer to Figures 10 and 11 on the previous page for logout instructions.

To Log in to the Program:

1. Open Bertec® Balance Advantage®. Arrive at the login screen, shown in Figure 12.
2. Click on the correct username within the Operator box.
3. Make sure the desired operator is highlighted in blue.
4. Type in the password that was set for the selected operator.
5. Click the "Login" button, or press the Enter key to arrive at the clinician home screen. Refer to the following page for information regarding the clinician home screen.



Figure 12: Software Login Screen.

Clinician Home Screen

The clinician home screen is the first screen seen immediately after the operator (or administrator) logs in. Upon logging in, the operator will automatically be shown the *Patients* tab and be able to see the system's list of patients. The screen is split into three main regions, or tabs, described below.

1. Patient Information: Patient information is displayed within the *Patients* tab. This is the primary interface for loading a patient, creating a patient, and viewing a patient's history.

2. Assessments: All of the balance protocols available with the system are located within the *Assessments* tab. Each protocol is represented by an easily identifiable icon that can be dragged and dropped into a test series.

3. Training: A wide range of options are available to help rehabilitate a patient in the *Training* tab. These options include:
   - Weight shifting
   - Seated
   - Mobility
   - Closed Chain
   - Quick Training

Once a patient is selected, an operator may complete assessments or training by clicking on the *Assessments* or *Training* tabs. The clinician home screen is illustrated in Figure 13: the top bar highlights the tabs, whereas the bar on the left shows where patient information is stored.

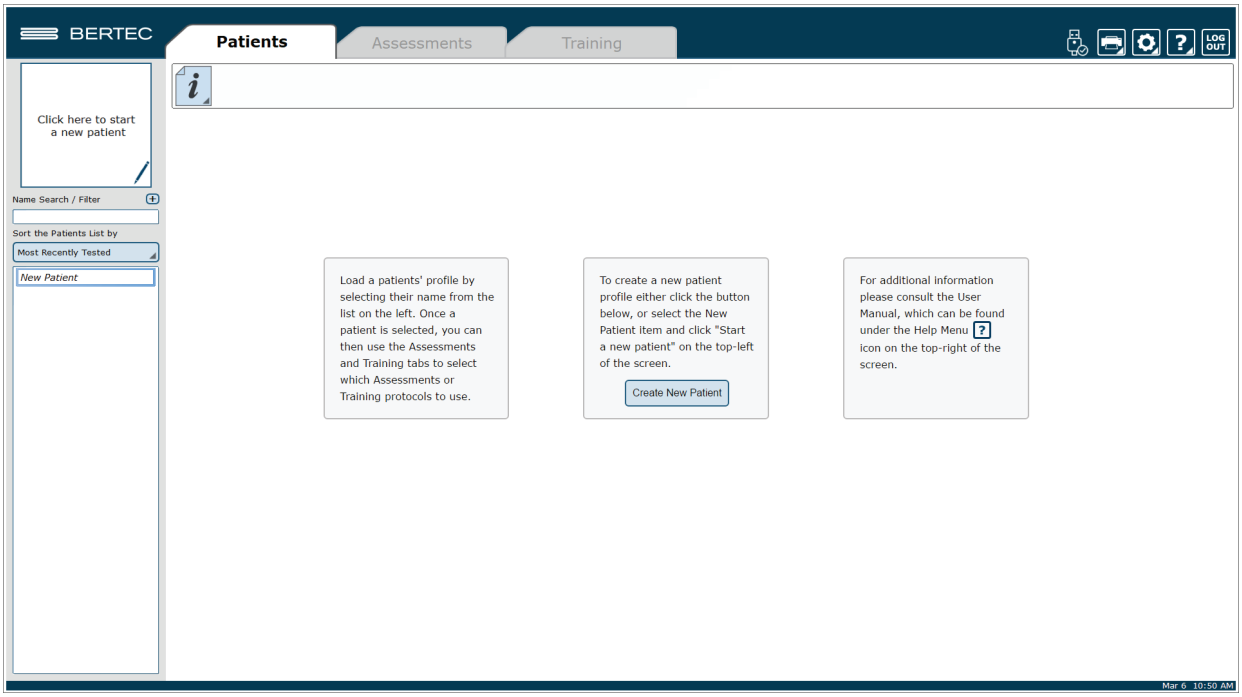


Figure 13: Clinician Home Screen.

It is crucial that all operators learn to navigate the clinician home screen.

Facility Setup and System Configuration

Note: Only Operators Granted the Role of Manager or Super/Admin Operator Can Access these Configuration Options.

In the initial setup, the administrative operator will need to configure the software to best suit the needs of the facility. Units of measurement, report headers, and facility information needs to be selected and entered. After initial setup, the configuration options area can still be accessed by operators granted permission to do so (see note above).

Options Setup

The operator must select the gear icon in the upper right corner of the screen and then click on Configuration. In doing so, the operator will load the configuration options screen in a new window where General Settings, Test Settings, Additional Fields, Test Series, Operators, Security Roles, and the Database can be configured (Figure 14).

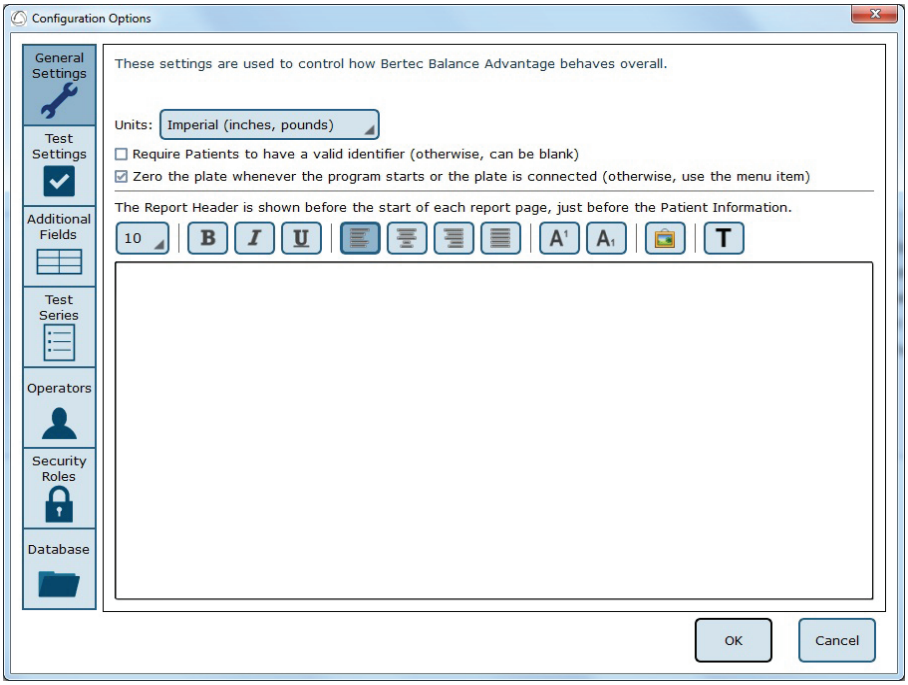


Figure 14: Configuration Options Screen. The General Settings Field is Currently Selected.

General Settings

The General Settings configuration options are used to change how the program behaves. Here the operator can change the units of measurements (pounds/feet/inches vs. kilograms/meters/centimeters), and other options, such as the requirement that patients must have a valid identifier and what report header will be contained at the top of each report page. Finally, the program can be set to automatically zero the plate when the system starts or a plate is connected (this option should always be enabled unless directed otherwise by Bertec Support).

The Report Header allows the operator to change the font size, style, alignment, and color of the text. A user can also insert a reference to an image, such as an office logo into the header. The image file must be accessible to the Windows computer in order for it to be displayed – the image is not saved in the Report Header. The image, therefore, must present on or downloaded to the local hard drive.

Test Settings

The Test Settings configuration options, shown in Figure 15, are used to control how tests behave. One customizable setting is to turn the sounds used to indicate the start, stop, or test failure on or off. Additionally, the type of sound the system plays can be changed in this section to any .WAV file contained on the computer.

The operator can adjust the Center of Pressure display in some test protocols to how sensitive the plates react to initial pressure on the plate. By default, approximately 25 pounds of pressure change is required for a plate to react and start tracking data. Adjusting the slider towards “Very Sensitive” will make the plate react to less pressure, down to approximately 2 pounds; adjusting the slider towards “Less Sensitive” will make it react to a minimum pressure of approximately 65 pounds. This has nothing to do with how fast or slow the display updates; it only affects how much pressure on the plate is required to make the Center of Pressure start tracking.

The Configuration Box for Test Settings (above the Center of Pressure display) also allows the operator to save all test data for both assessments and trainings. All assessment data, even the channels of data not used to generate the reports, is saved in the database by default. Even so, no training data is stored (however, results are retained). When this setting is checked, all raw data is saved for both assessments and trainings. This can be valuable if COG or COP traces for the trainings is desired, but it also means the database size will grow much more quickly.

Additionally, the screen DPI for the Vision Tracker and sensitivity of the Jump Analysis can be changed in this window from their corresponding options, as seen in Figure 15.

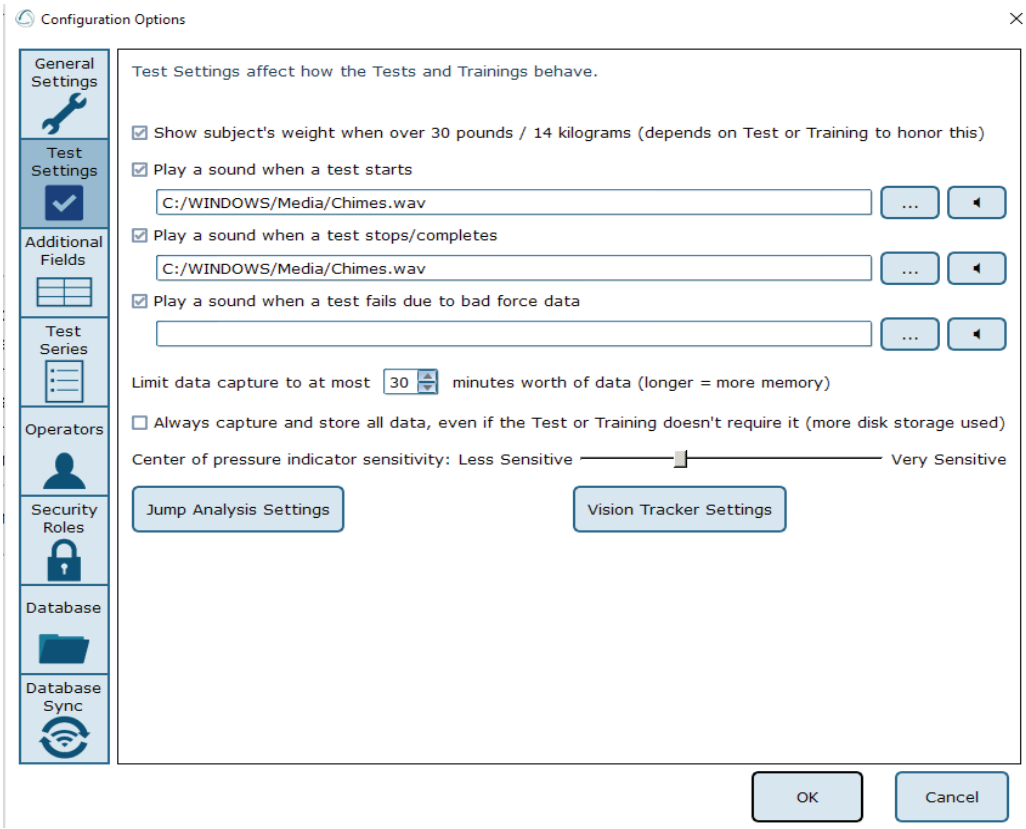


Figure 15: Data Size Notification.

Additional Fields

Additional fields allow the operator to attach information to each patient record. Any fields that have the “Required” column checked are must-have fields which must be filled in by the operator before the patient record can be saved. Additional fields may also be configured to contain user-generated lists associated with specific fields. One example of this is the pre-configured list of ICD-9 codes already on the system. The operator may edit these fields/lists, create or delete lists, and specify which additional fields use the lists. These options are located on the bottom of the Additional Fields window.

Edit Field: Selecting a current field in the system list (at the top of the box) will activate the Edit Field button. This allows the operator to set the type of text that appears in the box (either operator-input text or text from user-created lists), set where in the list the field will appear, and check whether or not it is a required field. Figure 16 shows the Edit Field options menu.

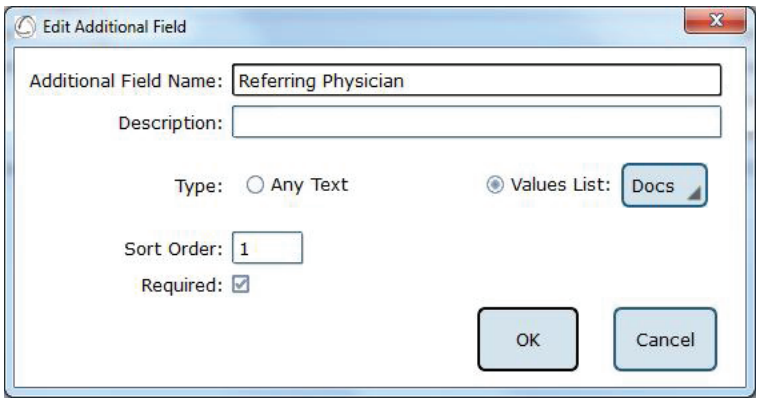


Figure 16: Edit Field Options Menu.

New Field: The New Field button will create a new field that appears in the list of additional fields. This field can be used for whatever information the operator would like to record—this information becomes attached to patient records. When creating the new field, all of the other field-specific options should be specified (ex: order, required or not, list/no list).

Delete Field: The Delete Field button will delete the currently selected field from Additional Fields.

Values Editor: Operator-created lists are generated and saved through the Values Editor. When clicked, a new window will appear that lists the currently saved lists for additional fields (located on the left). When a list is selected on the left, the contents of the list are displayed on the right. A full view of the Value Editor is shown in Figure 18 on the following page.

To create a new list: the operator should first select Add New List. This will add <New Entry> to the list of Saved Lists. The operator can change the list’s name from <New Entry> to a desired name from the Name Text line. Additionally, the operator can select whether multiple items in the list can be selected through checking the Allow Multiple Selections box, shown in Figure 17. If selected, the operator can begin typing in the contents of the list in the text box, as every new line would then coincide with a new possible selection (by default the information is only for one field). When finished, select Ok to save the new field/update.

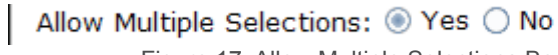


Figure 17: Allow Multiple Selections Box.

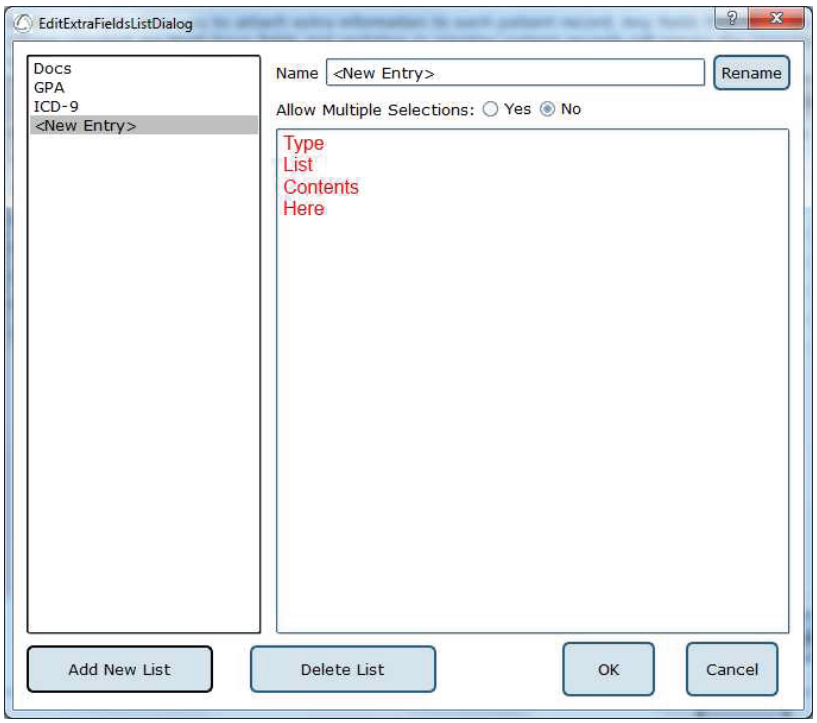


Figure 18: Values Editor Window.

Test Series

The operator can click on the Test Series box to bring up all of the test series on the system that have been created and saved by operators, or system users. The operator can remove or rename saved lists by selecting the saved test series and then either clicking Delete Series or Rename Series.

Operators

Operators are Balance Advantage® login accounts that can perform specific actions, such as perform assessments, generate reports, and work with patient records. Each operator can have a security role (access rights) assigned to them that limits or grants what they can and cannot do.

To edit or delete an operator, the current operator can click on an entry and then click either Edit Operator or Delete Operator. To create a new operator, the operator can click New Operator. Clicking on edit Operator or New Operator will open the window link shown in Figure 19.

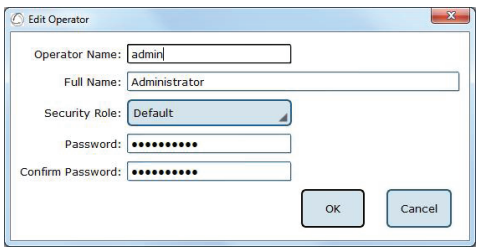


Figure 19: Edit Operator Profile Window.

The Operator Name is required, as it is used to identify the operator and to allow said operator to log into the system at the login screen. The optional Full Name is shown where needed, but if it is not provided, the system will default to the Operator Name.

The Security Role is populated from the security roles configuration screen (see Security Roles below for more information). Only one security role can be assigned to an operator, but multiple (or all) operators can use the same security role.

The Password is used to log the operator into the system. To change the password, enter the same password twice. Note that blank (no text) passwords are allowed, but discouraged. The operator, if signed in, can change their password from the Balance Advantage® system menu. See Appendix D for more information.

Security Roles

Security roles allow access rights to be configured for operators. These access rights are shared between operators, so changing what one access right does for a security role will affect all operators that are assigned to that security role.

To edit or delete a security role, first click on an entry and then either click Edit Security Role or Delete Security Role. To create a new security role, click New Security Role. Clicking Edit Security Role or New Security Role will open a new window, as shown in Figure 20.

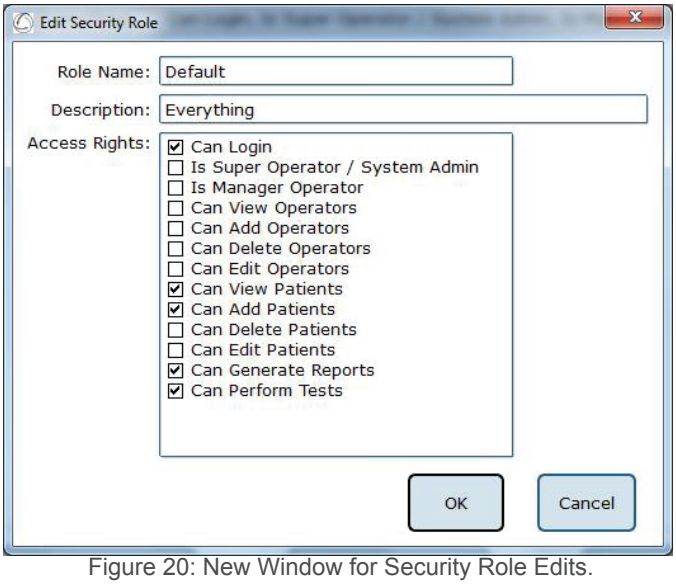


Figure 20: New Window for Security Role Edits.

The Role Name is required and is used to identify the security role. The optional description is provided to allow the operator to write a description of what the role is for. The Access Rights check boxes define what the role can or cannot do. By default, a new security role can do nothing. Unless the “Can Login” right is set, any operator account assigned this role cannot log into the system.

The Is Super Operator/System Admin access right is for a very high-level account. It should only be set for accounts that can change system settings, and more importantly, create, edit, and delete operators and security roles.

The Is Manager Operator access right is similar to the System Admin access right in that it also has access to the configuration screen and settings, but it cannot add, change, or delete operators or security roles. It also, by default, does not grant access to the patient lists nor tests and reports.

The View/Add/Delete operator's rights may be granted to Manager Operators or to Super Operators/System Admins only.

An operator without View/Add/Delete patient rights will have no access to patients, and, by extension, will not be able to use the system at all. It is recommended that the right to view patients are assigned to all security roles, in addition to the right to log into the system.



Note: Remember to give all operators and security roles the right "Can Log in." Operators without this role will be unable to use the system.

Establishing New Patients

Note: It is recommended that a test patient, obviously named so, is created on the database for training purposes.

To Create a New Patient:

1. Click on the New Patient button in the center of the screen immediately after logging into the system and arriving at the clinician home screen. Alternatively, select New Patient from the patient list and then click on the Click here to Start a New Patient square (located in the upper left corner of the screen). Both options are shown in Figure 21.
2. After clicking, a popup window will appear with empty patient information fields. Illustrated in Figure 22.
3. Fill in all required fields. These fields are colored yellow. Afterwards, fill out any desired optional fields.
4. (Optional): Take the patient's photo by clicking on the Turn on Camera button, wait for the live camera image to appear, and then clicking on the Take Picture button.
5. Click on the Save Changes button to establish the new patient profile.

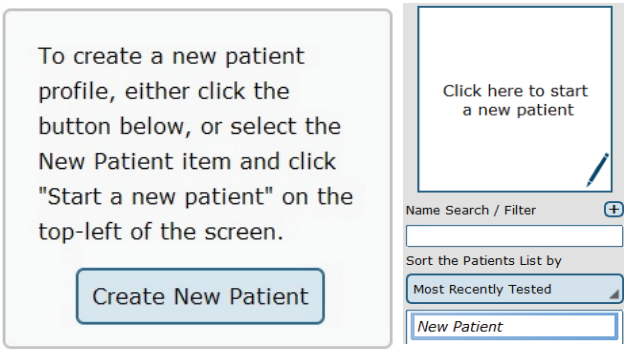


Figure 21: Creating New Patients.

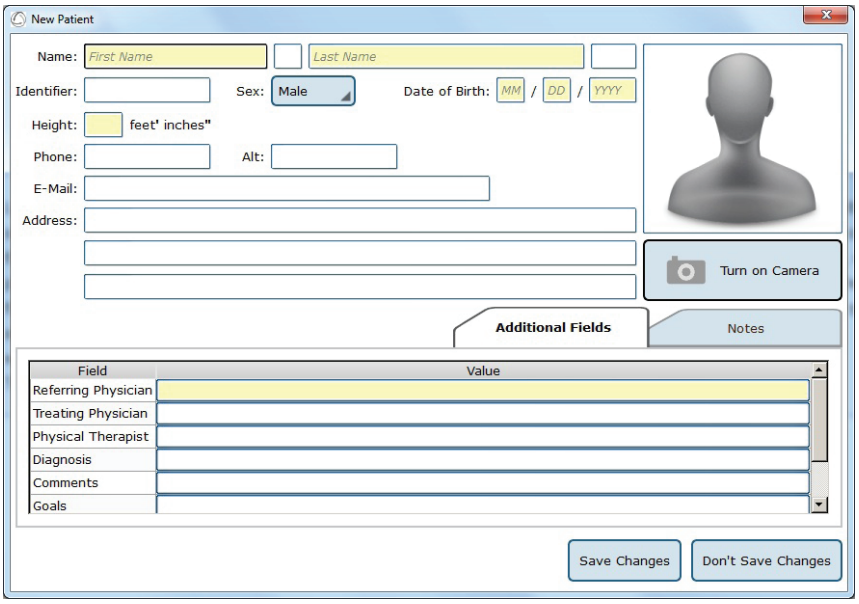


Figure 22: The New Patient Window.

Recalling Existing Patients

To Select a Patient who is Already in the System:

1. Click on the *Patients* tab.
2. A list of patients will appear on the left side of the screen. By default, this list is sorted by the most recently used profile.
3. Click to select the patient. The patient's information will appear in the center of the screen. Above the patient's information are the dates of previous tests (if any were performed). Click to reveal further information.
4. (Optional): The operator can sort this list in a different way, such as by alphabetical order, by clicking on the button under "Sort the Patients List by" and selecting the method to sort by.

Filtering by Additional Fields

If Additional Fields have been created that contain lists, the patient records can also be filtered by these list items.

For example, if a list has been created for Physical Therapist containing John, April and Joanne, the patient list can be filtered to show only Joanne's patients. To do this, click on the + sign (shown in Figure 23) next to Name Search / Filter, then click on Physical Therapist, then on the box next to Joanne. This screen is shown in Figure 24. Once the item to filter by has been selected, click OK. Multiple items can be added to the "filter by" list, just continue clicking on the + sign next to Name Search / Filter and repeating the same process as before. To remove an unwanted filter, click on the – sign that appears next to the filter label.

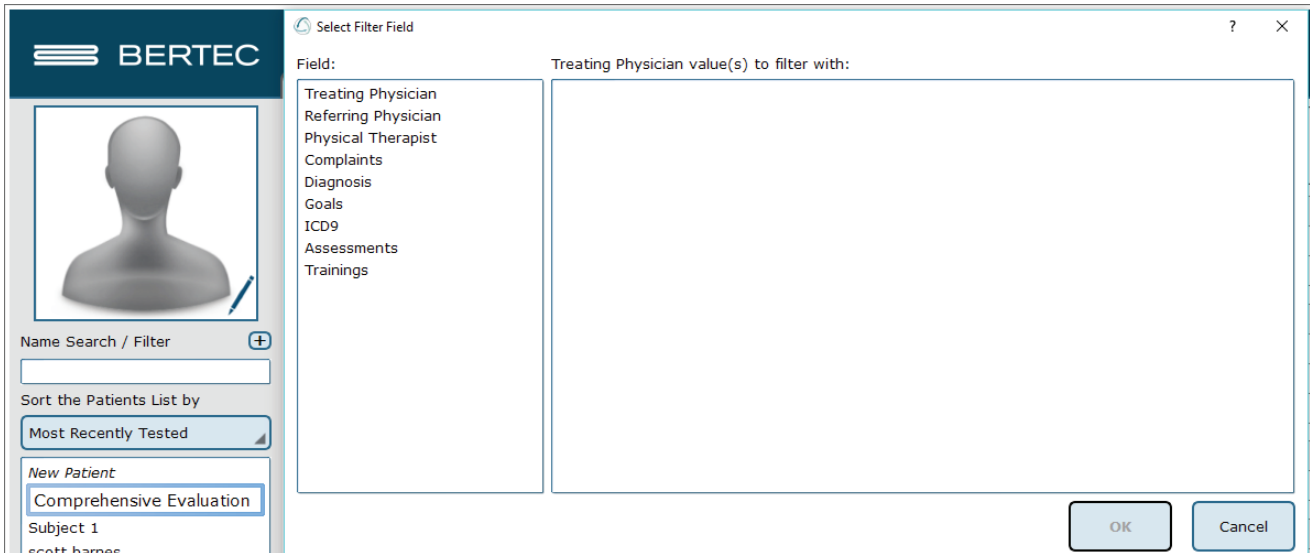


Figure 24: Select Filter Field - Patient List.

New Plate Configuration

When an unrecognized plate is connected to the system, a pop-up window will appear immediately after the operator logs into the software, as shown in Figure 25. The operator should click on the image matching the plate that has just been plugged in and select OK. It is critical the correct plate is selected; an incorrectly identified plate will result in skewed test calculations.

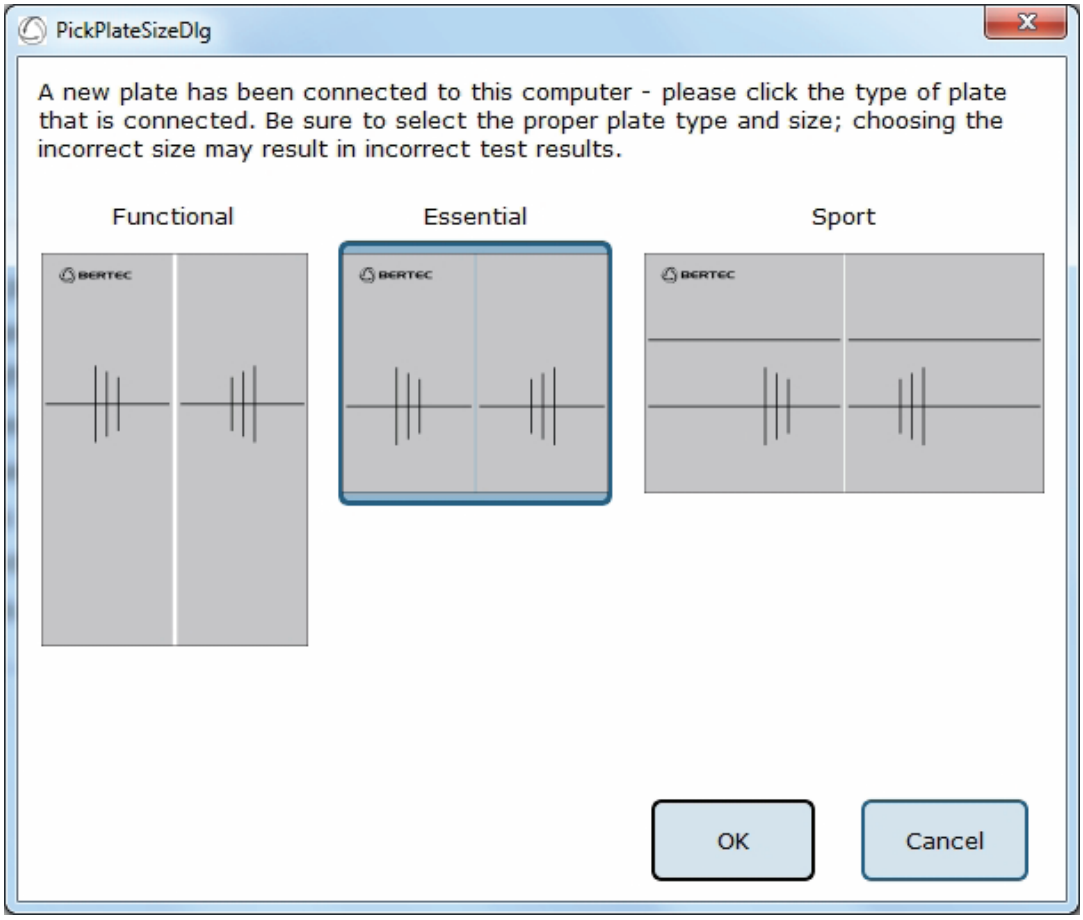


Figure 25: Pop-up Window.

If, for any reason, the operator selects the incorrect plate type, the plate type may be reset by clicking the gear icon and then choosing Re-select Plate Size from the dropdown list. Then, the operator can select the appropriate plate by clicking on the picture.

In addition to configuring unrecognized plates, Balance Advantage® systems using functional balance plates require the plate order to be configured at initial installation/setup, when the system is moved to a different location, or when a plate is disconnected and then reconnected. To orient the plates, click the gear icon and then choose Configure Dual Plates from the drop-down list. Figure 26 on the following page shows the orientation screen.

The operator should follow the on-screen instructions by standing on the plate furthest from the monitor. Wait for the plate in the picture to turn green, then select Ok. If any confusion arises, follow the on-screen instructions.

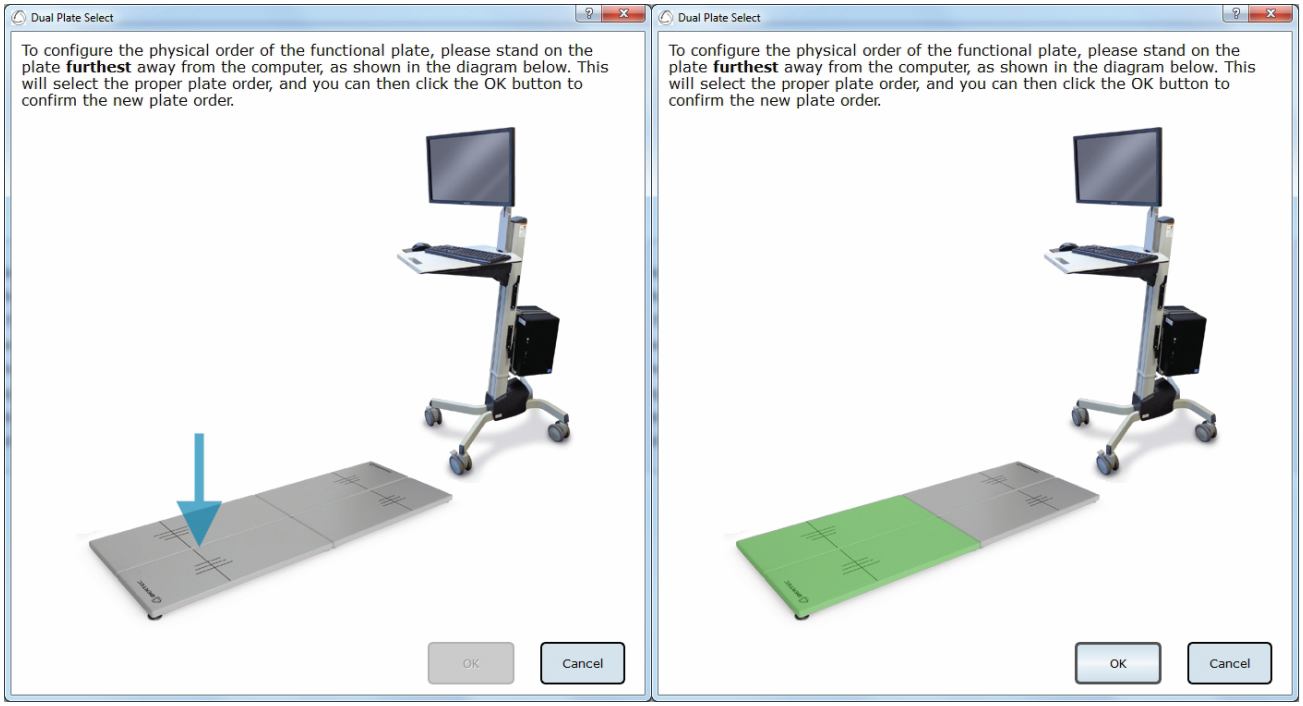


Figure 26: Configure Functional Plate Order.

Patient Assessment

To Start a Patient Assessment:

1. Create a New Patient (instructions on page 19) or access an Existing Patient (directions on page 21).

2. To perform new assessments, click the *Assessments* tab, shown in Figure 27, then drag and drop the desired assessment(s) into the Test Series List, located on the left.

   Note: Assessments can be re-ordered within the test series by clicking and dragging the test name to a new position.

   For a description of an assessment, refer to the appropriate chapter devoted to that assessment further in this manual, starting on page 46.

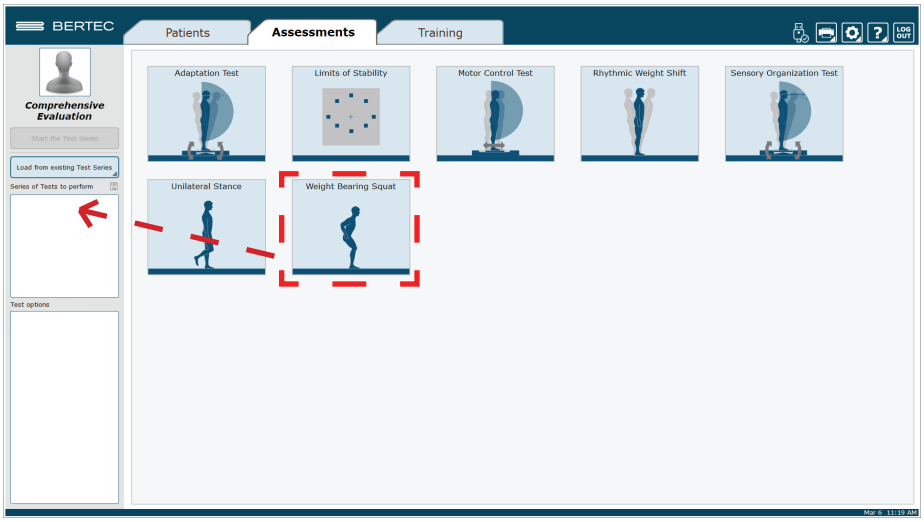


Figure 27: Assessment Tab: Test Setup.

3. After setting up the order to perform the assessments, select Start the Test Series, located directly below the patient's name in the top left corner.

