

Bertec® Balance Advantage® CDP/IVR™ User Manual



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Notice: Any serious incident that has occurred in relation to the Balance Advantage Static, Dynamic, or BVA systems should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Bertec® Balance Advantage®
A Division of Bertec® Corporation

Software Version 2.3.0 and 2.4.0

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-

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- 7.1 Licensor's maximum liability for any claims, damages, actions or causes of action, arising out of this Agreement, shall be limited to the original cost of the Product. NEITHER PARTY SHALL BE LIABLE TO THE OTHER OR THIRD PARTIES FOR ANY INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE, OR CONSEQUENTIAL DAMAGES, INCLUDING LOST PROFITS, ARISING OUT OF OR RESULTING FROM THIS AGREEMENT EVEN IF THE OTHER PARTY HAS BEEN ADVISED OF THE POSSIBLE EXISTENCE OR DEVELOPMENT OF SUCH DAMAGES. THE FOREGOING SHALL APPLY REGARDLESS OF THE NEGLIGENCE OR OTHER CONDUCT OF EITHER PARTY AND REGARDLESS OF WHETHER SUCH LIABILITY ARISES IN CONTRACT, NEGLIGENCE, TORT, OR ANY OTHER THEORY OF LEGAL LIABILITY. THE ENTIRE RISK FOR THE PERFORMANCE, NON-PERFORMANCE OR RESULTS OBTAINED FROM USE OF THE PRODUCTS, RESTS WITH LICENSEE.
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-

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-

Bertec Balance Advantage Privacy Policy

Bertec Balance Advantage Privacy Policy Bertec is committed to delivering the best possible experience to our customers. To achieve this, we request your permission to share specific data with us, which will help us improve our Bertec Balance Advantage Software. This privacy policy describes how Bertec Balance Advantage Software uses, stores, and transmits your information and data.

Data Security and Privacy:

Your privacy and data security are our top priorities. We adhere to the highest standards, implementing robust measures to securely store and process your information. It is essential to acknowledge, that despite our stringent efforts, we cannot guarantee absolute immunity from malicious attacks or compromises. Users should be aware that the transmission of data is inherently at their own risk. Our practices not only align with data protection laws but also assure that your data remains confidential. There is a strict policy against sharing your data with any third parties, except in cases of mandatory disclosures required to comply with court orders or applicable laws. It's important to note that, regardless of the user's country of residence, their information will be subject to the laws of the United States.

Why We Collect Your Data:

We believe that by collecting and analyzing data, we can enhance our Bertec Balance Advantage Software and better serve your clinic's needs. Your data will contribute to the improvement of future Balance Advantage features and products.

Data We Collect from You:

The data you share with us will be used exclusively to improve our Bertec Balance Advantage Software. Only The following information will be shared with Bertec:

- Login Count
- Devices being used with Balance Advantage Software
- Database Creation Date
- Downloaded Software Version
- Data Export Usage
- E-STOP Usage
- Number of Assessments Completed
- Number of Trainings Completed
- Training Option's usage

Bertec will not collect patient information, test results, session notes, nor additional fields stored in the patient's profile.

How We Collect Your Data:

Data is collected during the normal operation of Bertec Balance Advantage. This data is anonymized and uploaded to a secure server under Bertec's sole and direct control, where the data is further summarized for analysis.

Opt-In and Consent:

We value your right to choose. Your data sharing is entirely voluntary, and we ask for your explicit consent before collecting any information.

Data Access and Control:

You have complete control over your data. You can turn off this data aggregation at any time, and request the previous collected data be removed.

Benefit to You:

Sharing your data enables us to provide you with a more tailored and effective experience. This means an improved user experience that optimizes patient care, and the development of product solutions that cater to your specific needs.

Changes to Our Privacy Policy

It is our policy to post any changes we make to our privacy policy in this window with a notice that the privacy policy has been updated in the About Window of Balance Advantage. If we make material changes to how we treat our users' personal information, we will notify you by email or through a notice on Bertec Balance Advantage About Window. Users who continue to interact with the software following a revision of Bertec's Privacy Policy will automatically be subject to new terms.

Privacy Questions:

If you have any questions, concerns, or require further information about our Privacy Policy, please do not hesitate to reach out to our support team at Support@Bertec.com or call +1 614.450.0331

Instructions for Use

This manual covers standard operating procedures for the following products:

- Bertec® Balance Advantage® CDP/IVR™



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.

Description of the product

The Computerized Dynamic Posturography (CDP) system is a clinical balance assessment device that collects and analyzes force and moment data from a balance plate. The balance plate is seated in a dynamic chassis that can move in both translational and rotational directions, under control of the Balance Advantage (BA) software program. The BA software contains both assessment and training modules that can be used during each session. Assessments have set run-times during which they collect data after the "Start" button is pressed, while trainings have customizable run-times varying from 1 minute to 15 minutes. The system is intended to be used by trained clinicians in a hospital or clinical (physical therapy or ENT) environment who operate the software and ensure the safety of the patient. The patient being assessed on the system is placed in a harness. There are three different harness sizes with varying weight limits that can be purchased with the system; standard harness supports up to 300lbs, pediatric is up to 100lbs, and the bariatric supports up to 450lbs. The mechanical components of the system are designed to support up to 500lb patients, but an after-market harness accommodating the weight would need to be purchased.

The optional Head-Shake Sensory Organization Test (HS-SOT) protocol additionally collects and analyzes velocity and positional data from a wireless head tracker in parallel with the balance plate data. HS-SOT is an enhanced variation of the standard SOT and is intended for patients with normal SOT who are still symptomatic or have sub-clinical findings in other balance tests.

Training Statement

Bertec offers both operational and clinical training upon the purchase of a Type 1001, CDP system. Operational training includes the basics of how to use and maintain the system and is typically performed at the time of installation by the install team. The two-day clinical training typically takes place at Bertec HQ in Columbus, OH and is delivered by a clinical specialist.

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.

- 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 CDP/IVR™ is intended to remain in place after installation. Bertec® Corporation must be contacted if, for any reason, the BBA CDP/IVR™ must be moved. BBA Static units (Functional, Sport, 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.



All protocols should be performed in stocking feet with hygienic foot covers.



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 balancesupport@bertec.com

Indications for Use

The Type 1001, Computerized Dynamic Posturography (CDP) System is intended as an objective platform used for monitoring, gathering, and characterizing movement of subjects with balance disorders or instability in order to assist with planning and evaluating therapy protocols.

Contraindications

Bertec CDP/IVR is contraindicated in patients who have major mobility impairments such as being in a wheelchair or needing walkers to stand up. Otherwise, there are no known contraindications as long the patient meets the weight and other device requirements.

Potential Adverse Effects

Patients may lose their balance during the test. If so, a harness will prevent an actual fall. Some patients may experience disorientation or dizziness during some parts of the assessment. These symptoms are temporary and will subside quickly. If necessary, the test can be discontinued.

General Maintenance

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

CLEANING INSTRUCTIONS (See Maintenance Manual)

CDP/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 anything other than a microfiber cloth or supplied brush.
- Periodically vacuum air vents on the projector.
- Wipe down the balance platform with 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.
- For good hygiene, patients should wear footies.

Preventative Maintenance

Bertec recommends and provides a preventative maintenance service to be performed yearly on your Bertec equipment. The preventative maintenance service includes the following procedures to ensure your system is performing as designed.

- PC Performance Checkup
- Balance Advantage Software Update
- Software Database Quality Control
- Network Connection
- Merge and Sync Connection Management
- Remote Programming
- Balance Plate Quality Assurance
- Rotational and Translational Positioning Realignment
- Internal Electronics Testing
- Internal Dynamic Controls and Mechanics Testing
- Projector Light, Filter, and Lifecycle Status Check with As Needed Replacement
- Dome Positioning and Dome Image Re-alignment
- System Internal and External Cleaning

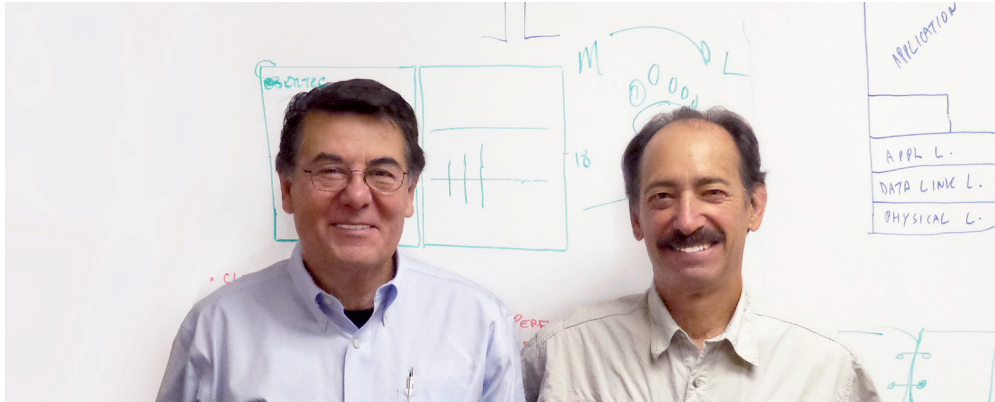
Please contact Bertec Support for more information on how to schedule your preventative maintenance service this year.

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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® User Manual. This is a concise, easy-to-use guide for implementing and utilizing a Bertec® Balance Advantage® Package, along with its related components.

About Bertec® Balance Advantage® Packages



The Bertec® Balance Advantage® packages which incorporate balance plates include the Essential, the Functional, the Prime IVR™ and the CDP/IVR™; all are designed to assist clinicians in assessing and rehabilitating patients. These packages are illustrated and described in their associated manuals based on whether they offer static or dynamic assessments. 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	Dynamic Plate Assessments	Portability Option	COBALT Option	IVR Training Modules	Balance & Mobility Training Modules
CDP/IVR™	✓	✓	X	X	✓	✓
Prime IVR™*	✓	X	X	X	✓	✓
Essential*	✓	X	✓	✓	X	✓
Functional*	✓	X	✓	✓	X	✓

This CDP/IVR™ User Manual only covers the features offered by the Bertec® Balance Advantage® CDP/IVR™. This package is illustrated on the following pages, along with its corresponding features and technical details. Static plate assessments and trainings can be found in the Static System User Manual, provided with the purchase of a Bertec® Balance Advantage® Static package.

Operating Environment

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

Standards

Safety: IEC 60601-1, Class I, Type B, IPX0
System: IEC 60601-1
EMC: IEC 60601-1-2

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

Bertec® Balance Advantage® CDP/IVR™

Bertec® Balance Advantage® Packages

Standard Package

- Bertec Balance Advantage® software
- Dynamic base with dual-balance plate
- Immersive virtual environment visual surround
- Integrated safety harness structure
- Height adjustable clinician workstation
- Dedicated computer
- Touchscreen monitor
- Wireless keyboard
- Wireless pointing device/ mouse
- Included Accessories
- Foam balance pad (18" x 20" x 4")



Figure 1: Bertec® Balance Advantage® CDP/IVR™

SPECIFICATIONS

Features	Options	Solution
Immersive virtual environments	Bertec® Vision Advantage®	Intuitive software
Expanded assessment and treatment protocols	Functional dual-balance force plate (20" x 60")	Configured to meet your needs Unsurpassed classroom education
Low 4" step height onto an 18" x 20" dual-balance force plate	Pediatric safety harness Bariatric safety harness	Ongoing support 500 lb load capacity
High-sensitivity dual-balance plate	Extended Warranty	One year parts and labor warranty

Training

Quick Training

Mobility

Closed Chain

Weight Shifting

Input Voltage Configuration (configured at factory)

Input (50/60 Hz)	Output
100 VAC, 16A	120 VAC
120 VAC, 13.3A	120 VAC
220 VAC, 7.3A	120 VAC
240 VAC, 6.7A	120 VAC

⚠ Warning: Check input voltage label before starting system

Specifications	
Average Sensitivity (Fz, Vertical Force)	0.02kg
Average COP Accuracy (COPx and COPy)	± 0.25 mm
Motion Base Rotation (AP)	± 10 deg rotational displacement
	± 50 deg/sec max rotational velocity
Motion Base Translation (AP)	± 2.5 in translational displacement
	± 6 in/sec max translational velocity
Data Output Method	Analog
Data Output Rate	1000 Hz
Balance Plate Connection Port	9-pin D-Sub
Bilateral Balance Plate COP	Measures each subject foot independently
Immersive Visual Surround	Computer generated VR based graphics are displayed on a projection screen which remains stationary
Balance Plate Weight	13 lbs (6 kg)
Balance Plate Dimensions	18 x 20 x 1.5 in (457 x 508 x 38mm)
CDP/IVR System Weight	575 lbs
Motion Base Step Height	4 in (102 mm)
Fully assembled system	76 x 67 x 102 in (1.9 x 1.7 x 2.6 m)
Clinical Workstation Dimensions (W x L x H)	20 x 29 x 69 in (0.5 x 0.7 x 1.7 m)
Touchscreen display for clinician	22" 1080p Optical Touch monitor
Minimum Ceiling Height	102 in (2.59 m)
Maximum Patient Weight	450 lbs (204 kg)
Maximum Patient Height	80 in (2.0 m)
Electrical Requirements	Dedicated 110 V 20 Amp NEMA5-20R outlet/power source

Safety

- Easily accessible E-stop control/switch
- Sturdy safety harness structure
- Standard adjustable safety harness (max weight capacity 350 lb)
- Bariatric safety harness (max weight capacity 500 lb)
 - Optional pediatric harness available
- Integrated medical grade power isolation transformer

Fundamental Operations

Turning on the CDP/IVR™



Note: Only for CDP/IVRs™. Other system users should refer to the following page for starting their system(s).



The CDP/IVR™'s base needs to be initialized so that the computer and system can be turned on.

To Initialize the Base of the CDP/IVR™:

1. Flip the green switch by pushing it on the side marked with a “|” symbol.

Note: The base, turned on, is shown in Figure 2. To turn off the entire base, press the opposite end of the switch marked with an “0”. Do not turn off the base unless Bertec® Support recommends doing so, as turning off the base harm the computer and the Balance Advantage® software.



After several seconds, the Emergency Stop button on the base and the remote pendant will flash.

To Respond to the Flashing Light:

1. Push the white Enable button on the remote pendant to release the brakes.



Note: The white Enable button is highlighted in Figure 3.

The last piece of equipment to initialize is the projector.

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 4. 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 (the power button is on the front of the remote, colored green). If the projector does not turn on after successive tries, change the remote's batteries and try again.



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

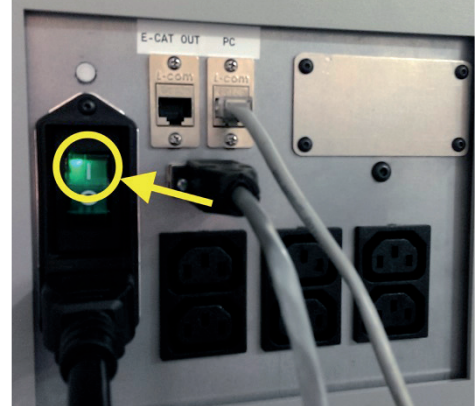


Figure 2: Base Turned On



Figure 3: White Enable Button



Figure 4: Power Button

Initial Startup and Login



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



Note: CDP/IVR™ systems need their base turned on prior to the following steps; refer to the previous page.

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

Press the power button on the front of the tower, located directly above the LIANLI logo.

The power button will glow once the system is turned on.

Login to the desktop.

On the desktop, click on the Bertec® Balance Advantage® logo to load the software.

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).

Refer to page 13 for help navigating the clinician home screen. Refer to pages 14-19 to setup/configure the system.

To Turn on and Log into a Portable (Laptop) System for the First Time:

Press the power button on the side of the laptop (circled in Figure 5).

Log into the desktop.

On the desktop, click on the Bertec® Balance Advantage® logo to load the software.

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).

Refer to page 13 for navigating the clinician home screen. Refer to pages 14-19 to setup/configure the system.



Figure 5: 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 logout of the system:

Click on the logout button, located in the upper right corner of the screen (shown in Figure 6).

Click on the exit button (shown in Figure 7).



Figure 6: Software Logout Button

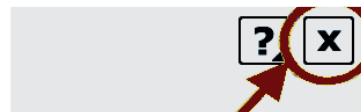


Figure 7: Exit Button

Once the system has been setup, the system administrator (admin operator) can create operator accounts for other staff members/clinicians. Refer to page 13 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 Startup the System:

1. Push the computer's power button. Refer to Figure 5 (for laptops) on the previous page to locate the power button.
2. Log into 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 successfully logs into the system.
5. If the plate is disturbed during this process, refer to Appendix F or logout of the program. Refer to Figure 6 and Figure 7 on the previous page for logout instructions.

To Log into the Program:

1. Open Bertec® Balance Advantage®. Arrive at the login screen, shown in Figure 8.
2. Click on the correct username within the Operator box. This is directly under the Bertec® logo and towards the middle of the screen.
3. Make sure the correct username is highlighted in blue.
4. Type in the correct password.
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.

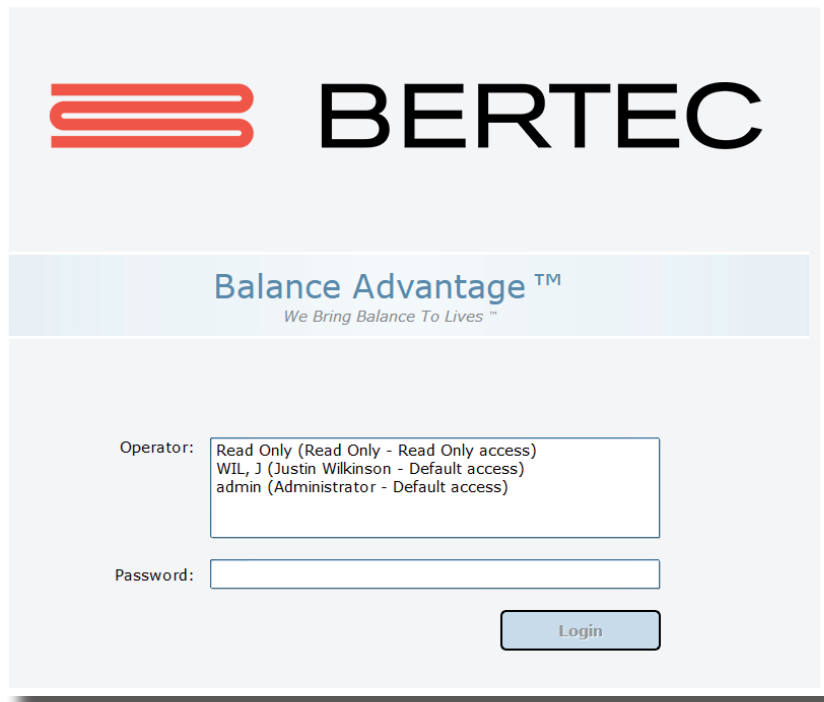


Figure 8: Software Login Screen

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.