4. Properly position the patient's feet on the balance plate. For most assessments, a patient will position their feet such that their medial malleoli are aligned with the line running from left to right and the lateral calcanei are aligned with the small, medium, or large lines. This will be indicated on the clinician screen. In general, the patient is allowed to splay their feet equilaterally so that they are standing comfortably. Proper foot placement is illustrated in Figure 28.

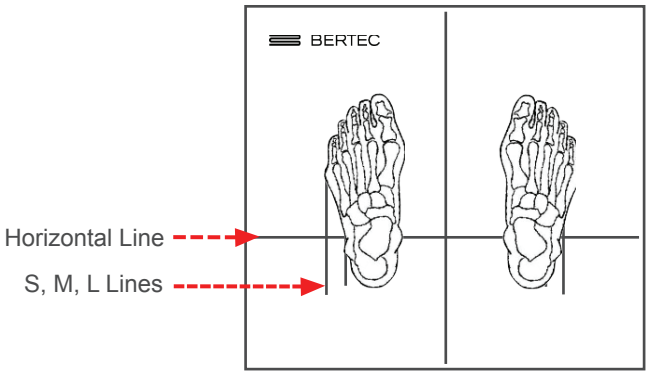


Figure 28: Proper Foot Placement.

5. Perform the assessments as directed on the computer screen. At any point during an assessment, the clinician may input notes by clicking in the Test Notes area, located on the bottom left corner of the screen. Figure 29, located on the following page, shows this screen.

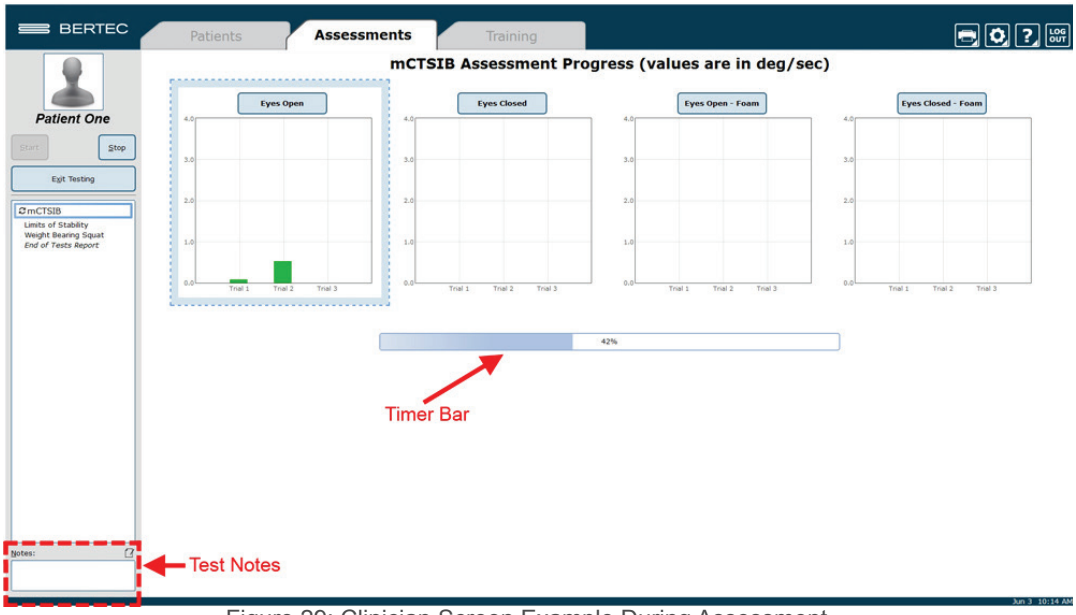


Figure 29: Clinician Screen Example During Assessment.

To View and Print Reports of Completed Assessments:

1. Navigate to the patient tab and confirm the correct patient is selected.
2. Above the patient information is a timeline that displays a date for each day a record has been recorded for the patient. Click on the date and the assessment to select the proper report.
3. Once the desired assessment report is pulled up, click on the print icon located in the upper right corner of the screen.
4. Progress reports can be viewed by clicking on the 'i' icon and selecting a progress report (if one is available).

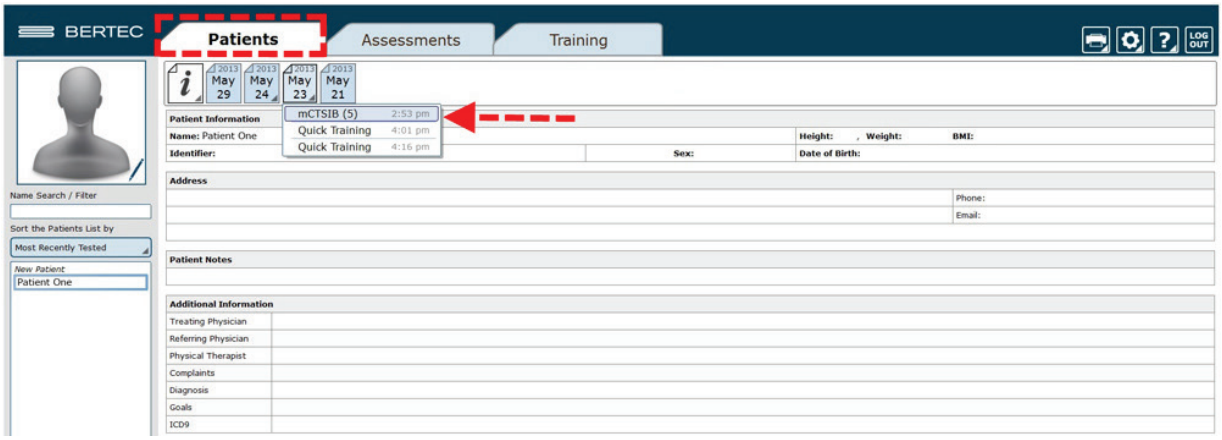


Figure 30: Return to Patient Screen to View Test Reports.

Re-collecting Trials

Trials may be discarded and data re-collected in the event of patient non-compliance (ex. sneezes, asks a question, opens their eyes, etc. while a trial is being collected).

To repeat a trial:

1. Hold down the Control (Ctrl) button and press the Delete (Del) button.
2. In the popup window that appears, shown in Figure 31, choose either Yes, I want to delete the last collected trial, or No, I do not want to delete the last collected trial.
3. Only the most recently collected trial will be deleted.

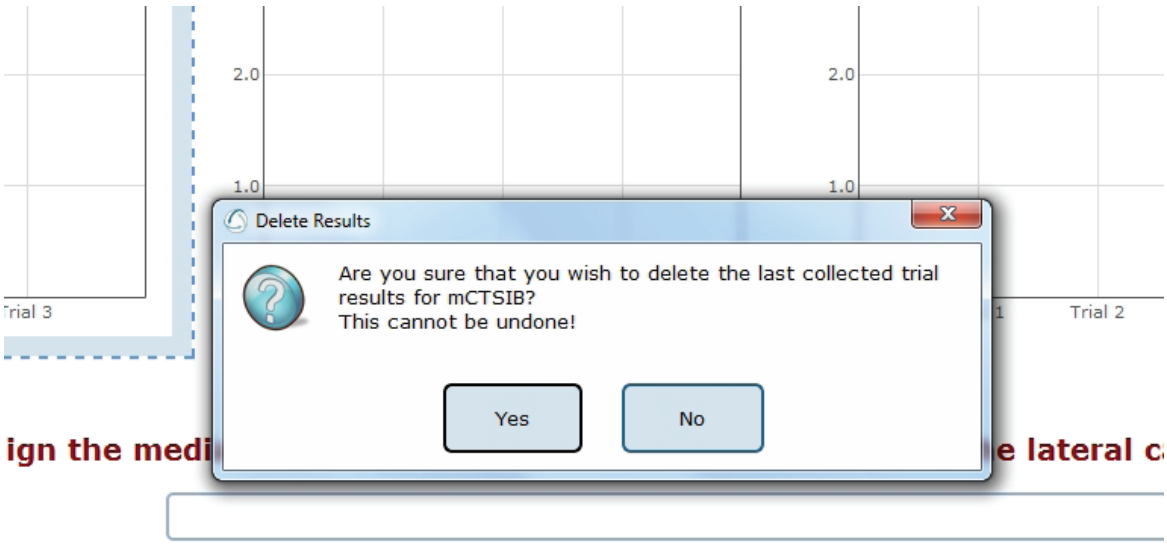


Figure 31: Delete Trial Verification.

Saving and Loading a Test Series

The Balance Advantage® software allows the operator to create a series of assessments and trainings that may be saved for future use with any patient.

To Save the List:

1. Select the assessments/trainings by placing them in the left column (under Series of Tests to perform).
2. Set the options for each test.
3. Select the Save icon.
4. Provide the Test Series with a unique name.

Selecting an existing Test Series:

1. Select the *Assessments* or *Trainings* Tab.
2. Select Load from existing Test Series (on the left of the screen, under the patient image and name).
3. Select the desired Test Series to be used.

Figure 32 illustrates the menu for saving and selecting saved lists. Both assessments and trainings can be combined to a comprehensive list. Simply select the assessments that are to be performed, switch to the *Training* tab to select the trainings to perform, and then save the list.

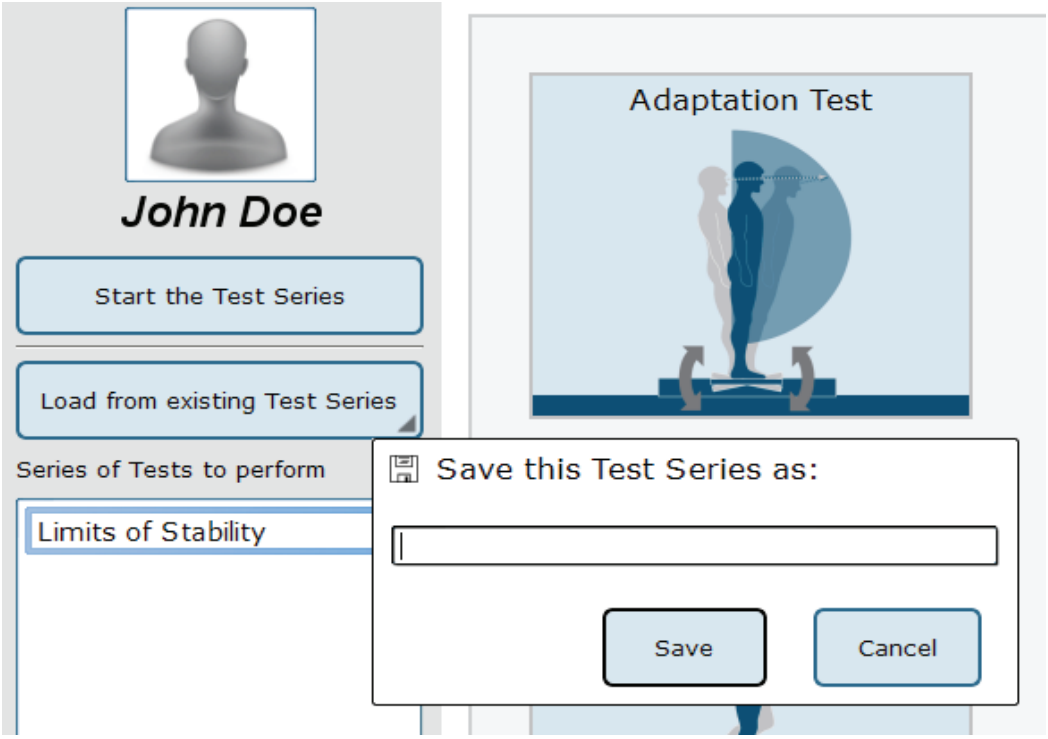


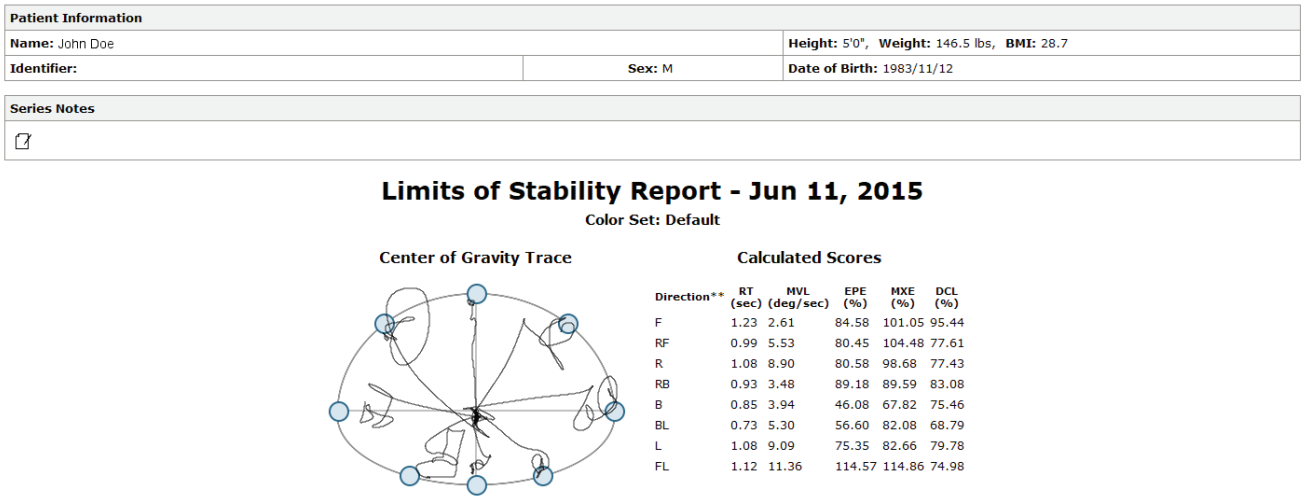
Figure 32: List Interface. Note that the bar to save tests is open.

Assessment Reports

Assessment results may be presented through a variety of report types: Individual Test Reports, Combined Reports, Daily Training Reports, and Progress Reports. Additionally, the report legend is discussed in this session, as well as exporting ASCII data.

Individual Test Reports

Individual Test Reports present the results from a single assessment performed on a specific day. An individual test report may be generated for any single assessment or training. Figure 33 is an example of a Limits of Stability Individual Test Report.



Patient Information		
Name: John Doe		**Height:** 5'0", **Weight:** 146.5 lbs, **BMI:** 28.7
Identifier:	**Sex:** M	**Date of Birth:** 1983/11/12

Series Notes

Limits of Stability Report - Jun 11, 2015

Color Set: Default

Center of Gravity Trace

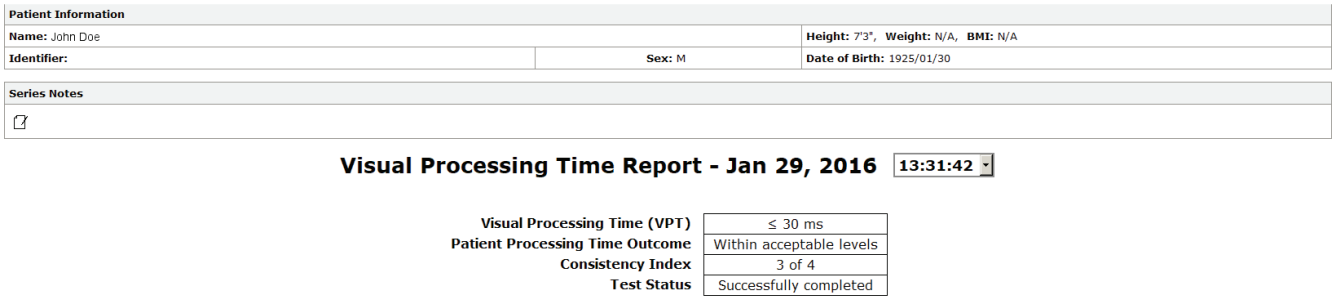
Calculated Scores

Direction**	RT (sec)	MVL (deg/sec)	EPE (%)	MXE (%)	DCL (%)
F	1.23	2.61	84.58	101.05	95.44
RF	0.99	5.53	80.45	104.48	77.61
R	1.08	8.90	80.58	98.68	77.43
RB	0.93	3.48	89.18	89.59	83.08
B	0.85	3.94	46.08	67.82	75.46
BL	0.73	5.30	56.60	82.08	68.79
L	1.08	9.09	75.35	82.66	79.78
FL	1.12	11.36	114.57	114.86	74.98

Figure 33: Limits of Stability Individual Test Report.

Combined Reports

Combined Reports merge the results multiple assessments—yielding a one-page report. The tests to be combined must have been performed on the same day and in the same session.



Patient Information		
Name: John Doe		**Height:** 7'3", **Weight:** N/A, **BMI:** N/A
Identifier:	**Sex:** M	**Date of Birth:** 1925/01/30

Series Notes

Visual Processing Time Report - Jan 29, 2016 13:31:42

Visual Processing Time (VPT)	≤ 30 ms
Patient Processing Time Outcome	Within acceptable levels
Consistency Index	3 of 4
Test Status	Successfully completed

Figure 34: Visual Processing Time Combined Test Report.

Daily Training Reports

This report is a cumulative record of the patient's exercises performed throughout the training session. The exercise, the difficulty settings, the parameters, and the patient's score may be printed with this report. Figure 35 is an example Leftward VMS Daily Training Report.

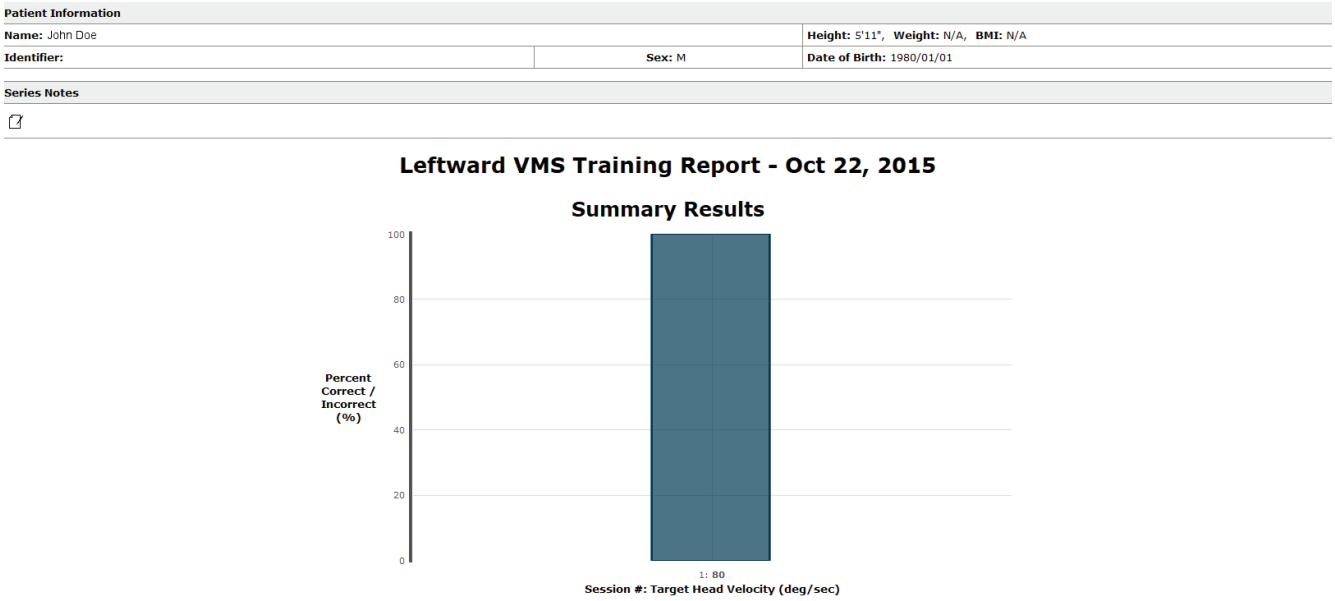


Figure 35: Leftward VMS Daily Training Report.

Progress Report

A Progress Report charts the patient's performance over time for one particular test. The patient must have performed the assessment or training multiple times during the selected time frame in order for a Progress Report to be available. An example Sensory Organization Test Progress Report is included in Figure 36.

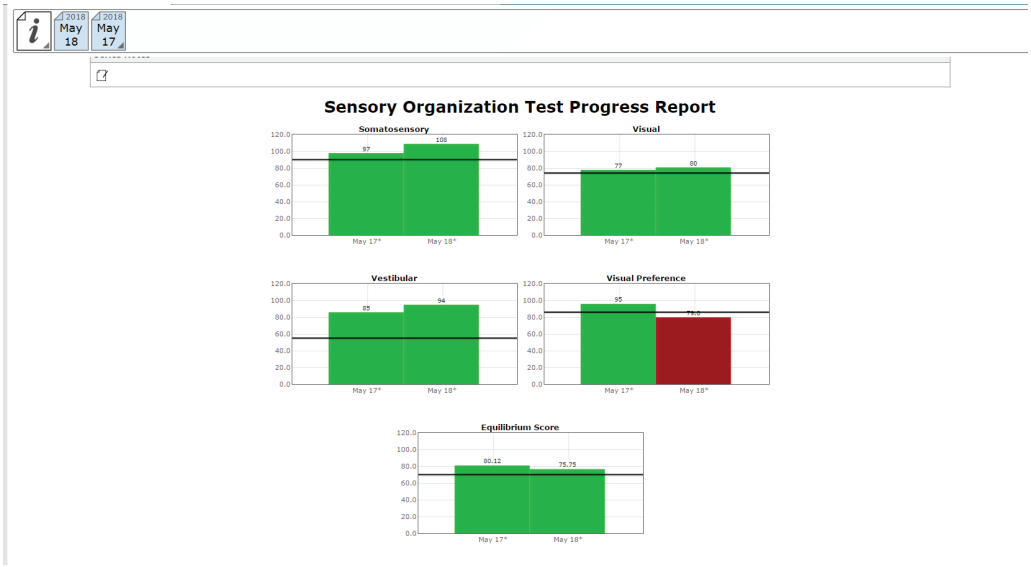


Figure 36: Sensory Organization Test Progress Report.

Report Legend

All reports adhere to the same general outline for presenting information. Gray bars represent normative data[1] associated with the age range the patient falls within. Green bars represent scores that are within the normative range and red bars represent scores outside (falling outside of the 5th percentile) of the age-matched normative range. A sample report legend is shown in Figure 37.

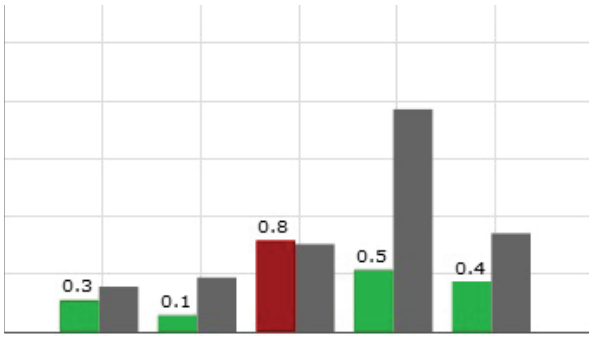


Figure 37: Report Legend.

ASCII Data Export

Data export may be initiated by holding down the Ctrl+F6 keys on the keyboard while viewing a test report from the *Patients* tab; performing this keystroke will open the Data Export viewer. Within this screen, a range of options are available to the user. Available options include choosing to export the current patient or all patients, the type of tests to be exported, how to organize exported information, export between which dates, and where to save the exported information. All exported data is saved in common comma-separated values (CSV) files and can be opened with other data analysis programs. The data export screen is shown in Figure 38. The exported data cannot be re-imported back into the Bertec® Balance Advantage® software. For details on performing a system back-up, please refer to the Database Maintenance section (page 33).

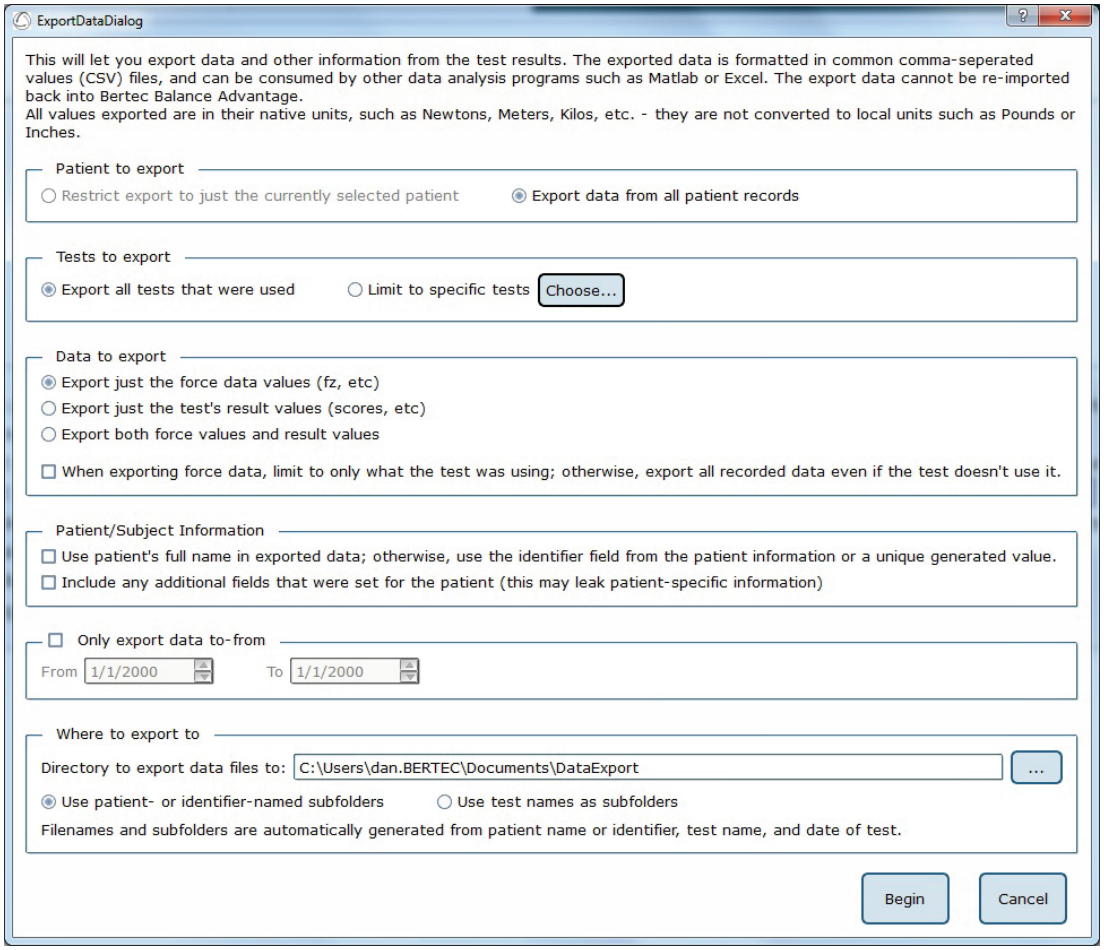


Figure 38: Data Export Screen.

Patient Screen Layout

In general, the patient screen will display either relevant target information, such as the Limits of Stability circle, or picture examples of how the test should be performed during assessments. Some patient screens will display starting cues or other instructions. The Limits of Stability test is used as an example below.



Figure 39: “Hold Still” Message before the Patient Moves.

“Begin” message indicating to begin movement

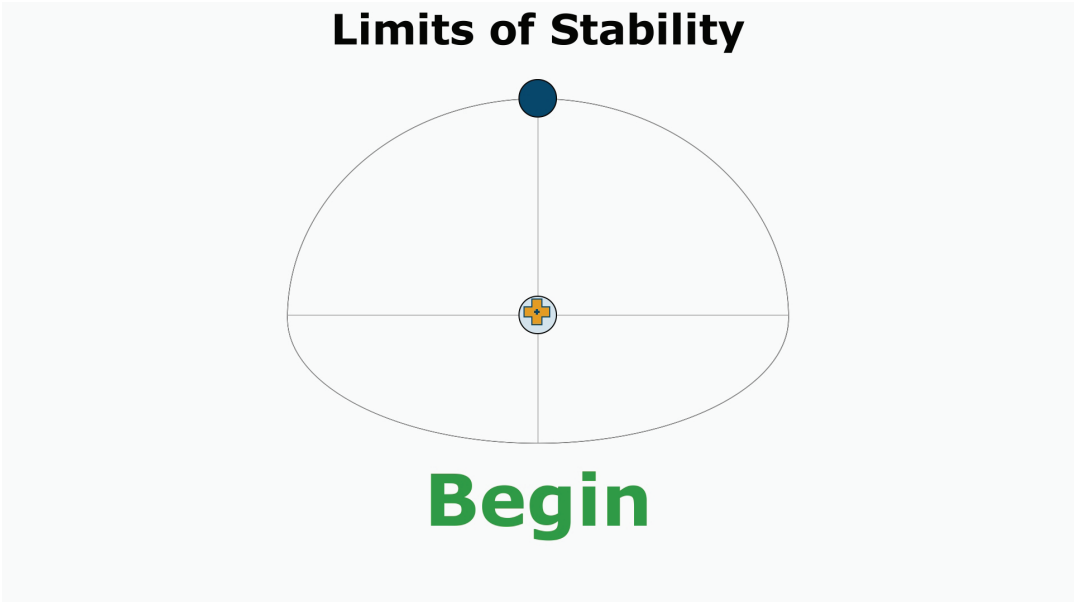


Figure 40: “Begin” Message Indicating to Begin Movement.

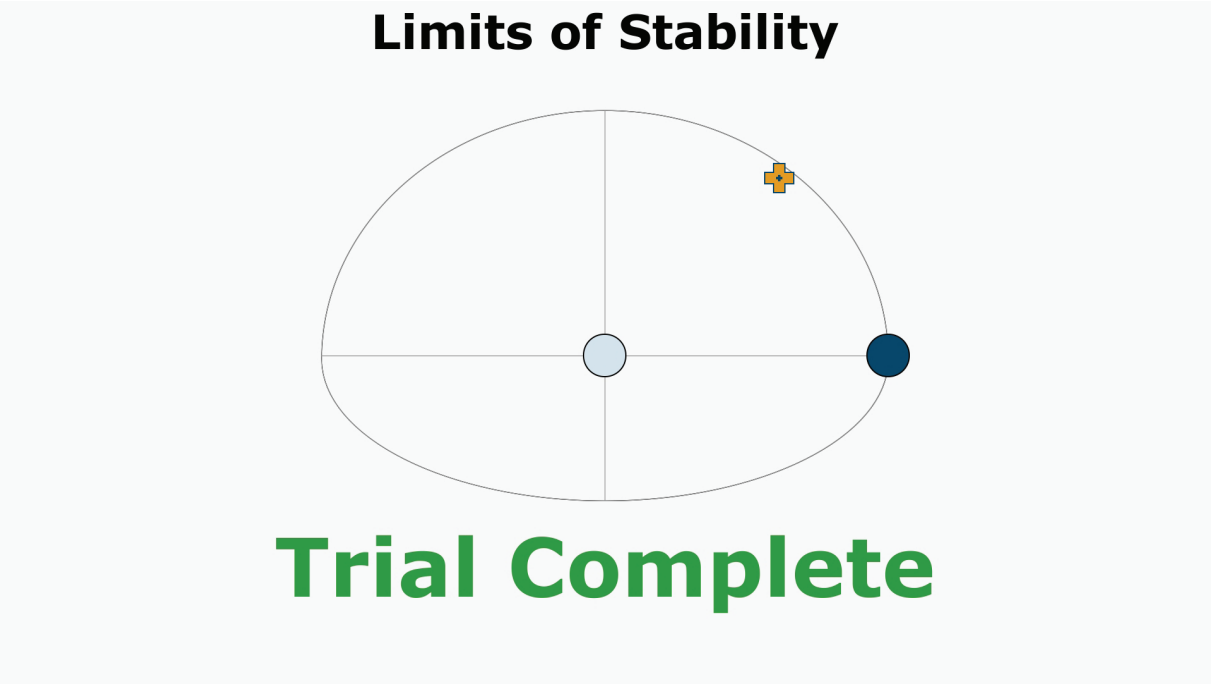


Figure 41: “Trial Complete” Message when a Trial has been Completed.

Database Maintenance

Note: Only operators granted the role of super operator/system admin can access these configuration options.

To Access the Database Configuration Page:

1. Click on the Gear System icon (located in the top right corner of the screen).
2. Select the Database Maintenance option (in the dropdown menu) to open the Database Configuration page in a new window.
3. If the database section is disabled, exit the Balance Advantage® program (refer to Figures 47 and 48 on page 37). Afterwards, right click on the Balance Advantage® icon (from the computer's desktop). Select the Run as Administrator option from the dropdown list to open the program. Login once more and repeat steps one and two.

The Database Configuration page, shown in Figure 42, is where the Current Database Statistics, Schedule Automatic Backups, Manually Backup and Restore the Database, and Configure and Perform Database Merge operations can be accessed.

Note: It is recommended that the "Automatic Archive" checkbox is checked. Checking this box will make the How Frequently, Start Time, and Folder Options become available.

- The How Frequently option controls how often automatic backups are conducted. This can either be daily, weekly, or monthly.
- The Start Time schedules the time the automatic backups will start (i.e. 9pm).
- The Folder Options controls where automatic system archives will be saved on the computer.

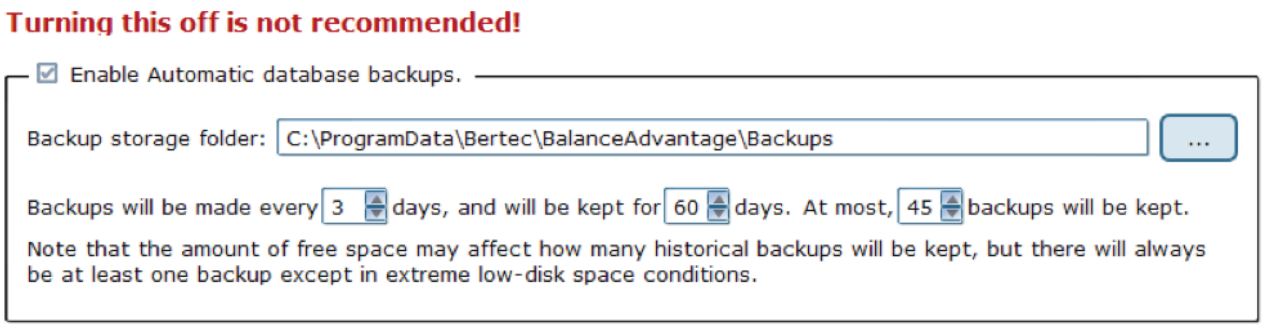


Figure 42: Configurations Options: Database.

Backup/Restore Database

Before changing database settings, backing up the current database is strongly recommended. Additionally, it is recommended that database backups are routinely instated: see the previous page for additional information.

To Backup the Database:

1. Click on the Perform Database Archive Now button (on the bottom left of the Database Configuration page).
2. Select a folder to save the archive in. This includes removable media, so long as the device is not removed until the archiving process is finished. The default folder location is: C:\ProgramData\Bertec\BalanceAdvantage.
3. The archiving process can be canceled at any time by clicking the Cancel button. Canceled archives will not be saved.

After the archive is complete, the Balance Advantage® system will show the name of the archived file and offer to open the folder which contains it. It is recommended that the archive is copied to a removable flash drive upon completion.

To Restore an Archived Database:

1. Click the Merge or Restore Database from Archive button (on the bottom right of the Database Configuration page).
2. Browse for and select the correct archive. Databases can be restored from archives stored on removable media (so long as the removable media remains connected to the computer for the duration of the database restoration process).
3. Select the option to Overwrite the current database. This option is directly below the option to Merge, displayed in Figure 43.
4. As a safety feature, the restoration function will default to creating a backup of the current database before it starts overwriting the current database. To skip the backup step, uncheck the “Create an archive backup...” option.
5. Click Ok. A confirmation message will be displayed.
6. Read the message to be sure the right option was selected.
7. Click Yes to logout while the database is restored.

Warning! Restoring a database from an archive will completely replace the current database contents. Only perform this action if there is a legitimate reason to do so, such as moving a database from one computer to another, or replacing a corrupted database due to hard drive failure or other issues. This operation cannot be undone!

Warning! Database files and database archives are encrypted and cannot be read or modified by other programs. Do not attempt to modify the database files or database archives through a third-party program, otherwise data loss will occur.

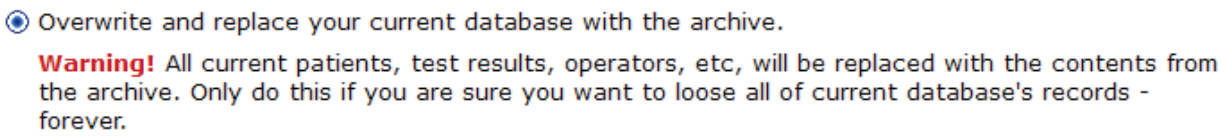


Figure 43: Overwrite Option.