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.

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 an assessment list.

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 (top of the screen next to the Bertec® logo). The clinician home screen is illustrated in Figure 9: the top bar highlights the tabs, whereas the bar on the left shows where patient information is stored.

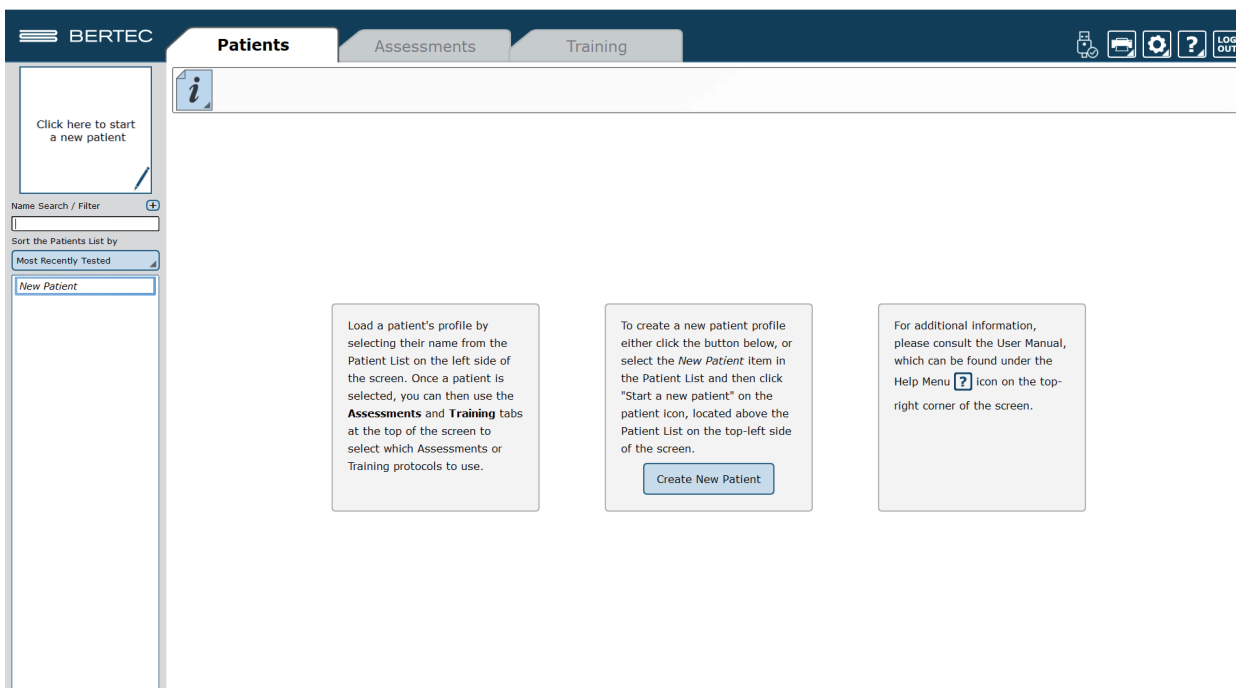


Figure 9: Clinician Home Screen

It is crucial that all operators learn to navigate the clinician home screen. To setup the system from the clinician home screen, refer to the following page. Information about adding/recalling patients begins at page 20.

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 (preferably from the clinician home screen) and then click on the Configuration bar. 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 setup. The configuration options screen is shown in Figure 10.

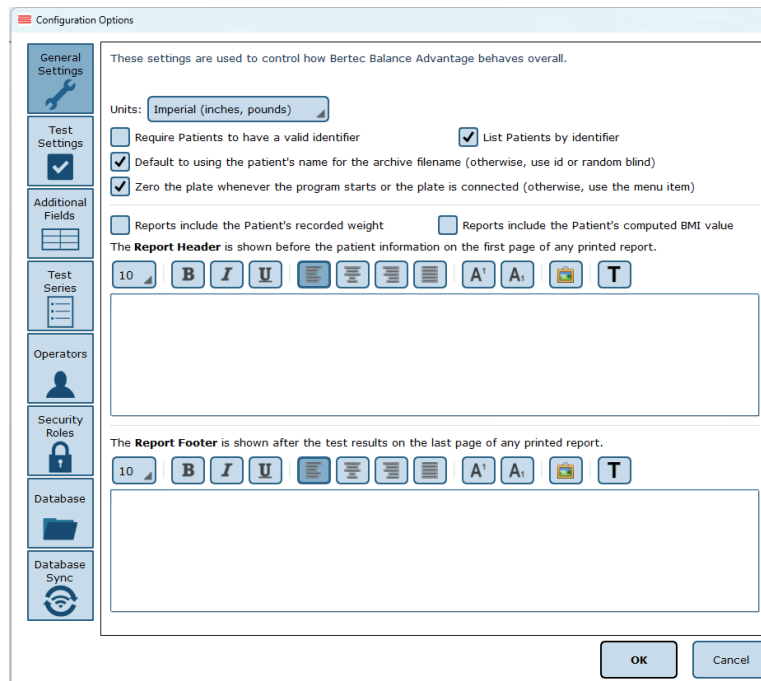


Figure 10: General Settings Configuration

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. The operator can change how patient names appear in the patient list. If "List Patients by identifier" is checked, valid Patient Identifiers will be displayed in the patient list, for patients that have a valid ID in their patient profile. Patient profiles without identifiers will still display the patient name the patient list. 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 10, 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, and 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 11.

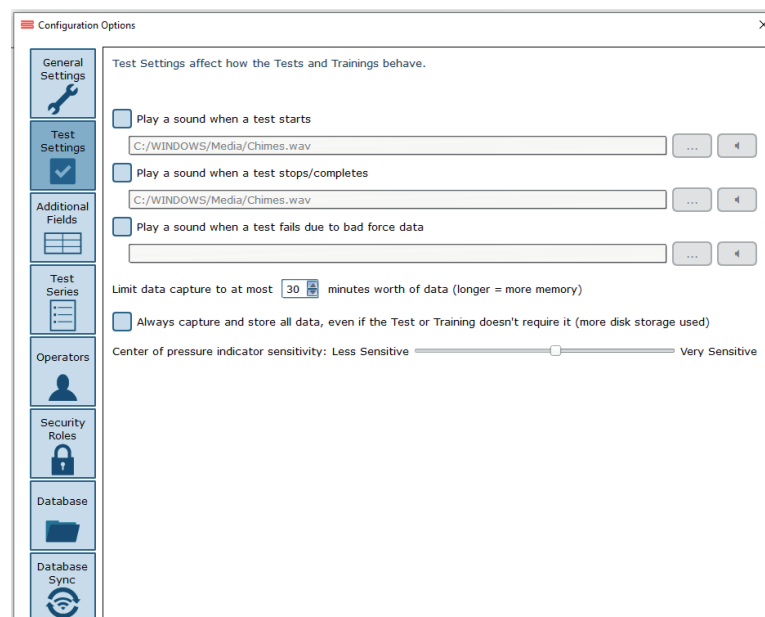


Figure 11: Data Size Notification

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 12 shows the Edit Field options menu.

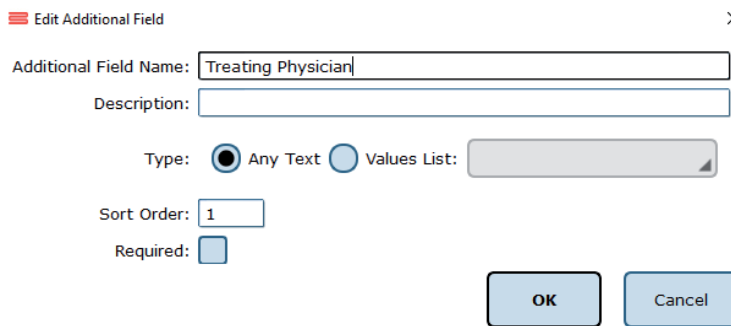


Figure 12: Edit Field Options Menu

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 14 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 13. 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.

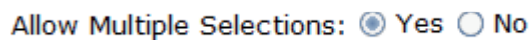


Figure 13: Allow Multiple Selections Box

Figure 14: 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. Over time, this list may become long and cluttered with sets of lists that are no longer used on a recurring basis. 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 15.

Figure 15: 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 16.

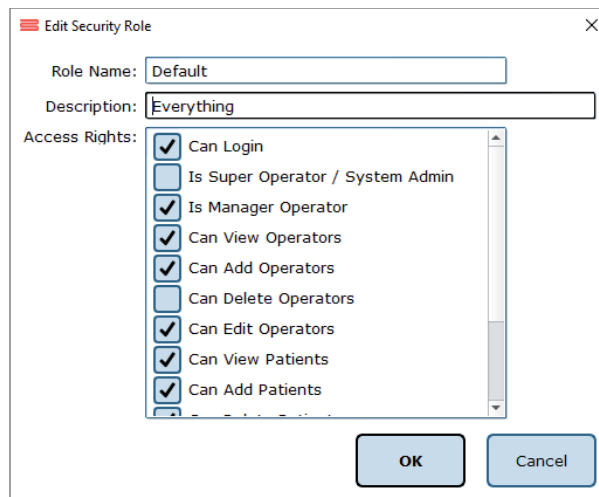


Figure 16: New Window for Security Role Edits

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. By default, the system admin access right does not grant access to editing/deleting patient records and performing tests or generating reports.

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 Login." Not doing so will render the system unusable for all operators without this role.

Balance Advantage Software Updates

Systems that are connected to the internet will receive a notification within the software, notifying the operator that a new software version has been released. Upon receiving the notification, the operator can click "Learn More" and enter their information to receive an email containing instructions on how to download the latest software, comprehensive release notes, and a download link for the updated version. The operator will receive an email from BalanceAdvantageUpdates@Bertec.com within 5 minutes after submitting their information.

To disregard the notification, the operator can choose either "Remind me later" or "Do not remind." Opting for 'Remind me later' triggers an additional notification to be sent a week later. Opting for "Do not Remind" instructs the system to refrain from sending update notifications until the next software version is released.

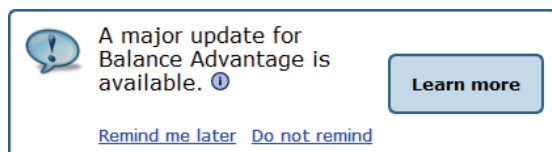


Figure 17: Balance Advantage Update Notifications

Figure 18: Software Update Instruction Request

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:

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, or 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, typically where the patient profile image is located). Both options are shown in Figure 19. After clicking, a popup window will appear with empty patient information fields. The popup window is illustrated in Figure 20. Fill in all required fields. These fields are colored yellow. Afterwards, fill out relevant (but optional) information fields. (Optional): Take the patient's photo by clicking on the Turn on Camera button, waiting for the live camera image to appear, and then clicking on the Take Picture button. Click on the Save Changes button to establish the new patient profile.



Figure 19: Creating New Patients

Field	Value
Treating Physician	
Complaints	
Diagnosis	
Goals	

Figure 20: The New Patient Window

Recalling Existing Patients

To Select a Patient who is Already in the System:

Click on the Patients tab.

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.

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.

(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 21) next to Name Search / Filter, then click on Physical Therapist, then on the box next to Joanne. This screen is shown in Figure 22. 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.

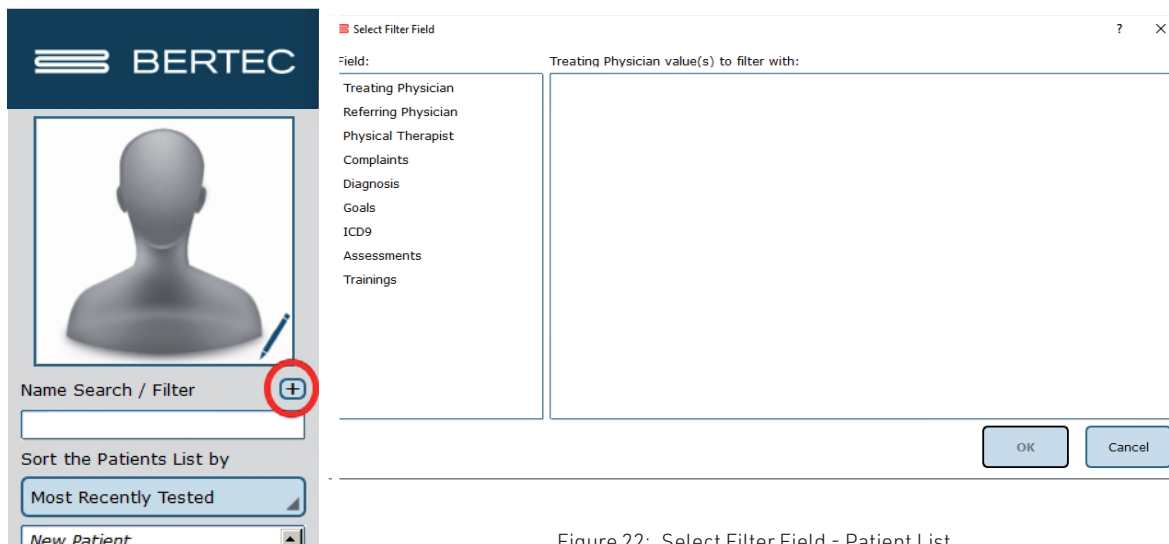


Figure 22: Select Filter Field - Patient List

Figure 21: Sorting Patients.

Patient Assessment

To Start a Patient Assessment:

Create a New Patient (instructions on page 16) or access an Existing Patient (directions on page 17).

To perform new assessments, click the Assessments tab, shown in Figure 23, then drag and drop the desired assessment(s) into the Test Series List, located on the left.

For a description of an assessment, refer to the appropriate chapter devoted to said assessment further in this manual, starting on page 39.

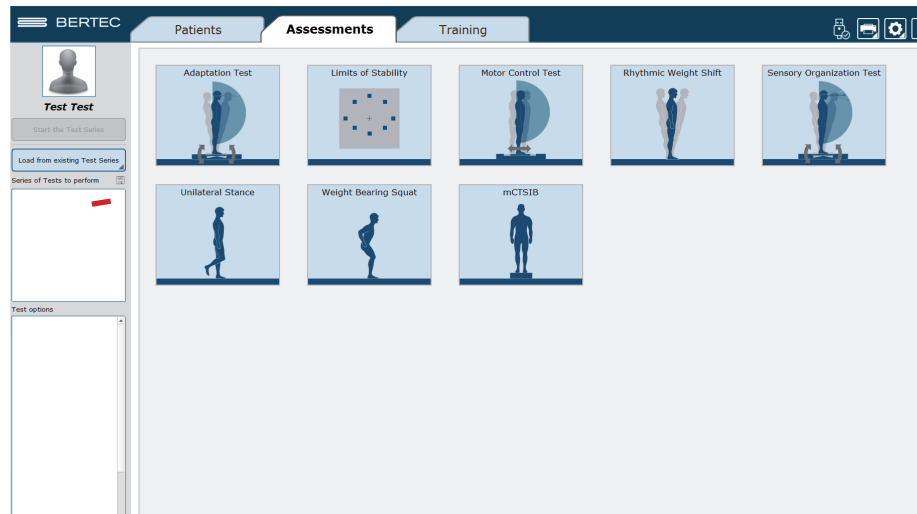


Figure 23: Assessment Tab: Test Setup

1. 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.
2. 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 24.
3. 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 25, located on the following page, shows this screen.

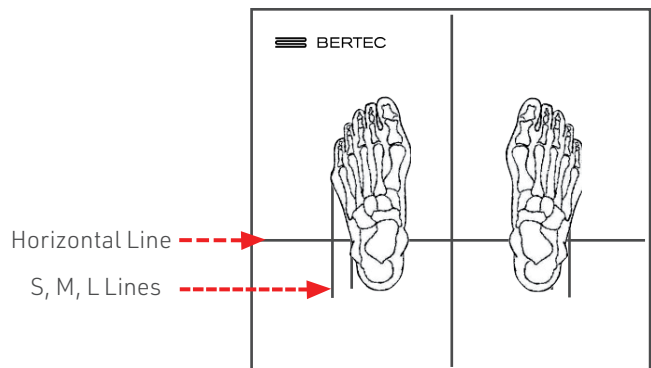


Figure 24: Proper Foot Placement

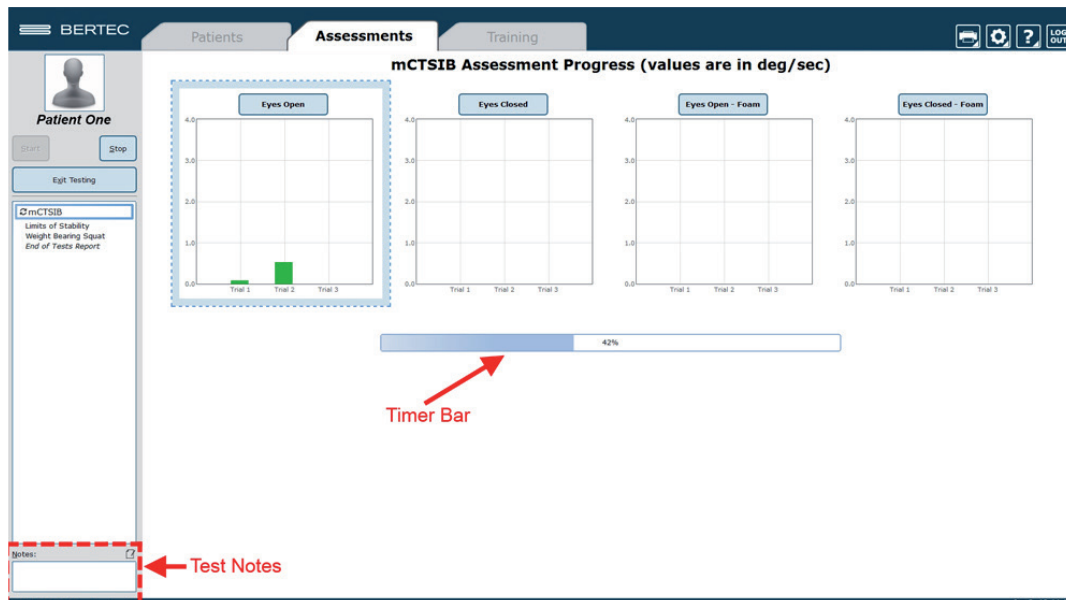


Figure 25: Clinician Screen During Assessment

Assessment results are printed directly from viewing the reports.

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 returning to the Patients tab, shown in Figure 26.

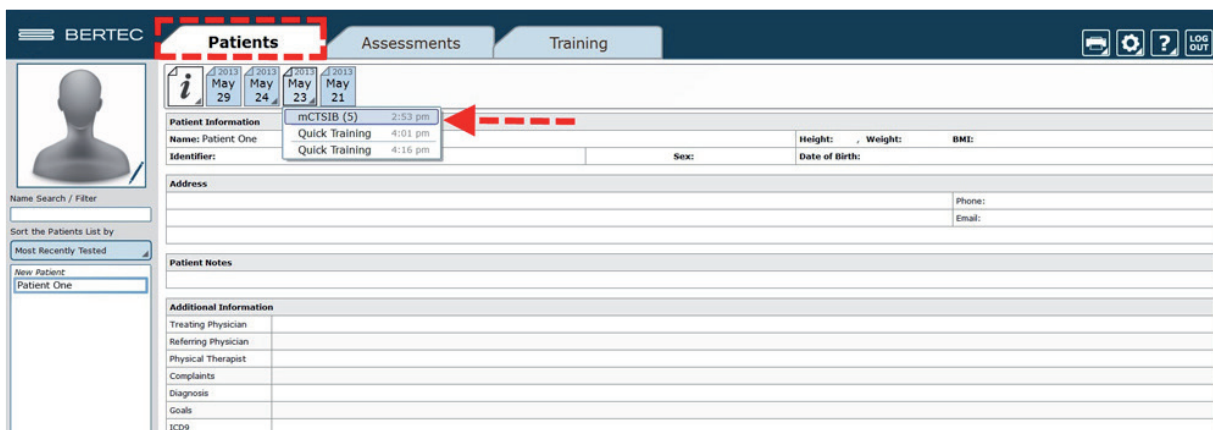


Figure 26: Return to Patient Screen to View Progress Reports

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 27, 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 last collected trial will be deleted.

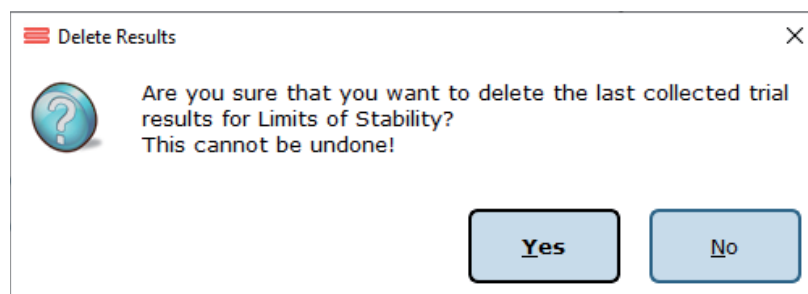


Figure 27: Delete Trial Verification

Saving and Loading a List of Assessments

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

Saving: any list of assessments that has been selected may be saved for use with any patient.

To Save the List:

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

Selecting a Saved List:

1. Select the Tab.
2. Select Load from existing Test Series (on the left of the screen, under the patient image and name).
3. Add the series to use.

Figure 28 illustrates the menu for saving and selecting saved lists. It is also possible to combine both assessments and trainings into a comprehensive list. No additional steps need to be completed to do this, just select the assessments that are to be performed, switch to the tab to select the trainings to perform, and then save the list.

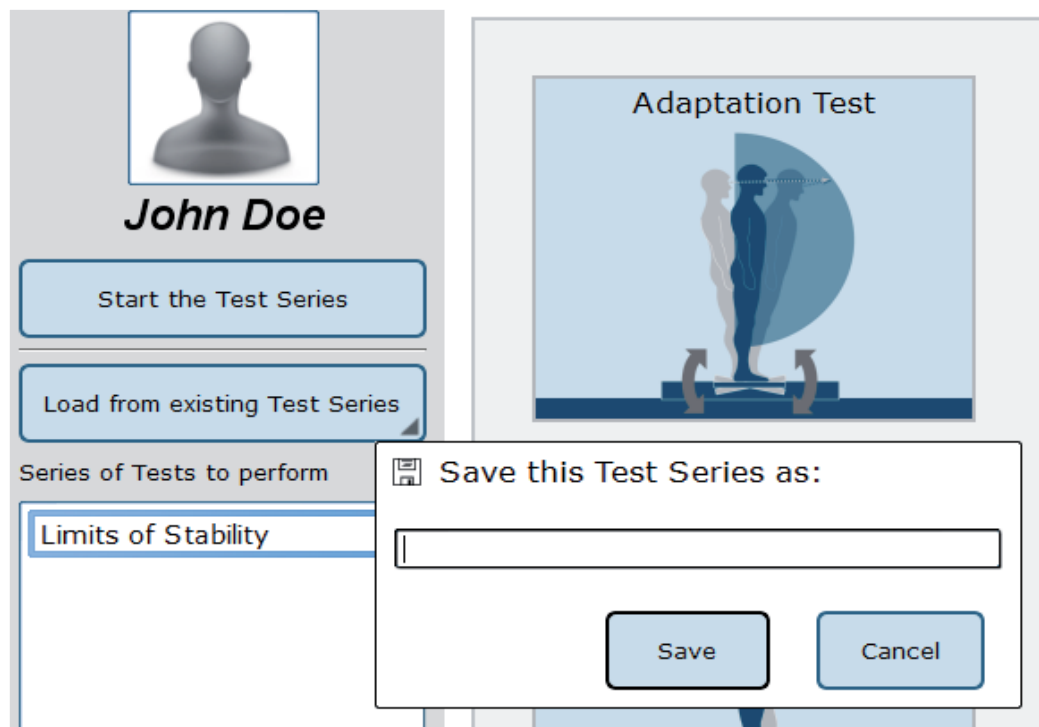



Figure 28: List Interface. Note that the bar to save tests is open

Assessment Reports

Assessment results may be presented through a variety of report types: Individual Test Reports, Combined Reports, Daily Training Reports, Progress Reports, and a Balance Performance Evaluation Note. 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 29 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

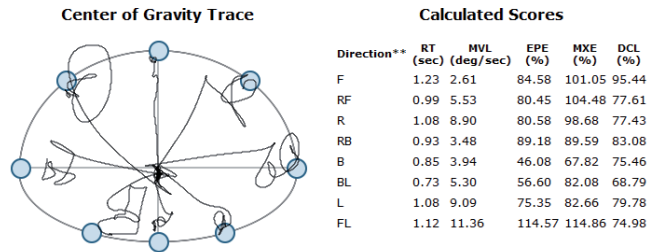



Figure 29: Limits of Stability Individual Test Report

Combined Reports

Combined Reports merge the results of sensory assessments with those of motor assessments—yielding a one-page report. The tests to be combined must have been performed on the same day and in the same session. Figure 30 is an example of a Visual Processing Time Test Combined Report.

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 30: 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 31 is an example Leftward VMS Daily Training Report.

Patient Information		
Name: John Doe		Height: 5'11", Weight: N/A, BMI: N/A
Identifier:	Sex: M	Date of Birth: 1980/01/01
Series Notes		
<input type="checkbox"/>		

Leftward VMS Training Report - Oct 22, 2015

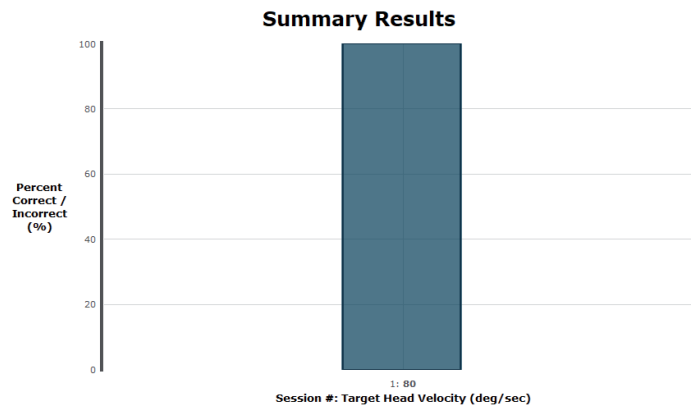


Figure 31: Leftward VMS Daily Training Report

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 32.

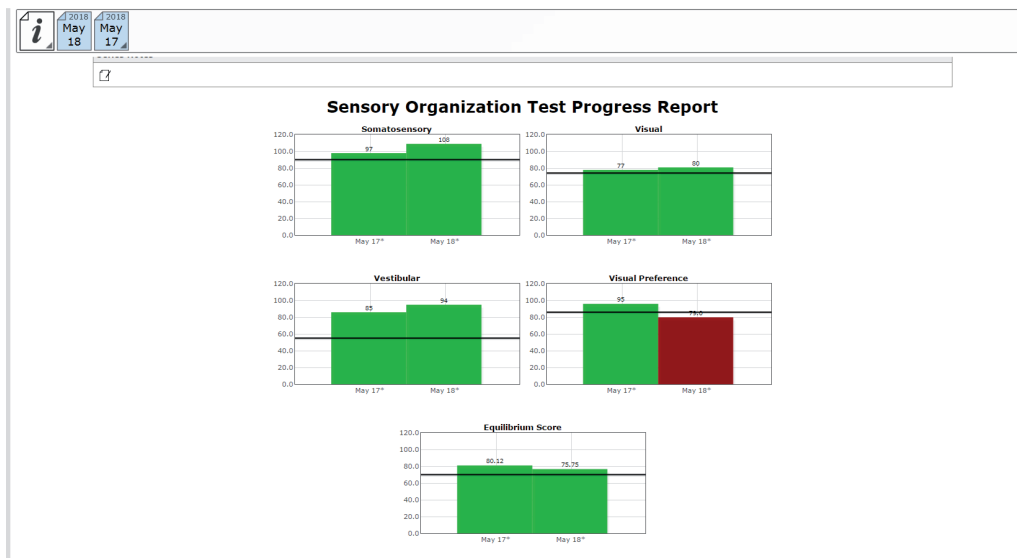


Figure 32: Sensory Organization Test Progress Report

Report Legend

All reports adhere to the same general outline for presenting information. Gray bars represent normative data¹ 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 under the 5th percentile) of the age-matched normative range. A sample report legend is shown in Figure 33.

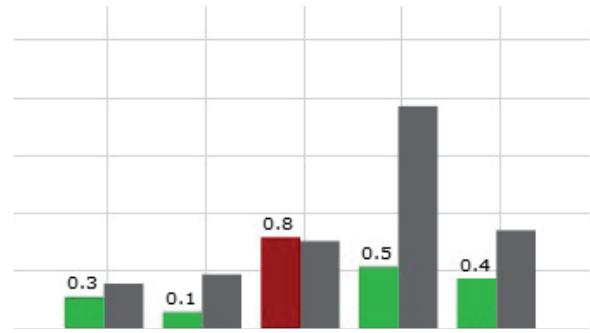


Figure 33: Report Legend

Balance Performance Evaluation

The Balance Performance Evaluation Note offers a concise overview of assessments completed on a specific day, presenting both assessment scores, results and the corresponding explanations. This report is located in the drop-down menu alongside other end-of-test reports. The Performance Evaluation report will only be available if assessments were completed that day, training results will not be included.

Note: Score explanations are derived from patient results in comparison to the normative data.

Patient Information		
Name: Test Patient		Height: 5'8"
Identifier: 5	Sex: F	Date of Birth: 1999/10/18

Balance Performance Evaluation November 28 2023

Baseline Visual Acuity (BLVA)

Baseline Visual Acuity measures a patient's visual acuity while looking straight ahead with the head in a neutral position. The results are used to compare visual acuity assessments while the head is moving (DVA and GST).


Time	BLVA Results	Explanation
4:58 PM	Normal	The patient's Baseline Visual Acuity was -0.30 logMAR

Visual Processing Time (VPT)

Visual Processing Time is the minimum time (in msec) that the optotype must be presented for the brain to process the information; VPT ensures that the patient can process the optotype stimuli quickly enough to use the DVA and GST protocols accurately.

Time	VPT Results	Explanation
4:59 PM	Normal	The patient's visual processing time was 30.00 ms , which is within acceptable levels.

Analysis and Recommendation to Care Plan:

 Right-click to create/edit the Care Plan and Signature

Signature: Operator Signature Date: 2024-01-17

*Note: Specialized tests and measures of balance performance were completed as described. Patient was instructed before and during testing to maximize and standardize performance. Results were analyzed and a plan of care was set with the patient present.

Total Session Time: 4 seconds

Figure 34: Balance Performance Evaluation Report

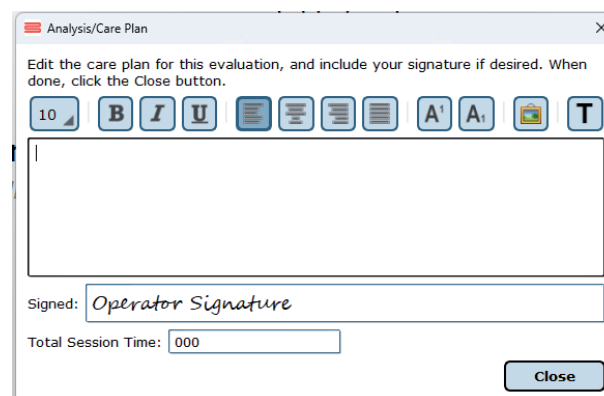


Figure 35: Edit Analysis/Care Plan

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 36. The exported data cannot be re-imported back into the Bertec® Balance Advantage® software; for performing a system back-up, please refer to the Database Maintenance section.

Export Data [X]

This will let you export data and other information from the test results. The exported data is formatted in common comma-separated values (CSV) files, and can be consumed by other data analysis programs such as Matlab or Excel. The export data cannot be re-imported back into Bertec Balance Advantage.
All values exported are in their native units, such as Newtons, Meters, Kilos, etc. - they are not converted to local units such as Pounds or Inches.

Patient to export

Restrict export to just Test Patient Export data from all patient records (uses current filters, if any)

Tests to export

Export all tests that were used Limit to specific tests **Choose...**

Data to export

Export just the force data values (fz, etc)
 Export just the test's result values (scores, etc)
 Export both force values and result values

Export files as Tab-separated (.txt) Comma-seperate (.csv)

Limit exported data to only what the test required (if not checked, will export all data captured as per Configuration Options).

Only export data to-from

From To

Patient/Subject Information

Use patient's full name in filenames and exported data contents
 Include any additional fields that were set for the patient (this may leak patient-specific information)

Where to export to

Directory to export data files to: **...**

Use patient- or identifier-named subfolders Use test names as subfolders

Filenames and subfolders are automatically generated from patient name or identifier, test name, and date of test.

Begin **Cancel**

Figure 36: Data Export Window

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. Also, all patient screens will display the starting cues "Hold Still," as shown in Figure 37, and "Begin," as shown in Figure 38. At the conclusion of a trial, the patient and clinician screen will display the message "Trial Complete," as shown in Figure 39 on the following page, indicating the data collection has ended and the trial is over. The Limits of Stability test is used as an example for all screens.



Figure 37: "Hold Still" Message before the Patient Moves



Figure 38: "Begin" Message Indicating to Begin Movement

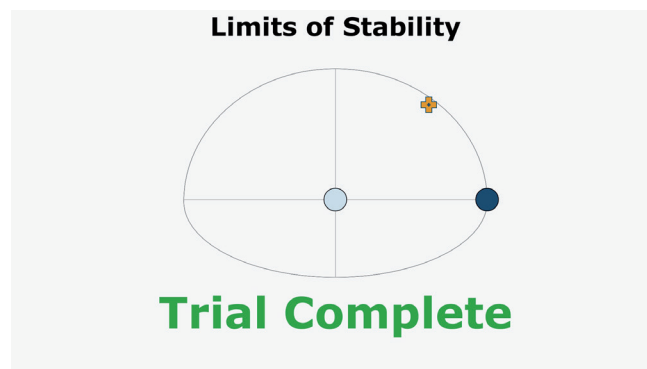



Figure 39: "Trial Complete" Message when a Trial has been Completed

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 Figure 6 and Figure 7 on page 07). 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 40, 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.

Turning this off is not recommended!

Enable Automatic database backups.

Backup storage folder:

Backups will be made every days, and will be kept for days.

At most, backups will be kept.

Note that the amount of free space may affect how many historical backups will be kept, but there will always be at least one backup except in extreme low-disk space conditions.

Currently, there are 5 backups taking up 2 GB in space. There is space for 502821 backups, and the folder has 152 GB free.

The last backup was made today. The next backup will be made 3 days from today.

Figure 40: 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 41.
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 conformation 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! When restoring a database which contains only one patient, both the current and restored databases will automatically merge if the current database contains one patient as well.



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.

- Overwrite and replace your current database with the archive.**

Warning! All current patients, test results, operators, etc, will be replaced with the contents from the archive. Only do this if you are sure you want to loose all of current database's records - forever.

Figure 41: 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 42 shows where this option is located. Refer to Figure 44 on page 32 if having trouble finding this option.

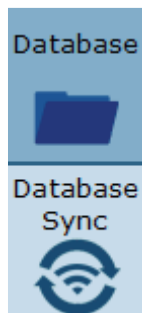


Figure 42: Database Merge Options

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.

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

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 (so long as it remains connected to the computer for the duration of the merge).

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 archived file to merge.
2. Navigate to the correct 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 filled in as seen in Figure 43.
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.

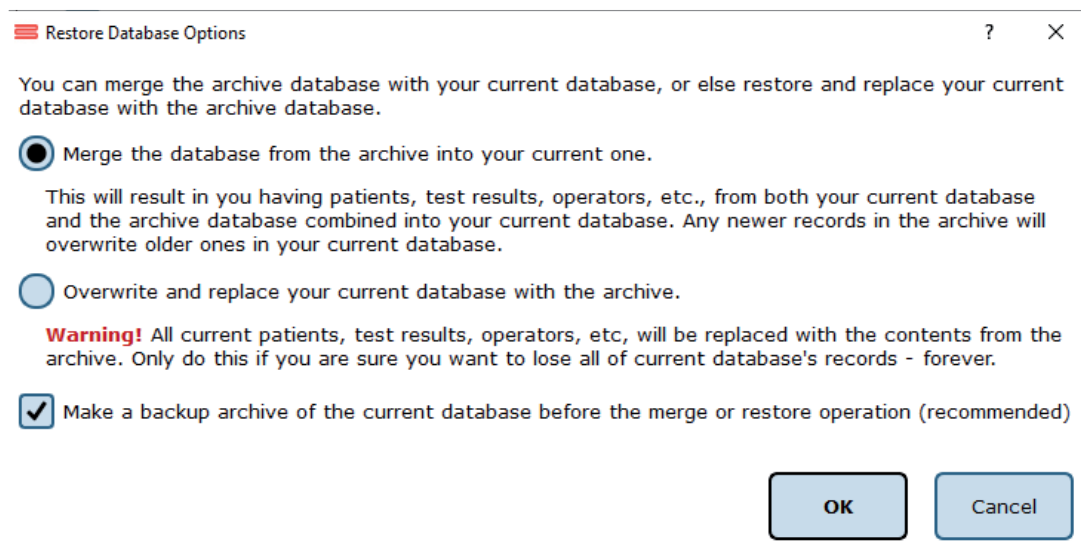



Figure 43: Merge/Archive Options

Two-way Merging—Merging Over the Network

The two-way merge operation requires that compatible Balance Advantage® systems are enabled to be accessible for merging.