Merge Options

A merge can be performed through either a one-way (from a database archive) or a two-way (from another local or remote system) operation. The method chosen will depend upon the office's setup; typically, if two or more Bertec® computers are connected via a local area network, the two-way operation should be used. The Database Configuration page is used for one-way merging; to access the two-way merging feature, click on the database sync option on the bottom left of the screen. Figure 44 shows where this option is located.

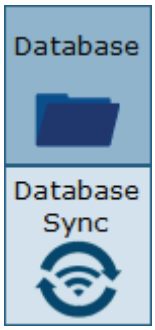


Figure 44: Database Merge Options.

Two-way mergers are conducted via the computer's network and/or the internet. Bertec medical electrical safety tests only permit Bertec computers to support wireless connection to the internet. The process runs in the background (once properly setup) so that scheduled database mergers are not required. Instead, new patients and information are constantly updated. Multiple systems can merge together.

A one-way merger is conducted from the computer's software, including attached removable devices. Only one file can be merged with the current database at a time.

Note: Merging databases between systems only works if both systems run the same version of Balance Advantage® software.

One-way Merging–Merging from an Archive

When merging from a database archive file – a one-way merge operation – an existing database archive will need to be selected by the operator. Typically, this will either be on a USB thumb drive or a network shared drive, but any media that the archive file is stored on will work. The media containing the archive file must remain connected to the computer for the entire merge operation.

To Conduct a One-Way Merge:

1. Click on the Merge or Restore Databases from Archive button in the bottom right hand corner of the Database Configuration page to select an archive to merge.
2. Navigate to the file. Click on the file to select it, then click on the Open button.
3. The program should default to merging, not restoring, an archive. Even so, ensure that the Merge circle is selected. (Figure 45)
4. As a safety feature, the one-way merge will default to creating a backup of the current database before it starts the merge operation. To skip the backup step, uncheck the “Create an archive backup...” option.
5. Click on the Next button to proceed to the final confirmation page.
6. Read the message to ensure the right option was selected.
7. Confirm the operation to begin the merge.

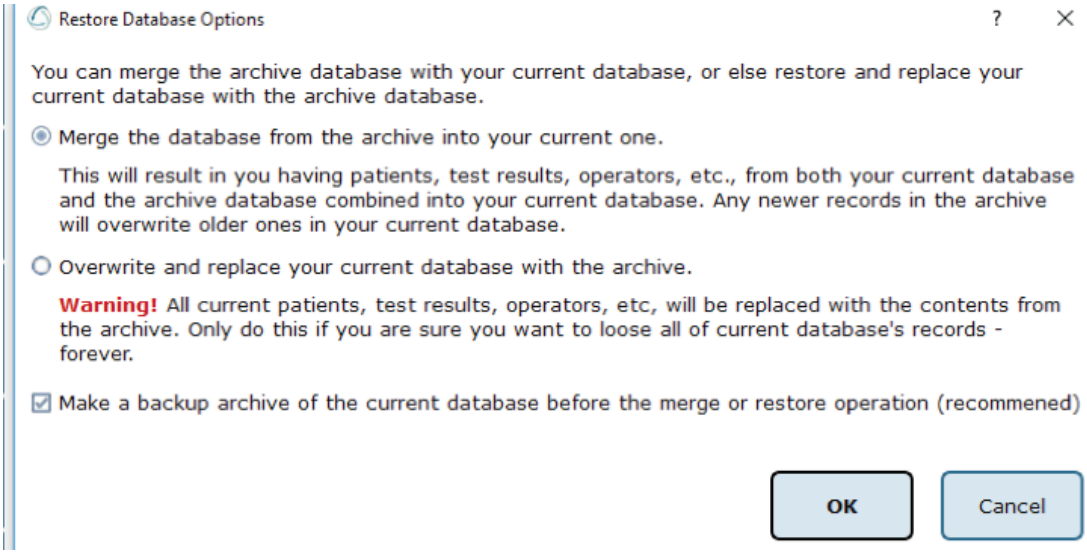


Figure 45: Merge/Archive Options.

Two-way Merging–Merging Over the Network (Database Sync)

The two-way merge operation requires that compatible Balance Advantage® systems are enabled to be accessible for merging. If your facility is in a hospital or university setting, please contact Bertec support to discuss your specific environment and conditions, so that we may provide the best solution for syncing databases.

To Configure Two-way Merge Accessibility:

1. From the Database Configuration page, click on the Database Sync option (located on the bottom left of the screen). Refer to Figure 44 on page 33.
2. On the Database Sync page (shown in Figure 46), check the Enable Database Sync box.
3. Type in the name of the sync group. If this is the first computer to be setup for two-way merging, create a sync group name for use with other computers. The computers will ideally be on the same network and have Network Discovery turned on.

   If Network Discovery is Turned Off/Syncing with Computers Outside of the Local Network: Enter the IP address(es) of the computer(s) desired to connect with the system as well (i.e. 24.123.134.172). A quick Google search of "What is my IP Address" will reveal a computer's IP address.
4. (Optional): Adjust how often in minutes sync happens and how often in days a full merge happens.
5. Click Ok to update the system.
6. (Optional): Contact the other computer owner(s) to update their IP address list to include the new system.
7. Two-way merging is complete. Look for a WiFi signal to appear on the bottom left of the screen once data is entered. If it does not appear (and patients do not merge onto the new device), try entering the IP address(es) of the systems to merge with. Contact Bertec® support if problems persist.

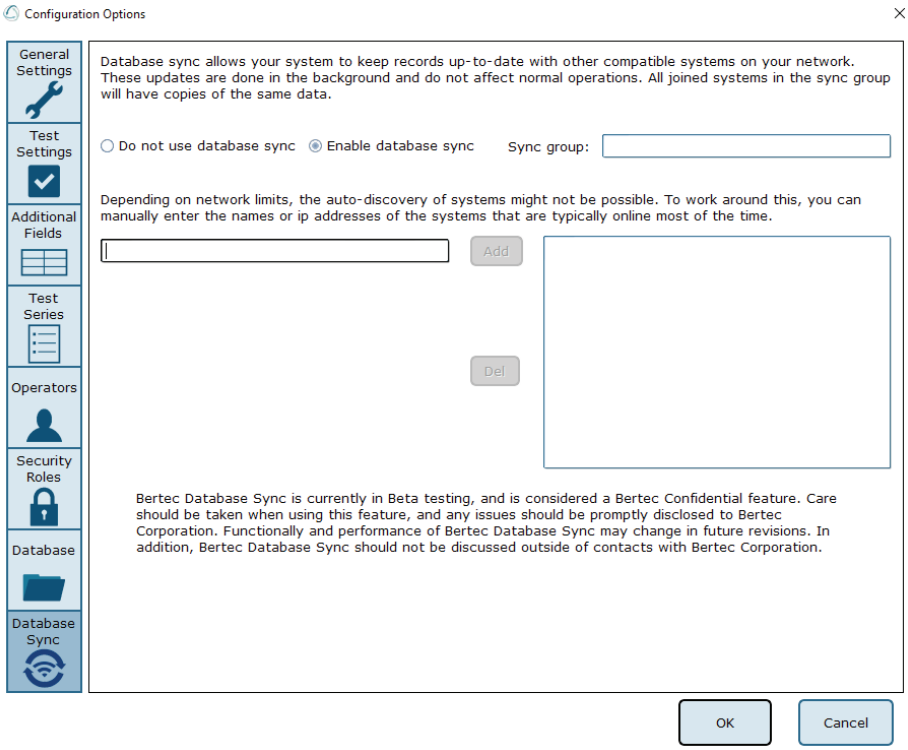


Figure 46: Two-way Merge Options.

Turning the System Off

It is highly recommended that the system's computer, in addition to the Prime IVR's dome projector, are turned off each night to promote both software and hardware longevity.

To Turn off the Computer:

1. If signed into a Bertec® operator account, click the Logout button (Figure 47). It is located on the upper right corner of the screen. If a popup window appears, click Yes to confirm the logout.
2. From the Bertec® login screen, click on the [X] button in the upper right corner of the screen (Figure 48).
3. Select the power button (or power options button, depending on the version of Windows), and click on the option to Shut Down.
4. Prime IVR Systems: Refer to page 10 to turn off the dome's projector.

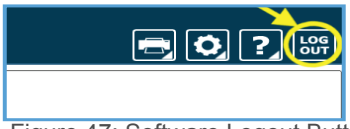


Figure 47: Software Logout Button.


Figure 48: Exit Button.

Static Plate Assessments

Each assessment is described in-depth and contains 1) a figure of the assessment's icon, as it appears in the Assessment tab on the Balance Advantage® software, 2) an image of the clinician's screen before testing, and 3) a sample report of output information.

The following three tests are the foundation for a static balance evaluation. They are designed to assess a patient's capacity to process sensory signals and make proper adjustments to maintain balance. They can be run on all plates and packages.

- Modified Clinical Test of Sensory Interaction on Balance (mCTSIB)
- Limits of Stability (LOS)
- Rhythmic Weight Shift (RWS)

In addition to the three foundational assessments, a variety of other static plate assessments are available to consider a patient's balance performance. The following tests are designed to represent everyday activities.

- Unilateral Stance (US)
- Weight Bearing Squat (WBS)
- Sit to Stand (STS)
- Walk Across (WA)
- Tandem Walk (TW)
- Step Quick Turn (SQT)
- Step Up Over (SUO)
- Forward Lunge (FL)

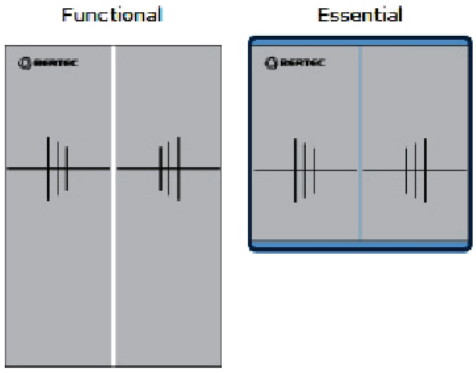


Figure 49: Recommended Plates/Packages.

Modified Clinical Test of Sensory Interaction on Balance (mCTSIB)

IMPORTANT! - Please make sure you are in a position to help the patient if they begin to lose their balance, as the clinician is responsible for the safety of himself or herself, the patient, others in the surrounding area, and the equipment.

Compatible Packages:

Bertec® Balance Advantage® Functional and Essential packages; Prime IVR™.

Goal:

The goal is to evaluate postural stability under different visual, vestibular, and somatosensory sensory conditions.

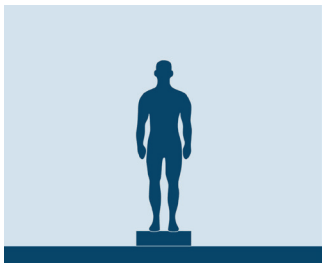


Figure 50: mCTSIB Icon.

Protocol:

The patient will be asked to stand quietly in four conditions including: Eyes Open on Firm Surface, Eyes Open on Foam Surface, Eyes Closed on Firm Surface, and Eyes Closed on Foam Surface. The patient's postural sway velocity is quantified and compared to normal individuals' scores. It is recommended a total of three trials are completed for each test condition.

Prime IVR: Visual Scene

The visual scene used for mCTSIB is the Oval scene, which provides a consistent background during testing. Other consistent background options are available to use including the Rock Wall and the Neutral Scene.

Patient Instructions:

"Please stand still while you look forward and keep your arms at your sides. Keep your feet shoulder width apart, lined up with the plate's grooves. I will give you further instructions as needed."

Protocol Performance:

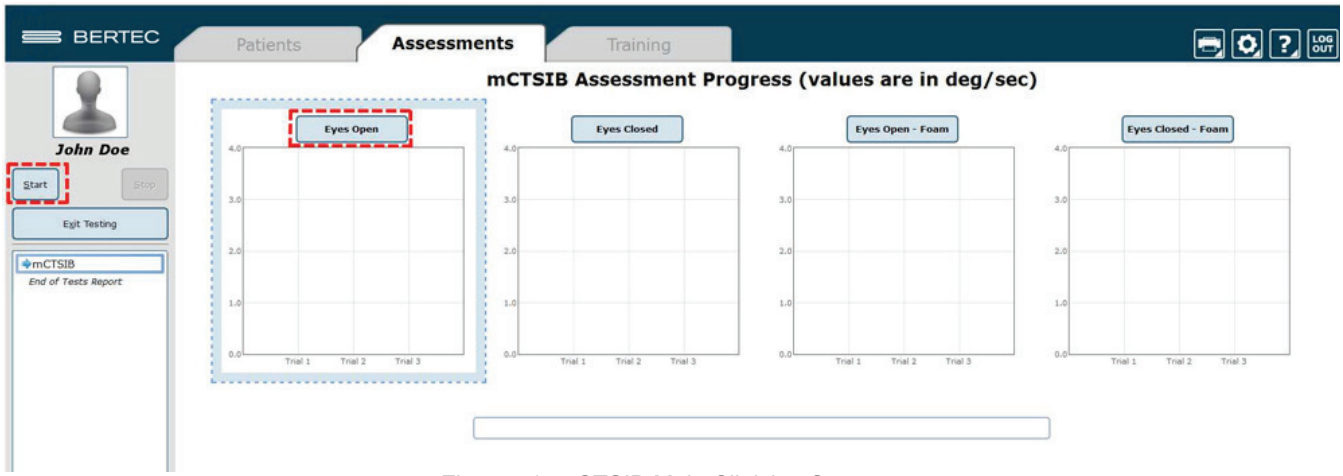


Figure 51: mCTSIB Main Clinician Screen.

- Eyes Open on Firm Surface
  - Click on the Eyes Open button on the clinician screen.
  - Instructions for proper foot alignment are given on the clinician screen, as the patient's feet need to be placed apart at specific lines on the balance plate.
  - When the patient is in the proper position, the test period is activated by the clinician clicking Start or the third button on the wireless remote (shown in Figure 47).
  - Patient is asked to stand steady for 10 seconds.
  - Recommended: repeat for a total of 3 trials before moving to next condition.

- Eyes Closed on Firm Surface
  - Click on the Eyes Closed button on the clinician screen.
  - When the patient is in the proper position (see Eyes Open on Firm Surface), the test period is activated by clicking Start or the third button on the wireless remote.
  - Patient is asked to stand steady with eyes closed for 10 seconds.
  - Recommended: repeat for a total of 3 trials before moving to next condition.



Figure 52: Remote Button.

- Eyes Open on Foam Surface
  - The foam pad is placed on the balance plate (ensure the lines on the plate and foam match one another).
  - Click on the Eyes Open – Foam button on the clinician screen.
  - Instructions for proper foot alignment are given on the clinician screen, as the patient's feet need to be placed apart on specific lines on the foam pad.
  - When the patient is in the proper position, the test period is activated by the clinician clicking Start or the third button on the wireless remote.
  - Patient is asked to stand steady on foam for 10 seconds.
  - Recommended: repeat for a total of 3 trials before moving to next condition.

- Eyes Closed on Firm Surface
  - Click on the Eyes Closed – Foam button on the clinician screen.
  - When the patient is in the proper position (see Eyes Closed on Firm Surface), the test period is activated by the clinician clicking Start or the third button on the wireless remote.
  - Patient is asked to stand steady with eyes closed on foam for 10 seconds.
  - Recommended: repeat for a total of 3 trials before moving to next condition.

Caution/General Assessment Information:

- Trials may be interrupted at any time by selecting the Stop button on the clinician screen or the third button on the wireless remote (see Figure 52 above). When a trial is stopped, the software will prompt whether the operator wants to keep or discard the data. Data should be discarded if the patient does not follow patient instructions (talking, keeping eyes open, sneezing, etc...). Data should be kept if the test is completed according to the patient instructions.
  - When the trial is stopped, the clinician will be prompted to choose Fall or Discard.
  - If FALL is selected:
    - The trial is then saved as a FALL with the time of the event captured.
    - If a fall has taken place, the maximum value for sway velocity will be included in the numerical data allowing for the sway velocity to be averaged (6 deg/sec).
    - The patient will then need to be repositioned to insure proper foot placement for additional trials.
  - If DISCARD is selected:
    - The trial will not be saved.

- The patient will then need to be repositioned to insure proper foot placement for additional trials.

> Assessment notes may be created at any time in the Notes text box (lower left corner).

> If trial is marked STEP or PULL:

- Our software monitors the presence of the patient staying consistently on the plate. Outside of a FALL marked by the clinician, when the program detects a reduction in of weight, it will be recognized as two possible scenarios: a PULL or a STEP.
- PULL – The software recognized that a vertical force was reduced. The patient was able to transfer their body weight upwards, most likely by “pulling” or resting on the harness.
- STEP – The software recognized that weight was both shifted and reduced off the plate. The patient most likely “stepped” off the plate during testing.
- In both cases, the clinician has the option to keep the data or redo the test`

Test Completion Protocol:

> At the completion of the task(s), the test may be closed or the next test may be initiated.

> It is recommended that final comments are added at this time.

> Click on a test in the list (i.e. Eyes Closed on Firm Surface) to perform it.

Test Analysis:

> Generated Reports will Include:

> Center of Gravity (COG): Indicates the sway velocity in degrees per second.

> Mean Center of Gravity Sway Velocity for each condition.

> Composite Sway Score: Average over the trials.

> Center of Gravity Alignment: Indicates the patient’s Center of Gravity position in relation to the center of the base of support at the start of each of the trials.

> Red/Green Bars: Results falling outside of the normal values will be represented by solid red bars, whereas results falling inside of the normal values will be represented by solid green bars.

Reports:

> Summary Reports

> Summary of the patient’s performance during one trial or trial series.

> Center of Gravity sway tracings are shown with the average COG sway velocity and time duration of each trial.

> The Mean Center of Gravity Sway Velocity is given with a comparison to the normative data.

> The Center of Gravity Alignment Scores are placed on a graph.

> Test comments, if entered, are included at the end of the report.

> Progress Reports

> Summary of the patient’s performance for a series of trials conducted at different times.

> To view progress reports, click the information icon *i* in the patient’s timeline.

> A drop-down menu will appear and list the available progress reports.

> The progress a patient makes on a report is given with progress reports that chart their performance scores over time.

> Printing/Saving

> Select the desired protocol report from the patient’s timeline.

> While viewing the report, select the printer icon  to either save a PDF file or print to a regular printer.

Practical Considerations:

Abnormal Sway or Fall	Implications
None	Normal individuals have minimal sway on the firm surface either with eyes open or closed. Also, normal individuals have increased sway on the foam surface, but they do not usually lose balance or fall.
C1 and C2 (plus C3 and C4)	Abnormal sway on the firm surface indicates that the patient has difficulty incorporating somatosensory information in balance control. Patients with abnormal responses on the firm surface almost always have abnormal responses on the foam surface. In such cases, aphysiological causes should be ruled out.
C3 only	Abnormal sway or fall with eyes open on the foam surface indicates that the patient has difficulty incorporating visual information in balance control.
C4 only	Abnormal sway or fall with eyes closed on the foam surface indicates that the patient has difficulty incorporating vestibular information in balance control.
C3 and C4	Abnormal sway or fall with both eyes open and closed on the foam surface indicates that the patient has difficulty incorporating visual and vestibular information in balance control.

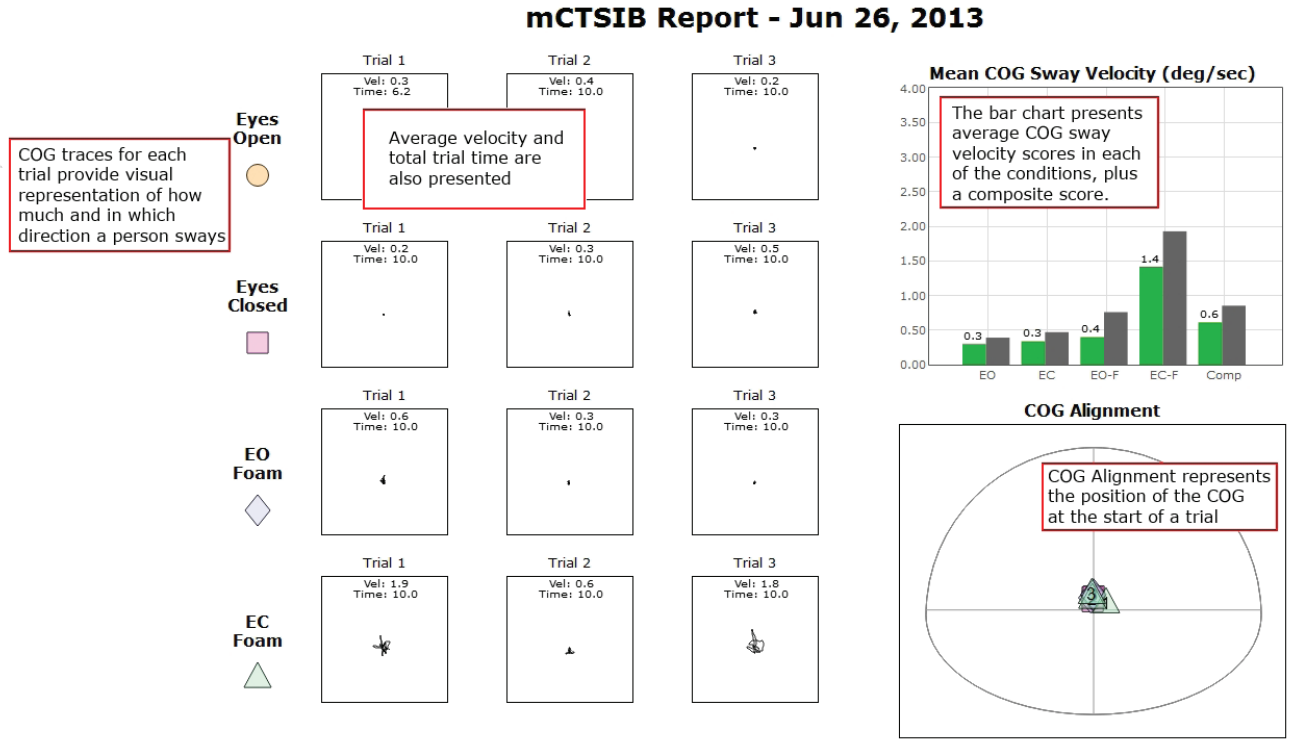


Figure 53: mCTSIB Report Information.

Limits of Stability (LOS)

IMPORTANT! - Please make sure you are in a position to help the patient if they begin to lose their balance, as the clinician is responsible for the safety of himself or herself, the patient, others in the surrounding area, and the equipment.

Compatible Packages:

Bertec® Balance Advantage® Functional and Essential packages; Prime IVR™.

Goal:

The goal is to determine the maximum distance that the patient is able to displace his/her center of pressure from the primary vertical position in different directions without losing balance.

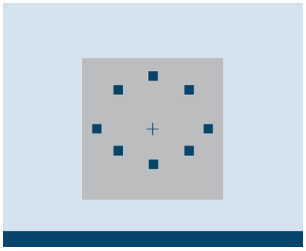


Figure 54: LOS Icon.

Protocol:

This assessment requires the patient to lean at the ankles (not bend at the waist or knees) forward, backward, and side to side. A healthy individual can lean 6.25 – 8 degrees to the front, 4.5 degrees to the back, and 8 degrees to either side.

Patient Instructions:

“Please stand still while you look forward and with arms at your sides. When I press Go, you will see “Hold Steady” appear on the screen. Continue to stand still until you see the command to “Begin!” At the “Begin!” command, move as quickly to the targets as you can, keeping the cursor as close to the target as possible until the test is complete. Your feet should remain firmly planted on the plate and your hands should be kept at your sides throughout the test. I will give you further instructions as needed.”

Protocol Performance:

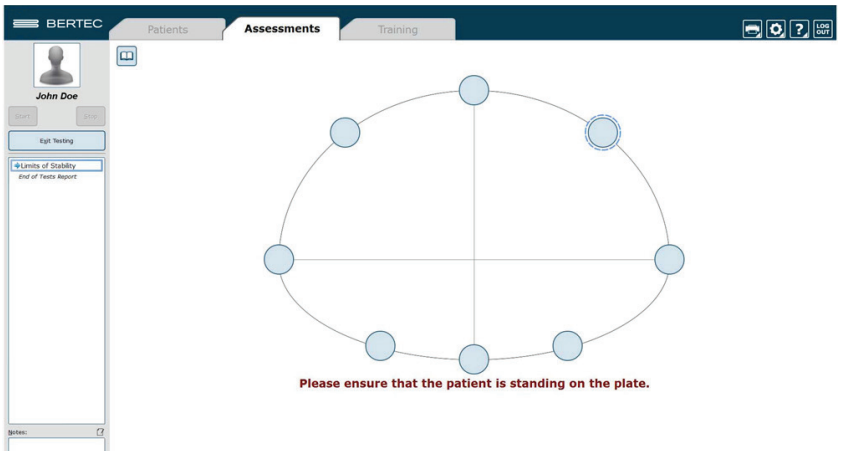


Figure 55: LOS Main Clinician Screen.

- Test Sequences
  - A total of 8 different directions are tested during the assessment.
    - Trial 1: Forward
    - Trial 2: Forward – Right
    - Trial 3: Right
    - Trial 4: Backward – Right
    - Trial 5: Backward
    - Trial 6: Backward – Left
    - Trial 7: Left
    - Trial 8: Forward – Left

- Test Performance
  - For each test direction, the patient is instructed where to place their feet and how to perform the assessment.
  - The patient should practice this test several times before data is collected. This is to ensure that the patient clearly understands how to perform the test.
  - The clinician should repeat for each direction until all eight trials are complete.

General Assessment Information:

- Trials may be interrupted at any time by selecting the Stop button on the clinician screen or the third button on the wireless remote (see Figure 52 on page 40). When a trial is stopped, the software will prompt whether the operator wants to keep or discard the data. Data should be discarded if the patient does not follow patient instructions (talking, keeping eyes open, sneezing, etc...). Data should be kept if the test is completed according to the patient instructions.
- Assessment notes may be created at any time in the Notes text box (lower left corner).
  - If trial is marked STEP or PULL:
    - Our software monitors the presence of the patient staying consistently on the plate. Outside of a FALL marked by the clinician, when the program detects a reduction in of weight, it will be recognized as two possible scenarios: a PULL or a STEP.
    - PULL – The software recognized that a vertical force was reduced. The patient was able to transfer their body weight upwards, most likely by “pulling” or resting on the harness.
    - STEP – The software recognized that weight was both shifted and reduced off the plate. The patient most likely “stepped” off the plate during testing.
    - In both cases, the clinician has the option to keep the data or redo the test

Test Completion Protocol:

- At the completion of the task(s), the test may be closed or the next test may be initiated.
- It is recommended that final comments are added at this time.
- Click on a test in the list (i.e. Forward) to perform it.

Test Analysis:

- Generated Reports Will Include:
  - Directional Control (DCL): A measurement of how much of the patient’s movement was in the target direction.
  - End Point Excursion (EPE): A measurement of how far the patient leans towards the target on his or her first attempt.
  - Maximum Excursion (MXE): A measurement of the maximum amount the patient leaned during the trial.
  - Reaction Time (RT): A measurement, in seconds, of the time taken by the patient to respond to the command to move

towards the target.
- Mean COG Velocity (MV): A measurement, in degrees/second, of the speed at which the patient moved towards the target.
- Red/Green Bars: Results falling outside of the normal values will be represented by solid red bars, whereas results falling inside of the normal values will be represented by solid green bars.

Reports:

- Summary Reports
  - Summary of the patient's performance during one trial or trial series.
    - Center of Gravity sway tracings are shown for each of the directions.
    - Results from each trial are displayed in a table to the right of the COG sway tracings.
    - Calculated scores for each of the primary directions (Forward, Backward, Left, Right), as well as the Composite score, are given in bar graphs for each of the measures. The Composite score is the average of the trials, whereas the Calculated scores factor and weigh data from each trial.
    - Test comments, if entered, are included at the end of the report.
- Progress Reports
  - Summary of the patient's performance for a series of trials conducted at different times.
    - To view progress reports, click the information icon *i* in the patient's timeline.
    - A drop-down menu will appear and list the available progress reports.
    - The progress a patient makes on a report is given with progress reports that chart their performance scores over time.
- Printing/Saving
  - Select the desired protocol report from the patient's timeline.
  - While viewing the report, select the printer icon  to either save a PDF file or print to a regular printer.

Practical Considerations:

The LOS test provides information about the volitional motor control in dynamic conditions. Abnormalities in the LOS test indicate an increased risk of falling.

Abnormalities in the LOS test can be caused by:

Abnormality	Implications
Reduced EPE or MXE or DCL	Limited range of motion, weakness, and other musculoskeletal impairments. Consider biomechanical limitations as a cause of restricted stability limits.
Reduced MVL	Neuromuscular impairments caused by stroke, Parkinson's disease, etc.
Increased RT	Cognitive impairments, anxiety, and fear of falling often due to aging.
General	Patients with acute symptoms of dizziness may be unwilling or fearful of approaching limits of stability. Also consider aphysiological causes, such as not providing the best effort (or exaggeration).

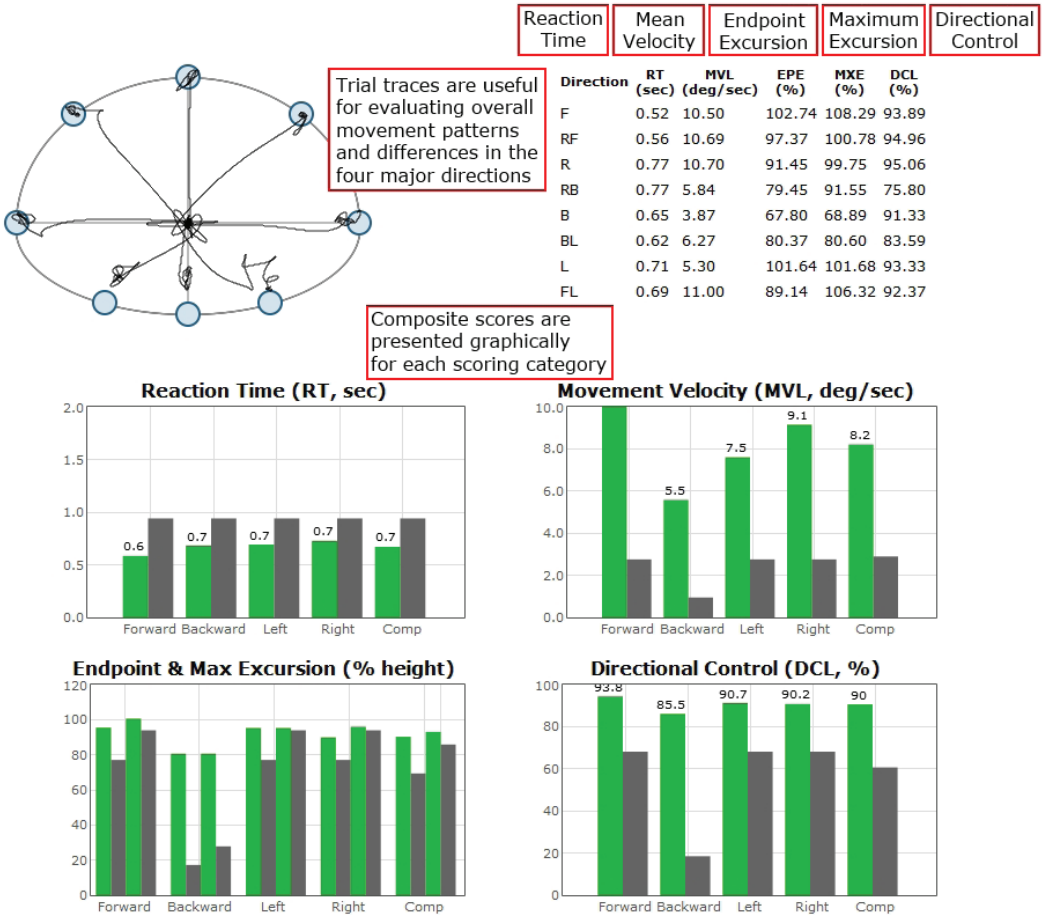


Figure 56: LOS Report Information.

Rhythmic Weight Shift (RWS)

IMPORTANT! - Please make sure you are in a position to help the patient if they begin to lose their balance, as the clinician is responsible for the safety of himself or herself, the patient, others in the surrounding area, and the equipment.

Compatible Packages:

Bertec® Balance Advantage® Functional and Essential packages; Prime IVR™.

Goal:

The goal is to determine the ability of the patient to rhythmically move their center of pressure in the anterior-posterior and lateral directions at different paces.

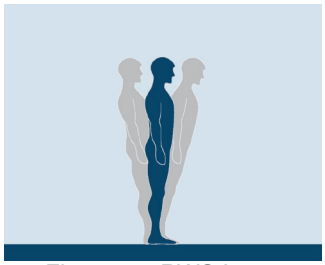


Figure 57: RWS Icon.

Protocol:

The patient will be asked to voluntarily move at specific pacing (1, 2 and 3 sec. transitions) in a specific direction (either anterior/posterior or lateral). The center of gravity sway velocity, measured in degrees per second, is quantified and compared to normal individuals' scores based on pace and direction.

Patient Instructions:

"While looking forward, transfer your weight either from side to side or front to back; doing so will move the cursor side to side or front to back on the screen. Attempt to keep pace with and stay within the boundaries of the moving target. I will give you further instructions as needed."

Protocol Performance:



Figure 58: RWS Main Clinician Screen.

- Test Sequences
  - Anterior/Posterior: Slow (3 second pacing between boundaries).
  - Anterior/Posterior: Medium (2 second pacing between boundaries).
  - Anterior/Posterior: Fast (1 second pacing between boundaries).
  - Lateral: Slow (3 second pacing between boundaries).
  - Lateral: Medium (2 second pacing between boundaries).
  - Lateral: Fast (1 second pacing between boundaries).

- Test Performance
  - The patient will be asked to stand on the balance plate.
  - Instructions for proper foot alignment are given by the clinician screen.
  - The patient is then requested to transfer their weight between the boundary lines in sync with the ball.
  - Give the patient an adequate amount of time to practice this activity.
  - It is important that the patient has been able to have time to learn how to perform this activity. The consequence of not giving adequate practice time is the measurement of the ability to learn the activity, not degree of impairment.
  - Trials will last different amounts of time (in total). Slow pacing lasts 18 seconds, Medium pacing lasts 12 seconds, and Fast pacing lasts 6 seconds.

General Assessment Information:

- Trials may be interrupted at any time by selecting the Stop button on the clinician screen or the third button on the wireless remote (see Figure 52 on page 40). When a trial is stopped, the software will prompt whether the operator wants to keep or discard the data. Data should be discarded if the patient does not follow patient instructions (talking, keeping eyes open, sneezing, etc...). Data should be kept if the test is completed according to the patient instructions.
- Assessment notes may be created at any time in the Notes text box (lower left corner).
  - If trial is marked STEP or PULL:
    - Our software monitors the presence of the patient staying consistently on the plate. Outside of a FALL marked by the clinician, when the program detects a reduction in of weight, it will be recognized as two possible scenarios: a PULL or a STEP.
    - PULL – The software recognized that a vertical force was reduced. The patient was able to transfer their body weight upwards, most likely by “pulling” or resting on the harness.
    - STEP – The software recognized that weight was both shifted and reduced off the plate. The patient most likely “stepped” off the plate during testing.
    - In both cases, the clinician has the option to keep the data or redo the test

Test Completion Protocol:

- At the completion of the task(s), the test may be closed or the next test may be initiated.
- It is recommended that final comments are added at this time.
- Click on a test in the list (i.e. Lateral: Slow) to perform it.

Test Analysis:

- Generated Reports will Include:
  - Directional Control graph provides an indication of the smoothness and the coordination of the COG movement in each of the pacing and direction combinations.
  - The bar graph at the bottom of the page will provide the on-axis velocity for each of the trial combinations categorized

by direction.
- The direction scores are presented based on the patient's pacing.
- A composite score is given per direction which is the mean average over the trials.
- Red/Green Bars: Results falling outside of the normal values will be represented by solid red bars, whereas results falling inside of the normal values will be represented by solid green bars.

Reports:

- Summary Reports
  - Summary of the patient's performance for a series of trials conducted at different times.
    - Directional Control graph provides an indication of the smoothness and the coordination of the COG movement in each of the pacing and direction combinations.
    - The bar graph at the bottom of the page will provide the on-axis velocity for each of the trial combinations categorized by direction.
    - The direction scores are presented based on the pacing.
    - A composite score is given per direction which is the mean average over the trials.
- Progress Reports
  - Summary of the patient's performance for a series of trials conducted at different times.
    - To view progress reports, click the information icon *i* in the patient's timeline.
    - A drop-down menu will appear and list the available progress reports.
    - The progress a patient makes on a report is given with progress reports that chart their performance scores over time.
- Printing/Saving
  - Select the desired protocol report from the patient's timeline.
  - While viewing the report, select the printer icon  to either save a PDF file or print to a regular printer.