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 42 on page 30.
2. On the Database Sync page (shown in Figure 44), 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.

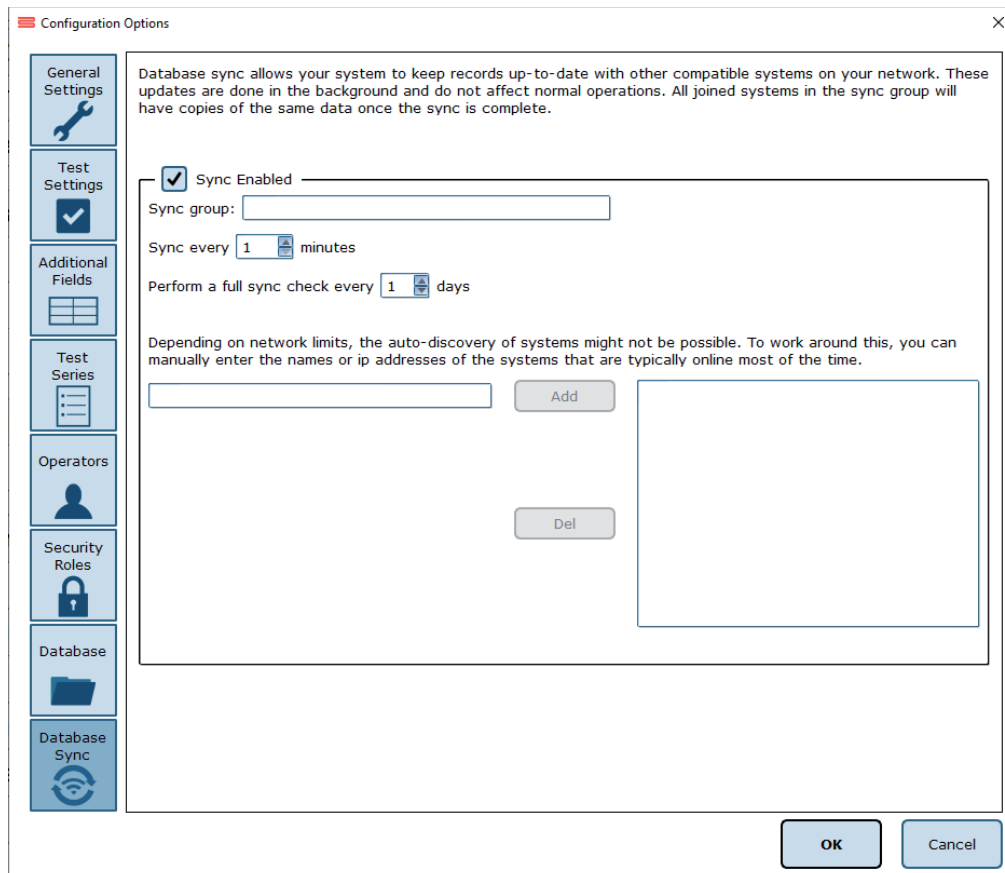


Figure 44: Two-way Merge Options

Turning the System Off



It is extremely recommended that the system's computer or computers, in addition to the CDP/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 (illustrated in Figure 45). It is located on the upper right corner of the screen. If a popup window appears, click Yes to confirm the logout.
2. If on the Bertec® login screen, click on the [X] button in the upper right corner of the screen (illustrated in Figure 46).
3. From the computer's desktop, push the Windows key on the keyboard (on the bottom left of the keyboard, between the Ctrl and Alt keys).
4. Locate the power button (or power options button, depending on the version of Windows).
5. Click the aforementioned button.
6. If another list appears, click on the Shut Down button.
7. CDP/IVR™ Systems: Refer to page 06 to turn off the dome's projector. Figure 4, also located on page 06, highlights the remote's power button.



Figure 45: Software Logout Button

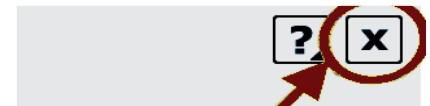


Figure 46: Exit Button



Note: Do not turn off the base of the CDP/IVR™ system (shown in Figure 2 on page 06) unless instructed to do so by Bertec® Support. Doing so may damage the computer and the Balance Advantage® software.

If the computer is frozen and will not turn off after successive tries, the operator will need to conduct a hard shutdown.

To Conduct a Hard Shutdown:

1. Hold down on the computer's power button until the computer turns off. Refer to Figure 5 on page 07 to locate the computer's power button.
2. Determine what caused the computer to require a hard shutdown (i.e. Leaving the computer on too long often results in freezes). It is recommended that the operator(s) keep a log of hard shutdown instances.
3. If hard shutdowns are required on a semi-regular basis, contact Bertec® for additional support. Contact information is included in Appendix I. Information regarding Bertec®'s support features can be found in Appendix G.



Note: Hard shutdowns will cause unsaved data to be irreversibly deleted, possibly even corrupting Bertec®'s patient database. Proceed with caution. Only conduct a hard shutdown when there is no other option.



Note: It is recommended that the operator give the computer around 15 minutes of time (untouched) before conducting a hard shutdown, as it may just need some time to process excess of information.

CDP/IVR™ Balance Harness Instructions

Note: Only for CDP/IVR™ Systems.

Operator Responsibilities

The clinician assumes all responsibility for the patient's safety while using the Bertec® Balance Advantage® system.



To help ensure patient safety, the safety harness must be worn during dynamic assessment and is recommended for use during dynamic training. The harness and shoulder straps, together with the support structure, are designed to prevent the patient from falling while performing any test on this device.



Warning: A harness appropriate for the weight of the patient shall be selected to ensure patient safety during use.

Included are:

- A complete harness – already assembled and ready to be worn. The maximum weight capacity is 300 lb.
- Two shoulder straps to connect the harness to the support structure are included as well.

Important Safety Information: Read Before Using Harness

- The harness should only be used under the direct supervision and assistance of a qualified health care provider.
- The harness is not designed to be a fall arrest device, but rather a fall prevention device. Never allow slack in the line supporting the patient.
- This device should not be used if pressure around the abdomen, thighs, groin, or shoulders is contraindicated.
- Never use the harness without checking the comfort levels (both physical and psychological) of the client frequently.
- The harness is not designed as a passive lifting device. Use only with patients who can participate actively in the therapeutic process and can bear a majority of their own weight through their lower extremities once standing.
- The bariatric harness has a maximum load capacity of 450 lb.
- Inspect all components of the harness on a regular basis to ensure safety. Replace harness at first sign of wear.
- Hand wash all components of the harness in a mild sanitizing detergent and air dry

Helpful Hints and Tips

- Loosen all straps sufficiently prior to applying harness, especially the back straps on the waist belt.
- Some readjustment and tightening of the harness may be needed.
- Practice manipulating and adjusting the buckles, straps, and harness prior to using it on a patient.

For video instructions, please visit www.rehabharness.com

Limitation of Liability

Our total liability for any and all claims, whether in contract, warranty, tort (including negligence but excluding willful misconduct or gross negligence), product liability, or otherwise, for any damages arising out of, connected with, or resulting from the equipment provided under this Agreement or from the manufacture, sale, or use of the equipment or parts thereof, shall not exceed the purchase price of the equipment. In no event, whether as a result of breach of contract, warranty, tort (including negligence but excluding willful misconduct or gross negligence), product liability, or otherwise, shall we be liable for any special, consequential, incidental, resultant or indirect damages (including, without limitation, loss of use, revenue, profit or goodwill, or cost of replacement equipment) or punitive or exemplary damages.

We have not made and do not make any representation or warranty of fitness for a particular use or purpose, and there is no implied condition of fitness for a particular use or purpose. We make no express warranties. No one is authorized to change the terms of this contract or to create for us any other obligation or liability in connection with this equipment. Some states and provinces do not allow the exclusion or limitation of incidental consequential damages or do not allow limitations on how long an implied warranty or condition lasts, so the above limitations or exclusions may not apply to you. The provisions of this contract are in addition to and not a modification of or subtraction from any statutory warranties and other rights and remedies provided by law.

Dynamic Balance Harness Configuration and Components

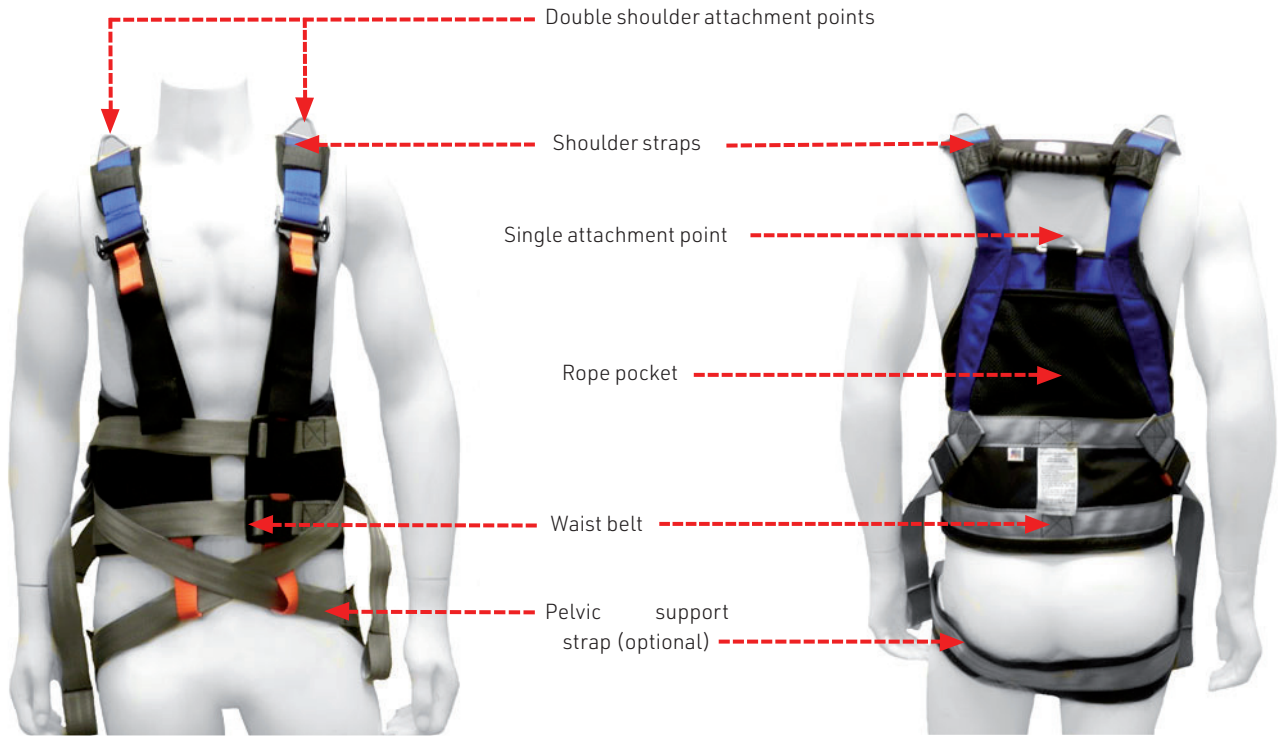


Figure 47: Front of Harness

Figure 48: Back of Harness

Application

1. Place the vest on the patient and tighten waist belt buckles.



Figure 49: Waist Belt Buckles

2. Adjust the length of shoulder straps by lifting up on orange webbing.



Figure 50: Shoulder Straps

3. Pull down on black webbing as needed to properly position the waist belt around the patient's lower trunk and keep shoulder pad in place.



Figure 51: Black Webbing

Attaching Harness to Overhead Support

Depending on patient support needs and the type of overhead system, the vest can be attached to either a single point between the shoulders or to the two shoulder point attachments via a spreader bar. If using a rope based system, excess rope can be placed in the pocket in the back of the vest.



Figure 52: Harness Attachments

Use of Pelvic Support Strap (PSS)

The optional pelvic support strap (PSS) can be used when there is a concern for the harness riding up on the patient's torso and/or when some body weight support is desired.

1. Place the PSS behind the patient centering the rubberized section of the strap under the patient's gluteal fold.

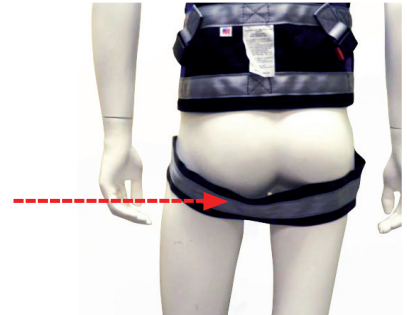


Figure 53: Pelvic Support Strap

2. Thread the PSS buckles through the orange webbing loops on the front of the harness so they can hang in place without falling out.

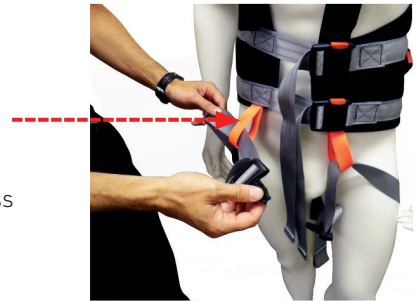


Figure 54: Webbing Loops

3. Attach the buckles one at a time by crisscrossing them in front of the patient and attaching them to the angled side buckles.

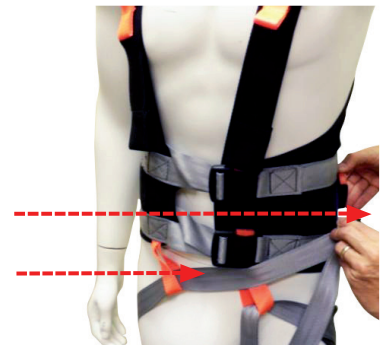


Figure 55: Attaching Buckles

4. While holding the buckles with one hand, use the other hand to take up slack in the webbing to obtain a snugger fit (if needed).



Figure 56: Tightening Harness

Note: To quickly remove the harness, unlatch the buckles, open the harness, and have the patient step forward.

Dynamic Assessments



Note: Dynamic assessments are only available on CDP/IVR™ systems.



Caution! The CDP/IVR™ System should only be operated by a user who has been trained on both the system's functionality and safety protocols.

Information regarding dynamic assessments can be found from pages 61 to 70. 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.
3. A sample report of output information.

Furthermore, most sections contain additional relevant figures.

The following three dynamic tests are designed to assess the patient's capability to process sensory signals and make proper adjustments to maintain balance using dynamic (moving) balance plates and visual environments.

- Sensory Organization Test (SOT)
- Motor Control Test (MCT)
- Adaptation Test (ADT)



Figure 57: CDP/IVR™ System

Sensory Organization Test (SOT)



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.

Goal:

The goal is to systematically evaluate the sensory mechanisms and their interaction that contribute to postural stability. The sensory inputs include visual, vestibular, and somatosensory systems.

Protocol:

The patient is required to complete up to eighteen trials, divided into three trials for each of six different sensory scenarios. These different conditions include:

1. Eyes open, fixed VR environment and support surface.
2. Eyes closed, fixed VR environment and support surface.
3. Eyes open, moving VR environment and fixed support surface.
4. Eyes open, fixed VR environment and moving support surface.
5. Eyes closed, fixed VR environment and moving support surface.
6. Eyes open, moving VR environment and moving support surface.



Figure 58: SOT Icon

Patient Instructions:

“Please stand on the balance plate, placing your feet on the lines as indicated on the screen or by the clinician. Plan to complete a series of trials. During each of the trials, please try to stand as still as possible while staring straight ahead and with your arms at your sides. I will give you further instructions as needed.”

Protocol Performance:

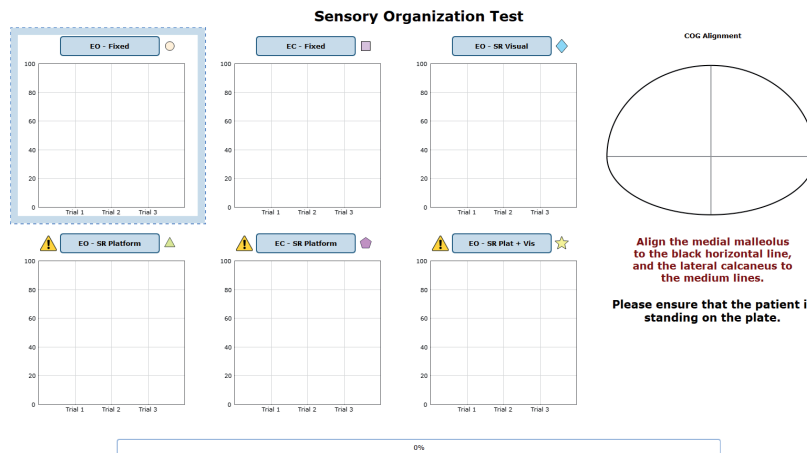


Figure 59: SOT Main Clinician Screen

- The screen for the patient will display one of three virtual reality environments (Oval, Simple Room, or Infinite Tunnel); any patient specific instructions will be displayed on this screen.
- The screen on the clinician's monitor will display trial history and control the start (or stop, if needed) of a trial.
- A total of eighteen trials are available for completion: three for each sensory condition. The clinician will decide how many trials to complete.

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 (Appendix E). 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.
- 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).
- Warning! The machine will move as soon as the Start button is pressed.

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:

- Equilibrium Score
 - The score provides quantitative evaluation of the patient's sway during the trial.
- Strategy Analysis
 - The Strategy Analysis provides an approximation of the patient's implementation of either a hip strategy or ankle strategy in maintaining balance.
 - Higher scores indicate more of an ankle strategy and lower scores indicate more of a hip strategy.
- COG Alignment
 - The initial starting position of the patient's center of gravity.
- 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.

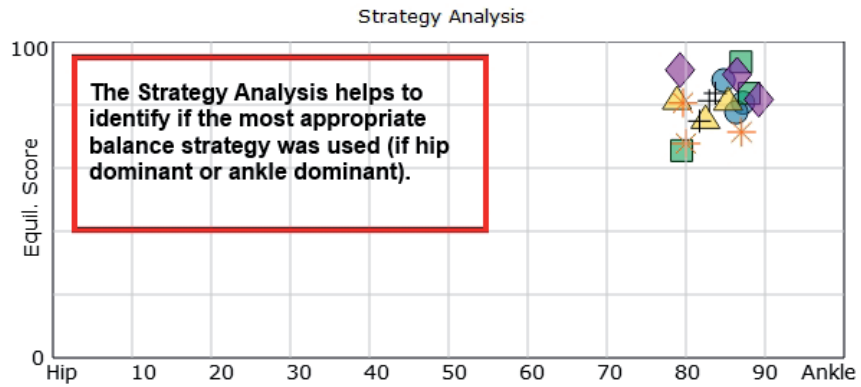
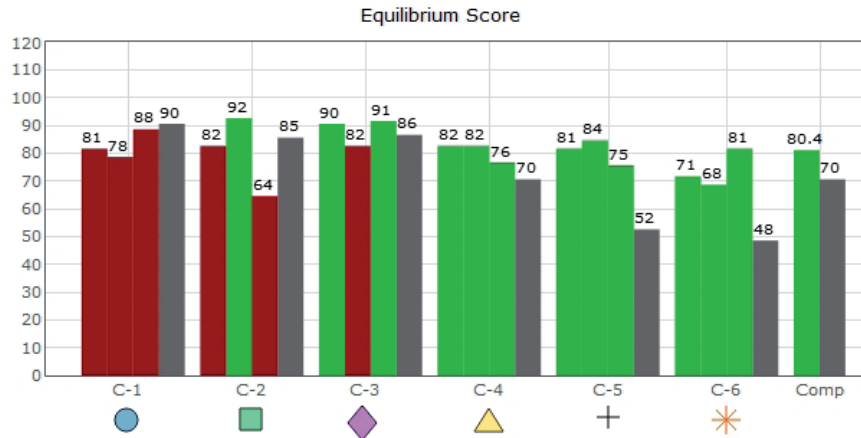
Reports:

- 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.
 - 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  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.

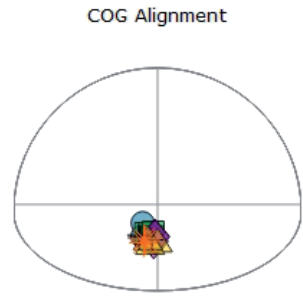
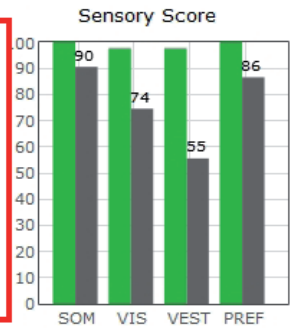
Practical Considerations:

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 sway-referenced support and/or with sway referenced visual surround but they do not usually lose balance or fall.
C1-C6	Abnormal sway on all conditions indicates severe postural control impairments. These patients often exhibit motor abnormalities in the MCT test. In these cases, aphysiological causes should be ruled out.
C5 and C6	Abnormal sway or fall in condition 5 and 6 indicates that the patient has difficulty incorporating vestibular information in balance control.
C4, C5, and C6	Abnormal sway or fall in conditions 4, 5, and 6 indicates that the patient has difficulty incorporating somatosensory information in balance control.
C2, C3, C5, and C6	Abnormal sway or fall in conditions 2, 3, 5, and 6 indicates that the patient has difficulty incorporating vestibular and somatosensory information in balance control.
C3 and C6	Abnormal sway or fall in conditions 3 and 6 indicates that the patient is excessively dependent on the visual system for balance control.

Equilibrium Scores of individual trials are presented to assess performance while the different sensory systems are challenged



Sensory Score provides a systematic average score, assisting in the identification of which system is impaired



Sensory Organization Test data traces can be printed with the Sway Energy bar charts by selecting the button located in the top right corner of the report.

Figure 60: SOT Report Information

Motor Control Test (MCT)



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.

Goal:

The goal is to assess the ability of the patient to recover from translational disturbances of the support surface. The responses are considered pre-programmed automatic responses with minimal voluntary intervention. Patients with abnormal MCT results are considered to be at higher risk of falling.

Protocol:

The patient completes up to six different test conditions that move the balance platform forward or backward with three different magnitudes (small, medium, and large). Position the patient on the balance platform so that their feet are aligned with the proper lines on the plate (see clinician screen for specific instructions). Patients are instructed to stand as still as possible throughout the trials.

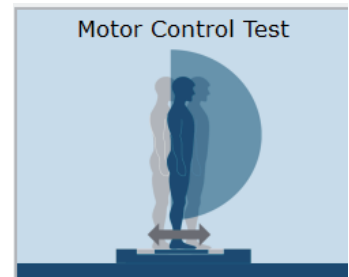


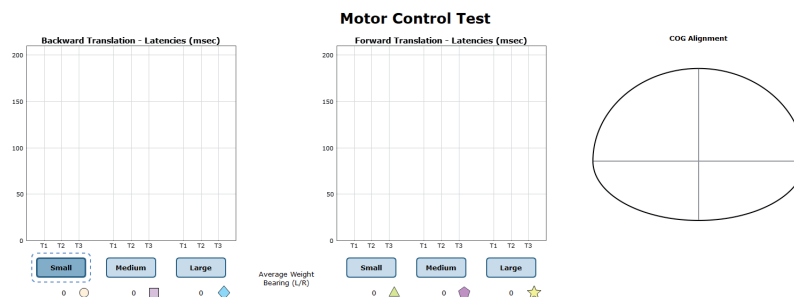
Figure 61: MCT Icon

Once patient is positioned, select the direction and magnitude of translation to perform. A typical progression is to test forward translations in increasing order (small, medium, large). After hitting start, the test will perform three translations in the selected direction/magnitude automatically. If it is likely a patient will have extreme difficulty performing this assessment (requiring repositioning due to movement), it is advised to make sure auto-advance is not selected so that the clinician can control when a translation starts.

Patient Instructions:

“Please stand on the balance plate, positioning your feet on the lines as instructed by the clinician. During the assessments, the platform will move beneath your feet in either a forward or backward direction. Please stand as still as possible as the platform moves.”

Protocol Performance:



Warning: All trials will involve movement of the plate in a forwards-backwards translation. **Align the medial malleolus to the black horizontal line, and the lateral calcaneus to the medium lines.**



Please ensure that the patient is standing on the plate.

Figure 62: MCT Main Clinician Screen

- The screen for the patient will display a virtual reality environment and any patient specific instructions.
- The screen on the clinician's monitor will display trial history and control the start of a trial or trials.
- A total of six test conditions are available for completion--three for forward translations and three for backward translations. It is up to the clinician to decide how many they would like to complete.

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 (Appendix E). 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.
- 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).
- Warning! The machine will move as soon as the Start button is pressed.

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:

- Latency
 - This measures the time it takes for a patient to respond to a translation (measured in milliseconds).
- Weight Symmetry
 - A measurement of the average amount of weight carried by each leg during the translations.
- Amplitude Scaling
- 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**

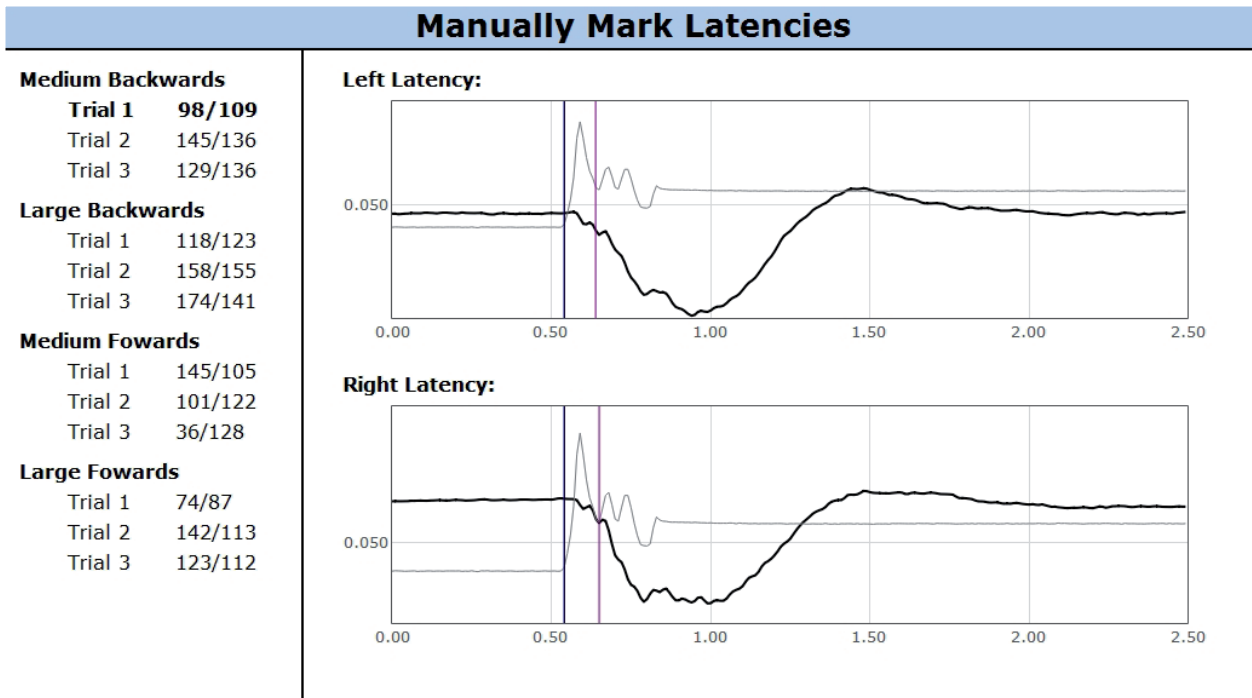
- Summary of patient’s performance during one trial or trial series.
- A graphic depiction of each of the three areas of analysis with numeric data given above each bar in the bar graphs.
- Scores are compared to age-matched normative data.
- Test comments (if entered) are available for inclusion in 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.
- **Manually Marking Latency Values**
- At times, latency scores must be manually marked. Within the MCT report, click on the “Manually Mark Latencies” button.
- The popup window contains the available trials for re-scoring, the COP line charts for the left and right leg, and the Save/Close buttons.
- To select a new latency score, click on line graph where the correct latency should be marked. Once a new score is marked for all trials requiring an updated score, click Save.



- Select a trial from the left by clicking on a trial name or score pairing.
- The **purple** vertical line represents the current latency score.
- The **black** vertical line represents the start of plate movement.
- To re-score a trial, click on the graph at the location where the latency should be scored. A **blue** vertical line will appear.
- To remove the value, right-click on the graph.

Save

Close

Figure 63: Manually Mark Latencies Utility

Practical Considerations:

Abnormality	Implications
None	Normal individuals can exert approximately symmetrical force against the support within a short period of time after the onset of movements to recover and maintain postural stability. Because of the automatic nature of the responses, aphysiological and exaggerated responses may be identified.
Increased Latency	Increased latencies indicate impairment in the long-loop neural pathways. The cause is usually central abnormalities but they can also occur in musculoskeletal problems.
Abnormal Amplitude Scaling	Abnormal Amplitude Scaling indicates inadequate, inappropriate, or asymmetrical level of force exerted during the recovery from the support disturbance. It indicates non-specific neuromuscular or musculoskeletal impairment.

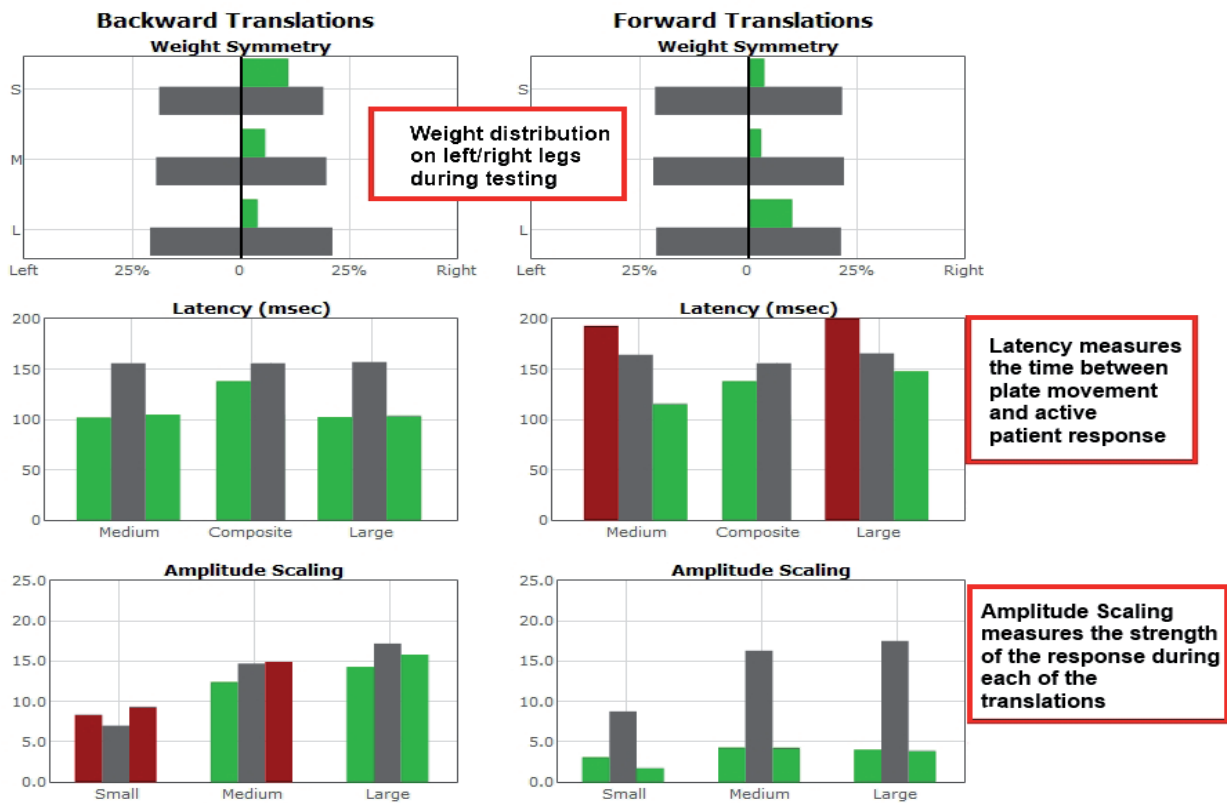


Figure 64: MCT Report Information

Adaptation Test (ADT)



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.

Goal:

The goal is to assess the patient’s ability to reduce sway and increase postural stability in response to repeated rotations of the support surface.

Protocol:

The patient completes two different test conditions that rotate the balance platform up or down. Position the patient on the balance platform so that their feet are aligned with the proper lines on the plate (refer to the clinician screen for specific instructions). Patients are instructed to stand as still as possible throughout the trials.

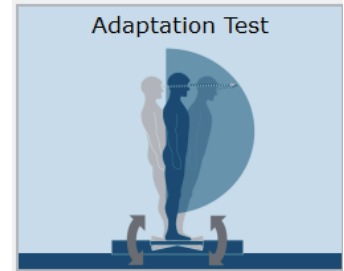


Figure 65: ADT Icon

Once the patient is positioned, select the direction of rotation to perform. After hitting start, the test will perform five rotations in the selected direction automatically. The time between each rotation is randomized to prevent patients from predicting when the next rotation will begin.

Patient Instructions:

“Please stand on the balance plate positioning your feet on the lines as instructed by the clinician. During the assessments, the platform will rotate beneath your feet in either an upward or downward direction. Please stand as still as possible as this happens.”

Protocol Performance:

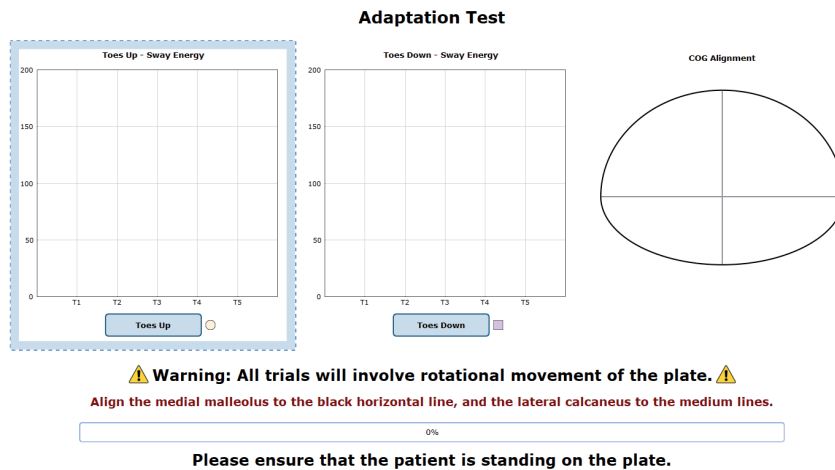


Figure 66: ADT Main Clinician Screen

- The screen for the patient will display the virtual reality environment and any patient specific instructions.
- The screen on the clinician's monitor will display trial history and control the start of a trial.
- A total of two test conditions available for completion: one rotating the surface forward and one rotating the surface backward. It is up to the clinician to decide how many trials they would like to complete of each 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 (Appendix E). 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.
- 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).
- Warning! The machine will move as soon as the Start button is pressed.

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:

- Adaptation Score
- 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.
- 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.

Practical Considerations:

Abnormality	Implications
None	Normal individuals can quickly adapt to the repeated support rotations. The sway is reduced and the postural stability improves progressively after each exposure to the support disturbance.
Abnormal ADT	Abnormal ADT scores indicate failure to adapt to repeated rotations for the support surface. It occurs in patients with orthopedic problems involving the ankle range of motion and lower leg muscle strength, as well as in patients with impaired motor control strategies. Abnormal ADT, especially for the toes up condition, is associated with increased risk of falls.

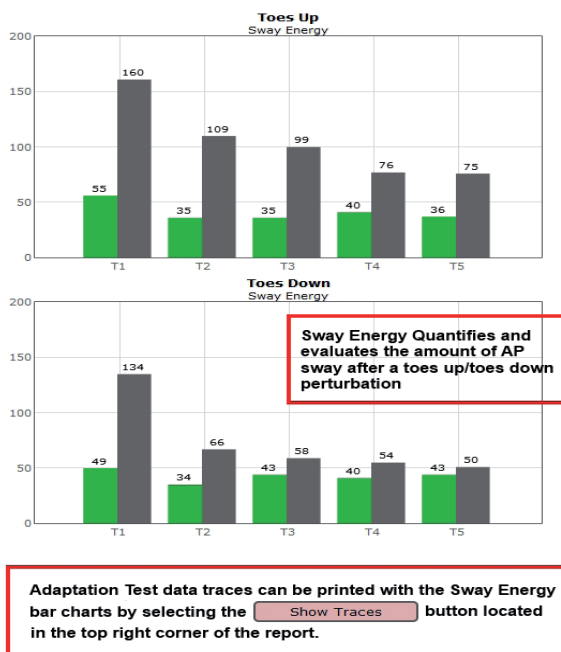


Figure 67: ADT Report Info

Static Assessments

In-depth information regarding each static assessment can be found in the following section 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 assessments 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.