Practical Considerations:

Abnormality	Implications
None	Normal individuals are able to maintain an appropriate pace during rhythmic weight shifts with adequate velocity and minimal off-axis displacements.
Reduced velocity or directional control	Patients with a variety of motor control impairments may exhibit reduced velocity, poor directional control, or both during rhythmic weight shifts. These patients usually have difficulty in activities of daily living that require fast-paced movements (e.g., crossing the street), weight shifts (e.g., stepping in out of escalators), or rapid direction changes (e.g., avoiding collision with an object or another person).

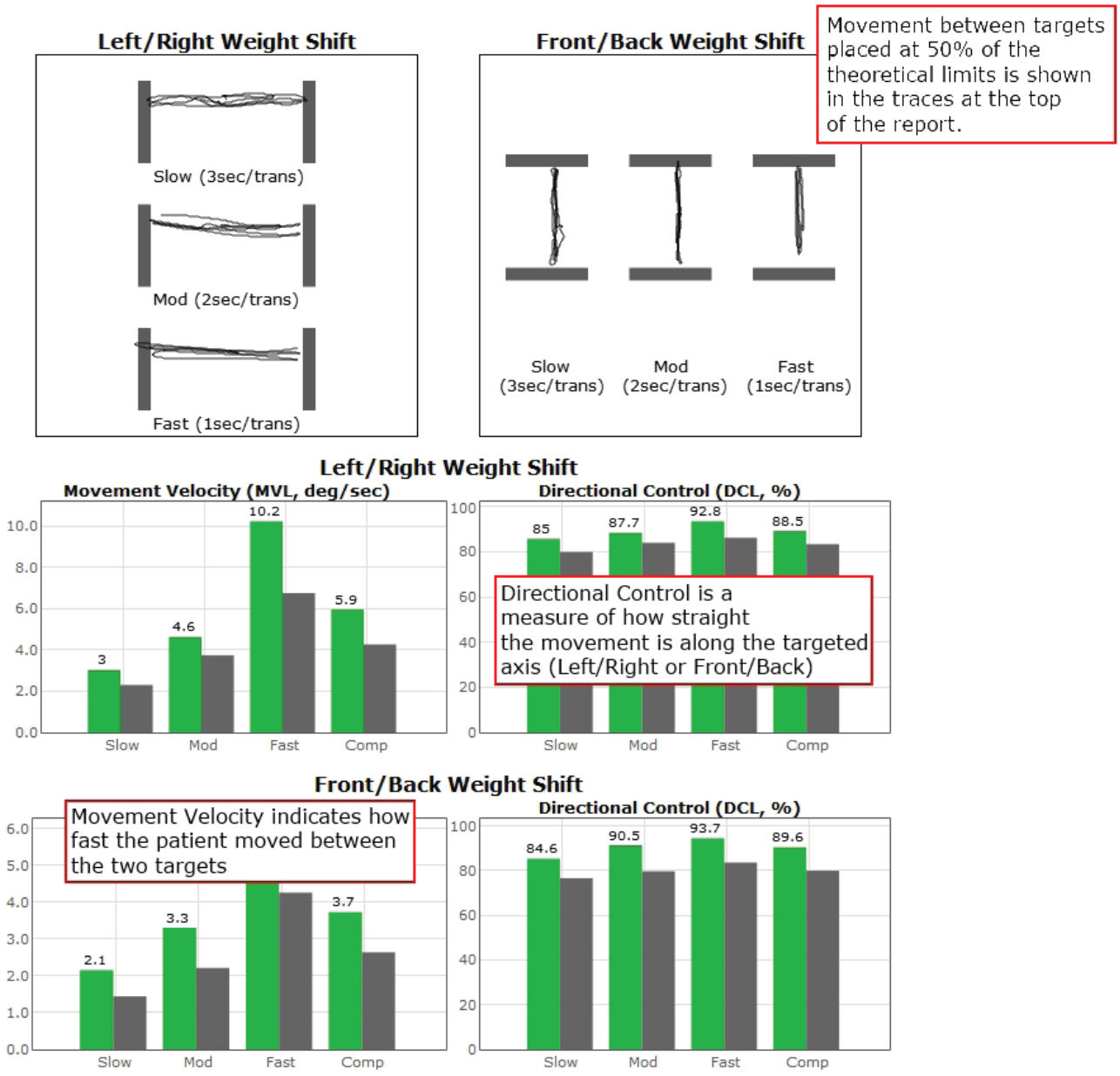


Figure 59: RWS Report Information.

Unilateral Stance (US)

IMPORTANT! - Please make sure you are in a position to help the patient if they begin to lose their balance, as the clinician is responsible for the safety of himself or herself, the patient, others in the surrounding area, and the equipment.

Compatible Packages:

Bertec® Balance Advantage® Functional and Essential packages; Prime IVR™.

Goal:

The goal is to assess the patient's postural control while standing on one leg on a firm surface with eyes open and closed.



Figure 60: US Icon.

Protocol:

Maintain a steady one-legged stance in the following conditions:

- Eyes open, firm surface, Left foot
- Eyes closed firm surface, Left foot
- Eyes open firm surface, Right foot
- Eyes closed firm surface Right foot

It is recommended that a total of three trials are collected for each of these test conditions.

Patient Instructions:

"Stand steady on right (left) foot for 10 seconds with your eyes open (closed) on the balance plate. When you are instructed, lift your right (or left) foot. I will give you further instructions as needed."

Protocol Performance:

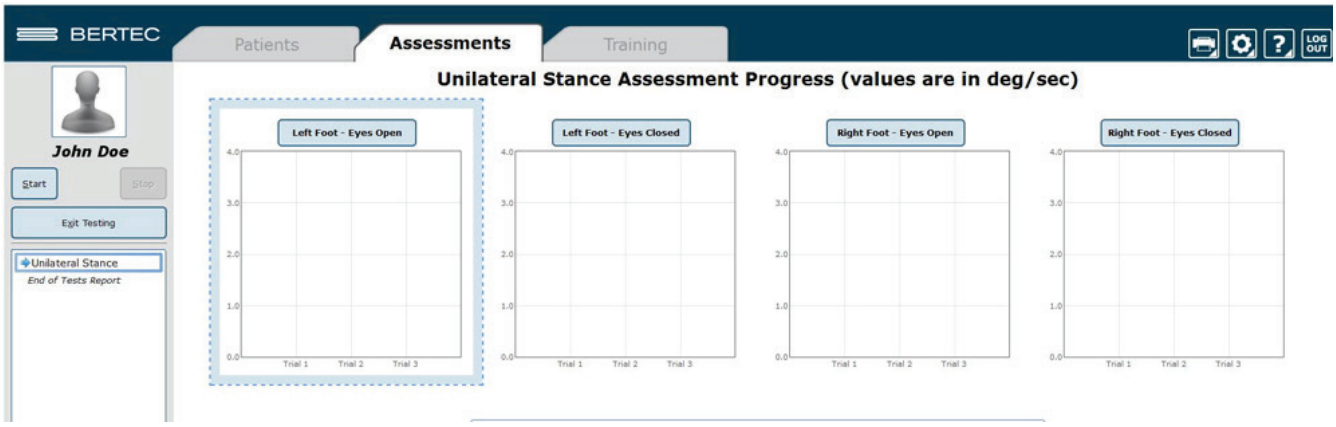


Figure 61: US Main Clinician Screen.

- Eyes Open on Left Foot
  - Click on the test condition.
  - Instructions for proper foot alignment are given on the patient screen.
  - When the patient is in the proper position, the test period will be activated.
  - Patient is requested to stand steady with eyes open on their left foot for 10 seconds.

- Eyes Closed on Left Foot
  - Click on the test condition.
  - Instructions for proper foot alignment are given on the patient screen.
  - When the patient is in the proper position, the test period will be activated.
  - Patient is requested to stand steady with eyes closed on their left foot for 10 seconds.

- Eyes Open on Right Foot
  - Click on the test condition.
  - Instructions for proper foot alignment are given on the patient screen.
  - When the patient is in the proper position, the test period will be activated.
  - Patient is requested to stand steady with eyes closed on their right foot for 10 seconds.

- Eyes Closed on Right Foot
  - Click on the test condition.
  - Instructions for proper foot alignment are given on the patient screen.
  - When the patient is in the proper position, the test period will be activated.
  - Patient is requested to stand steady with eyes closed on their right foot for 10 seconds.

Caution/General Assessment Information:

- The patient being assessed is required to remain on one foot during the 10 second trial.
  - Assist the patient if a fall begins to occur.
- If there is a toe touch of less than 1 second, the trial may be accepted.
- If there is a toe touch of greater than 1 second, the trial should be stopped and marked as a FALL or DISCARDED. When the trial is stopped, the clinician will be prompted to choose Fall or Discard.
- If FALL is selected:
  - The trial is then saved as a FALL with the time of the touch captured.
  - If a fall has taken place, the maximum value for sway velocity will be included in the numerical data allowing for the sway velocity to be averaged.
  - The patient will then need to be repositioned to insure proper foot placement for additional trials.
- If DISCARD is selected:
  - The trial will not be saved.
  - The patient will then need to be repositioned to insure proper foot placement for additional trials.
- Assessment notes may be created at any time in the Notes text box (lower left corner).
- If trial is marked STEP or PULL:
  - Our software monitors the presence of the patient staying consistently on the plate. Outside of a FALL marked by the clinician, when the program detects a reduction in of weight, it will be recognized as two possible scenarios: a PULL or a STEP.
  - PULL – The software recognized that a vertical force was reduced. The patient was able to transfer their body weight upwards, most likely by “pulling” or resting on the harness.
  - STEP – The software recognized that weight was both shifted and reduced off the plate. The patient most likely “stepped” off the plate during testing.
  - In both cases, the clinician has the option to keep the data or redo the test

Test Completion Protocol:

- At the completion of the task(s), the test may be closed or the next test may be initiated.
- It is recommended that final comments are added at this time.
- Click on a test in the list (i.e. Eyes Closed on Left Foot) to perform it.

Test Analysis:

- Generated Reports Will Include:
  - Center of Gravity tracings with the trial's average sway velocity and time length.
  - A mean COG sway velocity for the Left and Right foot with eyes open with the percent difference.
  - A mean COG sway velocity for the Left and Right foot with eyes closed with the percent difference.
  - Red/Green Bars: Results falling outside of the normal values will be represented by solid red bars, whereas results falling inside of the normal values will be represented by solid green bars.

Reports:

- Summary Reports
  - Summary of the patient's performance during one trial or trial series.
    - Includes traces for each of the trials, along with bar graph for each of the four assessment conditions.
    - The mean Center of Gravity sway velocity for Eyes Open is presented in comparison to normal ranges and as a bilateral comparison of left foot to right foot.
    - The mean Center of Gravity sway velocity for Eyes Closed is presented in comparison to normal ranges and as a bilateral comparison of left foot to right foot.
    - Scores are given in a color-coded format to indicate scores within or outside of the normal range.
    - Test comments (if entered) are available for inclusion in the report.
- Progress Reports
  - Summary of the patient's performance for a series of trials conducted at different times.
    - To view progress reports, click the information icon *i* in the patient's timeline.
    - A drop-down menu will appear and list the available progress reports.
    - The progress a patient makes on a report is given with progress reports that chart their performance scores over time.
- Printing/Saving
  - Select the desired protocol report from the patient's timeline.
  - While viewing the report, select the printer icon  to either save a PDF file or print to a regular printer.

Practical Considerations:

Abnormality	Implications
None	Normal individuals have more sway and difficulty when standing on one leg. The sway and postural instability increases with eyes closed.
Abnormal sway velocity or loss of balance	Abnormal sway velocity or falling while standing on one leg is a sensitive indicator of a motor impairment, but it does not provide information about the nature of the impairment. Possible causes include musculoskeletal (e.g., lower leg weakness), neuromuscular (e.g., Parkinson's disease), or sensory impairments (e.g., somatosensory impairment). These patients have difficulty in activities that require single leg standing, such as dressing.

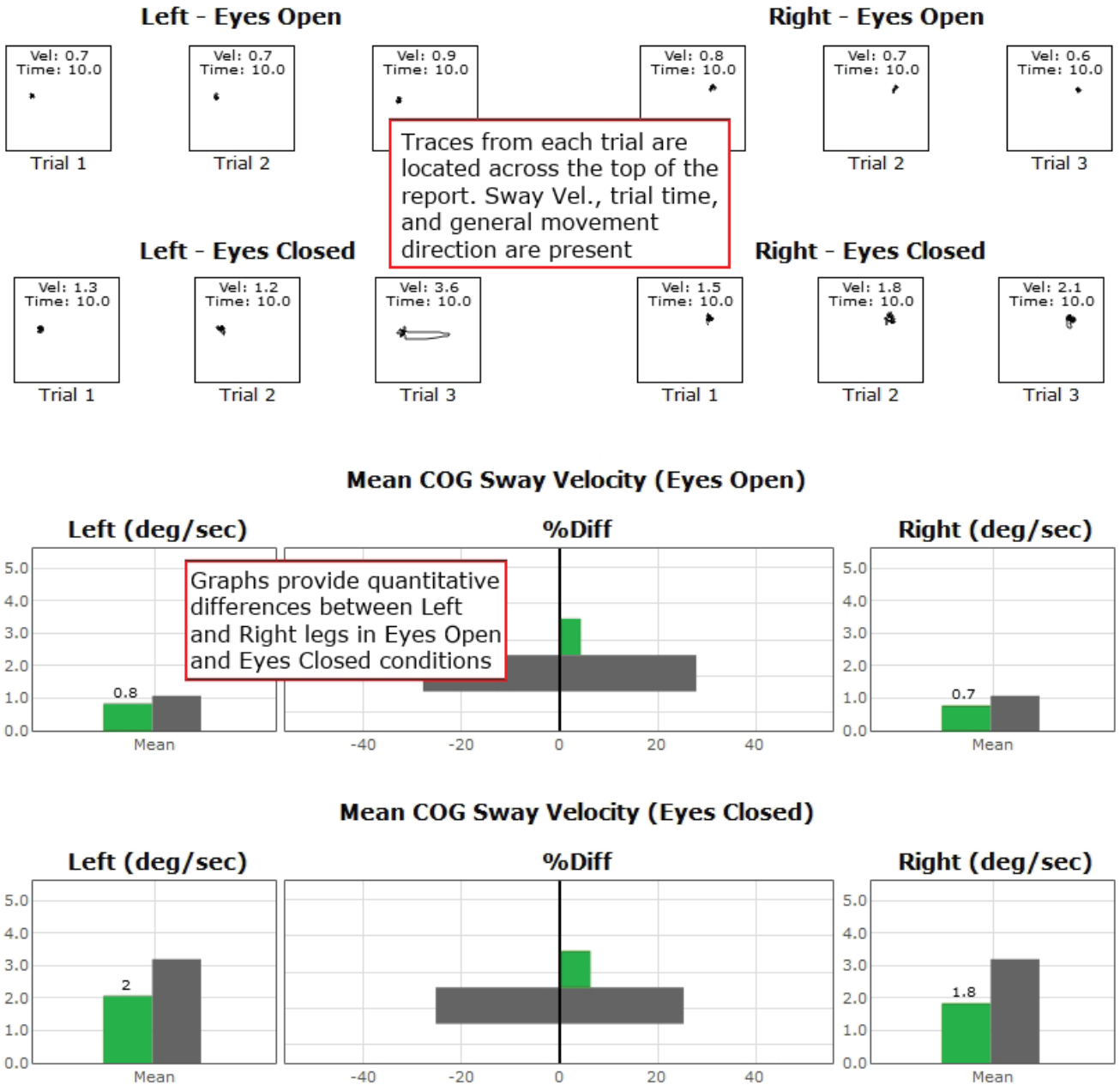


Figure 62: US Report Information.

Weight Bearing Squat (WBS)

IMPORTANT! - Please make sure you are in a position to help the patient if they begin to lose their balance, as the clinician is responsible for the safety of himself or herself, the patient, others in the surrounding area, and the equipment.

Compatible Packages:

Bertec® Balance Advantage® Functional and Essential packages; Prime IVR™.

Goal:

The goal is to assess the ability of the patient to maintain symmetrical weight bearing in neutral, 30, 60 and 90 degrees of knee flexion.

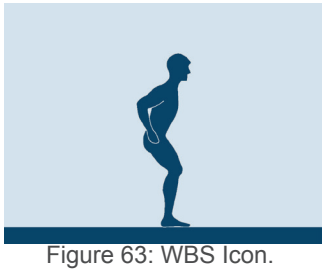


Figure 63: WBS Icon.

Protocol:

The patient will be asked to stand in the neutral, 30, 60, and 90 degrees of knee flexion positions with weight evenly distributed over each foot. The data will be gathered immediately after the start button is pressed. Data collection only lasts for a fraction of a second.

Patient Instructions:

“While looking forward, stand steady with your weight evenly distributed over each foot. You will be asked to stand in neutral, 30, 60, and 90 degrees stances (angles relative to your knee’s bend). I will give you further instructions as needed.”

Protocol Performance:

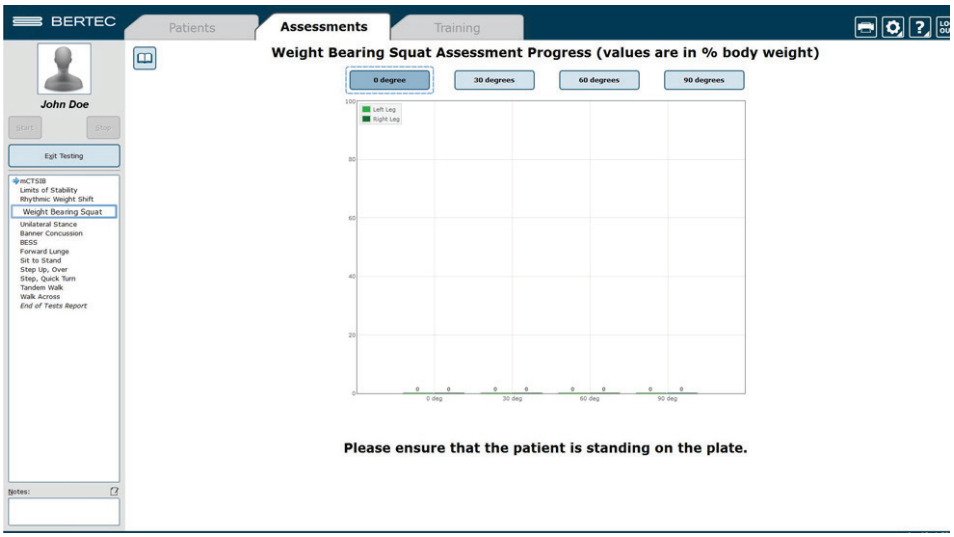


Figure 64: WBS Main Clinician Screen.

- There will be Four Trials in the Test Sequence
  - Standing with knees fully extended.
  - Standing with knees in 30 degrees of flexion.
  - Standing with knees in 60 degrees of flexion.
  - Standing with knees in 90 degrees of flexion.

- Test Performance
  - Select the condition to perform.
    - Ex. “30 Degrees”
  - The patient will be asked to stand on the balance plate.
  - Proper patient positioning and instructions for proper foot alignment are given on the patient screen.
  - The patient is then requested to look forward, stand steady, and distribute their weight evenly over each foot.
  - After each data collection, the patient will be asked to change their degree of knee flexion.

General Assessment Information:

- Trials may be interrupted at any time by selecting the Stop button on the clinician screen or the third button on the wireless remote (see Figure 52 on page 40). When a trial is stopped, the software will prompt whether the operator wants to keep or discard the data. Data should be discarded if the patient does not follow patient instructions (talking, keeping eyes open, sneezing, etc...). Data should be kept if the test is completed according to the patient instructions.
- Assessment notes may be created at any time in the Notes text box (lower left corner).

Test Completion Protocol:

- At the completion of the task(s), the test may be closed or the next test may be initiated.
- It is recommended that final comments are added at this time.
- Click on a test in the list (i.e. 30 Degrees of Flexion) to perform it.

Test Analysis:

- Generated Reports Will Include:
  - Percentage of weight bearing for left and right leg per squat position.
  - Red/Green Bars: Results falling outside of the normal values will be represented by solid red bars, whereas results falling inside of the normal values will be represented by solid green bars.

Reports:

- Summary Reports
  - Summary of the patient’s performance during one trial or trial series.
    - The body weight percentages are shown in a bar graph format.
    - Above each bar the numeric data is given for each of the positions.
- Progress Reports
  - Summary of the patient’s performance for a series of trials is conducted at different times.
    - To view progress reports, click the information icon *i* in the patient’s timeline.
    - A drop-down menu will appear and list the available progress reports.
    - The progress a patient makes on a report is given with progress reports that chart their performance scores over time.
- Printing/Saving

> Select the desired protocol report from the patient's timeline.
> While viewing the report, select the printer icon to either save a PDF file or print to a regular printer.

Practical Considerations:

Abnormality	Implications
None	Normal individuals distribute their weight approximately equally between the right and left feet for different squatting positions.
Asymmetrical weight bearing	Patients with musculoskeletal or somatosensory impairments can exhibit asymmetrical weight bearing during squatting. However, the asymmetries may not become apparent for mild impairments—unless the lower extremities are subjected to more challenging positions during squatting.

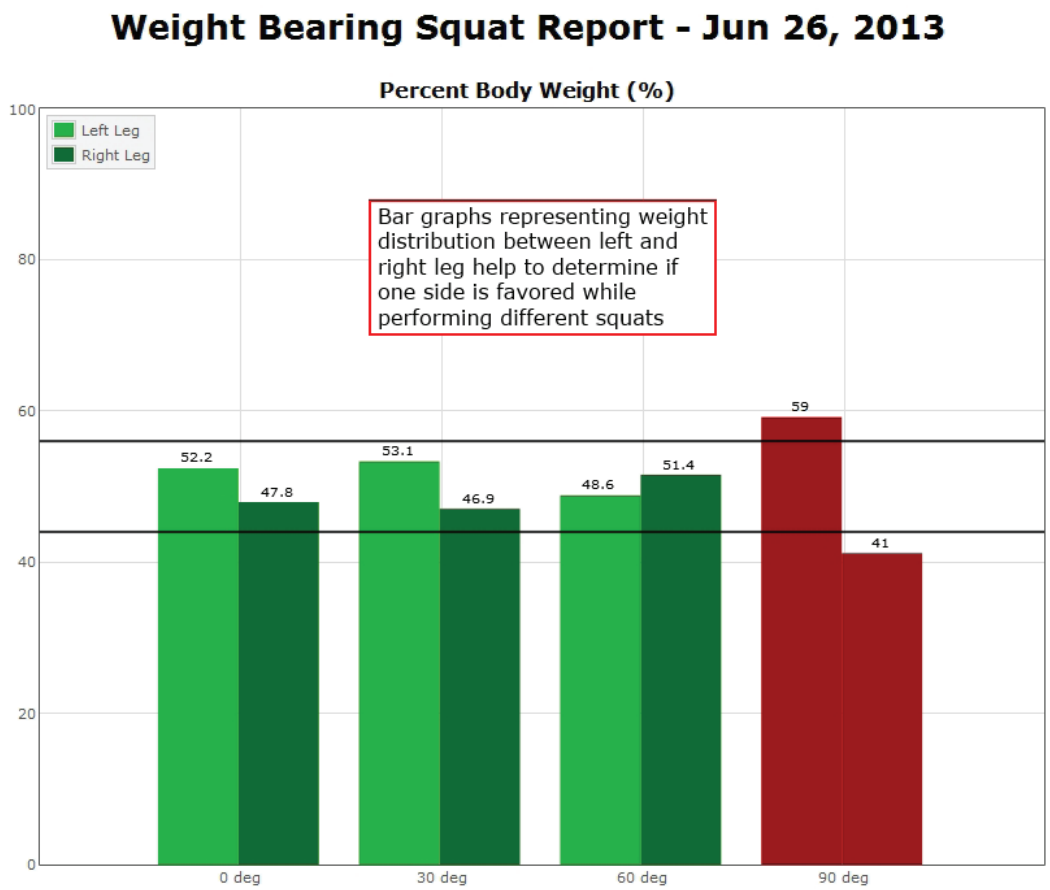


Figure 65: WBS Report Information.

Sit to Stand (STS)

IMPORTANT! - Please make sure you are in a position to help the patient if they begin to lose their balance, as the clinician is responsible for the safety of himself or herself, the patient, others in the surrounding area, and the equipment.

Compatible Packages:

Bertec® Balance Advantage® Functional and Functional Portable.

Goal:

The goal is to assess the ability of patients to control and transfer their center of pressure from a seated to a standing position.

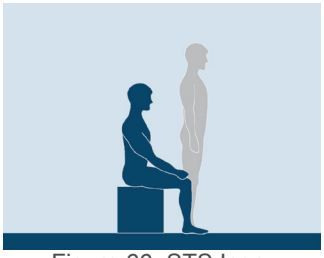


Figure 66: STS Icon.

Protocol:

The patient is seated on the provided blocks in the middle of the balance plate. At the given cue, the patient stands as quickly as they feel comfortable without using their hands. A total of three trials may be collected.

Required Accessories:

12” and 4” stacked blocks to form a seat

Patient Instructions:

“Sit still looking at the screen until you see the “Begin!” command. Upon seeing “Begin!”, stand as quickly as you feel comfortable doing. Keep your hands placed on your legs; do not use them to assist in standing. Continue to remain standing still until data collection has stopped. I will give you further instructions as needed.”

Protocol Performance:

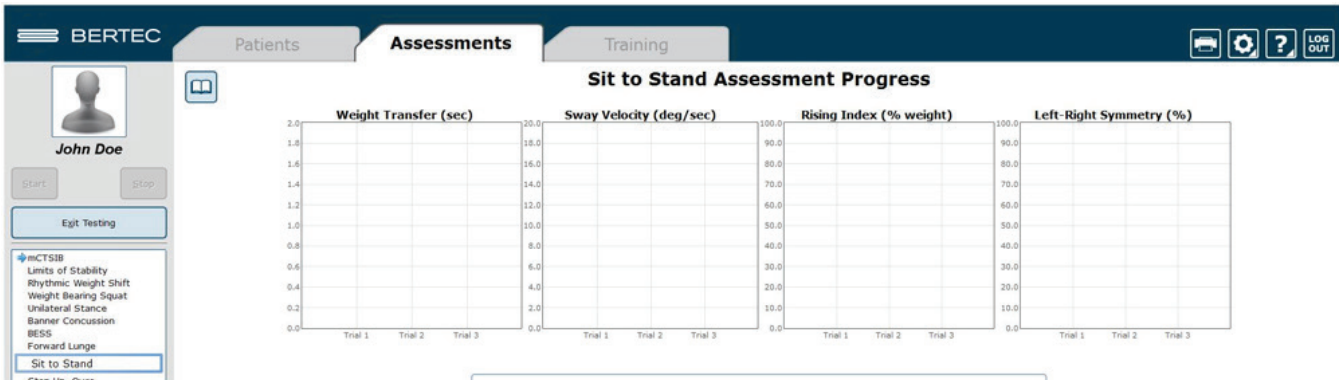


Figure 67: STS Main Clinician Screen.

- Stack the 4” and 12” blocks and place in the middle of the long balance plate.
- The patient sits on the stacked blocks facing the patient screen.
- Upon hitting start, “Hold Still” will be displayed on the patient screen.
- When the “Begin!” command is shown, the patient should stand as quickly as possible. Ensure that the patient does not use their hands to assist in standing.
- Repeat for up to three trials.

General Assessment Information:

- Trials may be interrupted at any time by selecting the Stop button on the clinician screen or the third button on the wireless remote (see Figure 52 on page 40). When a trial is stopped, the software will prompt whether the operator wants to keep or discard the data. Data should be discarded if the patient does not follow patient instructions (talking, keeping eyes open, sneezing, etc...). Data should be kept if the test is completed according to the patient instructions.
- Assessment notes may be created at any time in the Notes text box (lower left corner).

Test Completion Protocol:

- At the completion of the task(s), the test may be closed or the next test may be initiated.
- It is recommended that final comments are added at this time.

Test Analysis:

- Generated Reports Will Include:
  - Weight Transfer (Sec.): The time it takes for a patient to move from a seated to standing position, starting from when the patient’s feet begin to bear weight.
  - Rising Index: The amount of force used to propel the individual into a standing position.
  - COG Sway Velocity: The amount of sway during the rising phase and five seconds after.
  - Weight Symmetry: Shows the patient’s weight distribution while rising.
  - Red/Green Bars: Results falling outside of the normal values will be represented by solid red bars, whereas results falling inside of the normal values will be represented by solid green bars.

Reports:

- Summary Reports
  - Summary of the patient’s performance during one trial or trial series.
  - The body weight percentages are shown in a bar graph format.
  - Above each bar, the numeric data is given for each of the positions.
- Progress Reports
  - Summary of the patient’s performance for a series of trials conducted at different times.
    - To view progress reports, click the information icon *i* in the patient’s timeline.
    - A drop-down menu will appear and list the available progress reports.
    - The progress a patient makes on a report is given with progress reports that chart their performance scores over time.
- Printing/Saving
  - Select the desired protocol report from the patient’s timeline.
  - While viewing the report, select the printer icon  to either save a PDF file or print to a regular printer.

Practical Considerations:

Abnormality	Implications
None	Normal individuals use their legs to exert necessary force during the rising phase and then bring the center of pressure under control over the base of support when reaching the standing position. The force during the rising phase is approximately symmetrical for the right and left legs.
Increased time for weight transfer, reduced exertion force during rising, excessive sway during standing, or asymmetrical force exertion	Patients with abnormal findings during STS can have a variety of musculoskeletal impairments, including reduced range of motion and flexibility, reduced trunk and lower body strength, or movement control impairments. These patients have difficulty in transitioning from the sitting to the standing position and may require assistance during the transition to prevent falls and injuries.

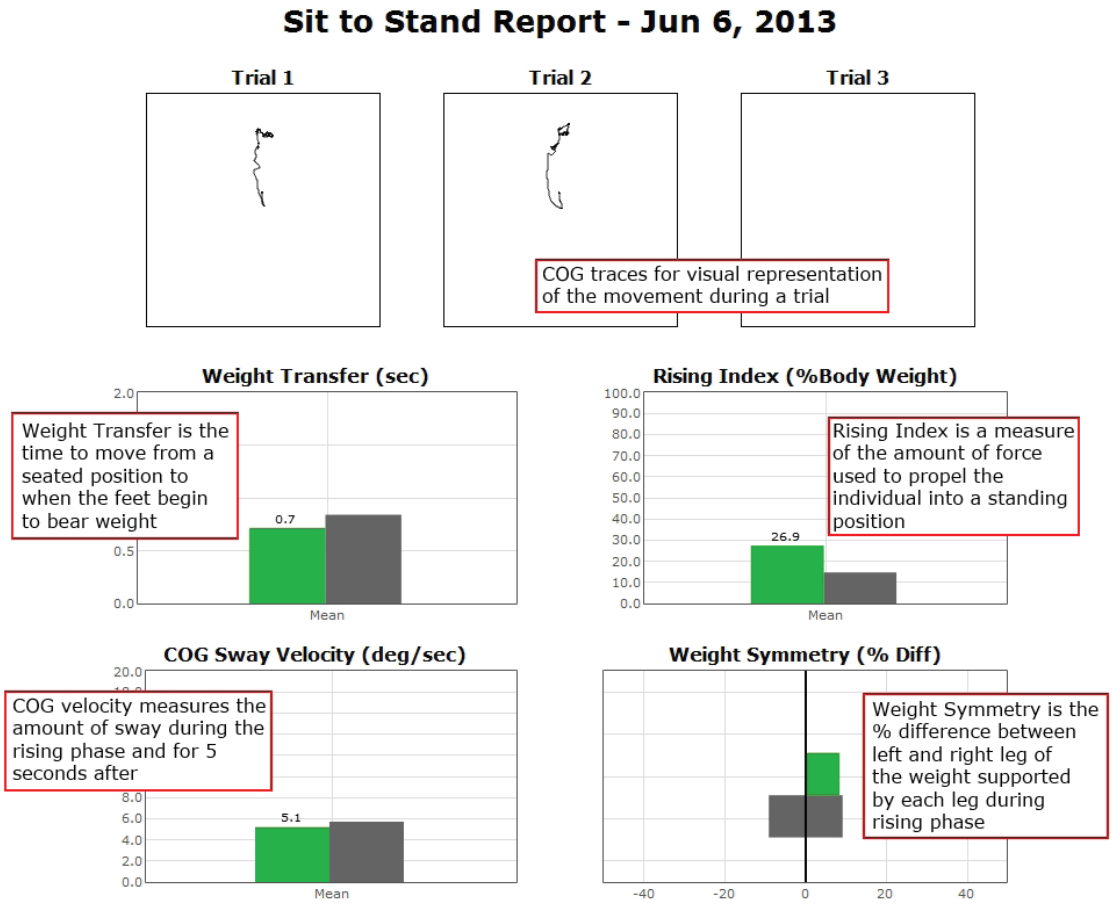


Figure 68: STS Report Information.

Walk Across (WA)

IMPORTANT! - Please make sure you are in a position to help the patient if they begin to lose their balance, as the clinician is responsible for the safety of himself or herself, the patient, others in the surrounding area, and the equipment.

Compatible Packages:

Bertec® Balance Advantage® Functional package and Portable Functional.

Goal:

The goal is to determine average width and length of each step, symmetry of right and left step lengths, and the gait speed during a steady state walk across the balance plate.



Figure 69: WA Icon.

Protocol:

The patient is required to walk the length of the balance plate as quickly as possible. A total of three trials may be collected.

Patient Instructions:

“Stand steady (on one side of the plate) before crossing the balance plate. When you are instructed to start, begin walking across the balance plate and stop when you have reached the end of the balance plate. I will give you further instructions as needed.”

Protocol Performance:

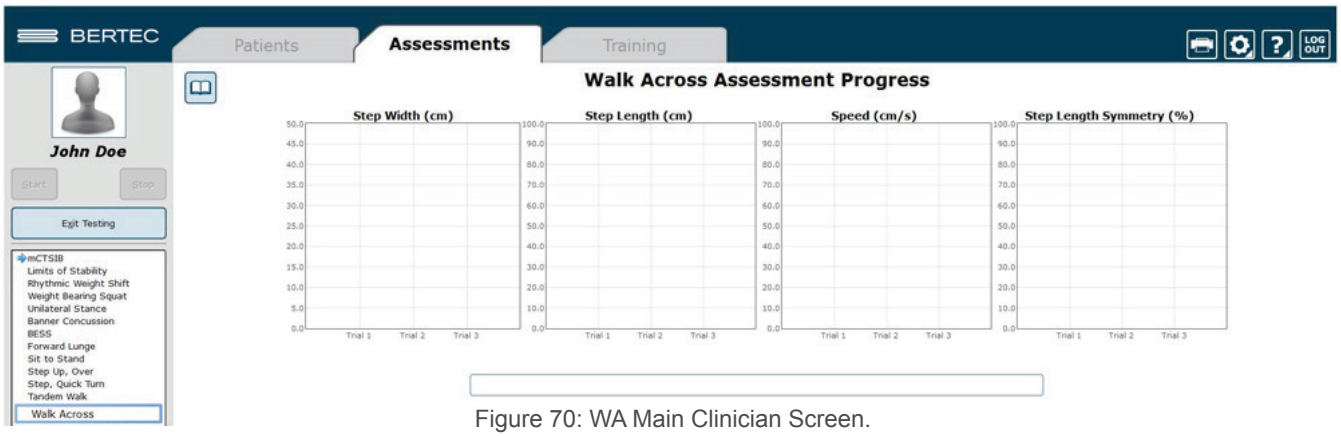


Figure 70: WA Main Clinician Screen.

- Protocol should be completed with two functional plates connected in tandem.
- Position the patient off the balance plate on the side opposite the patient screen.
- Upon hitting start, the patient is to walk across the plate as quickly as possible. The patient should walk completely across and stop at the edge of the plate

Caution/General Assessment Information:

- This assessment may not be appropriate for highly fit individuals.
- The assessment may be terminated if the patient begins to fall by manually stopping the test.
  - Do not allow a patient to fall—assist as needed.
- If a fall begins to occur, the clinician can stop the test—trial data can be kept or discarded.
  - If the trial is stopped, the clinician will be prompted to choose Fall or Discard.
  - If FALL is selected:
    - The trial is then saved as a FALL.
    - The patient will then need to be repositioned to insure proper foot placement for additional trials.
  - If DISCARD is selected:
    - The trial will not be saved.
    - The patient will then need to be repositioned to insure proper foot placement for additional trials.
- Assessment notes may be created at any time in the Notes text box (lower left corner).

Test Completion Protocol:

- At the completion of the task(s), the test may be closed or the next test may be initiated.
- It is recommended that final comments are added at this time.

Test Analysis:

- Generated Reports will Include:
  - Center of Gravity tracing
  - Width of Step
    - Lateral distance between each foot on successive steps
    - Measured in centimeters
  - Length of Step
    - The distance between successive heel strikes
    - Measured in centimeters
  - Velocity
    - Forward advancement
    - Measured in centimeters per second
  - Symmetry of Step Length
    - Bilateral comparison of step length
    - Percentage of the total stride length (left and right)

Reports:

- Summary Reports
  - Summary of the patient's performance during one trial or trial series.
    - A graphic depiction of each of the four areas of analysis.
    - The Center of Gravity tracing for each traverse is given.
    - Scores are not compared to normal.
    - Test comments (if entered) are available for inclusion in the report. Additional test comments may also be added.
- Progress Reports
  - Summary of the patient's performance for a series of trials conducted at different times.
    - To view progress reports, click the information icon *i* in the patient's timeline.
    - A drop-down menu will appear and list the available progress reports.
    - The progress a patient makes on a report is given with progress reports that chart their performance scores over time.
- Printing/Saving
  - Select the desired protocol report from the patient's timeline.
  - While viewing the report, select the printer icon  to either save a PDF file or print to a regular printer.

Practical Considerations:

Abnormality	Implications
None	The gait parameters, in particular gait speed, have been associated with the activities of daily living (ADL).[2] It has been shown that those with gait speed of over 55 cm/sec are successful in 100% of ADL. In addition, step length, width, and symmetry are important factors in control of postural stability during gait.
Increased step width, decreased step length, increased step asymmetry, and decreased gait speed	Abnormal findings in the WA test are sensitive indicators of impairments in gait and the overall balance function. They can be caused by non-specific musculoskeletal, neuromuscular, and cognitive impairments.

Table 2: WA Activity Predictions.

Gait Requirements		
Daily Life Activity	**Velocity**	**Step Length**
Crossing a street	Above 120 cm/s	----------
Normal casual gait	Above 98 cm/s	----------
Unlimited community	Above 80 cm/s	----------
Unlimited household	Above 27 cm/s	----------
Independent on all surfaces	Above 65 cm/s	45 cm
Independent on level surfaces	Above 40 cm/s	38 cm
With supervision	Above 17-24 cm/s	22 - 32 cm
With physical assistance	Above 14-23 cm/s	20 - 22 cm

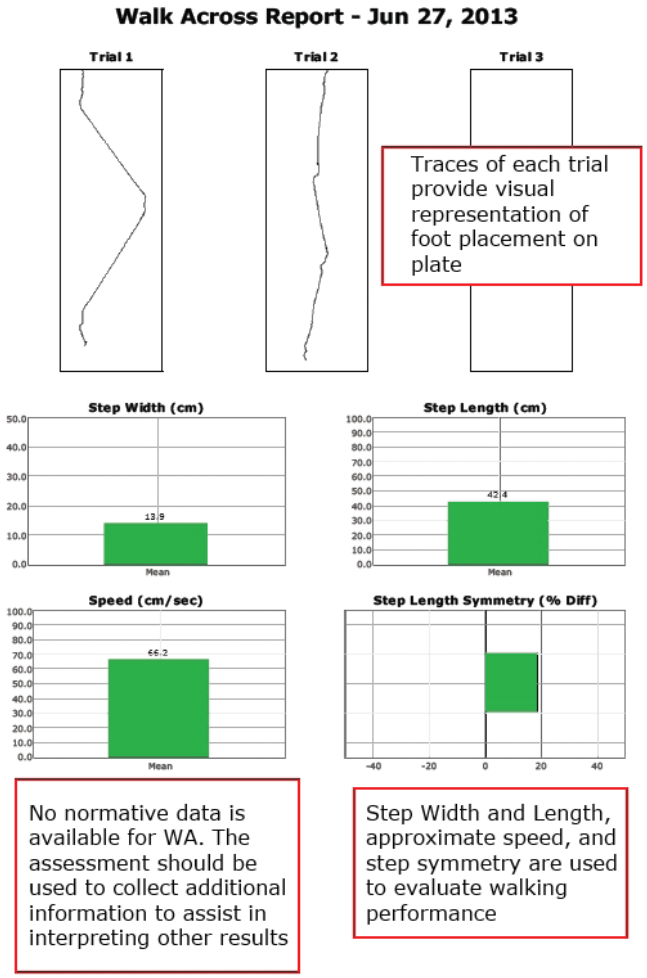


Figure 71: WA Report Information.

Tandem Walk (TW)

IMPORTANT! - Please make sure you are in a position to help the patient if they begin to lose their balance, as the clinician is responsible for the safety of himself or herself, the patient, others in the surrounding area, and the equipment.

Compatible Packages:

Bertec® Balance Advantage® Functional and Functional Portable.

Goal:

The goal is to determine the step width, gait speed, postural control while walking with a narrow base of support.

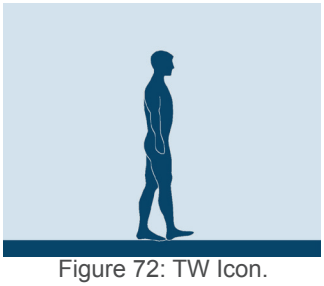


Figure 72: TW Icon.

Protocol:

The patient is positioned at one end of the plate and instructed to walk, heel to toe, across the length of the balance plate. Upon reaching the end, the patient stands still for several seconds until the trial ends. A total of three trials may be collected.

Patient Instructions:

“Upon seeing the “Begin!” command, walk heel to toe (placing one foot immediately in front of the other) across the plate. When you reach the end of the plate, stand as still as you can until the test is over. I will give you further instructions as needed.”

Protocol Performance:

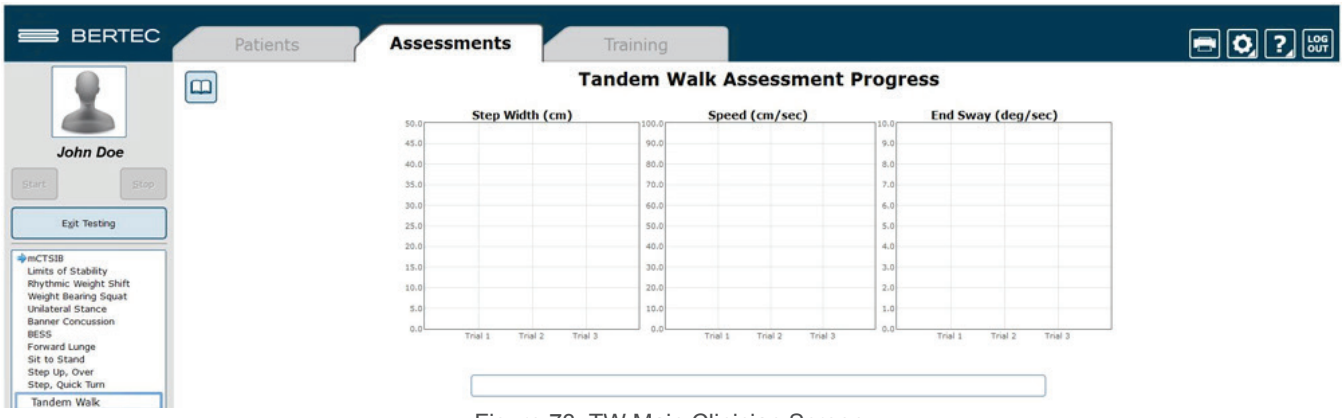


Figure 73: TW Main Clinician Screen.

- Protocol should be completed with two functional plates connected in tandem.
- Position the patient at the end of the plate, opposite from where the patient monitor is located.
- Upon hitting start, “Hold Still” will be displayed on the patient screen.
- When the “Begin!” command is shown, the patient should walk heel-to-toe as quickly as possible until they reach the end of the plate.
- At the other end of the plate, the patient should remain still until the trial ends.

General Assessment Information:

- Trials may be interrupted at any time by selecting the Stop button on the clinician screen or the third button on the wireless remote (see Figure 52 on page 40). When a trial is stopped, the software will prompt whether the operator wants to keep or discard the data. Data should be discarded if the patient does not follow patient instructions (talking, keeping eyes open, sneezing, etc...). Data should be kept if the test is completed according to the patient instructions.
- Assessment notes may be created at any time in the Notes text box (lower left corner).

Test Completion Protocol:

- At the completion of the task(s), the test may be closed or the next test may be initiated.
- It is recommended that final comments are added at this time.

Test Analysis:

- Generated Reports will Include:
  - Speed
  - Width of Step
    - Lateral distance between each foot on successive steps
    - Measured in centimeters
  - End Sway
- Red/Green Bars: Results falling outside of the normal values will be represented by solid red bars, whereas results falling inside of the normal values will be represented by solid green bars.

Reports:

- Summary Reports
  - Summary of the patient’s performance during one trial or trial series.
    - Traces for each of the trials.
    - Bar graphs comparing the results to normative data for Step Width, End Sway, and Speed.
- Progress Reports
  - Summary of the patient’s performance for a series of trials conducted at different times.
    - To view progress reports, click the information icon *i* in the patient’s timeline.
    - A drop-down menu will appear and list the available progress reports.
    - The progress a patient makes on a report is given with progress reports that chart their performance scores over time.
- Printing/Saving
  - Select the desired protocol report from the patient’s timeline.
  - While viewing the report, select the printer icon  to either save a PDF file or print to a regular printer.

Practical Considerations:

Abnormality	Implications
None	Tandem gait creates a more challenging task for postural control by narrowing the base of support.
Increased step width and decreased speed	Patients with abnormal findings in the TW test are at an increased risk of falls. Decreased speed may indicate fear of falls or sensory impairments.

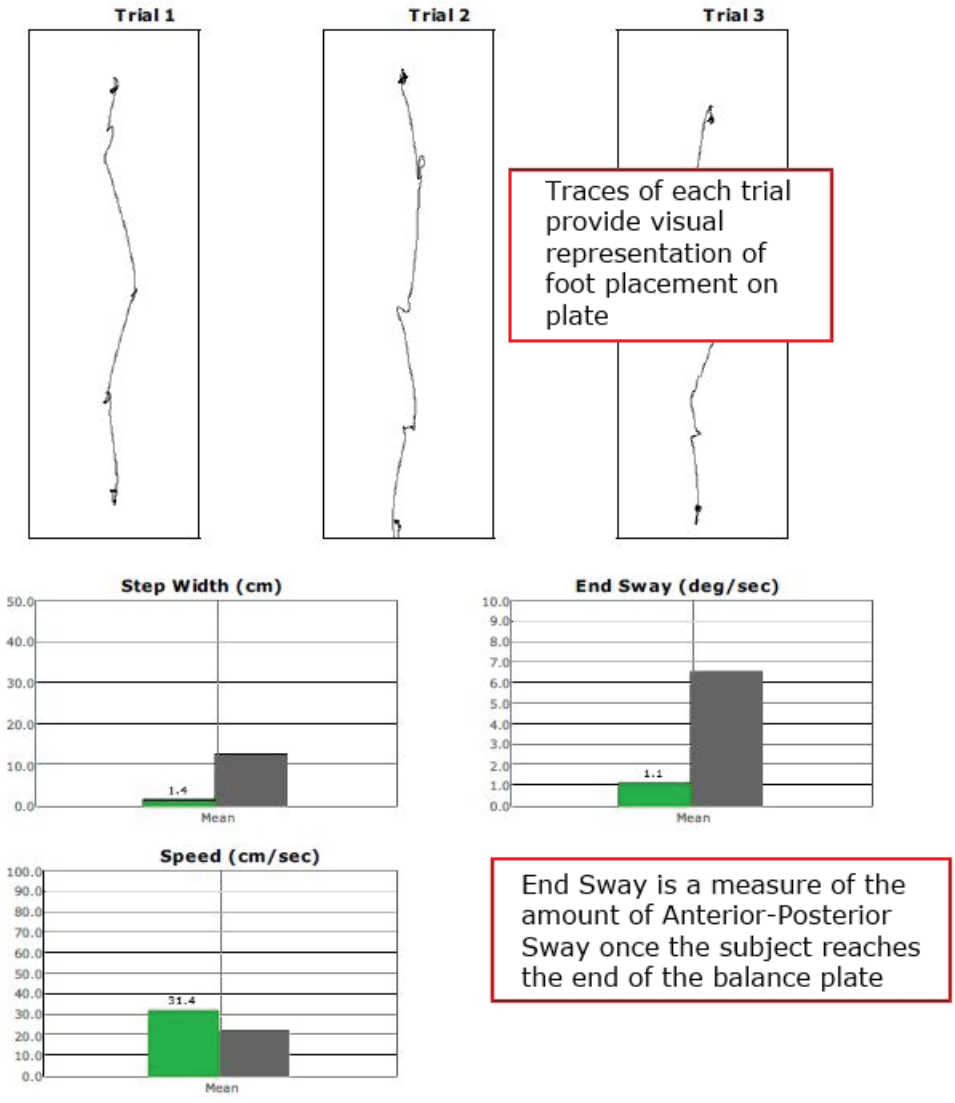


Figure 74: TW Report Information.

Step Quick Turn (SQT)

IMPORTANT! - Please make sure you are in a position to help the patient if they begin to lose their balance, as the clinician is responsible for the safety of himself or herself, the patient, others in the surrounding area, and the equipment.

Compatible Packages:

Bertec® Balance Advantage® Functional and Portable Functional.

Goal:

The goal is to assess the ability of the patient to maintain postural stability while taking two steps forward and making a quick turn either to the right or to the left.



Figure 75: SQT Icon.

Protocol:

The patient is required to complete up to six trials total; three trials where the patient is instructed to turn to the left and three where the patient is instructed to turn right. Specifically, the patient is to take two steps forward, turn, and then return to the starting position as quickly as possible.

Patient Instructions:

“Please stand still and wait for the cue to begin the trial. When you see the “Begin!” command, take two steps forward, turn around the stated direction, and then return to the starting position. You should perform this movement as quickly as possible. Once you return to the starting point, please stand still for several seconds. I will give you further instructions as needed.”

Protocol Performance:

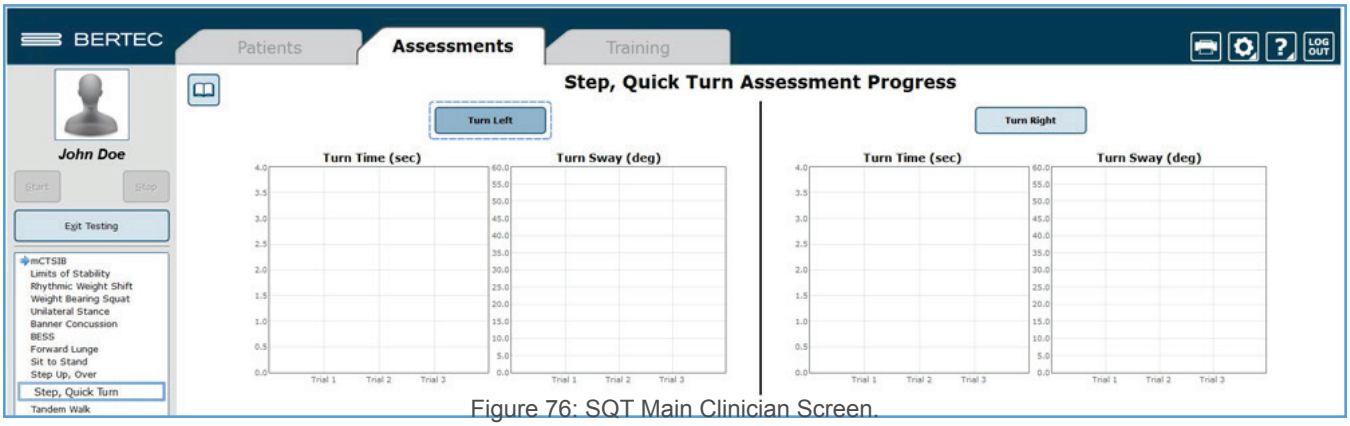


Figure 76: SQT Main Clinician Screen.

- Position the patient at the end of the plate on the side opposite from where the patient monitor is located (the patient faces the monitor).
- Select the type of turn to complete (Ex. Turn Left).
- Upon hitting start, “Hold Still” will be displayed on the patient screen.
- When the “Begin!” command is shown, the patient should take two steps, turn the chosen direction, and then return to the starting position as quickly as possible.
- When they have returned to the starting position, they should remain there until the trial is over.

General Assessment Information:

- Trials may be interrupted at any time by selecting the Stop button on the clinician screen or the third button on the wireless remote (see Figure 52 on page 40). When a trial is stopped, the software will prompt whether the operator wants to keep or discard the data. Data should be discarded if the patient does not follow patient instructions (talking, keeping eyes open, sneezing, etc...). Data should be kept if the test is completed according to the patient instructions.
- Assessment notes may be created at any time in the Notes text box (lower left corner).

Test Completion Protocol:

- At the completion of the task(s), the test may be closed or the next test may be initiated.
- It is recommended that final comments are added at this time.

Test Analysis:

- Generated Reports will Include:
  - Center of Gravity tracing.
  - Turn Time and the percent difference between left turns and right turns.
  - Turn Sway and the percent difference in Turn Sway for left and right turns.
  - Red/Green Bars: Results falling outside of the normal values will be represented by solid red bars, whereas results falling inside of the normal values will be represented by solid green bars.

Reports:

- Summary Reports
  - Summary of the patient’s performance during one trial or trial series.
    - A graphic depiction of each of the two areas of analysis.
    - The Center of Gravity tracing for each traverse is given.
    - Scores are compared to age-matched normative data.
    - Test comments (if entered) are available for inclusion in the report. Additional test comments may also be added.
- Progress Reports
  - Summary of the patient’s performance for a series of trials conducted at different times.
    - To view progress reports, click the information icon *i* in the patient’s timeline.
    - A drop-down menu will appear and list the available progress reports.
    - The progress a patient makes on a report is given with progress reports that chart their performance scores over time.
- Printing/Saving
  - Select the desired protocol report from the patient’s timeline.
  - While viewing the report, select the printer icon  to either save a PDF file or print to a regular printer.

Practical Considerations:

Abnormality	Implications
None	The ability to change direction while walking is important in many recreational activities, such as golfing or dancing. It is also essential in achieving normal gait and postural stability.
Increased time, sway or weight asymmetry	Patients with abnormal findings in the SQT test are at increased risk of falls during activities of daily living. Sensory impairments such as visual or vestibular impairments (as well as neurological disorders) can affect the performance in the SQT test.

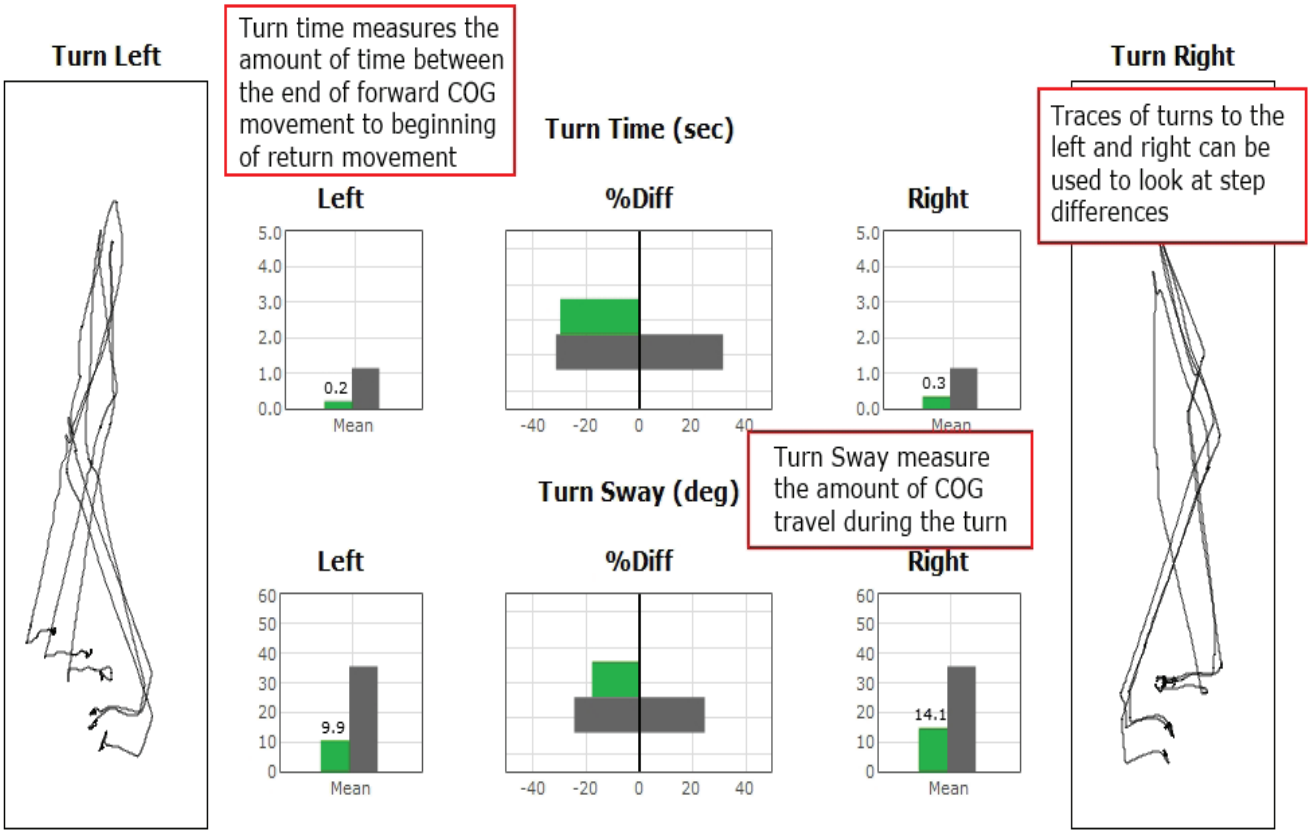


Figure 77: SQT Report Information.

Step Up and Over (SUO)

IMPORTANT! - Please make sure you are in a position to help the patient if they begin to lose their balance, as the clinician is responsible for the safety of himself or herself, the patient, others in the surrounding area, and the equipment.

Compatible Packages:

Bertec® Balance Advantage® Functional and Portable Functional.

Goal:

The goal is to assess the ability of the patient to maintain postural stability while stepping up and over obstacles.

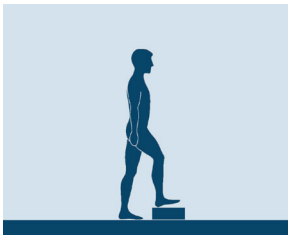


Figure 78: SUO Icon.

Protocol:

The patient is required to complete up to six trials total; three trials using the right leg to step up and three trials using the left leg to step up. Trials consist of the patient starting on the balance plate, stepping up onto the box, swinging their trailing leg up over the box and on to the ground on the other side. The trial finishes when the patient reaches the resting position.

Required Accessories:

4” block
8” block
12” block

Patient Instructions:

“Please stand still and wait to being the trial. When you see the command “Begin!”, take one step onto the box in front of you and then swing your opposite leg up, over the box, and down onto the plate. I will give you further instructions as needed.”

Protocol Performance:

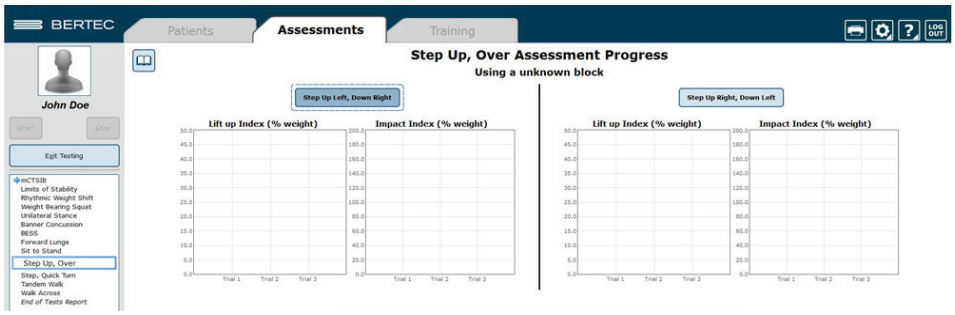


Figure 79: SUO Main Clinician Screen.

- Place the 4”, 8”, or 12” block in the middle of the long balance plate.
- Select the desired starting condition (Ex. Step Up Left, Down Right).
- Position the patient in front of the block, on the side opposite from where the patient monitor is located.
- Upon hitting start, “Hold Still” will be displayed on the patient screen.
- When the “Begin!” command is shown, the patient should step up, over, and down as quickly as possible.
- When the patient comes to rest on the other side of the block, they should remain still until the end of the trial.

General Assessment Information:

- Trials may be interrupted at any time by selecting the Stop button on the clinician screen or the third button on the wireless remote (see Figure 52 on page 40). When a trial is stopped, the software will prompt whether the operator wants to keep or discard the data. Data should be discarded if the patient does not follow patient instructions (talking, keeping eyes open, sneezing, etc...). Data should be kept if the test is completed according to the aforementioned specifications.
- Assessment notes may be created at any time in the Notes text box (lower left corner).

Test Completion Protocol:

- At the completion of the task(s), the test may be closed or the next test may be initiated.
- It is recommended that final comments are added at this time.
- Click on a test in the list (i.e. Step Up Left) to perform it.

Test Analysis:

The report will present the following:

- Center of Gravity tracing of each completed trial.
- Lift-up Index and the percent difference between the left and right leg when used as the lead leg.
- Movement Time and percent difference between the left and right leg.
- Impact Index and percent difference between the left and right leg.
- Red/Green Bars: Results falling outside of the normal values will be represented by solid red bars, whereas results falling inside of the normal values will be represented by solid green bars.

Reports:

- Summary Reports
  - Summary of the patient’s performance during one trial or trial series.
    - A graphic depiction of each of the three areas of analysis with numeric data given above each bar in the bar graphs.
    - The Center of Gravity tracing for each traverse is given.
    - Scores are compared to age-matched normative data.
    - Test comments (if entered) are available for inclusion in the report. Additional test comments may also be added.
- Progress Reports
  - Summary of the patient’s performance for a series of trials conducted at different times.
    - To view progress reports, click the information icon *i* in the patient’s timeline.
    - A drop-down menu will appear and list the available progress reports.
    - The progress a patient makes on a report is given with progress reports that chart their performance scores over time.

> Printing/Saving
  > Select the desired protocol report from the patient's timeline.
  > While viewing the report, select the printer icon to either save a PDF file or print to a regular printer.

Practical Considerations:

Abnormality	Implications
None	The ability to step up and over obstacles is critical in tasks such as climbing stairs or stepping over curbs. Normal SUO results depend on the strength and flexibility of lower legs as well higher-level motor planning.
Decreased lift index, increased movement time or impact index	Patients with abnormal findings in the SUO test are at increased risk of falls during climbing or ascending stairs or walking over curbs. Abnormal impact index is consistent with sensory-motor impairments involving lower extremity proprioception.[3]

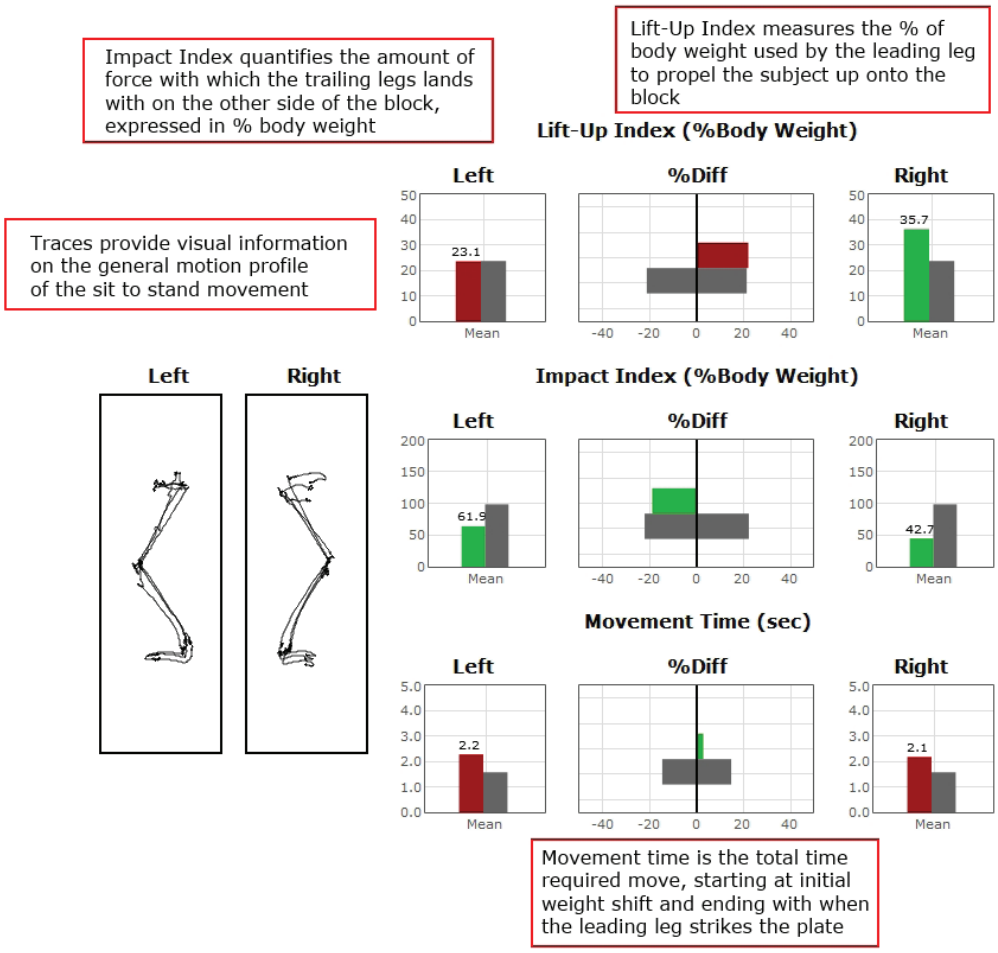


Figure 80: SUO Report Information.

Forward Lunge (FL)

IMPORTANT! - Please make sure you are in a position to help the patient if they begin to lose their balance, as the clinician is responsible for the safety of himself or herself, the patient, others in the surrounding area, and the equipment.

Compatible Packages:

Bertec® Balance Advantage® Functional and Portable Functional.

Goal:

The goal is to assess the ability of the patient to control postural stability while lunging forward with either right or left leg.



Figure 81: FL Icon.

Protocol:

The patient is required to complete up to three lunges, leading with both their left and right leg as the lead leg. They are instructed to lunge as far forward as possible and to return to the starting position as quickly as they are comfortable doing.

Patient Instructions:

“Stand still and wait for the cue to begin your lunge. When you see the “Begin!” command, lunge forward with either your left or right leg; return to the starting position as quickly as possible. I will give you further instructions as needed.“

Protocol Performance:

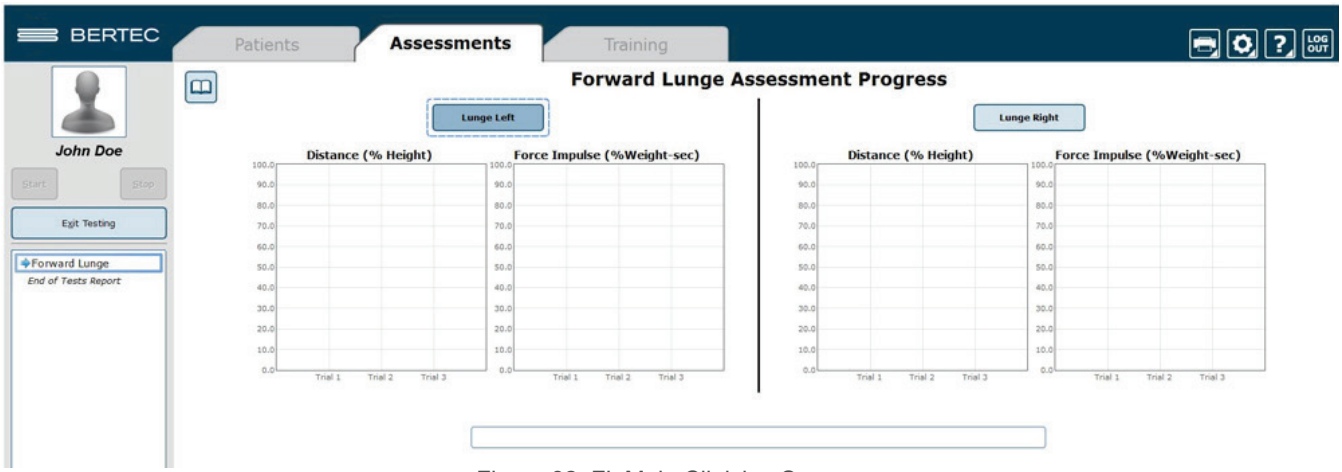


Figure 82: FL Main Clinician Screen.

- Position the patient at the end of the plate, opposite from where the patient monitor is located (patient faces the monitor).
- Select which leg should perform the lunge (Ex. Lunge Left).
- Upon hitting start, “Hold Still” will be displayed on the patient screen.
- When the “Begin!” command is shown, the patient should lunge forward and return to the starting position as quickly as possible.
- When they have returned to the starting position, they should remain there until the trial is over.

General Assessment Information:

- Trials may be interrupted at any time by selecting the Stop button on the clinician screen or the third button on the wireless remote (see Figure 52 on page 40). When a trial is stopped, the software will prompt whether the operator wants to keep or discard the data. Data should be discarded if the patient does not follow patient instructions (talking, keeping eyes open, sneezing, etc...). Data should be kept if the test is completed according to the patient instructions.
- Assessment notes may be created at any time in the Notes text box (lower left corner).

Test Completion Protocol:

- At the completion of the task(s), the test may be closed or the next test may be initiated.
- It is recommended that final comments are added at this time.
- Click on a test in the list (i.e. step up left) to perform it.

Test Analysis:

The report will present the following:

- The distance of the lunge and the percent difference between lunges with the left leg and right leg.
- Impact Index
  - The force exerted by the impact leg and the percent difference between left and right legs.
- Contact Time
  - The amount of time the lunge leg was in contact with the ground. Also report the percent difference between the left and right legs.
- Force Impulse
  - Takes into consideration the amount of force in the lunge leg and how long it was in contact with the ground, an estimation for how much work was done by the lunge leg.
- Red/Green Bars: Results falling outside of the normal values will be represented by solid red bars, whereas results falling inside of the normal values will be represented by solid green bars.

Reports:

- Summary Reports
  - Summary of the patient’s performance during one trial or trial series.
    - A graphic depiction of each of the four areas of analysis with numeric data given above each bar in the bar graphs.
    - The Center of Gravity tracing for each traverse is given.
    - Scores are compared to age-matched normative data.
    - Test comments (if entered) are available for inclusion in the report. Additional test comments may also be added.

- Progress Reports
  - Summary of the patient's performance for a series of trials conducted at different times.
    - To view progress reports, click the information icon *i* in the patient's timeline.
    - A drop-down menu will appear and list the available progress reports.
    - The progress a patient makes on a report is given with progress reports that chart their performance scores over time.
- Printing/Saving
  - Select the desired protocol report from the patient's timeline.
  - While viewing the report, select the printer icon to either save a PDF file or print to a regular printer.

Practical Considerations:

Abnormality	Implications
None	Forward lunge is a challenging task that requires lower extremity strength, flexibility, and motor coordination. Normal FL indicates the ability to participate in recreational and work-related activities that require rapid stepping tasks.
Decreased distance, increased contact time or force, and abnormal impact index	Patients with abnormal findings in the FL test are at increased risk of falls and injury during tasks that require rapid loading and unloading of lower extremities. Abnormal stepping strategies cause postural control deficits and lead to movement impairments.