- Limits of Stability (LOS)
- Rhythmic Weight Shift (RWS)

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

- Unilateral Stance (US)
- Weight Bearing Squat (WBS)

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, Sport, and Essential packages; CDP/IVR™ Systems (Not Recommended).

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.

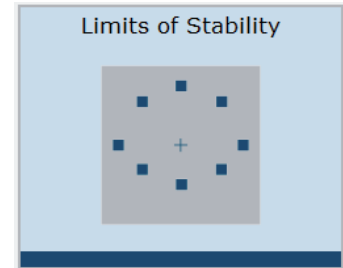


Figure 68: LOS Icon

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.”

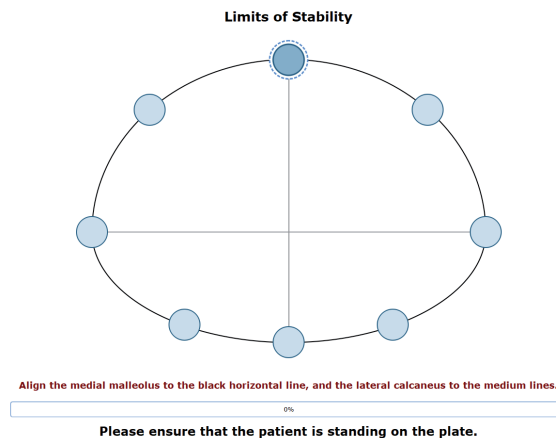


Figure 69: LOS Main Clinician Screen

Protocol Performance:

- 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 (Appendix E). 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).
- 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  in the patient’s time line.
- 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 time line.
- 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).

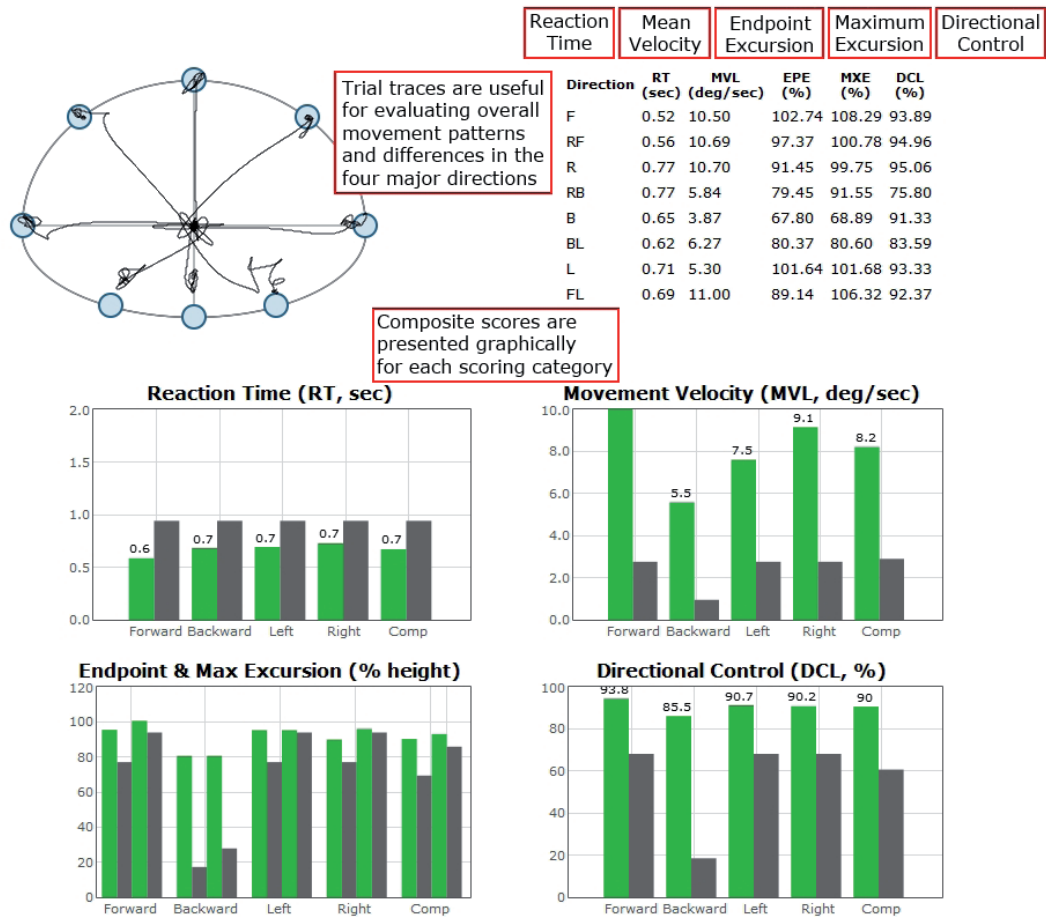


Figure 70: LOS Report Information

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, Sport, and Essential packages; CDP/IVR™ Systems (Not Recommended).

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.

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.

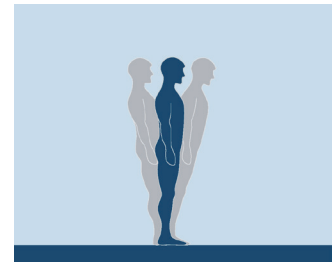


Figure 71: RWS Icon

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:

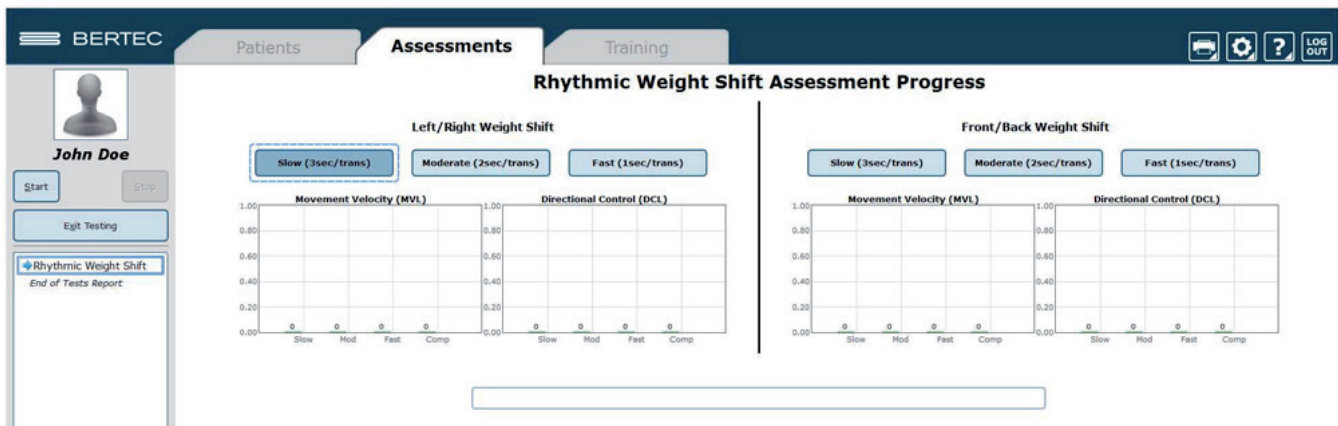


Figure 72: RWS Main Clinician Screen

>

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 (Appendix E). 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).
- 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 time line.
- 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 time line.
- 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).

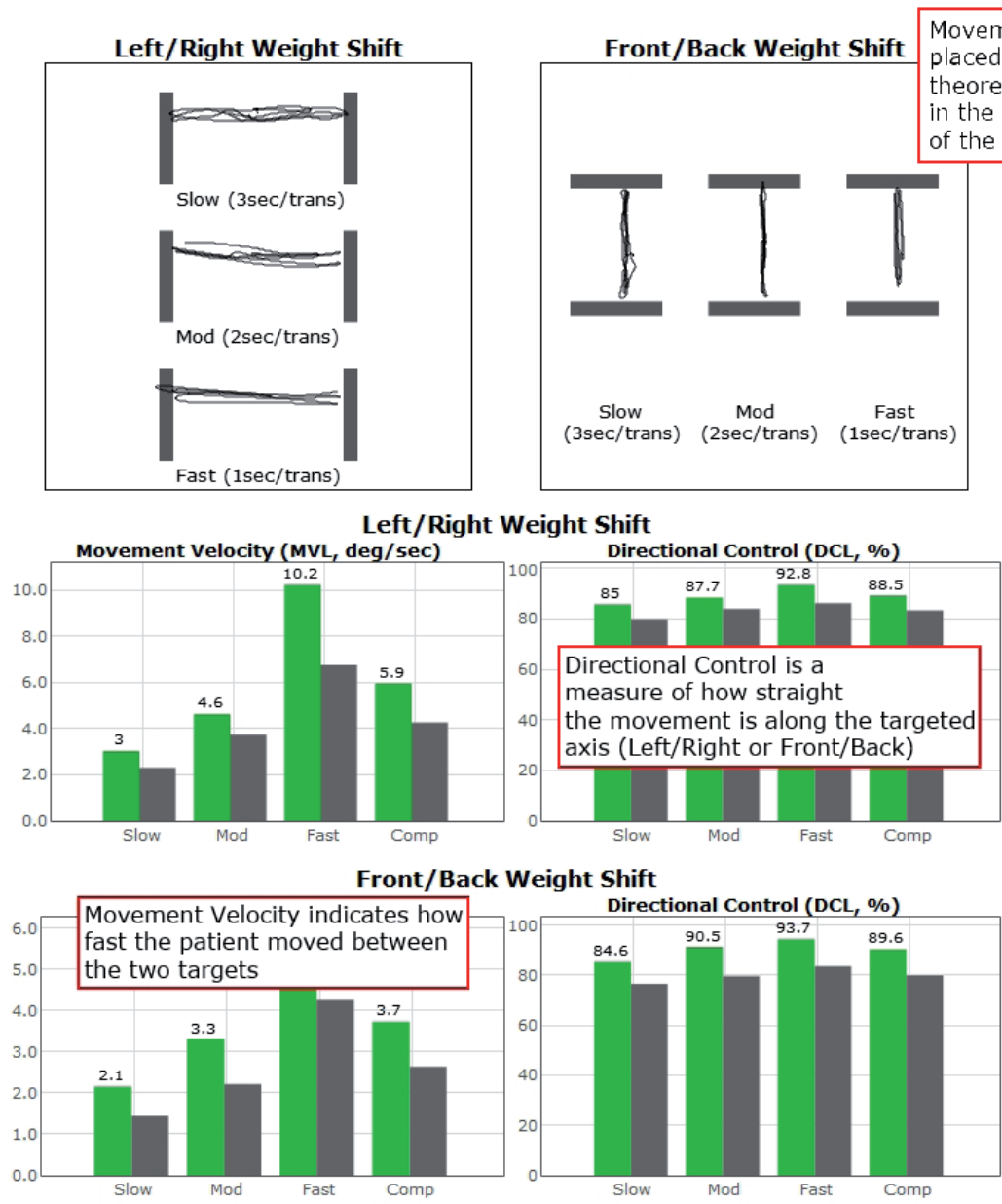


Figure 73: RWS Report Information

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, Sport, and Essential packages; CDP/IVR™ Systems (Not Recommended).

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.

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.

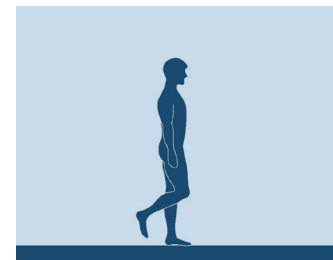


Figure 74: US Icon

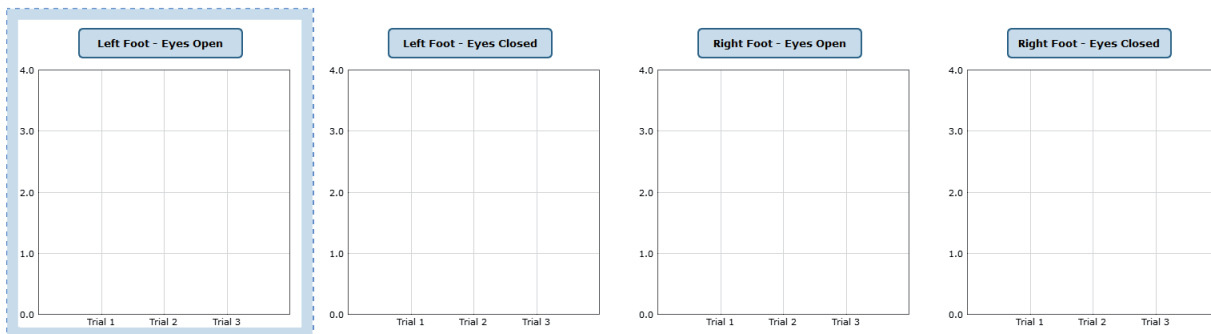
Patient Instructions:

"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."

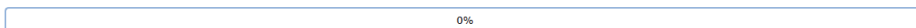


Unilateral Stance

values are in deg/sec



Align the medial malleolus to the black horizontal line, and the lateral calcaneus to the medium lines.



Please ensure that the patient is standing on the plate.

Figure 75: 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:

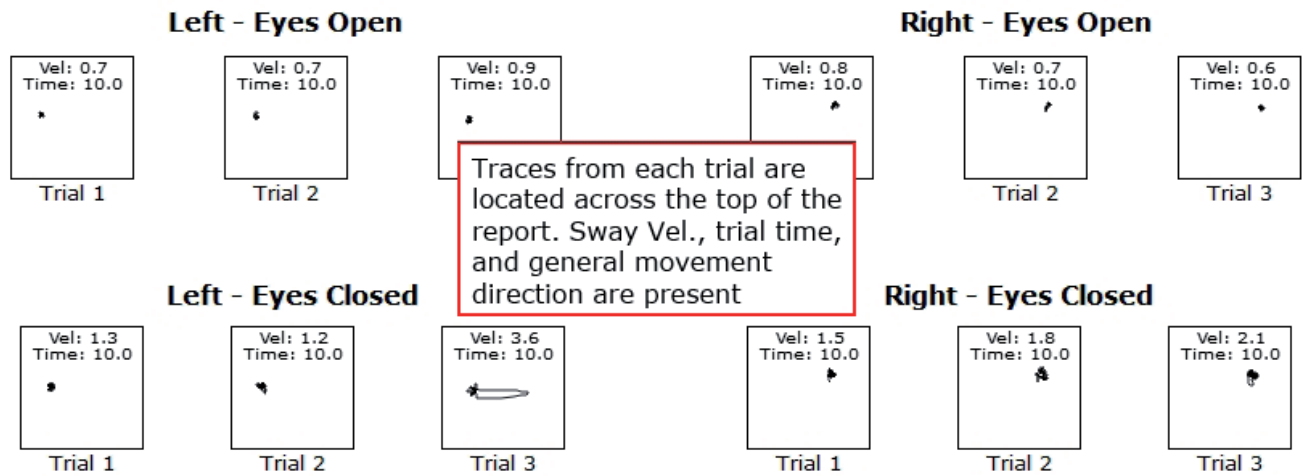
- Generated Reports Will Include:
 - Center of Gravity tracings with the trial’s average sway velocity and time length.
 - A mean COG sway velocity for the Left and Right foot with eyes open with the percent difference.
 - A mean COG sway velocity for the Left and Right foot with eyes closed with the 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:

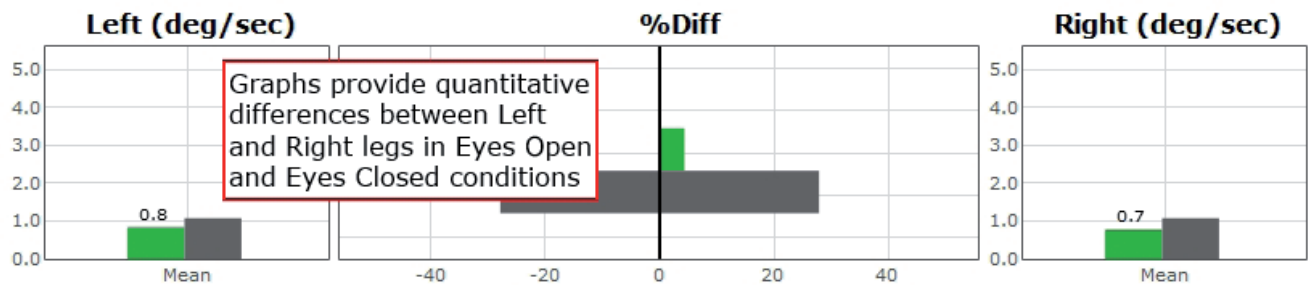
- Summary Reports
 - Summary of the patient’s performance during one trial or trial series.
 - Includes traces for each of the trials, along with bar graph for each of the four assessment conditions.
 - The mean Center of Gravity sway velocity for Eyes Open is presented in comparison to normal ranges 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  in the patient’s time line.
 - 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 time line.
 - 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.



Mean COG Sway Velocity (Eyes Open)



Mean COG Sway Velocity (Eyes Closed)

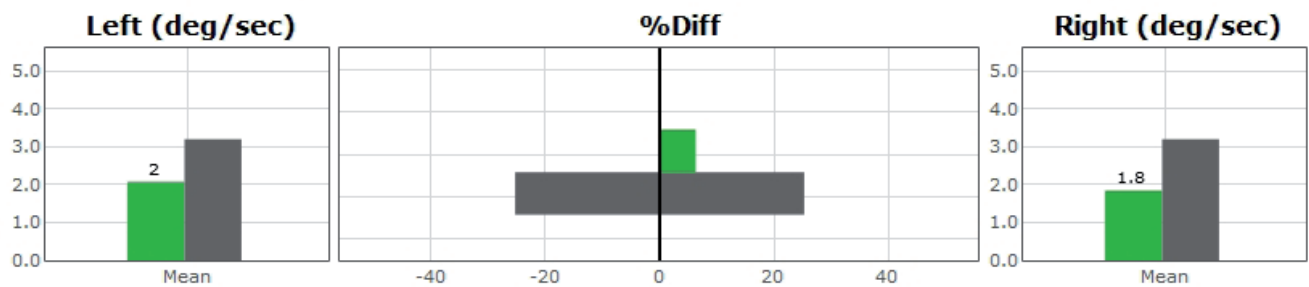


Figure 76: US Report Information

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, Sport, and Essential packages; CDP/IVR™ Systems (Not Recommended).