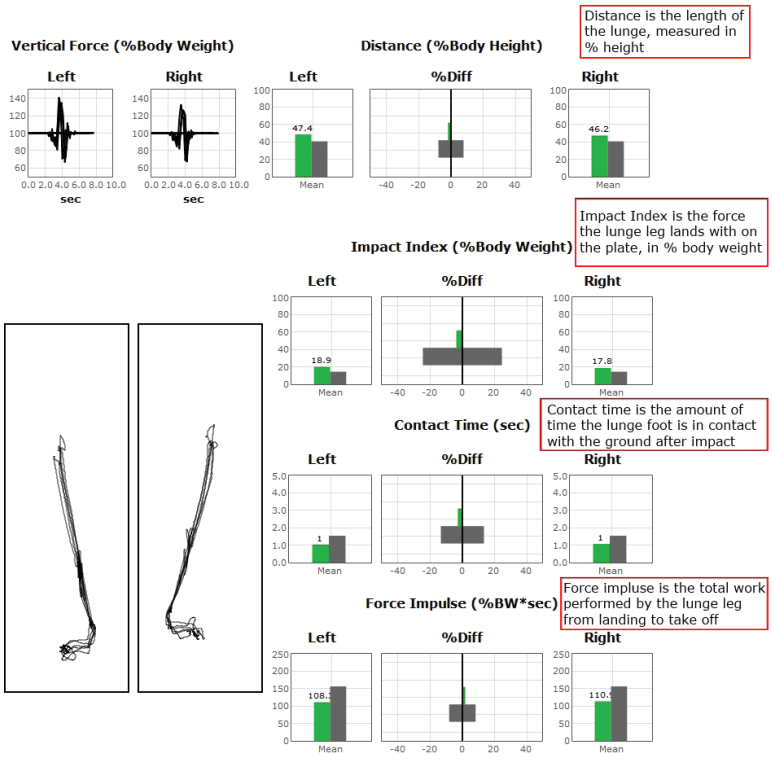


Figure 83: FL Report Information.

Additional Assessment Protocols

Several other protocols are available on select systems which assist in the evaluation of highly athletic patients or those who have been concussed. These include:

- Balance Concussion Test (COBALT)
- Instrumented Balance Error Scoring System (iBESS)

To add one of the above assessments onto a system, speak with a Bertec® Sales Representative.

Concussion Balance Test (COBALT)™

IMPORTANT! - Please make sure you are in a position to help the patient if they begin to lose their balance, as the clinician is responsible for the safety of himself or herself, the patient, others in the surrounding area, and the equipment.

Compatible Packages:

Bertec® Balance Advantage® Essential, Portable Essential, Tender Essential, Functional, Portable Functional.

Goal:

The Concussion Balance Test (COBALT) is a trademarked protocol for functional balance testing related to mild traumatic brain injury, also known as concussion. This protocol is designed to stimulate the visual, vestibular, and somatosensory systems. The patient is to stand as still as possible during each condition while the balance plate measures their degree of sway as each of the balance systems are stimulated.

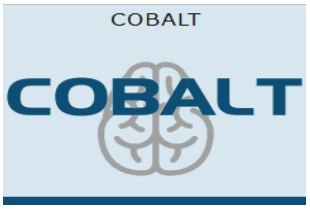


Figure 105: COBALT Icon.

Protocol:

Patients will be asked to stand directly on the balance plate for half of the conditions and on top of foam surface for the remaining conditions. A total of eight conditions are available for testing; each condition consists of two 20 second trials. Baseline tests should utilize four conditions, whereas it is recommended that post-injury tests should utilize all eight conditions. Data collection for each trial is initiated at the discretion of the operator.

Test Setup:

For the most accurate implementation of the protocol, the patient must rotate their head 30 degrees left/right from a neutral orientation (staring straight ahead). The COBALT wall hanging kit (included as an accessory, along with a tape measure) should be hung from a blank wall with the bottom edge measuring 2.5’ from the floor. This height should be adjusted to best accommodate the clinic’s patients. The balance plate should be centered 2’ from the wall. The purpose of this is to help guide the patient to move the full 60 degrees of motion from side to side.

Note: The wireless remote control used for COBALT was included in the purchase of a your static system. See Figure 106 below for a visualization of the remote’s functions. Note that, between trials, button 1 moves to the next trial and button 2 moves to the previous trial, while during trials button 1 and 2 both perform the same action of marking an error.



Figure 106: COBALT Remote Functions.

After placing COBALT in the Series of Tests to perform list, determine if the patient has had a concussion before. If the patient has, enter the date of patient's last concussion by selecting the Concussion Date on the bottom left of the screen (Figure 107). Clicking on the date will open a calendar menu. If the patient has not had a concussion before, ignore the previous step. Once a date has been entered for a concussed patient (or no date has been selected for an unconcussed patient), click on the Visit Type on the bottom left of the screen. If the patient has had a concussion before, select Post-Injury option after following the steps above. Afterwards, click Ok to enter the test screen. If the patient has not had a concussion before, select the Baseline option and click Ok to enter the test screen.

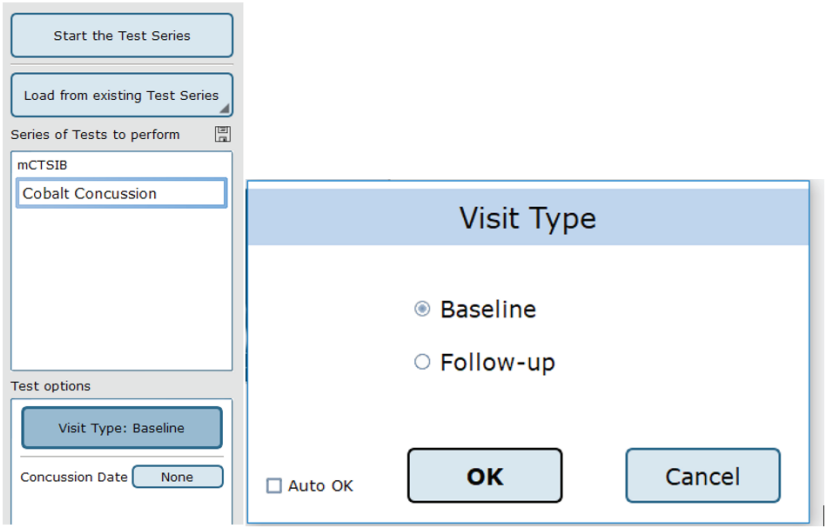


Figure 107: Setting up the COBALT Test.

After selecting Ok, click on the Start the Test Series button. The test initiation page will appear, as shown in Figure 108 below. To begin a trial, have the patient stand on the plate (as instructed) and click on the blue box which corresponds to the desired test. Patient instructions and test information can be found on the following pages.

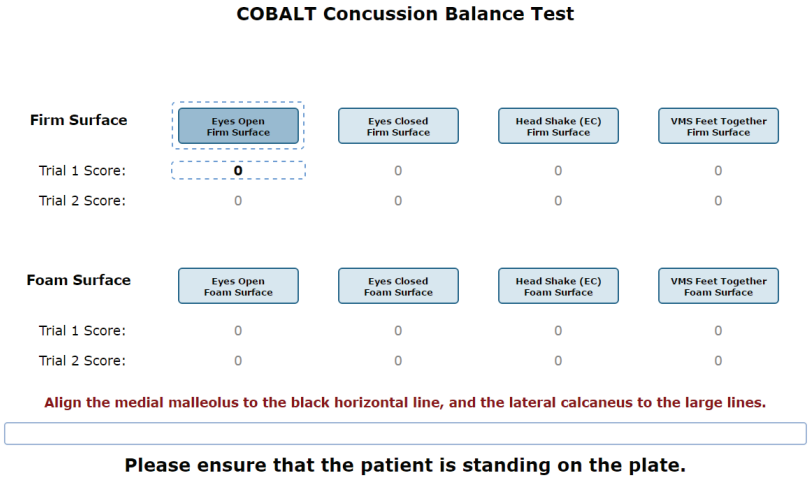


Figure 108: Test Initiation Page.

Patient Instructions:

Patients are instructed to stand still with their eyes open (or closed) and with their hands placed on their hips. Shoes, socks, and any athletic taping should be removed prior to the start of the evaluation. The following are considered errors:

- Stepping off the plate/foam during testing
- Moving one's feet on board/foam during testing
- Opening one's eyes during eyes closed portion of testing
- Moving hands off of hips during testing
- Stopping any portion of the required task during test performance (head turn, arm swing, feet position)

The test conditions are labeled below. Each condition is recommended to be performed twice.

Normal Stance: Eyes Open

- Patient is instructed to stand still with their feet placed according to the on-screen instructions, hands placed on their hips, and looking straight ahead with eyes open (The clinician should demonstrate the correct position).
- After instructing the patient, the clinician will begin the trial.
- Any time the clinician needs to mark an error, Button 1 or 2 on the wireless remote should be pressed.

Normal Stance: Eyes Closed

- Patient is instructed to stand still with their feet placed according to the on-screen instructions, hands placed on their hips, and eyes closed (The clinician should demonstrate the correct position).
- After instructing the patient, the clinician will begin the trial.
- Errors are recorded by the clinician as before.

Normal Stance: Eyes Open on Foam

- Place foam on the balance plate.
- Performed exactly the same as the first Normal stance -- Eyes Open trial.
- Errors are recorded by the clinician as before.

Normal Stance: Eyes Closed on Foam

- Place foam on the balance plate.
- Performed exactly the same as the first Normal Stance – Eyes Closed trial.
- Errors are recorded by the clinician as before.

Normal Stance: Head Shake + Eyes Closed

- Patient is instructed to stand still with their feet placed according to the on-screen instructions, hands placed on their hips, and eyes closed (same as Normal Stance: Eyes Closed).
- The patient is then asked to move their head in sync with a metronome (120 beats/min). Allow the patient to practice this before starting data collection.
  - Patient rotates their head +/- 30 degrees from neutral (center) position.
  - If the patient becomes symptomatic from the metronome ticks, the "M" key can be pressed to mute the sound.
- After instructing the patient, the clinician will begin the trial.
- Errors are recorded by the clinician as before.
- At the conclusion of the trial, allow for 10-20 seconds of rest before starting the next trial.

Narrow Stance: Visual Motor Sensitivity (VMS)

- Patient is instructed to stand at the center of the balance plate with feet together, both arms extended out in front of them with hands clasped together and thumbs straight up. (The clinician should demonstrate the correct position)

- While focusing on their thumbs, the patient rotates their entire body 30 degrees right/left (total excursion of 60 degrees) in sync with a metronome set to 40 beats/min.
- At the conclusion of the trial, allow for 10-20 seconds of rest before starting the next trial.
- Errors are recorded by the clinician as before.

Normal Stance: Head Shake + Eyes Closed on Foam

- Place foam on the balance plate.
- Performed exactly the same as the first Double Head Shake + Eyes Closed.
- At the conclusion of the trial, allow for 10-20 seconds of rest before starting the next trial.
- Errors are recorded by the clinician as before.

Narrow Stance: Visual Motor Sensitivity (VMS) on Foam

- Place foam on the balance plate.
- Performed exactly the same as the VMS test on the firm surface.
- At the conclusion of the trial, allow for 10-20 seconds of rest before starting the next trial.
- Errors are recorded by the clinician as before.

Test Completion Protocol

Once a trial is completed, the operator may correct the error score if they have inadvertently selected or had forgotten to score an error. To correct the error quantity, select the number of errors (the actual score) and type in the revised error quantity. This correction can only be made at the time of the test; the operator is not able to modify the error scores within the test report.

The clinician may move on to the next assessment trial once a test has been completed (preferably two or more times). Notes may be added any time by modifying the single day report.

Test Analysis:

The report will present the following:

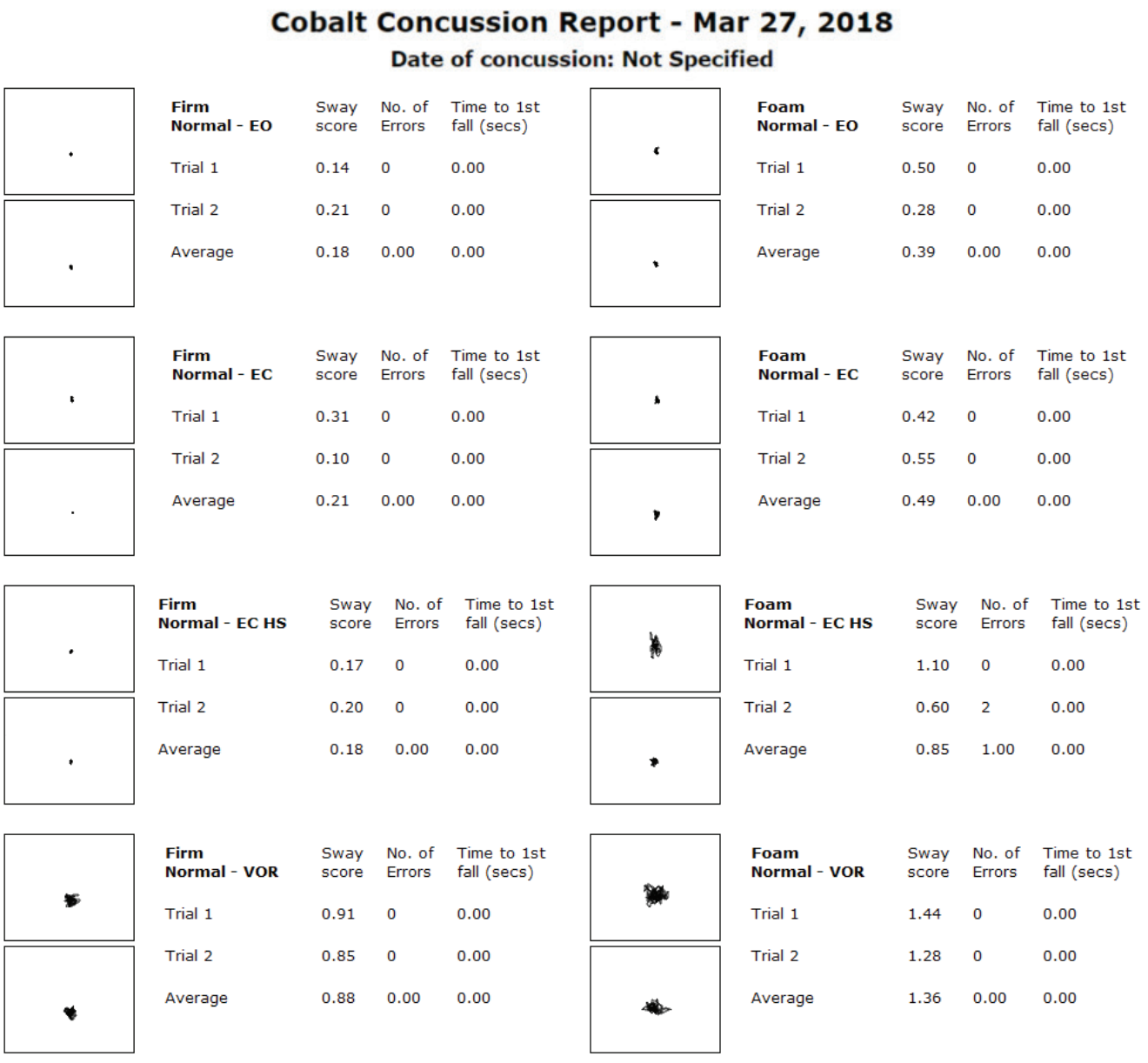
- Center of Pressure trace
- Sway Score
  - An objective assessment of COP movement during the trial.
- # of errors
  - How many times the patient moved out of the test position.
- Time to first error
- Red/Green Bars: Results falling outside of the normal values will be represented by solid red bars, whereas results falling inside of the normal values will be represented by solid green bars.

Reports:

- Summary Reports
  - Summary of patient's performance during one trial or trial series.
    - Report containing the COP traces, sway score, number of errors, and time until the first error for each trial.
    - Viewed from the patient's timeline. An example Single Day Summary Report is included on the following page.
- Progress Reports
  - Summary of patient's performance for a series of trials conducted at different times.

- To view progress reports, click the information icon *i* in the patient's timeline.
- A drop-down menu will appear and list the available progress reports.
- The progress a patient makes on a report is given with progress reports that chart their performance scores over time.

- Printing/Saving
  - Select the desired protocol report from the patient's timeline.
  - While viewing the report, select the printer icon to either save a PDF file or print to a regular printer.



Cobalt Concussion Report - Mar 27, 2018

Date of concussion: Not Specified

Firm Normal - EO	Sway score	No. of Errors	Time to 1st fall (secs)
Trial 1	0.14	0	0.00
Trial 2	0.21	0	0.00
Average	0.18	0.00	0.00

Foam Normal - EO	Sway score	No. of Errors	Time to 1st fall (secs)
Trial 1	0.50	0	0.00
Trial 2	0.28	0	0.00
Average	0.39	0.00	0.00

Firm Normal - EC	Sway score	No. of Errors	Time to 1st fall (secs)
Trial 1	0.31	0	0.00
Trial 2	0.10	0	0.00
Average	0.21	0.00	0.00

Foam Normal - EC	Sway score	No. of Errors	Time to 1st fall (secs)
Trial 1	0.42	0	0.00
Trial 2	0.55	0	0.00
Average	0.49	0.00	0.00

Firm Normal - EC HS	Sway score	No. of Errors	Time to 1st fall (secs)
Trial 1	0.17	0	0.00
Trial 2	0.20	0	0.00
Average	0.18	0.00	0.00

Foam Normal - EC HS	Sway score	No. of Errors	Time to 1st fall (secs)
Trial 1	1.10	0	0.00
Trial 2	0.60	2	0.00
Average	0.85	1.00	0.00

Firm Normal - VOR	Sway score	No. of Errors	Time to 1st fall (secs)
Trial 1	0.91	0	0.00
Trial 2	0.85	0	0.00
Average	0.88	0.00	0.00

Foam Normal - VOR	Sway score	No. of Errors	Time to 1st fall (secs)
Trial 1	1.44	0	0.00
Trial 2	1.28	0	0.00
Average	1.36	0.00	0.00

Figure 109: COBALT Report Information.

Instrumented Balance Error Scoring System (iBESS)

Developed by researchers and clinicians at the University of North Carolina's Sports Medicine Research Laboratory, Chapel Hill, NC 27599-8700

IMPORTANT! - Please make sure you are in a position to help the patient if they begin to lose their balance, as the clinician is responsible for the safety of himself or herself, the patient, others in the surrounding area, and the equipment.

Compatible Packages:

Bertec® Balance Advantage® Essential and Sport packages.

Goal:

The iBESS test provides clinicians with a quick and easy assessment tool for the objective evaluation of static postural stability. This assessment is a common component of concussion management systems.



Figure 113: iBESS Icon.

Protocol:

Patients will be asked to stand directly on the balance plate and on top of the foam surface throughout the evaluation. A total of eight trials will be collected with each trial lasting twenty seconds. Data collection for each trial is initiated at the discretion of the operator. Throughout the duration of the trial, the operator will look for and record specific patient errors.

Patient Instructions:

Patients are instructed to stand still with their eyes open and with their hands placed on their hips. Shoes and any athletic taping should be removed prior to the start of the evaluation; socks may be worn if the patient wishes to wear them.
Patient errors include:

- Moving hands off of hips.
- Opening eyes.
- Step, stumble, or fall.
- Abduction or flexion of the hip beyond 30 degrees.
- Lifting forefoot or heel off of the testing surface.
- Remaining out of the proper testing position for greater than 5 seconds.

Protocol Performance:

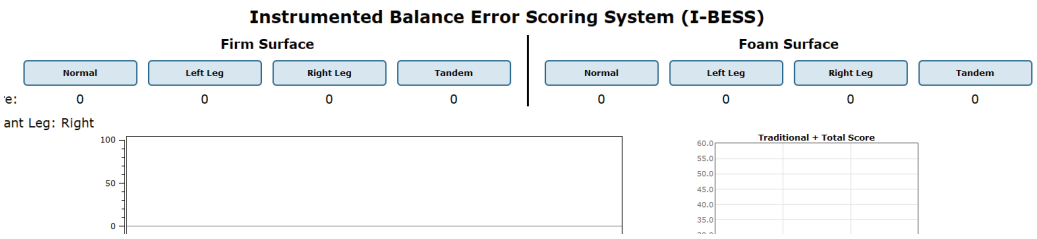


Figure 114: iBESS Main Clinician Screen.

Double Leg Stance – Eyes Closed

- Patient is instructed to stand still with their feet together (touching), hands placed on their hips, and eyes closed (the clinician should demonstrate the correct position).
- After instructing the patient on what he or she needs to do, the clinician will begin the trial.
- Any time the patient performs an error, the clinician will click button 1 or 2 on the wireless remote.

Tandem Stance – Eyes Closed

- The patient is instructed to stand heel-to-toe with their non-dominant foot in back, with weight evenly distributed between both feet.
- The patient also is instructed to stand with their hands on their hips and with their eyes closed.
- Errors are recorded by the clinician as before.

Tandem Stance – Eyes Closed on Foam

- Performed exactly the same as the first Double Leg Stance trial.

Single Leg Stance, Right – Eyes Closed

- Patient is instructed to stand still on their right leg with their hands on their hips and eyes closed.
- Errors are recorded by the clinician as before.

Single Leg Stance, Left – Eyes Closed

- Patient is instructed to stand still on their left leg with their hands on their hips and eyes closed.
- Errors are recorded by the clinician as before.

Double Leg Stance – Eyes Closed on Foam

- Performed exactly the same as the first Double Leg Stance trial.

Single Leg Stance, Right – Eyes Closed on Foam

- Performed exactly the same as the first Single Leg Stance trial - Right trial.

Single Leg Stance, Left – Eyes Closed on Foam

- Performed exactly the same as the first Single Leg Stance trial - Left trial.

Test Completion Protocol:

- At the completion of the task(s), the test may be closed or the next test may be initiated.
- It is recommended that final comments are added at this time.
- Click on a test in the list (i.e. Eyes Open, Fixed VR) to perform it.

Test Analysis:

The report will present the following:

- The Center of Gravity tracing for each traverse.
- Red/Green Bars: Results falling outside of the normal values will be represented by solid red bars, whereas results falling inside of the normal values will be represented by solid green bars.

Reports:

- Summary Reports
  - Summary of patient's performance during one trial or trial series.
    - A graphic depiction of each of the three areas of analysis with numeric data given above each bar in the bar graphs.
    - The Center of Gravity tracing for each traverse is given.
    - Scores are compared to age-matched normative data.
    - Test comments (if entered) are available for inclusion in the report. Additional test comments may also be added.
- Progress Reports
  - Summary of patient's performance for a series of trials conducted at different times.
    - To view progress reports, click the information icon *i* in the patient's timeline.
    - A drop-down menu will appear and list the available progress reports.
    - The progress a patient makes on a report is given with progress reports that chart their performance scores over time.
- Printing/Saving
  - Select the desired protocol report from the patient's timeline.
  - While viewing the report, select the printer icon to either save a PDF file or print to a regular printer.

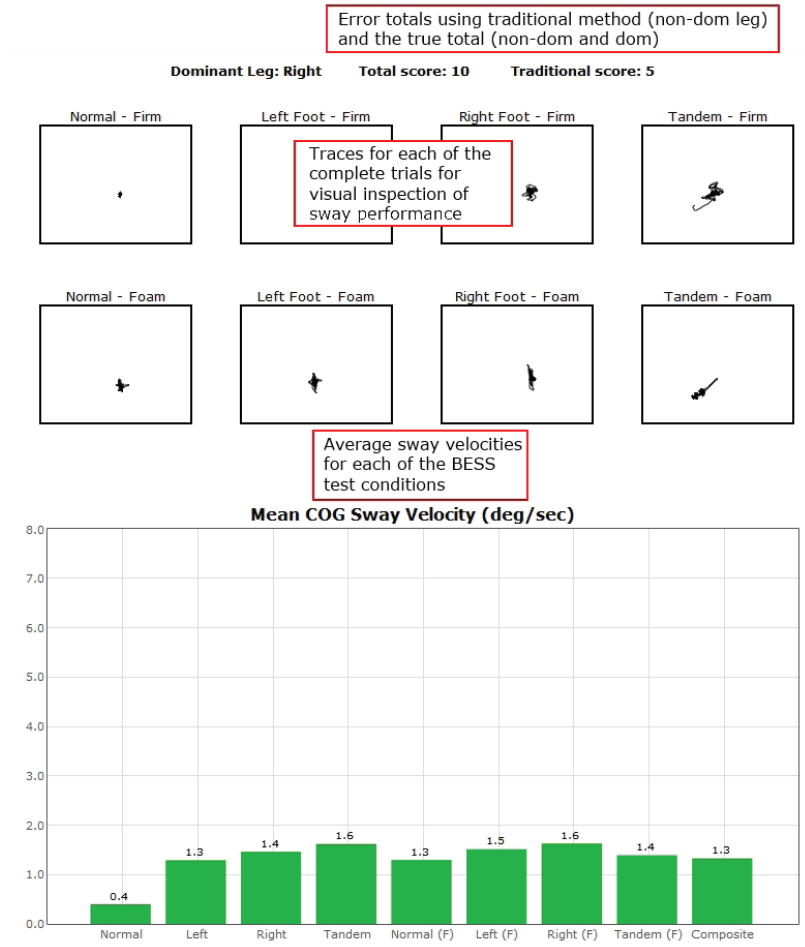


Figure 115: iBESS Report Information.

Training

A wide variety of balance training exercises are available on each balance plate package. All of the systems implement versions of Seated, Weight Shifting, Mobility, Closed Chain, and Quick training. Due to the smaller size of the Essential balance plates, their trainings are limited to exercises that require no lunges, successive stepping, or stepping onto or over obstacles. For these types of trainings, the Functional System offers the greatest flexibility and number of exercises.

Setting up a Training Session

Training screen templates are designed to be easy to use. To begin setting up a training session, follow these steps from the BBA program:

1. First, make sure the correct patient is selected from the patient list.
2. Next, select the *Training* tab, located across the top of the screen. This will open the view where all trainings can be found.
3. Trainings are ordered by 5 categories which appear across the top of the screen.
    - Closed Chain
    - Mobility
    - Quick Training
    - Seated
    - Weight Shifting
4. Select the appropriate training category from the categories across the top. Additional options may appear, such as direction for Weight Shifting, desired joint for Closed Chain, and type of Mobility training.
5. Once a training exercise group has been selected, icons representing the specific training will appear.
6. From the group of training icons now present on the screen, click and drag the desired training icon to the left side of the screen and drop it into the “Series of Tests to perform” box.
7. Note: Only one instance of each training module may be loaded in to a test series.
8. The specified training will then appear in the list.
9. Any options for the selected trainings will appear in the box titled “Test Options,” below the list of trainings to perform.
10. Some trainings require an initial test option to be selected before the test series can be started. Required options are highlighted in yellow.

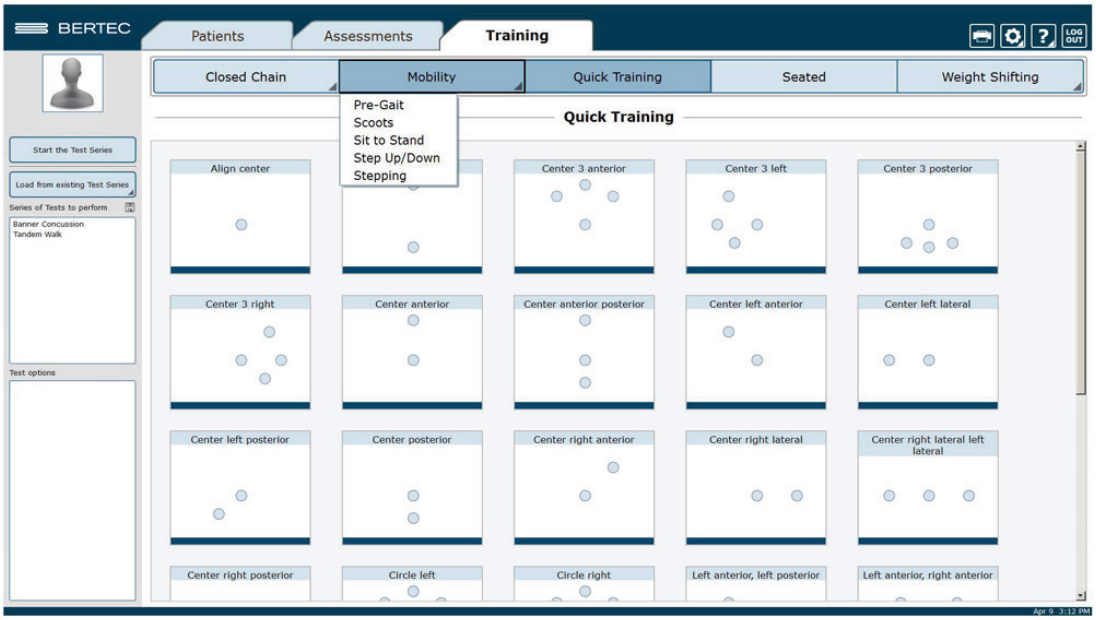


Figure 116: Training Tab Main View. Note the additional options for Mobility training.

Training/Test Options:

Additional Training options allow for the training conditions to be tailored to a patient's needs. Possible options are included below.

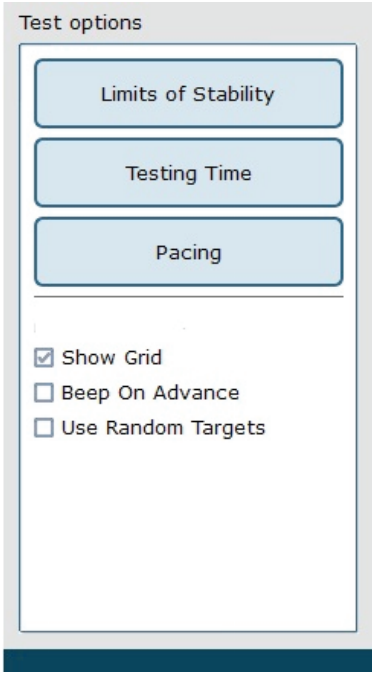


Figure 117: Test Options.

Accessories

The following accessories are available for many of the exercises.

- 4", 8" and 12" blocks
- Foam Block
- Rocker Board
- Swiss Ball

Left/Right + Percentage Weight Bearing

Closed Chain exercises for the Ankle, Knee, and Hip focus on the left or right leg. The Percent Weight Bearing appears in the same options box. Example: Left 30%.

Limits of Stability (LOS)

The patient may progress from 25% through 100% for additional levels of difficulty. Changing the percent of difficulty adjusts how far a patient must move to reach a target.

Training Time

The available time ranges from 1 minute through 10 minutes. Each individual exercise may have a specific time limit. If the "save all raw data" configuration option is checked, a warning message will appear in this window reminding the user that all data is being saved and that this option will accelerate the database's enlargement.

Pacing

Pacing ranges from 1 second through 15 seconds.

- On Demand: The target will move from one target to the next as each target is reached.
- Random Pacing: The target will move within a preselected range of time from 1 second through 15 seconds.
- No Pacing: The target will be stationary. The patient may be verbally instructed to make the changes between the targets or other stimuli may be used to instruct the patient to move between the targets. No compliance score is generated in this format.

Show Grid

The grid will display the LOS ellipse at the selected percentage of the theoretical maximum.

Beep on Advance

An audio indicator will be provided when the target is advanced. If this box is left unchecked, there will be no audio indicator.

Random Targets

A greater degree of difficulty is possible when the patient is unable to anticipate the location of the next target. To provide a greater degree of difficulty, check this box.

Stride Length

The Stride Length may be selected in several training exercises involving stepping. The adjustment of the level of difficulty is based on the stride length selection: Small, Medium or Large.

Saving, Loading, and Viewing a Training Report

Saving: any list of trainings that has been selected may be saved for use with multiple patients.

To save the list:

> Select the trainings by placing them in the left column.
> Set the options for each of the training exercises.
> Select the save icon  and provide the list with a unique name.

Selecting a Saved List:

> Select the Training Tab.
> Select Load from existing Test Series.
> Add the series to use.

To View a Saved List:

> Click on the *i* icon from the clinician home screen. If applicable, a list of previous training reports will be listed.

Compliance Score

Compliance Score: a means of tracking the patient performance and progress based on the following calculations.

> Specified Pacing exercises: a representation of the percentage of targets that were successfully reached during the training exercise. Example: if the pacing was set to 2 seconds and the training time is set to 1 minute, the target switches a total of 30 times. If the patient reaches the target 19 times within the 1 minute, the score of 63.3% is attained.

> No Pacing:
  - Single Target: The compliance score is given as a percentage of how long the patient is able to stay within the target.
  - Multiple targets: No compliance score is available.

> On Demand: As there is no pacing time selected and the movement from target to target is patient-initiated, the transition time is averaged and compiled as the compliance score.

Visual Training Options

The Bertec Prime IVR system includes an immersive dome. Additional visual options to display in the dome are available for trainings. This allows the user to vary the difficulty of the training selected.

Camera Gain

Controls how much the virtual environment rotates while performing a training protocol.

- A setting of 0 means the environment is stationary.
- A setting of 2 rotates the environment twice the amount the patient is leaning.
- A setting of -2 rotates the environment twice the amount the patient is leaning (but in the opposite direction).

Scene

Allows the user to select which scene to use for the specific training currently selected. The scenes that can be used as a background with most training modules are included in Figures 118, 119, and 120.

Scenes that can be used as a background with most training modules are included in Figures 118 and 119.

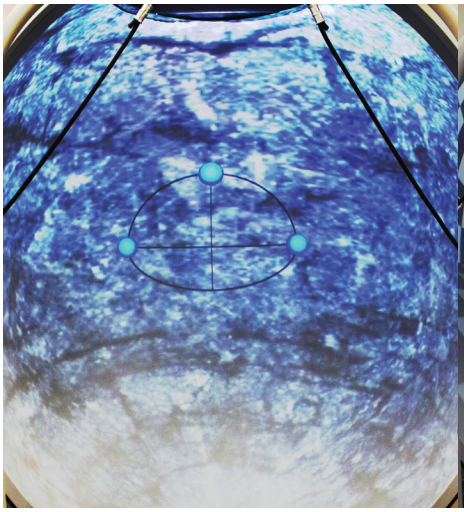


Figure 118: Rock Wall



Figure 119: Checkered Room



Figure 120: Optokinetics Flow

Movement Gain or Force Gain

Controls how much the COG cursor moves based on the patient's actual COG.

- A setting of 1 means the on-screen COG will move at the same rate as the patient's actual COG
- A setting of 2 means the on-screen COG will move at twice the rate of the patient's actual COG
- A setting of 0.5 means the on-screen COG will move at half the rate of the patient's actual COG

IVR Training Modules

The Bertec Prime IVR system includes an immersive dome. Additional vision training modules are available for this system.



Figure 121: Castle Scene

Vision

Castle Scene

Visual training designed to help the patient adapt to visual stimulus during balance training exercises.

- Goal: Based on clinician's preference, the goal is for the patient to hit or miss all the monster targets using the COG cursor.
- mStroop Test: During training, a word will flash for the patient to recognize one of two things; the color or the text. The clinician will then assess and record whether the patient's response was correct.

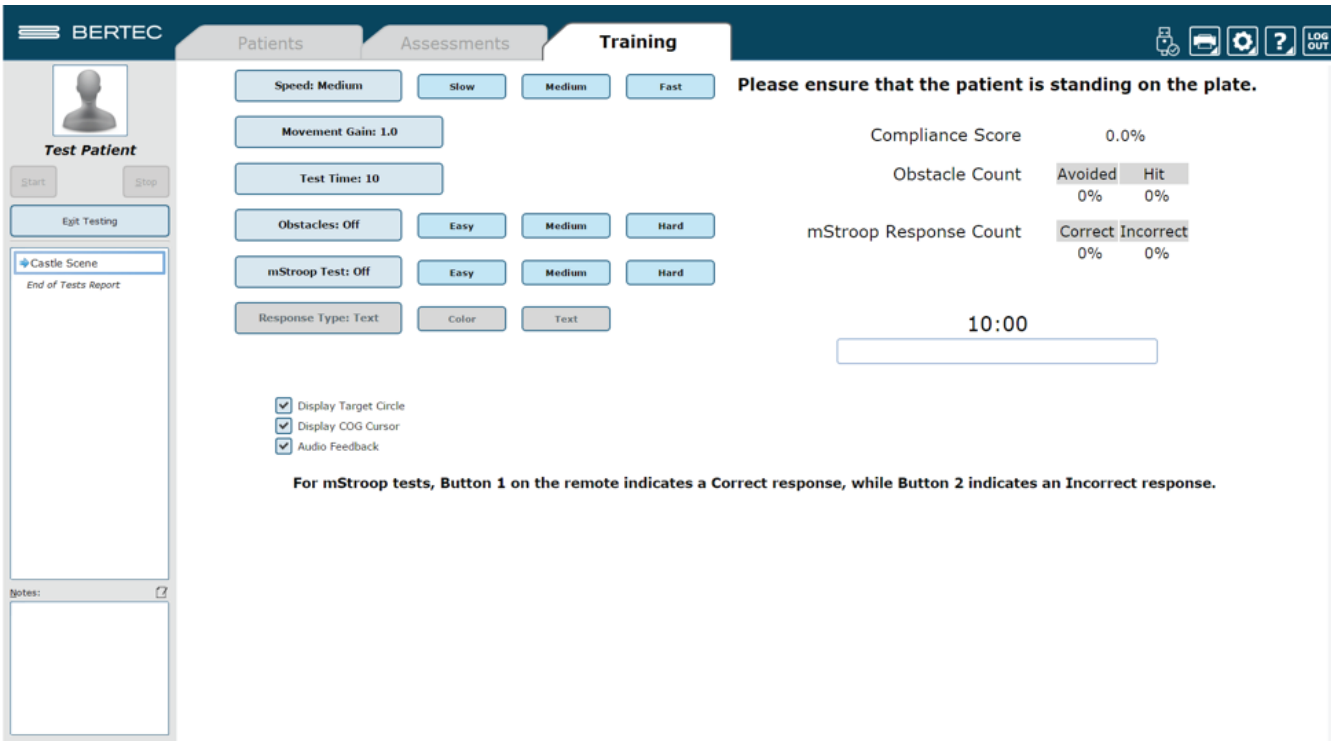


Figure 122: Castle Scene options

Flight

Visual training designed to help the patient adapt to visual stimulus during balance exercises.

> Goal: The patient should use their center of gravity to fly the plane through the golden rings.



Figure 123: Flight.

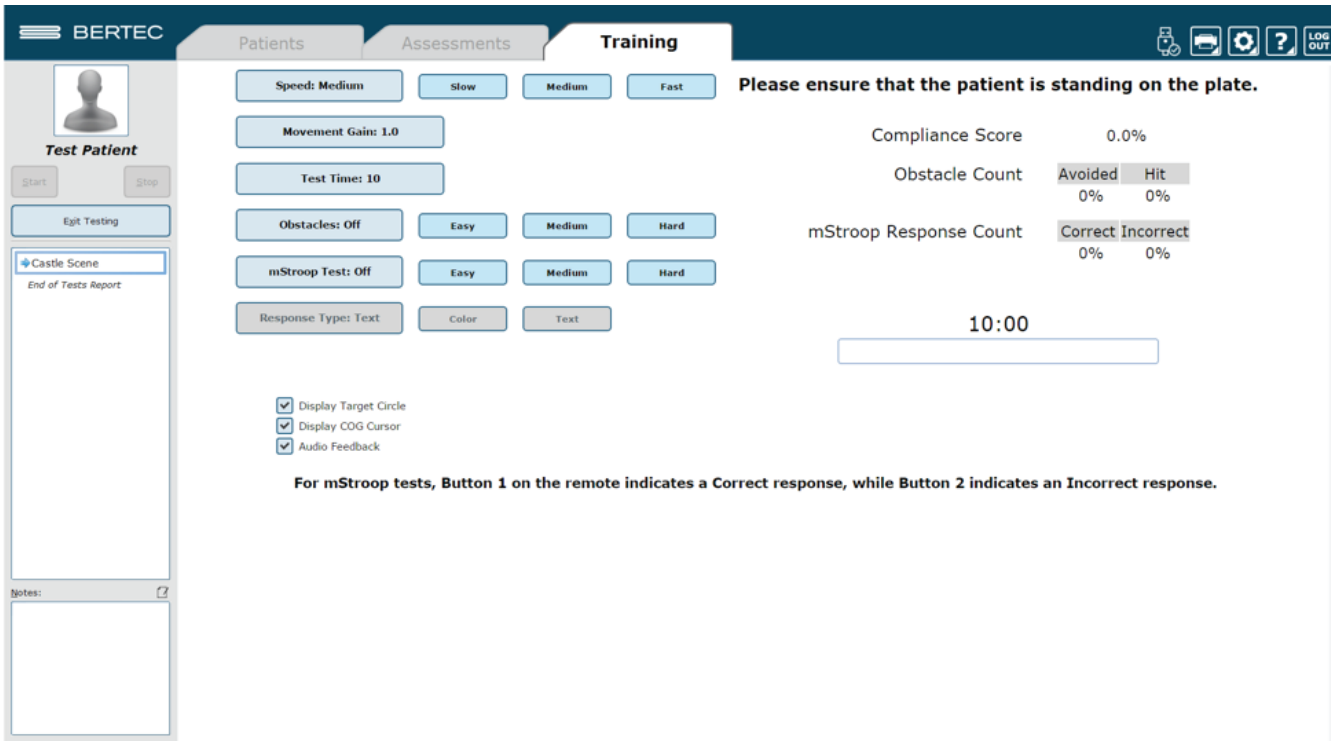


Figure 124: Flight Options

Grocery Aisle

Visual Scene designed to help the patient adapt to visual stimulus during balance exercises.

> Goal: The patient should use their COG to maintain balance and shift around the box targets if/when they approach.

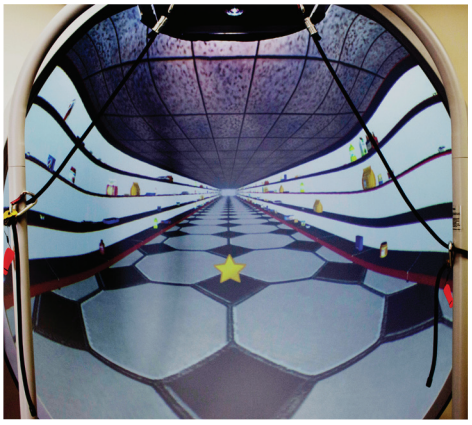


Figure 125: Visual Flow - Grocery.



Figure 126: Grocery Options

Optokinetic Flow and Infinite Tunnel

Visual scenes designed to help the patient adapt to visual stimulus during balance exercises.

> Goal: The patient should maintain balance while immersed in the scene.

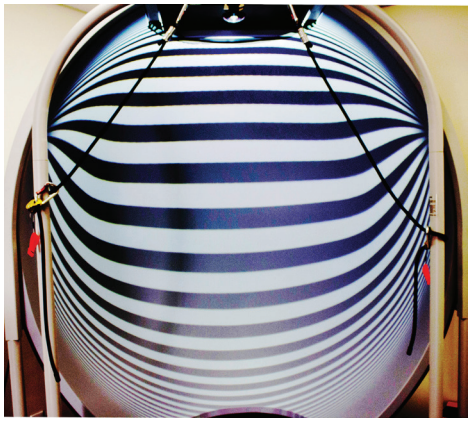


Figure 127: Optokinetic Flow



Figure 128: Optokinetic Flow options

Balance and Mobility Training

Quick Training

Training Exercises designed to quickly and easily meet the basic needs of training.

- Accessories: None
- Goal: Quick and easy access to basic training exercises
- Static Systems: All
- Sub-categories: None

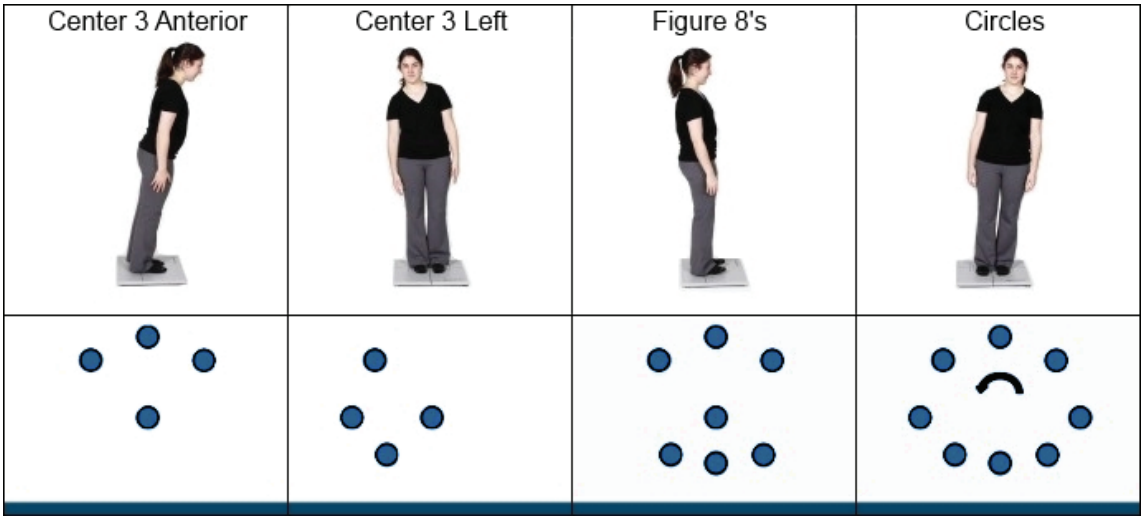


Figure 131: Examples of Quick Training.

Weight Shifting

Directional movements in the four cardinal directions (Forward, Backward, Left or Right)

- Accessories: Foam, Wooden blocks, Rocker Board
- Goal: Challenge the direction and distance of voluntary movement
- Static Systems: All
- Sub-categories: Forward, Backward, Left, Right

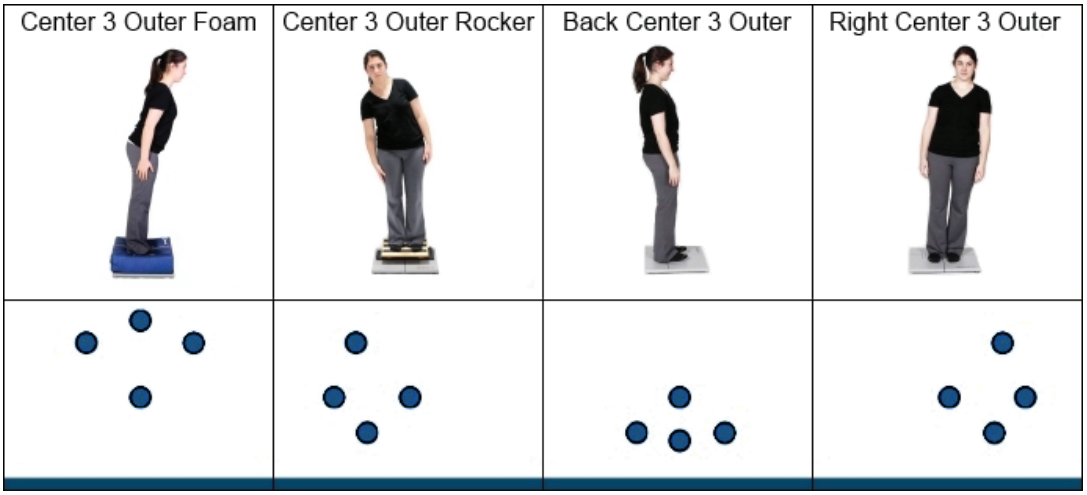


Figure 126: Examples of Weight Shifting Training.

Seated Training

Training performed in a seated position

- Accessories: Foam, Wooden blocks, Rocker Board
- Goal: Coordinate core stability, pre-ambulatory activities
- Static Systems: All
- Sub-categories: None, but generally broken down into Center Holds, Weight Shifts, Circles, Trunk Rotations, and Marching



Figure 124: Examples of Seated Training.

Mobility Training

Training activities from seated through full stepping motion

- Accessories: Foam, Wooden blocks, Rocker Board
- Goal: Coordination of the Sit to Stand movement, the initiation through the proficiency of daily living mobility activities
- Static Systems: Full Mobility Exercise Protocols are available on the Functional System, a selection of Mobility Exercise Protocols is available on the Static Systems
- Sub-categories: Scoots, Sit to Stand, Stepping, Step Up/Down

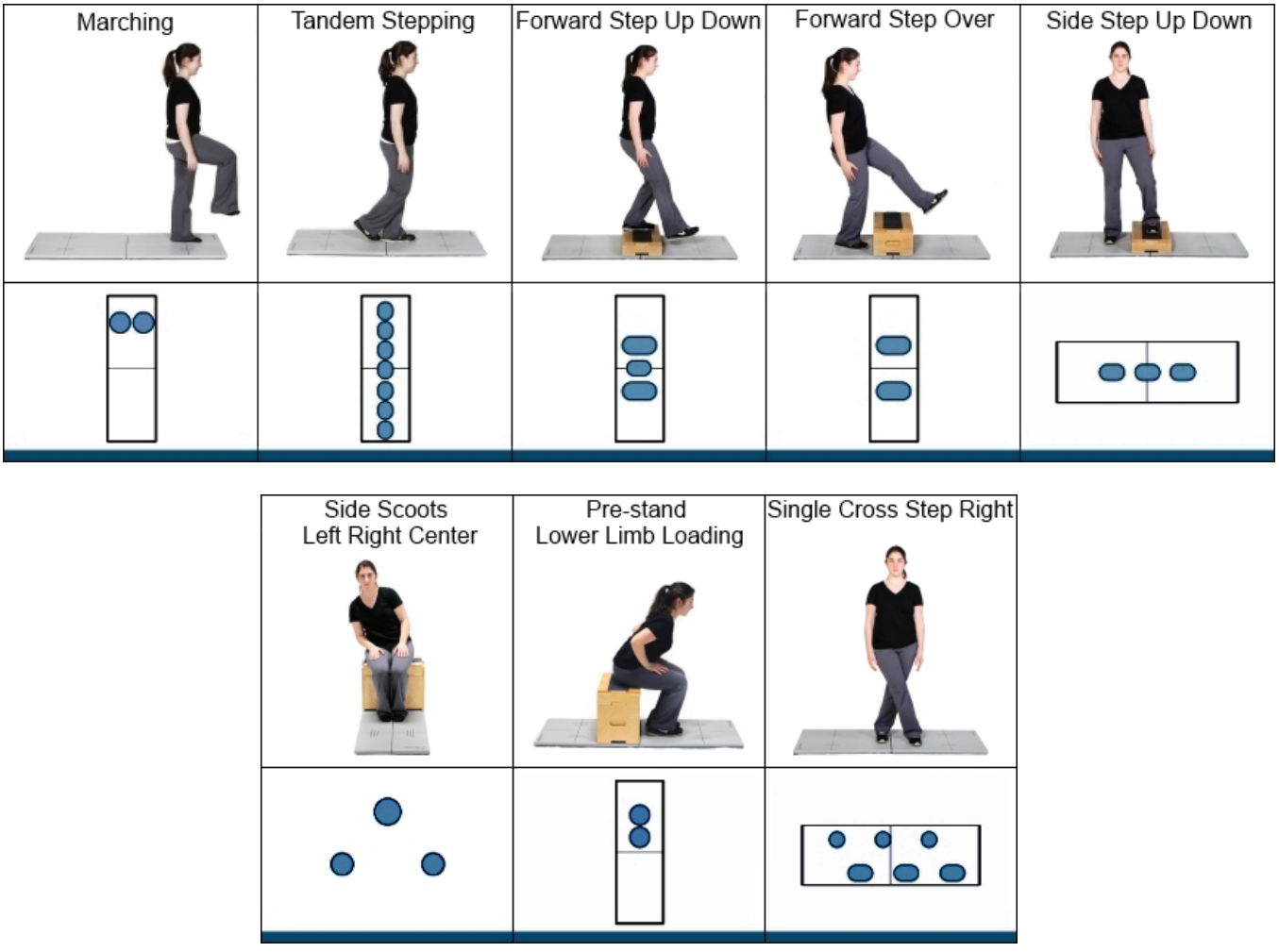


Figure 125: Examples of Mobility Training.

Closed Chain Training

Training Exercises specific to Ankle, Knee, Hip and Back weight bearing protocol

- Accessories: Foam, Wooden blocks, Rocker Board
- Goal: Increasing the Range of Motion and weight bearing capacity of selected area
- Static Systems: Full Closed Chain Exercise Protocols are available on the Functional System. A selection of Closed Chain Exercise Protocols is available on the Static Systems.
- Sub-categories: Ankle, Knee, Hip, Back

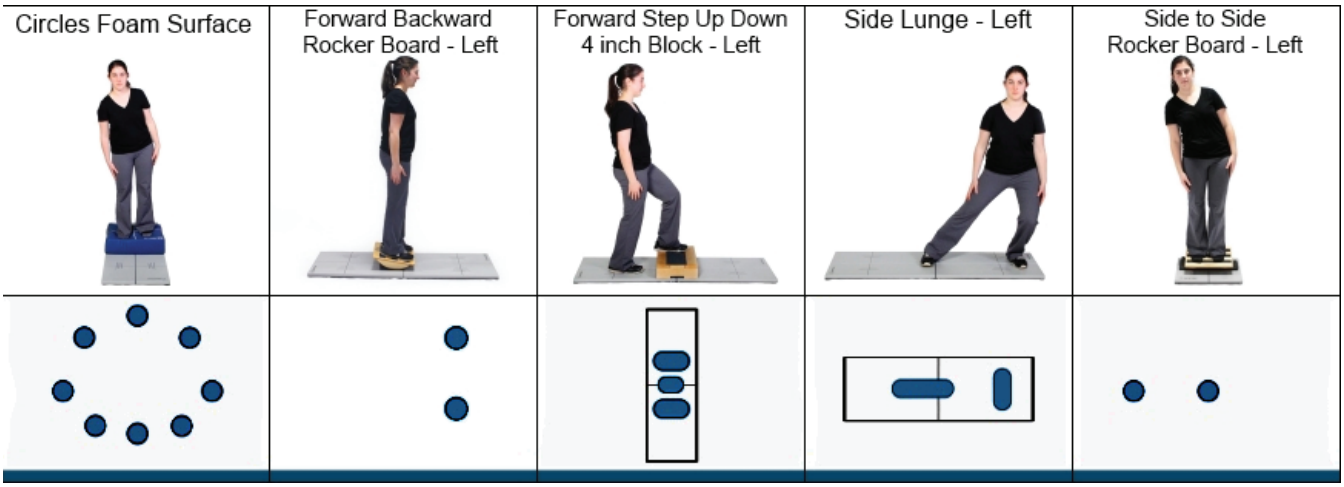


Figure 127: Examples of Ankle Training.

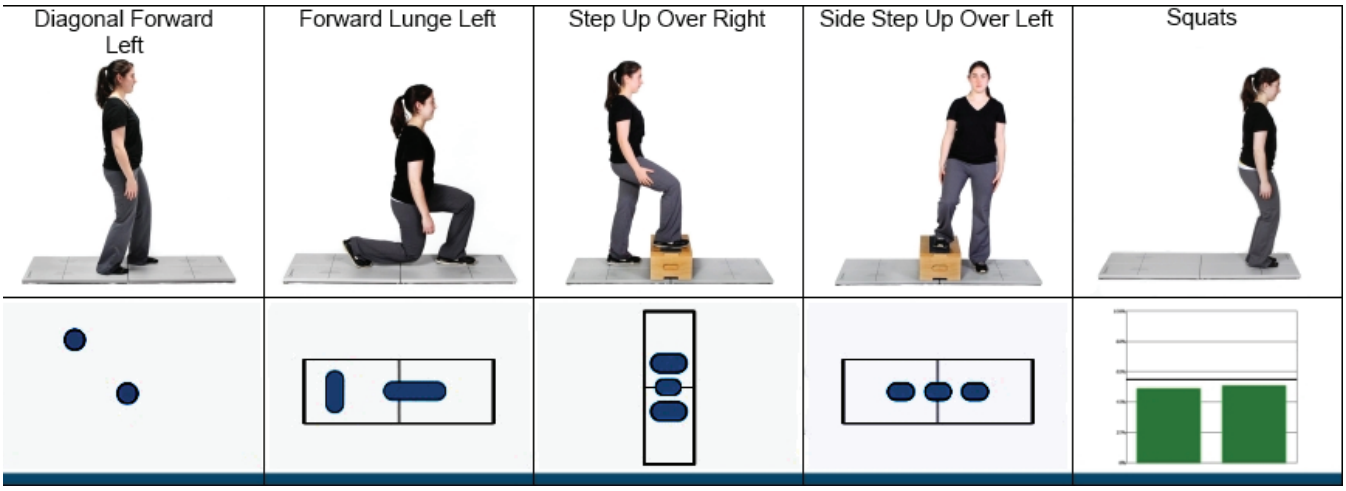


Figure 128: Examples of Knee Training.

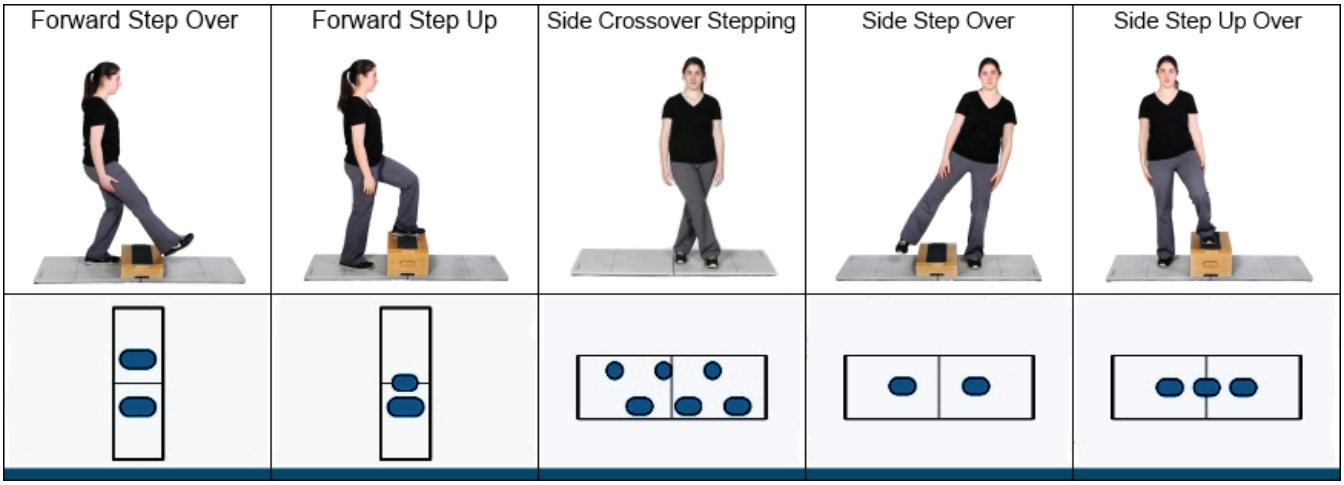


Figure 129: Examples of Hip Training.

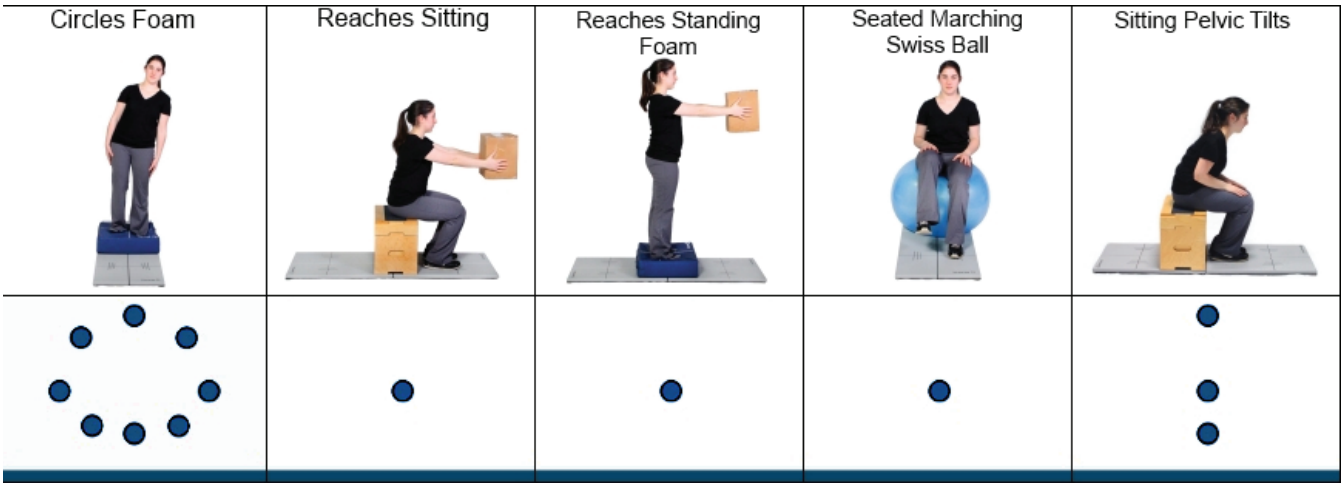


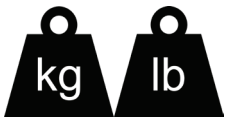
Figure 130: Examples of Back Training.

Bertec Balance Advantage Static System Safety

This guide contains information, cautions, and warnings which must be followee to ensure the safe performance of the static systems. Local government rules and regulations, if applicable, should be followed at all times.

Symbols Used

Symbol	Description
	Carefully read these instructions prior to use
	Caution
	Mandatory action
	High Voltage
	Power on
	Power off
	Earth (Ground)
	Alternating current
	Fuse
	Type BF Applied Part
	Complies with Medical Devices Directive 93/42/EEC and RoHS Directive (2011/65/EC)

Symbol	Description
	Electronic equipment covered by the Directive 2002/96/EC on waste electrical and electronic equipment (WEEE). All electrical and electrical products, batteries, and accumulators must be taken to separate collection at the end of their working life. The requirement applies in the European Union. Do not dispose of these products as unsorted municipal waste. You can return your device to Bertec or to any Bertec supplier. you can also contact you local authorities for advice on disposal.
	Your remote has been programmed to work with a static system.
	Your remote has been programmed to work with a dynamic system.
	Your remote has been programmed to work with Bertec Vision Advantage (BVA).
	Catalog Number (used in compliance with ISO 15223-1)
	Serial Number (used in accordance with ISO 15223-1)
	Authorized EC Representative in the European Community (used in accordance with ISO 15223-1)
	Consult Instructions For Use (used in accordance with IEC 60601-1)
	Indicates device manufacturer Includes name and address of the manufacturer (used in accordance with ISO 15223-1)
	Manufacturer build date (used in accordance with ISO 15223-1)
	Direct Current (used in accordance with IEC 60601-1)
	ON/OFF (Power/Stand-by) (used in accordance with IEC 60601-1)
	Equipment Safe Working Load XXX indicates specific weight (used in accordance with IEC 60601-1, Cl. 7.2.21)

Warning Notes

Bertec Balance Advantage products are not designed to be used in conjunction with any devices not approved by Bertec. All parts of the Bertec Balance Advantage system packages represented here are suitable for use within the patient environment.

Note 1 WARNING: Federal law restricts this device to sale or on the order of a medical practitioner. When pre scribed for therapeutic purpose, a physician should clearly define the parameters of use (i.e. total work, maximum heart rate, etc.) to reduce the risk of patient injury.

Note 2 Thoroughly read this user manual before using your Bertec® system. Failing to read the instructions prior to use may result in following improper test procedures, affecting test results.

Note 3 The BBA system should only be used as specified in the user manual.

Note 4 A gait belt must be worn by the subject at all times when they are completing a protocol on the BBA Prime IVR system. Proper use of the gait belt should be achieved using industry standard practices.

Note 5 Only use approved power supplies.

Note 6 WARNING: To avoid risk of electrical shock, BBA systems must only be connected to properly grounded power sources, such as the provided patient isolation transformer, as appropiate for your product. Only items that have been specified as part of the system, or compatible with the system, shall be connected.

Note 7 Use biocompatible foot covers with the system. Foot covers are single use and should be discarded after each patient.

Note 8 Ensure children are supervised around equipment and that unused receptacles are covered in pediatric enviornments.

Note 9 None of the Bertec system parts are user servicable. For the sake of safety, and in order not to void the warranty, the system should only be serviced by authorized service personel. In case of defects, please make a detailed description of the defect(s) and contact your supplier. Do not use a defective device.

Note 10 Keep Bertec Balance Advantage systems away from liquids. Do not allow moisture inside the device.

Note 11 Do not use the device in the presence of flammable anaesthetics (gases).

Note 12 No parts may be eaten, burnt, or in any way used for purposes other than posturography and balance test- ing.

Note 13 Bertec Balance Advantage Static Systems can be disposed of as normal electronic waste, according to local regulations.

Note 14 To comply with EN 60601-1-1, the computer, printer, etc. must be connected to the isolation transformer.

Note 15 Installation of any third party software (application, programs, or utilities) other than those specified by Bertec can compromise the safety of effectiveness of the system.

Note 16 The device is disconnected from the mains by pulling the plug from the wall outlet.

Note 17 The isolation transformer should be plugged into an outlet. Extenstion cords or power strips (MSPO) other than those provided with the system, should not be used in combination with the isolation transformer. Multiple-socket outlets that are provided as part of the system shall not be placed on the floor. The maxi mum load for the power strip provided with the system is 125V, 15A.

Note 18 Only the projector power supply, laptop/computer power supply, and printer power supply should be connected to the isolation transformer. Do not connect any other devices to the isolation transformer. Connecting other devices to the isolation transformer can overdrive the isolation transformer resulting in a blown fuse or damaging the isolation transformer beyond repair.

Note 19 Do not connect the Static Systems directly to the wall outlets. By not using the isolation transformer supplied, you put the patient and operator at risk to be exposed to power surges or electrical shock.

Note 20 The Static Systems need 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. The Static Systems may be interfered with by other equipment with CISPR emission requirements.

Note 21 The use of accessories and cables other than those specified in the Accessories List may result in increased emissions or decreased immunity of the system.

Note 22 The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals. If it is used in a residential enviornment (for which CISPR II class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take miti gation measures, such as reloacting or re-orienting the equipment.

Note 23 WARNING: No additional networking/data coupling is to be made outside of what has been designed for the Bertec Balance Advantage Dynamic System. According to IEC 60601-1 standards, this system will only be connected wirelessly to the internet. If your facility is a hospital or university setting, please contact Bertec support to discuss your specific enviornment and conditions so that we may provide the best solution for syncing databases.

Note 24 Prime IVR(TM) and static system balance plates are intended to only be connected to the specified com puter, which has been tested as part of the ME Equipment.

Responsibility of the Manufacturer

The manufacturer is to be considered responsible for the effects on safety, reliability, and performance of the equipment only if:

- All assembly operations, extensions, re-adjustments, modifications, or repairs are carried out by the equipment manufacturer or personel authorized by the manufacturer.
- The electrical installation to which the equipment is connected complies with EN/IEC requirements.
- The equipment is used in accordance with the instructions for use.

The manufacturer reserves the right to disclaim all responsibility for the operating safety, reliability, and performance of equipment serviced or repaired by other parties.

Operating Enviornment

These systems are suitable for use in the patient enviornment.
Temperature: +15° C to +35° C (+59° F to +95° F)
Rel. Humidity: 30 to 90%, non-condensing
Air Pressure: 600 hPa to 1060 hPa
Operations at temperatures below -20° C (-4° F) or above +60° C (+140° F) may cause damage

Isolation Transformer

Powertronix Isolation Station AC/DC Adapter
Input Voltage: 115(120)/ 230 (240) VAC - 50/60Hz
Input Current: 2.7A / 1.35A
Leakage Current: < 100-A
Output Voltage: 115 (120) / 230 (240) VAC
Output Current: 2.6A / 1.3A
Receptacle: IEC 320

Operating Mode

Warm-up time: <5 minutes
Mode of Operation: Continuous

Storage and Handling

Temperature: -20° C (-4° F) or above +60° C (+140° F)
Rel. Humidity: <90%, non-condensing
Air Pressure: 500 hPa to 1060 hPa

Standards

Safety: IEC 60601-1, Class I, Type BF, IPXO
System: IEC 60601-1
EMC: IEC 60601-1-2

Input Voltage Configuration

Configured at factory

Input (50/60 Hz)	Output
100 -120 VAC	120 VAC
220 - 240 VAC	120 VAC

⚠ Warning: Check input voltage before starting system

Guidance and Manufacturer's Declaration Tables

Bertec Balance Advantage Static Systems are part of a medical electrical system and is this subject to special safety precautions. For this reason, the installation and operating instructions provided in this document should be followed closely.

Guidance and manufacturer's declaration - electromagnetic emissions for all equipment and systems		
Bertec Balance Advantage Static Systems are intended for use in the electromagnetic environment specified below. The user of Static Systems should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	Bertec Balance Advantage Static Systems use RF energy only for internal functions. Therefore,RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	Bertec Balance Advantage Static Systems are suitable for use in industrial areas and hospitals. If it is used in a residential environment (for which CISPR II class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as reloacting or re-orienting the equipment.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity for all equipment and systems			
Bertec Balance Advantage Static Systems are intended for use in the electromagnetic environment specified below. The user of Static Systems should ensure that it is used in such an environment.			
Emissions Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	+/- 2 kV for power supply lines +/- 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Bertec Static Systems requires continued operation during very long power mains interruptions, it is recommended that the Static systems be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Swept Magnetic Fields per AAMI	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration - electromagnetic immunity - for equipment and systems that are NOT life-supporting			
Bertec Balance Advantage Static Systems are intended for use in the electromagnetic environment specified below. The user of Static Systems should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of Static Systems, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.17 \sqrt{P}$ $d = .5 \sqrt{P}$ (80 MHz to 800 MHz) $d = 1 \sqrt{P}$ (80 MHz to 2.5 GHz) where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (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 this symbol: 
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. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.			

Recommended separation distances between portable and mobile RF communications equipment and Bertec Balance Advantage Static Systems

Bertec Balance Advantage Systems are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Static Systems can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Ststic Systems as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter (m)		
Rated maximum output power of transmitter (W)	**150 kHz to 80 MHz**	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
Rated maximum output power of transmitter (W)	150 kHz to 80 MHz d = 1.17 √P (V1=3)	80 MHz to 800 MHz d = 1.17 √P (E1=7)	800 MHz to 2.5 GHz d = 1 √P (E1=7)
0.01	0.117	0.050	0.10
0.1	0.369	0.158	.316
1	1.167	0.50	1.00
10	3.689	1.58	3.16
100	11.667	5.00	10.00

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: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
Note 3: An additional factor of 10/3 has been incorporated into the formula used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.
Note 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Accessories and Cables

Item	Origin	Termination	No.
Shielded HDMI Cable (15 ft)	Projector	Tower PC	1
AC Power Cable with Ferrite (15 ft)	Projector	UPS	1
USB A to B Cable (10 ft)	Balance Plate	Tower PC/Laptop	1 or 2
USB A to B Cable (10 ft)	Inkjet Printer	Tower PC	1
AC Power Cable (5 ft)	Inkjet Printer	UPS	1
AC Power Cable (10 ft)	Wall Mains	Isolation Transformer	1
AC Power Cable (6 ft)	Tower PC/Laptop	UPS	1
AC Power Cable (6 ft)	Monitor	UPS	1
Cable Bundle - Audio, USB, DVI (6 ft)	Monitor	Tower PC	1

Part Number	Part Name
37P-0082	Projector Replacement Lamp
36P-0147	Remote Control for Projector
37P-0005	22-inch LED Touch Screen Monitor
37P-0019	Ergotron Power Strip, 6 Outlet, 125VAC 15A
37P-0003	Voyageur Complete System PC, Dynamic System
37P-0022	HP Envy 4520 e-All-in-One Printer
37P-0023	Corded Mouse and Keyboard, Logitech
37P-0024	Webcam 500 5MP Camera
80P-0009	Balance Advantage Static User Manual
80P-0001	Balance Advantage Quick Start Guide
20S-0560	Hygenic Foot Covers – 100 Count
37P-0029	SMKlink Wireless Remote
97P-0076	Standard Balance Advantage foam block with Cover
37P-0074	United States - APC Back-UPS Pro 1500VA UPS Battery Backup & Surge Protector (BR1500G)
31P-0139	Powertronix Transformer, Isolation, 115 to 230 VAC, 50/60 Hz, 1000 VA
31P-0140	Powertronix Transformer, Isolation, 115 to 230 VAC, 50/60 Hz, 600 VA
BP5046 Dual	Essential Balance Plate
BP5076 Dual	Functional Balance Plate
02P-0309	BP5076 Indexing Plate
37P-0053	4 Port USB Hub
97P-0031	Wooden Rocker Board for Balance Advantage Systems
97P-0032	Balance Block Set

Appendix A: Abbreviations and Glossary

Acoustic Neuroma: (Also called a vestibular schwannoma) A benign tumor growing on the vestibule-cochlear nerve. As it grows, it compresses the nerve. It may cause hearing loss, tinnitus, dizziness and loss of balance.

Ataxia: Incoordination.

Auditory: Having to do with hearing.

Benign Paroxysmal Positional Vertigo (BPPV): A condition resulting from loose debris (otoconia) that collects within a part of the inner ear. With head movement, the displaced otoconia shift: sending false signals to the brain.