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.

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.

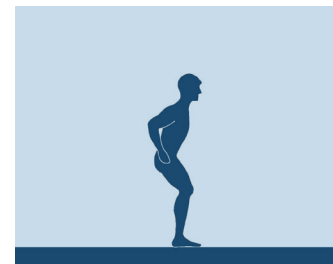


Figure 77: WBS Icon

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 78: 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 (Appendix E). 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. 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  in the patient's time line.
- 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 time line.
- 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.

Weight Bearing Squat Report - Jun 26, 2013

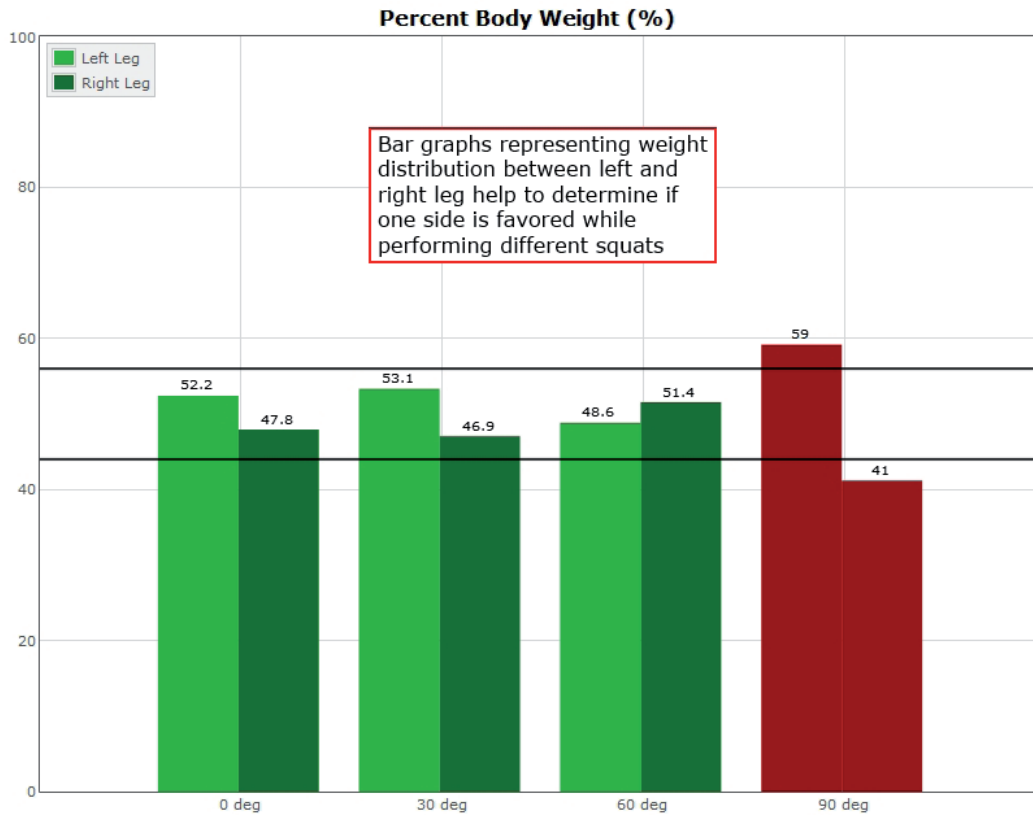


Figure 79: WBS Report Information

Additional Assessments

The following protocols are available for purchase to add on to your Bertec system and assist in the evaluation of patients:

- Head-Shake Sensory Organization Test (HS-SOT)

To add an option to your CDP/IVR system, speak with a Bertec® Sales Representative.

Head-Shake Sensory Organization Test (HS-SOT)



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® CDP/IVR™ package.

Goal:

The goal is to compare the patient's ability to maintain postural stability with the head stationary versus with the head moving rhythmically in the yaw, pitch, or roll plane. SOT Condition 2 (eyes closed, fixed platform) and Condition 5 (eyes close, sway-referenced platform) are used to assess the effect of head-shake. HS-SOT is an enhanced variation of the standard SOT and is intended for patients with normal SOT who are still symptomatic or have subclinical findings in other balance tests.



Figure 80: HS-SOT Icon

Protocol:

Turn on and connect the Head Tracking system. Follow the instructions below to do so.

1. Turn on the Head Tracking system by pushing the small switch in the corner. Use a pen (if necessary). Once on, the system's light will glow blue.
2. From the settings icon, click Pair Wireless Head Tracker.
3. Follow the instructions in the new window that appears.

Patients will be asked to stand directly on the balance plate while wearing the small Head Tracking system (the clinician should assist the patient in putting on the Head Tracking system). Once the patient is secure, a variety of options are available. Completing the tests below (with three trials for each test) will allow the program to calculate the patient's Equilibrium Score Ratio. Note that, if the SOT test was taken earlier, that the first two tests listed below will not need to be taken again.

- Eyes Closed: Fixed Platform (no head tracker required)
- Eyes Closed: Moving Platform (no head tracker required)
- Head Shake Eyes Closed: Fixed Platform
- Head Shake Eyes Closed: Moving Platform

Patient Instructions:

"Please stand on the balance plate, placing your feet on the lines as indicated on the screen or by the clinician. Plan to complete a series of trials. During each of the trials, please try to stand as still as possible with your arms at your sides; turn, shake, or roll your head as instructed. I will give you further instructions as needed."

Protocol Performance:

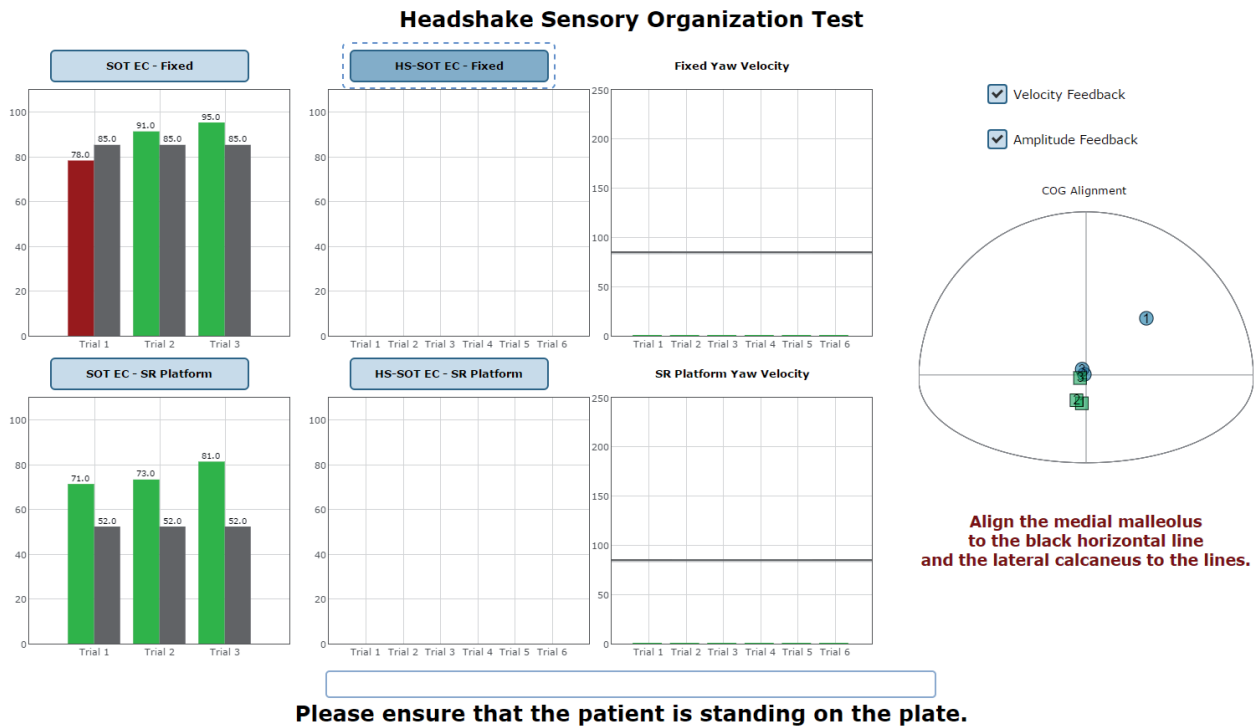


Figure 81: HS-SOT Test Screen

- The screen for the patient can display one of two virtual environments: neutral or oval.
- The screen on the clinician's monitor will display trial history and control the start (or stop, if needed) of a trial.
- The clinician will decide how many trials to 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 (Appendix E). 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. SOT EC - Fixed) and the Start button to perform it.

Test Analysis:

The report will present the following:

- Equilibrium Score Ratio
- Ratio comparing the equilibrium balance control score with head movement to the same scores calculated with the patient's head fixed.
- Ratio comparing the equilibrium balance control score with head movement to the same scores calculated with the patient's head fixed.
- SOT Equilibrium Scores
- The score provides quantitative evaluation of the person's sway during the SOT trial.
- HS-SOT Equilibrium Scores
- The score provides quantitative evaluation of the person's sway during the HS-SOT trial.
- HS-SOT Yaw Velocity
- This is the average velocity achieved in the selected direction during each of the recorded trials.
- COG Alignment
- The initial starting position of the patient's center of gravity.
- 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:

Headshake SOT Report - Jun 19, 2017

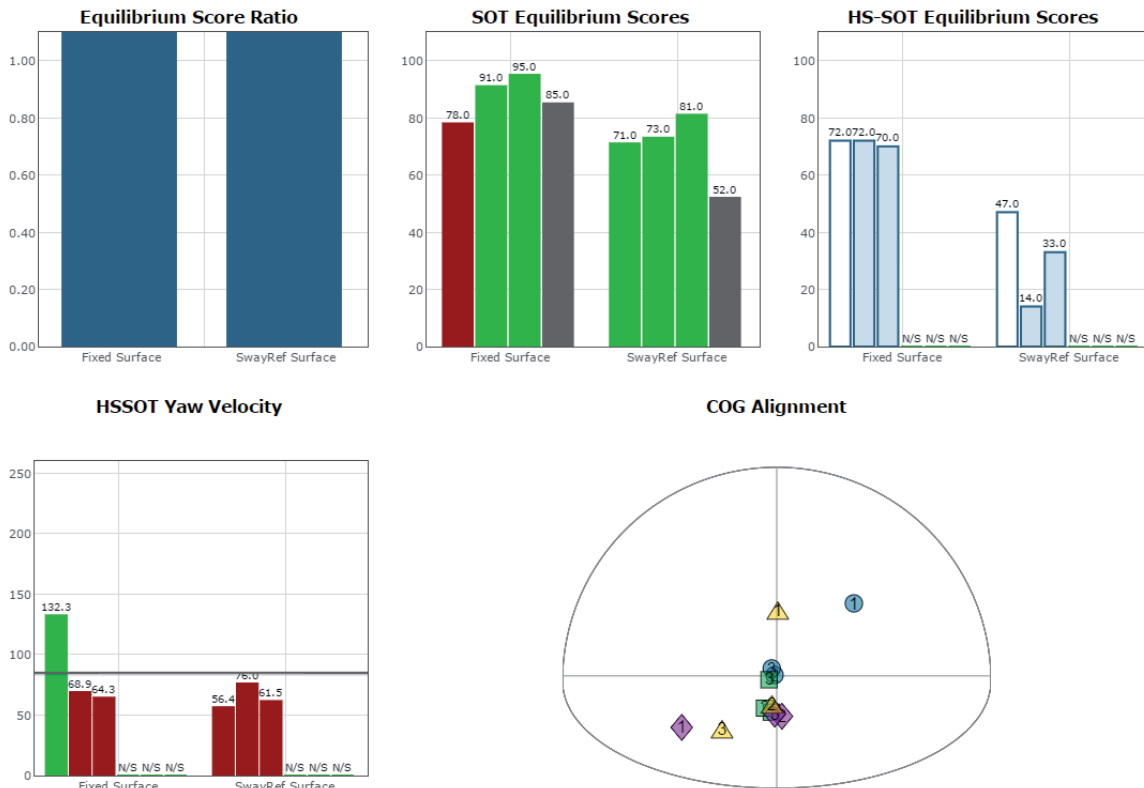


Figure 82: HS-SOT Report

- 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.
- 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.



Hygienic Bouffant Cap should be worn underneath the headband when performing this protocol.

Practical Considerations:

Abnormality	Implications
None	Normal individuals have modest increase in sway during HS-SOT especially with eyes closed. However, they can usually maintain postural stability and avoid falling. Athletes and other high performers may show minimal increase in sway in HS-SOT.
Abnormal HS-SOT	Patients with abnormal HS-SOT usually have subtle or compensated balance problems that can be unmasked only when the task is more challenging.

Training Fundamentals



A wide variety of balance training exercises are available on each balance package. All of the systems implement versions of Seated, Weight Shifting, Mobility, Closed Chain, and Quick training. The CDP/IVR™ also includes Vision training.

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 five categories across the top. Additional options may appear in the selection at this time. These will allow the selection of options, 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. The specified training will then appear in the list.
8. Any available options for the selected trainings will appear in the box titled "Test Options," located immediately below the list of trainings to perform.
9. All trainings require the appropriate level to be selected, based on the capabilities of the patient.

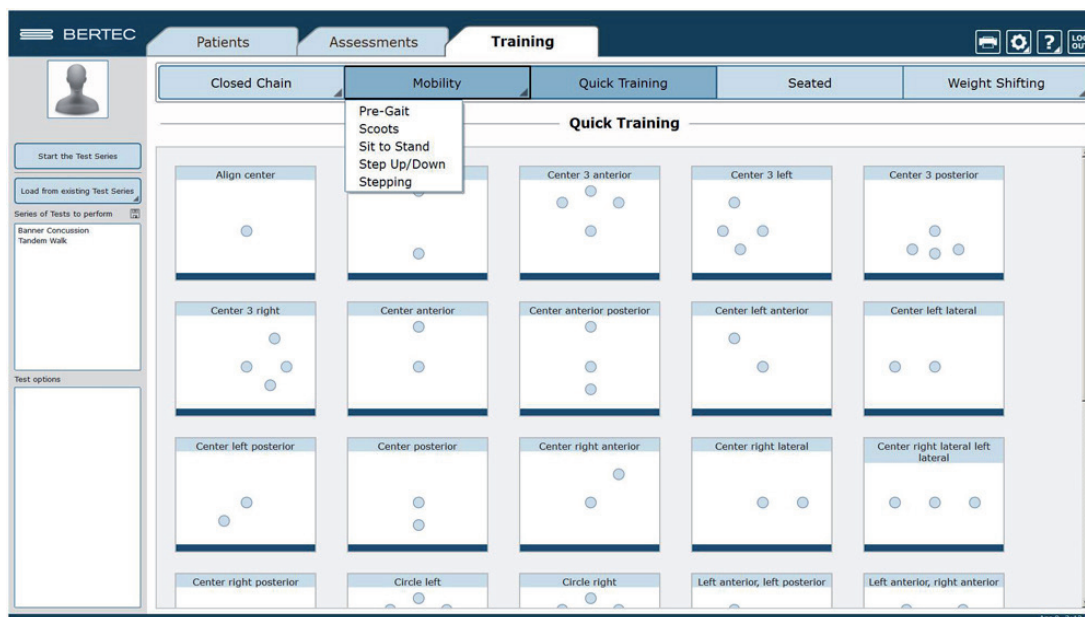


Figure 83: Training Tab Main View. Note the additional options for Mobility training

Training/Test Options:

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

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 15 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 100% LOS ellipse as well as the selected % LOS ellipse.

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.

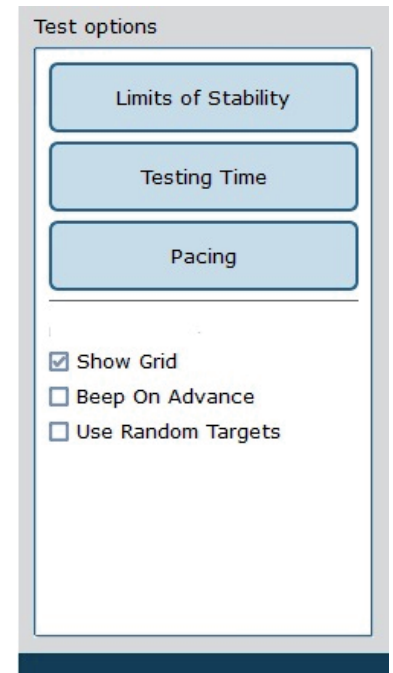


Figure 84: Test Options

Visual Training Options

The training types listed below are only available on the CDP/IVR™ system.

Sway Gain

Controls how much the plate moves while performing a training protocol.

- A setting of 0 means the plate does not move at all.
- A setting of 2 rotates the plate twice the amount the patient is leaning.
- A setting of -1 rotates the plate the same amount the patient is leaning (but in the opposite direction).

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 Figure 85, Figure 86, and Figure 87.



Figure 85: Rock Wall



Figure 86: Checkered Room




Figure 87: Optokinetics Flow

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  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 information, the transition time is averaged and compiled as the compliance score.

Types of Training

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.

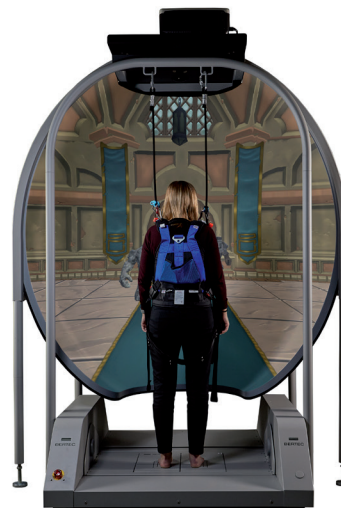


Figure 88: Castle Scene

BERTEC Patients Assessments **Training** LOG OUT

Test Patient
Start Stop
Exit Testing
Castle Scene
End of Tests Report
Notes:

Speed: Medium Slow Medium Fast
Movement Gain: 1.0 -2.0 0.5 2.0
Test Time: 2 minutes 1 minute 6 minutes 10 minutes
Obstacles: Off Easy Medium Hard
mStroop Test: Off Easy Medium Hard
Response Type: Text Color Text

Display Target Circle
 Display COG Cursor
 Audio Feedback

Please ensure that the patient is standing on the plate.