Canalith Repositioning Maneuvers: Treatments intended to move displaced otoconia from the affected semicircular canal to the utricle.

Center of Gravity: Represents the focus of gravitational forces on a person's body, typically located in a standing person at the S1-S2 level, just anterior to the ankle joint.

Center of Gravity Sway Velocity: The total distance traveled by the Center of Gravity divided by the time of the movement.

Cerebellum: Portion of the hindbrain that modulates balance, limb, and eye movement.

Cochlea: The snail shaped portion of the inner ear. The hair cells used in hearing are located here.

Composite Mean Center of Gravity Sway Velocity: The average of the Mean Center of Gravity Sway Velocity scores for all of the conditions, then divided by the number of conditions.

Diplopia: Double vision.

Directional Control: A measurement of how much of the patient's movement was in the target direction.

Disequilibrium: Subjective sense of unsteadiness.

Dizziness: Non-specific term encompassing feelings of imbalance, spinning and lightheadedness.

End Point Excursion: A measurement of how far the patient leans towards the target on his or her first attempt.

End Sway: Measured for Tandem Walk, the amount of sway of the COG at the end of the Tandem Walk trial.

Eustachian tube: The tube that runs from the middle ear to the pharynx. The function of the Eustachian tube is to protect, aerate, and drain the middle ear and mastoid. The Eustachian tube permits the gas pressure in the middle ear cavity to adjust to external air pressure.

Forward Lunge (FL): The assessment quantifies the patient's ability to control body weight while lunging forward with one leg. The patient is instructed to, on command, lunge/step forward onto one leg, then push backward with that leg to the original standing position. The FL measures separately for each leg, the distance of the lunge, as well as the profile of the vertical force exerted by the lunging leg (force impulse) during the landing and push off phases of the maneuver.

Habituation: An acquired tolerance gained by repeated exposure to a particular stimulus.

Imbalance: Observable unsteadiness.

Impact Index: Measured in Step Up/Over as the force of the trailing leg when it strikes the ground on the other side of the block.

Labyrinth: Refers to the inner ear which includes the cochlea and vestibular organs.

Labyrinthitis: An inflammation of the inner ear, which is caused by the spread of bacterial or viral infections from the head or respiratory tract into the inner ear, causing dizziness or feelings of motion sickness caused by disturbance of the sense of balance.

Lateropulsion: Tendency to fall to the side.

Lift-up Index: Force in the climbing leg used to propel the individual up over the block.

Limits of Stability (LOS): The protocol quantifies impairments in ability to intentionally displace the COG to the patient's stability limits without losing balance. The patient performs the task while viewing a real-time display of the COG position in relation to targets placed at the center of the base of support and at the stability limits. For each of eight directions, the test measures movement reaction time, movement velocity, movement distance, and movement directional control.

Mal De Debarquement: The sensation of rocking or movement that persists after a sea cruise or other form of travel.

Maximum Excursion: A measurement of the maximum amount the patient leaned during the trial.

Mean Center of Gravity Sway Velocity: The average of the Center of Gravity Sway Velocity scores from the combined trials in each condition; the sums of the scores are then divided by the number of trials.

Mean Speed: The average forward advancement (measured in inches/sec or centimeters/sec).

Mean Step Length: The distance between successive heel strikes combined and divided by the number of steps (measured in centimeters or inches).

Mean Step Width: Lateral distance between each foot on successive steps combined and divided by the number of steps (Measured in centimeters or inches).

Meniere's Disease: Involves abnormalities of quantity, composition or pressure of endolymph (one of the fluids within the inner ear).

Migraine Associated with Vertigo (MAV): Typically characterized by head pain with symptoms associated with vestibular impairment, such as dizziness, motion intolerance, spontaneous vertigo, sensitivity to light and sound, tinnitus, and spatial disorientation.

Modified Clinical Test of Sensory Interaction on Balance (mCTSIB): A modification of the original CTSIB or "Foam and Dome", the mCTSIB eliminates the "dome" and adds objective analysis of a patient's functional balance control to quantify postural sway velocity. Eyes open firm, eyes closed firm, eyes open foam, and eyes closed foam.

Movement Time: Total time taken to perform the step-up and over assessment, measured from the initial shift to begin the step to when the trailing leg impacts the plate.

Movement Velocity: A measurement, in degrees/second, of the speed at which the patient moved towards the target.

Nystagmus: Beating eye movement that leads to oscillopsia and is indicative of acute vestibular loss or brainstem/cerebellum abnormality.

Optikinetic: Generates eye movements in response to sustained rotations of objects that encompass a large portion of the visual field.

Oscillopsia: Subjective illusion of visual motion.

Otoconia: Calcium carbonate crystals embedded within the maculae within the otolith organs (utricle and saccule).

Ototoxic: Having a harmful effect on the labyrinthine structures.

Peripheral vestibular system: Parts of the inner ear concerned with balance and body orientation; consists of the semicircular canals, utricle, and saccule. Peripheral in this context means outside the central nervous system (brain and brainstem), to which the peripheral system sends information.

Postural Evoked Response (PER): The protocol analyzes responses of the gastrocnemius and tibialis muscles following an unexpected external balance perturbation. The three components are commonly referred to as the short latency (SL), medium latency (ML), and long latency (LL) responses. In patients with prolonged MCT response latencies, the latency information provided by the PER further differentiates between peripheral and central causes. The PER is also indicated in patients with suspected CNS deficits affecting peripheral and/or central sensorimotor pathway innervating the lower extremities.

Pulsion: The feeling of being pulled in a certain direction.

Reaction Time: A measurement, in seconds, of the time taken by the patient to respond to the command to move towards the target.

Rhythmic Weight Shift (RWS): The protocol quantifies the patient's ability to perform rhythmic movements of their COG from left to right and forward to backward at three distinct paces. During performance of each task, the patient views a real-time display of their COG position relative to a target moving at the desired pace and amplitude. For each direction and pace, the RWS measures movement velocity and directional control.

Saccades: Abrupt rapid eye movement of both eyes utilized to change the point of fixation.
Saccule: The saccule is a bed of sensory cells situated in the inner ear. The saccule translates head movements into neural impulses which the brain can interpret. The saccule is sensitive to linear translations of the head, specifically movements up and down (think about moving on an elevator).

Semicircular canals: Circular, fluid filled, ducts within the vestibular organ, responsible for the detection of angular accelerations.

Sit to Stand (STS): The assessment quantifies the patient's ability, on command, to quickly rise from a seated to a standing position. The STS quantifies time required to transfer weight from the buttock to the feet (weight transfer time), the strength of the rise (rising index), the symmetry of the rising effort between the left and right legs (weight symmetry), and the COG sway velocity in the standing position.

Smooth pursuit: Maintains image of a small moving target on the fovea.

Step/Quick Turn (SQT): The assessment quantifies turn performance characteristics. The patient is instructed to take two forward steps on command and then quickly turn 180 degrees to either the left or right and return to the starting point. The SQT enhances commonly used observational tests for turn stability by measuring separately for each direction of turning, the time required to execute the turn, and the velocity of COG sway during the turn.

Step Up/Over (SUO): The assessment quantifies the patient's ability to control their body weight and postural stability while stepping up on and down over a curb. The patient is instructed to step up onto a curb on command with one foot, swing the other foot over the curb while lifting their body through an erect standing position as quickly as possible, and the lower the body weight to land the swing leg as gently as possible. The SUO measures, for each leg, the strength of the rise (lift-up index), the movement time, and the impact of the swing leg landing (impact index).

Tandem Walk (TW): The assessment quantifies the stability and speed of the patient's gait while placing one foot directly in front of the other. The patient is instructed to walk heel to toe from one end of the balance plate to the other as quickly as possible, then stop and wait for the test to come to an end. The TW measures the average width of the patient's steps on the balance plate, the speed of the gait, and the patient's COG sway velocity following termination of the gait.

Tinnitus: A sound in one ear or both ears, such as buzzing, ringing, or whistling, occurring without an external stimulus and usually caused by a specific condition, such as an ear infection, the use of certain drugs, a blocked auditory tube or canal, or a head injury.

Torsion: Rotation of the eye around a roll (anterior-posterior) axis.

Turn Sway: Calculated for the Step Quick Turn assessment. This is the total distance traveled by a patient's center of gravity while making a turn.

Turn Time: Calculated for the Step Quick Turn assessment. Quantifies the time it takes for a person to stop their forward progress, turn, and begin the forward progression back towards the starting position.

Unilateral Stance (US): The assessment quantifies the patient's ability to maintain postural stability while standing on one leg at a time with eyes open and eyes closed. The US enhances the observational testing of single leg stance performance by providing an objective measure of patient sway velocity for each of the four task conditions. The length of each trial is ten seconds.

Vertigo: Dizziness characterized by a sense of spinning.

Vestibular Evoked Myogenic Potential (VEMP): Sound evoked muscle response, provides diagnostic information about the function of the saccule or the inferior vestibular nerve.

Vestibulo-Ocular Reflex (VOR): The reflex that induces eye movements in response to head rotation to keep the eyes fixated at a constant point in space.

Videonystagmography (VNG): Measurement of eye movements with the use of video.

Walk Across (WA): The assessment quantifies the patient's steady gait while walking across the balance plate. The WA enhances observational testing of gait by measuring the average width and length of the patient's steps on the balance plate,

the symmetry of left and right leg step lengths, and the patient's gait speed across the balance plate. Because the length of the balance plate, the test may not be appropriate for highly fit individuals whose stride lengths are greater than five feet.

Walking Mechanics: The manner in which a bipedal human ambulates, quantified through using numerous measures such as stride length and width, joint angles during stride and stance phase of gait, and muscle activation during walking. Sometimes described as "controlled falling," the purpose of walking is to move from one place to the next by displacing the body's center of gravity.

Weight Bearing Squat (WBS): The protocol quantifies the patient's ability to perform squats with knees at neutral and flexed at 30, 60 and 90 degrees, while maintaining equal weight on both legs.

Appendix B: References

[1] *Jacobsin GP, et al (1993). "Posturographic Testing." Handbook of Balance Function Testing 259-334.*

[2] *Branstater M, DeBruin HA, Sahrmann SA (1983). "Himparetic gait: Analysis of temporal variables." Arch Phys Med Rehab 64: 583-587*

Hassid E, et al (1997). "Improved gait symmetry in hemiparetic stroke patients induced during body weight-supported treadmill stepping." J Neuro Rehab 11:21-26.

Holden MK, Gil KM, Magliozi MR (1986). "Gait assessment for neurologically impaired patients. Standards for outcome assessment." Physical Therapy 66: 1530-1539.

J. M. Potter, A. L. Evans, G. DuncanGait speed and activities of daily living function in geriatric patients.Arch Phys Med Rehabil. 1995 Nov; 76(11): 997–999.

[3] *Stump TJ, Cavanaugh JT, Noonan DJ (2000). A comparison of the sensitivity of two separate forward step down test protocols for assessing functional strength deficits in the anterior cruciate ligament insufficient knee. Presented at the American Physical Therapy Association-Combined Sections Meeting, New Orleans, LA.*

Stump TJ, Cavanaugh JT, Noonan DJ (2000). Forward step down test. Presented at the American Physical Therapy Association-Combined Sections Meeting, New Orleans, LA.

[4] *Lockhart T.E. (2002). "Relationship between postural control and slip response among different age groups." Gait & Posture 16: S1 25-26.*

Appendix C: Frequently Asked Questions (FAQs)

Included below are answers to commonly asked questions.

Why use the digital copy of the manual?
Listed below are several reasons to use the digital copy of this manual.

- The digital copy of this manual is searchable. Holding the keyboard's Ctrl key and tapping the F key once will open a search form. Specific words and phrases can be directly identified in this manual through this form.
- The Table of Contents is clickable—clicking on a section will bring a user to that section.
- Reference notes are clickable—clicking a reference note will bring a user to the corresponding citation.
- Images are in color.

What is the default password to the Balance Advantage® program?
The default password is "password". Use all lower-case characters and do not include quotation marks.

How often should I turn off my computer?
The computer system should be turned off every night to promote software longevity and prevent database errors.

How do I export raw data?
Data export may be initiated by holding down the Ctrl+F6 keys on the keyboard while viewing a test report from the *Patients* tab. Refer to page 30 for additional information.

How do I move my setup?
Contact Bertec® Support for assistance.

My how do I fix my database?
Database issues are often caused from incorrectly shutting down a computer. Corrupt/damaged databases are almost always repairable, though. Contact Bertec® Support for assistance.

How do I archive a single set of patient data?
From the clinician home screen, select the patient to archive. Right click on the patient. In the dropdown list, select Create Patient Archive. Select where to save the archive to, then click the Save button.

How do I delete a single set of patient data?
From the clinician home screen, select the patient to delete. Right click on the patient. In the dropdown list, select Mark Patient Deleted. Click Yes to confirm. Deleted patients cannot be recovered.

Appendix D: Passwords and Security

Security Concerns

It is recommended that operators routinely change their Balance Advantage® account's password (i.e. every few months) for security. For an operator to change their own password, follow the steps listed below.

1. Log into the Balance Advantage® software. If the software is not pulled up, refer to page 12 for instructions on how to turn on the computer, load the program, and login.
2. Once logged in, locate and click on the Settings button (located in the upper right corner of the screen).
3. On the dropdown menu that appears, click on the Change Password option.
4. In the new window, type in the current password once and desired new password twice. Be sure the new password is the same in both fields.
5. Click Ok to finalize the password change. If an error message appears, click Ok and correct the new password field (make sure the password is entered in the exact same way both times).



Figure D1: Settings Button.

Forgotten Passwords

If an operator has forgotten a password, a system administrator or manager operator (given the permission to add/edit operators) will need to change the account password. Instructions for administrators/managers with the required permissions are included below.

1. Log into the Balance Advantage® software. If the software is not pulled up, refer to page 12 for instructions on how to turn on the computer, load the program, and login.
2. Once logged in, locate and click on the Settings button (located in the upper right corner of the screen).
3. On the dropdown menu, click on the Configuration option.
4. In the new window, click on the Operators button.
5. Select the affected operator in the list. On the bottom of the window, click on the Edit Operator button.
6. In the new popup window, change the operator's password in the Password and Confirm Password fields. Make sure the fields match.
7. Click Ok on both windows to finish changing the operator's password.

Appendix E: Plate Taring

Bertec® Corporation's balance plates have a reputation for rarely, if ever, requiring re-calibration. The balance plates in the Bertec® Balance Advantage® system perform a self-calibration diagnostic each time the system is turned on. However, the plates cannot be disturbed during this process. If a plate appears to have been disturbed, follow the steps below to restart the plate's self-calibration process.

1. Click on the settings button. (Figure F1)
2. In the dropdown menu, click on the Reset Sensors button, then click OK.
3. If this process does not appear to fix the plate, try again and ensure that there is no weight on the plate.
4. If the plate still does not appear to work or sends an error message, the plate may need to be manually calibrated. Refer to the section immediately below.



Figure F1: Settings Button.

Manual Calibration

If the steps above do not work, manual calibration could be necessary. Please call the customer support line for assistance if the plate is not working properly or has been damaged.

Appendix F: License and Support Features

The Bertec® Balance Advantage® software includes built-in license, support, and help features, all of which can be accessed from the ? symbol (located on the upper right-hand corner of the Clinician Screen, next to the Logout button). Clicking on this symbol will open a list of three to four different options, described in bold on the following pages. Immediately below are the different functions which can be completed from this tab—shown as step-by-step instructions on the following pages.

Functions: Register/Update License, Copy/Paste System Info, Upload System Info to Support, Opt Out of Sending Anonymous Program Reports to Bertec®, Schedule a Remote Support Session, Conduct a Remote Support Session.

About Bertec® Balance Advantage®: This option will open a new window, shown in Figure H1. The new window contains five different tabs: Version, Addons, System, License Agreement, and Support. These tabs are underlined/described below and on the following page.

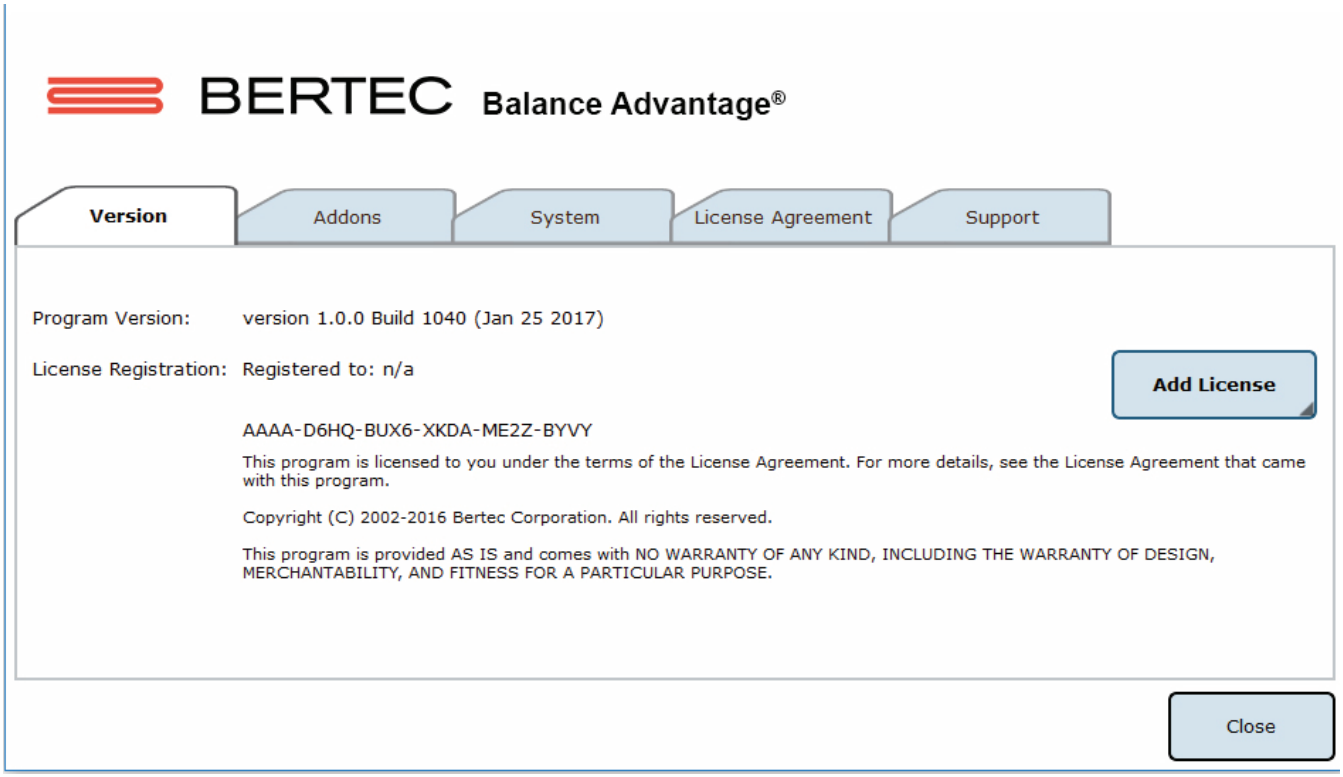


Figure H1: About Window Tabs.

Version: The Version tab displays the program's version, license registration, license number, and an Add License button.

To register or update a license:

1. Click on the Add License button.
2. Enter a valid license key, along with other optional fields, in the new window.
3. Click on the Register License button.
    a. System has access to the internet: If the license key is successfully registered, click Ok, then click Yes to exit and restart the software.
    b. No access to internet: contact Bertec support for assistance.

Note: The computer does not need to be connected to the internet to register a license key, however, an activation code obtained from the Bertec support team is required if registering offline.

Addons: The Addons tab displays the program's Plugins (along with version, build, and date), Extras Menu, Reports, and Tests in a list.

System: The System tab displays the Program's Application Name, System Operating System, Total Memory (and available memory), Primary Disk Space (total and available), the program's associated DLL files, and Device Information. This tab also contains two buttons: one to copy this information to the computer's clipboard and one to send this information directly to support.

To copy/paste this information from the clipboard

1. Click the Copy to Clipboard button. This information is now saved in the computer's clipboard.
2. To paste this information from the computer's clipboard, right click where the information should go (i.e. an email). On the dropdown list, select Paste.
3. Alternatively, select a text box to paste the information into, press and hold the Ctrl key on the keyboard, then tap the v key.

Note: It is okay to exit the program once the information has been copied to the clipboard.

To directly upload this information to support

1. Click on the Upload to Support button.
2. Fill out the name and email fields. The comment field is optional, but recommended.

Note: This information is extremely useful in the case that technical support is needed.

License Agreement: The License Agreement tab displays the license agreement, included in this manual.

Support: The Support tab includes information and instructions for contacting support, in addition to Bertec®'s address and the option to collect and report anonymous program performance data.

To opt out of sending anonymous program reports to Bertec®

1. Click on the box to the left of the phrase "Collect and report anonymous program performance data" so that no check-mark shows.
2. Close the window by clicking the Close button.



Note: Bertec® only collects data related to how the program is used by clinicians; all collected data is encrypted. No patient information is collected.



Note: If the system cannot be accessed, support contact information is also included in Appendix I.

Balance Advantage® User Manual: This option opens a digital copy of this manual outside of the Balance Advantage® program.



Note: Digital copies are searchable. Holding down the Ctrl key and tapping the 'f' key once will open a search menu. A word or phrase can be entered into this search bar to jump to every time that the word or phrase is used within the document.

Vision Advantage User Manual: This option opens a digital copy of the BVA manual outside of the Balance Advantage® program.



Note: This option is only available on systems which contain a license for the COBALT additional assessment protocol.



Note: Digital copies are searchable. Holding down the Ctrl key and tapping the f key once will open a search menu. A word or phrase can be entered into this search bar to jump to every time that the word or phrase is used within the document.

Remote Support: This option is used for Remote Support sessions. Clicking this option will open a new window which asks if the operator has a remote session scheduled.

If the operator does not have a remote session scheduled

1. Click the No button.
2. Email or call Bertec® Support to schedule. Contact information will appear once the operator clicks the No button.

If the operator does have a remote session scheduled

1. Click the Yes button.
2. Fill out the fields for Your Name, Email and Facility Name. The phone number field is optional, but recommended.
3. Click the Ok button.
4. Click the Yes button if Windows asks if it is okay for the program to make changes to the computer.
5. Wait approximately 30 seconds for the session code to load.
6. Fill out the Your Name field
7. Wait for Bertec® to connect to the desktop.
8. Once the representative attempts to connect to the computer, select the Allow button within 30 seconds.



Note: If the Bertec® Remote Support window disappears once the operator clicks away from the screen, click on the Windows key (between the Ctrl and Alt keys) to reveal the computer's open programs. Click on the Remote Support window (blue and white square symbol) to open it again.



Note: It is recommended that the operator calls and talks with a Bertec® representative during this process.

Appendix G: Aligning the Prime IVR System

The position of the Bertec Balance Advantage Essential or Functional with respect to the Prime IVR dome can be adjusted using our built-in alignment pattern found in the Balance Advantage software. To find the alignment pattern, follow the steps below.

Setting up a Training Session

Training screen templates are designed to be easy to use. To begin setting up a training session, follow these steps from the BBA program:

1. Click on the settings button (Figure F1)
2. In the dropdown menu, click on the Configure Dome Projector button.
3. Ensure that the 1 meter dome with fisheye lens option is selected
4. Select the check box that says “Show Alignment Pattern” as seen in Figure F2.
5. The pattern (illustrated in Figure F3) will mostly project on the dome, however part of it will also project on the floor directly underneath the lens. The + symbol labeled 90* from the alignment pattern on the floor should be centered on the Essential balance plate. This will fall just above the balance plate’s horizontal line. Similarly for the Functional balance plate, center the + symbol just above the horizontal line.
6. Once the position of the balance plate is set, click OK for the alignment pattern to close.



Figure F1: Settings Button.

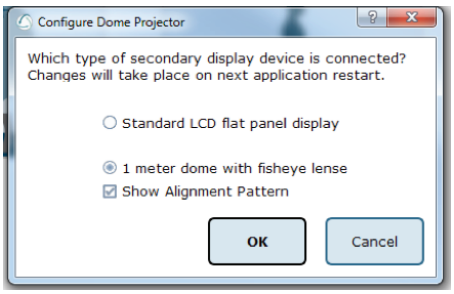


Figure F2: Configure Dome Projector



Figure F3: Alignment pattern

Appendix H: Error Messages

Error Message	Possible Cause/Solution
Bertec Balance Advantage is currently running without a valid license and is in read-only report mode. For more information click here.	Balance Advantage has either lost its license key activation, or was not assigned a license key. The key should either be recovered or a new key can be requested from Bertec Support.
You have multiple plates connected. Both plates must be of the same type and size.	When using the Functional Option with the CDP system, two Functional balance plates are required to run the protocols.
WARNING: All data is being stored - ong timer periods can impact database size.	When the option to store all data is selected, performing long trainings can cause the database size to increase more quickly.
We are sorry, but the program is unable to communicate with the server at this time. Error code: Unable to communicate with server.	This error occurs when you are trying to communicate with the website for activation of your license key, uploading support files, or using the remote support option.
The software license key XXX-XXX has been used on too many systems, and has been deactivated.	If you attempt using a license key on multiple systems, this error will be presented to inform you that the key has been deactivated.
The hardware serial number is not valid.	The serial number on the computer you are currently using is not valid. Please contact Bertec Support to investigate.
The software license key XXX-XXX is not valid.	The license key you are attempting to use is not valid. Please contact Bertec Support to investigate.
Unable to validate the software license key.	When registering a new license key, validation error may occur if the key is entered incorrectly or if it is already being used on another system.
This installation is currently without a valid license, and is in read-only report mode.	Balance Advantage is in read-only mode. Patient records on the system can be viewed, but no new data can be collected.
There are no test or training protocols currently installed. Without these protocols, Balance Advantage will not be able to process or display results, and importing of previous data will fail. Click OK to continue anyways, Cancel to exit, or Ignore to stop showing this message.	Balance Advantage needs to be re-installed. There are critical files missing that are necessary for software operation.
The database has become corrupted and Balance Advantage cannot continue until this is fixed. Balance Advantage can attempt to perform an automatic recovery but there is a risk that some of the most recent data will be lost. Please contact Bertec Technical Support at: support@bertec.com before continuing.	The most likely cause of database corruption is sudden power loss to the PC. Automatic recovery tools built into the Balance Advantage software will likely be able to restore collected patient results with the most likely candidate for loss being newly created data. Please contact Bertec Support to investigate.
The database has been recovered. The original database has been renamed. Click OK to restart Balance Advantage with the recovered database.	Database recovery tools built into the software are usually able to recover all data during a database corruption situation. Restarting the program with the newly constructed database is necessary for verification.
The database was not able to be recovered. Balance Advantage cannot continue and you will need to contact Bertec Technical Support at support@bertec.com for further assistance.	In the unlikely case that the built-in database recovery tools are unable to completely recover a corrupted database immediately, please contact Bertec Support for assistance. Our team will do everything we can to reconstruct your complete set of patient files.

Balance Advantage is unable to open the database - the database format is incompatible. Please contact Bertec Technical Support at support@bertec.com for assistance.	The database structure is incompatible with your software version. This can happen immediately upon performing a major update, but is uncommon. The Bertec Support team should be contacted to provide assistance.
The license for Balance Advantage has been changed. In order for the new license to take effect, Balance Advantage must be restarted. Exit Balance Advantage and restart it now?	Any time a license key is recovered, registered or activated Balance Advantage must be restarted to let the change take effect.
The E-stop button has been pressed for the Balance Advantage software. Please make sure the patient is in a safe and stable position, then rotate the E-stop button clockwise to release. Once released, press the white Start button on the pendent.	Follow the provided directions to reset the system after removing any weight from the balance plate. If the patient is not removed from the balance plate before resetting the E-Stop, you will need to tare (See Manual Appendix) the balance plate before continuing to test.
The XXXTestXXX has failed (reason:) and has been stopped. Please make sure the patient is in a safe and stable position, and check the device before resetting it.	Reset the Balance Advantage system base by removing any weight from the balance plate, then turning the E-stop button to the right to release it, and pressing the white “Enable” button on the pendent.
The current password you typed does not match. Please re-type the current password.	To change the password on the system, the current password must first be entered correctly on the system.
The passwords you typed do not match. Please type the same passwords into both Password and Confirm Password.	To change the password on the system, the new password must first be entered twice correctly on the system.
Automatic database backups unavailable in read-only report mode.	The automatic backup feature is not available in read-only mode. The system needs an active license key to perform automatic backups. Manual backups can be performed in this state.
Unable to validate the software license key.	When registering a new license key, validation error may occur if the key is entered incorrectly or if it is already being used on another system.
This installation is currently without a valid license, and is in read-only report mode.	Balance Advantage is in read-only mode. Patient records on the system can be viewed, but no new data can be collected.
You cannot delete the currently logged in operator.	The user who is logged into the software cannot be deleted. Only other operators who are not currently using the system can be deleted through Configuration Options.
You cannot delete the Administrator account.	The Administrator account cannot be deleted because this account is necessary for basic use of the software.
You cannot delete a security role that is currently in use.	A security role assigned to the user who is currently logged into the software cannot be deleted. Only security roles not in use can be deleted through Configuration Options.
Attempting to save the Additional Patient Fields failed.	There was an error with the Additional Patient fields that you attempted to create and save. Please try again. If you continue having problems, consult the manual and then contact Bertec Support.
Attempting to save the Operator “XXXX” failed.	There was an error with the Operator that you attempted to create/modify and save. Please try again. If you continue having problems, consult the manual and then contact Bertec Support.

Attempting to save the Security Role “XXXX” failed. Attempting to save the Security Role “XXXX” failed because the identifier is null.	There was an error with the Security Role that you attempted to create/modify and save. Please try again. If you continue having problems, consult the manual and then contact Bertec Support.
Attempting to delete the Security Role “XXXX” failed.	There was an error with the Security Role that you attempted to delete. Please try again. If you continue having problems, consult the manual and then contact Bertec Support.
Merging the database from XXDatabaseNameXX. Your existing database was not merged with the other database, and is unchanged. Click OK to continue working with the current, unchanged, database. failed to complete Merge Failed	The merge function encountered an error and the original version of your database has instead been kept without changes or problems. You may continue using it or try performing the Merge again. If problems are still experienced, contact Bertec Support.
Restoring the database from XXDatabaseNameXX. The existing database was not replaced. Click OK to continue testing with the current, unchanged, database. Restore Failed	The Merge and Restore function encountered an error and the original version of your database has instead been kept without changes or problems. You may continue using it or try performing the Restore again. If problems are still experienced, contact Bertec Support.
The integrity check did not find any errors with the database.	An Integrity Check can be run on the system’s database to ensure that nothing in the structure is problematic or has the potential to become a problem in the future.
There appears to be some problem with the database - you may want to restore from a backup copy or use the Rebuild Database feature.	Unknown issue identified with your system’s database. Restoring from a recent backup through the Merge and Sync options or utilizing the Rebuild Database built-in tool are both viable options before contacting Bertec Support.
The database was not able to be optimized; this may be due to lack of disk space or memory.	The “Optimize” option in the Database tools was not able to perform its function. Likely, more free space is needed on your PC. Old backups can be moved off of the PC or automatic backup features can be directed to save the file in another location. Please contact Bertec Support for assistance in setting this up.
The database was not able to be recovered, possibly due to lack of disk space. Your original database has been left intact, and you should contact Bertec Technical Support at support@bertec.com for further assistance. Recovery Failed	A recovery operation was requested, but could not be completed. If the PC’s hard drive is too full of information, this error can occur. Consider removing old backups and then trying the recovery process again.
The additional field “XXAdditionalFieldXX” is already being used. Please enter a new name for this additional field. Name error	You cannot name two Additional Fields the same thing when you are creating them in the Configuration Options dialog. Each field must have a unique name.
The operator name “XXOperatorNameXX” is already being used. Please enter a new name. Name error	The software does not support two Operators with the same name when you are creating them in the Configuration Options dialog. Each name must be unique.

The Balance Advantage Database needs to be upgraded. If you do not have a recent backup copy of the database, we recommend that you perform a backup now. Backup the database before performing the database upgrade?	Before upgrading the structure of your database, it is always wise to create a copy of your current database so that no information can be lost. The upgrade should not need the back-up copy, but it is good to have in case.
The License Key that you have entered is invalid. Please check to make sure that you have entered the correct license key. If you believe that you have, then please contact Bertec Corporation at support@bertec.com to obtain a valid License Key.	The license key activation process is multi-step and requires that your key be entered into a specific field. If there is any error in the key entry, this error will occur. If you believe this message is occurring in error, please contact Bertec Support for assistance.
It appears that the program is unable to register your information automatically online - would you like to register your license key via phone or email? If you believe that this message is in error, please check the license key and registration information that you have entered, or %2 for support and resolution with this matter. The Activation Code that you have entered is invalid or empty. Please check to make sure that you have entered the correct activation code. If you believe that you have, then please contact Bertec Corporation at support@bertec.com to obtain a valid activation code. Invalid Activation Code	The license key activation process is multi-step and requires that your PC be connected to the internet. If you are not able to obtain an internet connection, please contact Bertec Support to manually register your license key over the phone. All information must be entered correctly for the manual registration process to work. The Activation Code is only necessary when manual activation is used, and this error is usually due to a typo.
The operator “XXOperatorXX” cannot be logged in. Please check that the operator name and password are correct, and that operator “XXOperatorXX” has the proper access rights. Please click OK and re-enter the operator name and password in order to log into the system Login Error	There are several reasons that a Login Error can occur. The system does not limit login attempts. The Operator name and password must match, and the appropriate access rights for the Operator must be assigned to allow login.
It looks like there is no email client program installed or configured to send email. This is common if you are using some form of web-based email such as Google Mail, Hotmail, Yahoo Email, or similar. You would like to save the PDF report to your Documents folder so that you can send it yourself using your web-based email? Mail send failure	This error appears when the Support Report form cannot be sent because the Balance Advantage software cannot gain access to an email client on its own. The software is requesting to save the document as a PDF that you can email to support using your email client of choice.
One or more of the required patient fields are blank or incorrect. Please complete the fields and press Save again. Unable to commit	There is information missing in the Patient Information profile that you are creating. The required fields preventing the commit are highlighted in yellow.h

One or more of the required Additional Fields values are blank. Please complete the fields and press Save again. Unable to write patient additional field records to database. Changes have not been saved.	There is information missing in the Patient Information profile that you are creating. The required Additional Fields preventing the commit are highlighted in yellow.
The entered patient identifier is already in use by another patient - please check the patient list to make sure that you do not already have a patient by this name or identifier already entered. Changes have not been saved.	When creating a New Patient profile, you cannot use the same patient identifier as one that already exists. Please use a unique identifier and try to Save again.
Unable to write the patient picture to database. However, the other changes have been saved.	There is an error in saving the image information for the patient's picture to the database, but the rest of the Patient Information will be retained. Close out of the program and try taking the picture again.
Do you really want to delete XXPatientNameXX? This operation cannot be undone! Delete Patient	Marking a patient as deleted means that their information will no longer be visible to any Operator that logs into the system. This information is still in the database, but will not ever be available again unless you contact Bertec Support for assistance in retrieving it.
Are you really sure that you wish to restore the archive from XXArchiveNameXX? If you click Yes, then you will be logged out of the program, and any existing Patients, Operators, Test Results, and everything else will be replaced with the database archive. This operation cannot be undone! Anything you currently have in the database will be <b>gone forever! This is your last chance to change your mind!	Restoring the database from an archive will completely replace all existing information with the information in the archive that you are restoring it to. The operation comes with an ample number of warnings to ensure that the operator understands that data will be lost during this process if the archive that is being restored does not have everything that they need.
Note: during and after this operation, the Database Sync will be turned off. After the restore or merge has completed, you will need to manually turn the Database Sync option back on.	The database sync function is turned off during the restore operation so that no other sync'd databases are effected by the operation. Sync will need to be manually re-activated through the Database Maintenance menu after the restore operation is complete.
This test was completed successfully. Are you sure that you want to redo it and overwrite the data? This cannot be undone!	This message only occurs if a successfully completed test is being overwritten by another test. There are very few protocols that allow this functionality.
Are you sure that you want to delete the last collected %1 results%2? This cannot be undone! Delete Results	This message occurs when a completed trial is deleted with the Ctrl+Bksp hotkey command to verify the operator wants to delete the most recent trial.

Appendix I: Contact Bertec®

If this manual does not satisfactorily answer a question, or if additional information or purchases are desired, contact Bertec® via email or phone. Our office hours are Monday-Friday 8am to 5pm Eastern Standard Time.

Phone: +1 (614) 543-8099

Support: +1 614-450-0331

Fax: +1 (614) 430-5425

Information: balanceinfo@bertec.com

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