Compliance Score 0.0%
Obstacle Count AVOIDED HIT
0% 0%
mStroop Response Count CORRECT INCORRECT
0% 0%

2:00
0%

For mStroop tests, Button 1 on the remote indicates a Correct response, while Button 2 indicates an Incorrect response.

Figure 89: Castle Scene options

Vision 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 90: Flight

BERTEC Patients Assessments **Training** LOG OUT

Test Patient
Start Stop
Exit Testing
Flight
End of Tests Report
Notes

Test Time: 2 minutes | 1 minute | 6 minutes | 10 minutes
Force Gain: 1.0 | 0.1 | 1.1 | 2.0
 Display Target Rings

Please ensure that the patient is standing on the plate.

Score: 0
2:00
0%

Key Commands:
I through **9**: change speed (current speed: 3)
P: toggle between plane and ground walk
L: toggle camera lock between plane and ground **World Fixed, Plane Rotates**
F: toggle between 1st/3rd person plane view
T: toggle target rings visible and active
A: toggle autopilot
W: skip current waypoint (autopilot only)
J: jump to next waypoint (moves plane, autopilot only)

Figure 91: Flight Options

Vision 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 92: Visual Flow - Grocery

BERTEC Patients Assessments **Training** [Icons: Home, Print, Settings, Help, Logout]

Test Patient
Start Stop
Exit Testing
Visual Flow - Grocery
End of Tests Report
Notes: [Icon]

Speed: Medium	Slow	Medium	Fast
Difficulty: Medium	None	Medium	Hard
Movement Gain: 1.0	-2.0	0.5	2.0
Test Time: 2 minutes	1 minute	6 minutes	10 minutes
Shelf Width: Normal	Narrow	Normal	Wide
Shelf Density: Medium	Empty	Medium	High
Floor Type: Tiled	Tiled	Blank	
Lighting Type: Global	Global	Point	

Please ensure that the patient is standing on the plate.

Score: 0.0%

2:00
0%

Figure 93: Grocery Options

Vision Optokinetic Flow

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.
- Scene Options:
 - o Stripes
 - o Infinite Tunnel
 - o Starfield
- Cognitive Task Options:
 - o Stroop Test
 - o Math Test



Figure 94: Optokinetics Flow

BERTEC Patients Assessments **Training** [Icons: Home, Refresh, Help, Log Out]

CDP/IVR Test User
Start Stop
Exit Testing
2:00
Optokinetics Flow
End of Tests Report
Questionnaires
Session Notes

Background: Stripes Stripes Infinite Tunnel Starfield
 Density: 3 1 6 10
 Speed: 5 0 15 25
 Direction: Top Left Right Top
 Testing Time: 2 minutes 1 minute 2 minutes 10 minutes
 Cognitive Task: Off Off Stroop Rand... Math
 Cognitive Frequency: Low Low Medium High

Display Visual Aid
 Require Balance Plate

Key Commands:
 ▲: increase speed
 ▼: decrease speed
 ▶: increase line density
 ◀: decrease line density
 D: toggle direction of flow
 O: toggle orientation of flow

For Cognitive Testing, Button 1 on the remote indicates a Correct response, while Button 2 indicates an Incorrect response.

**Align the medial malleolus to the black horizontal line, and the lateral calcaneus to the medium lines.
 Please ensure the patient is standing on the plate.**

⚠ Warning: Visuals in the Head Mounted Display may cause motion sickness or dizziness ⚠

Figure 95: Optokinetic Flow options

Vision Boardwalk

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 96: Boardwalk Scene

Patients
Assessments
Training

Test Patient

Start Stop

Ingt Tackling

2:00

Visual Flow - Boardwalk

End of Tests Report

Speed: Medium Slow Medium Fast

Test Time: 2 minutes 1 minute 6 minutes 10 minutes

Obstacles: Off Off Static Dynamic

Central Density: Simple Simple Hard

Peripheral Density: Medium Low Medium High

Distraction Frequency: Low Off Medium High

Cognitive Frequency: Off Off Medium High

Lighting

Display Target Circle

Display COG Cursor

Audio Feedback

Please ensure that the patient is standing on the plate.

Compliance Score	0.0%	
Obstacle Count	Avoided	Hit
	0%	0%
Cognitive Response Count	Correct	Incorrect
	0%	0%

2:00

0%

For Cognitive Testing, Button 1 on the remote indicates a Correct response, while Button 2 indicates an Incorrect response.

**Align the medial malleolus to the black horizontal line, and the lateral calcaneus to the medium lines.
Please ensure that the patient is standing on the plate.**

Figure 97: Boardwalk Training Clinician Screen

Vision Driving

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 98: Driving Scene

BERTEC Patients Assessments **Training**

Test Patient

Start Stop

Exit Testing

2:00

Vision Flow - Driving

End of Tests Report

Session Notes:

Speed: Medium Slow Medium Fast

Test Time: 2 minutes 1 minute 6 minutes 10 minutes

Obstacles: Off Off Static Dynamic

Central Density: Unmarked Unmarked Lane Dividers Worn Surface

Peripheral Density: Medium Low Medium High

Distraction Frequency: Low Off Medium High

Cognitive Frequency: Off Off Medium High

Camera Position: Cabin Cabin 1st Person 3rd Person

Lighting

Display Target Circle

Display COG Cursor

Audio Feedback

Please ensure that the patient is standing on the plate.

Compliance Score 0.0%

Obstacle Count	Avoided	Hit
	0%	0%

Cognitive Response Count	Correct	Incorrect
	0%	0%

2:00

0%

For Cognitive Testing, Button 1 on the remote indicates a Correct response, while Button 2 indicates an Incorrect response.

Align the medial malleolus to the black horizontal line, and the lateral calcaneus to the medium lines.

Please ensure that the patient is standing on the plate.

Figure 99: Driving Training Clinician Screen

Vision Park

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 100: Park Scene

BERTEC Patients Assessments **Training**

Test Patient

Speed: Medium Slow Medium Fast

Test Time: 2 minutes 1 minute 6 minutes 10 minutes

Obstacles: Off Off Static Dynamic

Central Density: Dirt Dirt Rock Brick

Peripheral Density: Medium Low Medium High

Distraction Frequency: Low Off Medium High

Cognitive Frequency: Off Off Medium High

Lighting
 Display Target Circle
 Display COG Cursor
 Audio Feedback

Please ensure that the patient is standing on the plate.

Compliance Score 0.0%

Obstacle Count	Avoided	Hit
	0%	0%

Cognitive Response Count

Correct	Incorrect
0%	0%

2:00
0%

For Cognitive Testing, Button 1 on the remote indicates a Correct response, while Button 2 indicates an Incorrect response.

**Align the medial malleolus to the black horizontal line, and the lateral calcaneus to the medium lines.
Please ensure that the patient is standing on the plate.**

Figure 101: Park Training Clinician Screen

Mobility

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

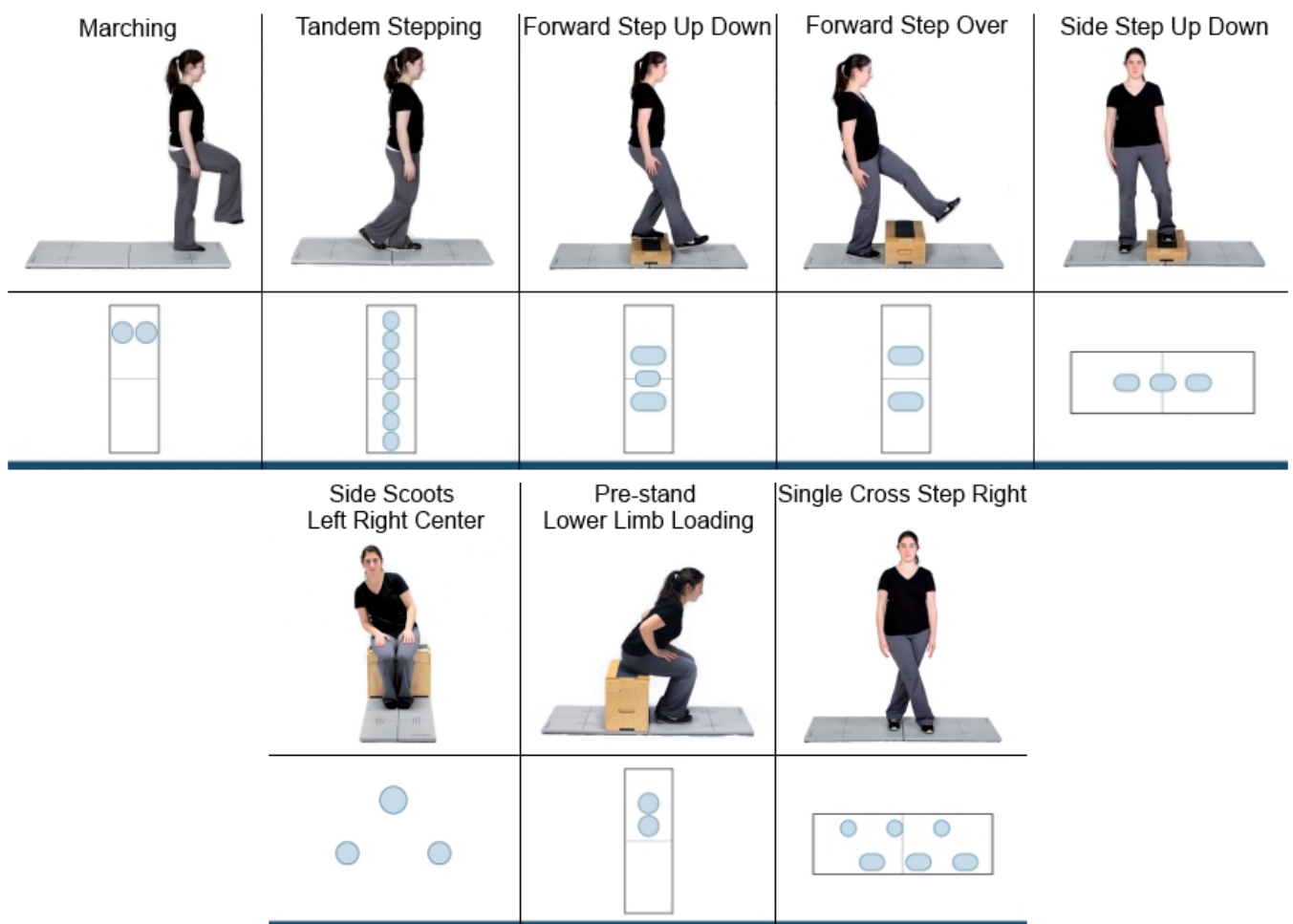


Figure 102: Examples of Mobility Training

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

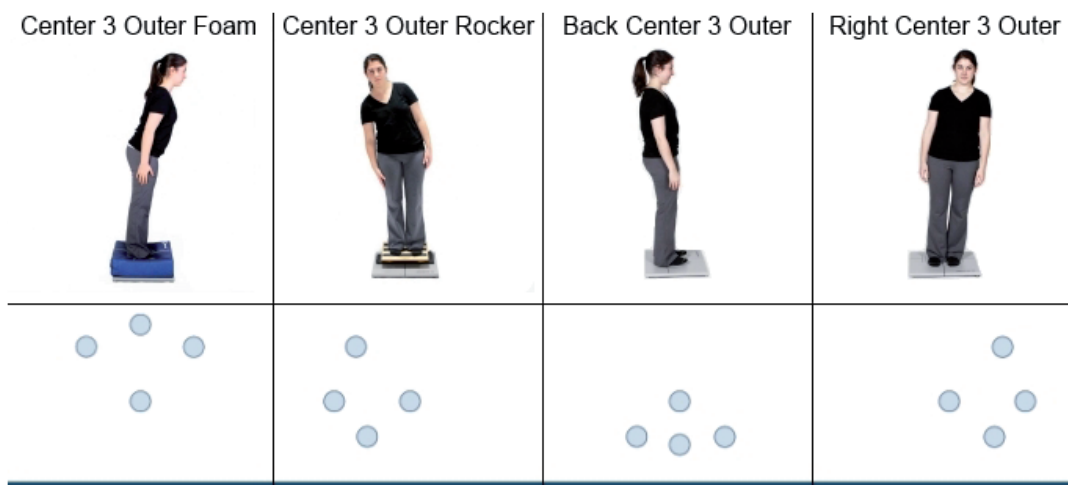


Figure 103: Examples of Weight Shifting Training

Closed Chain

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

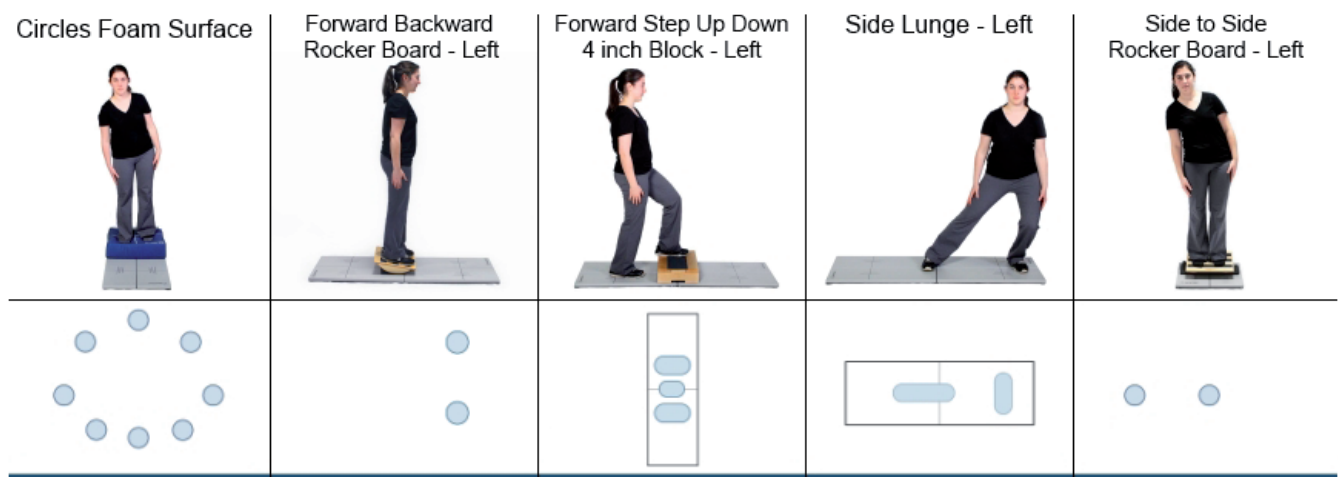


Figure 104: Examples of Ankle Training

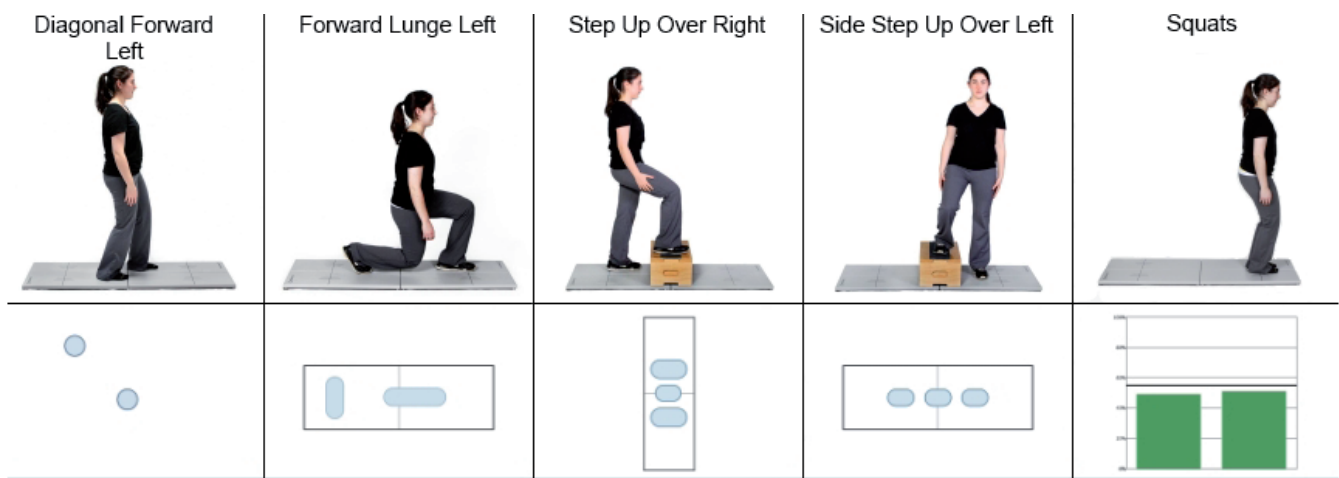


Figure 105: Examples of Knee Training

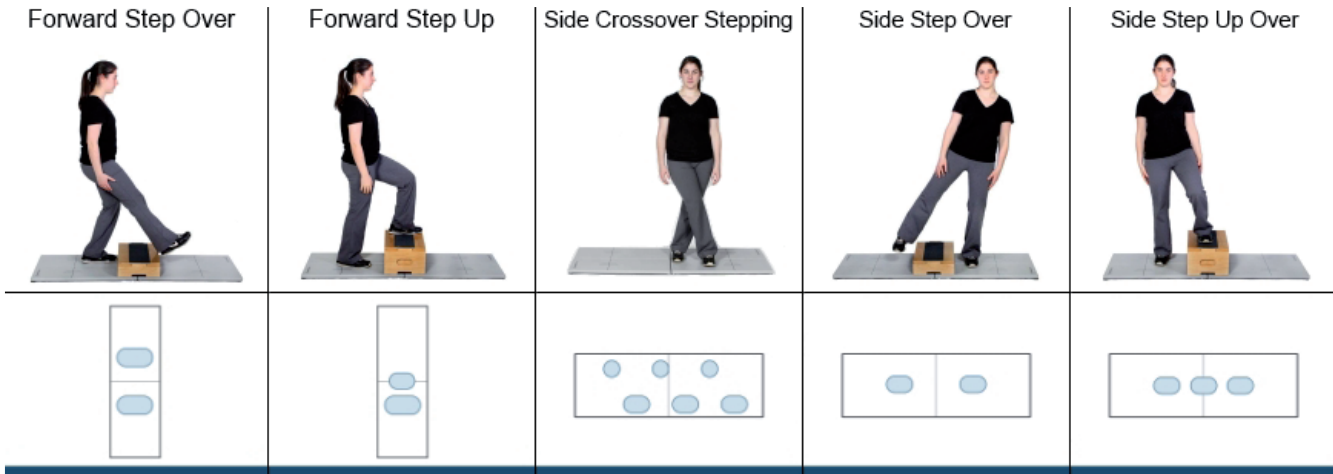


Figure 106: Examples of Hip Training.

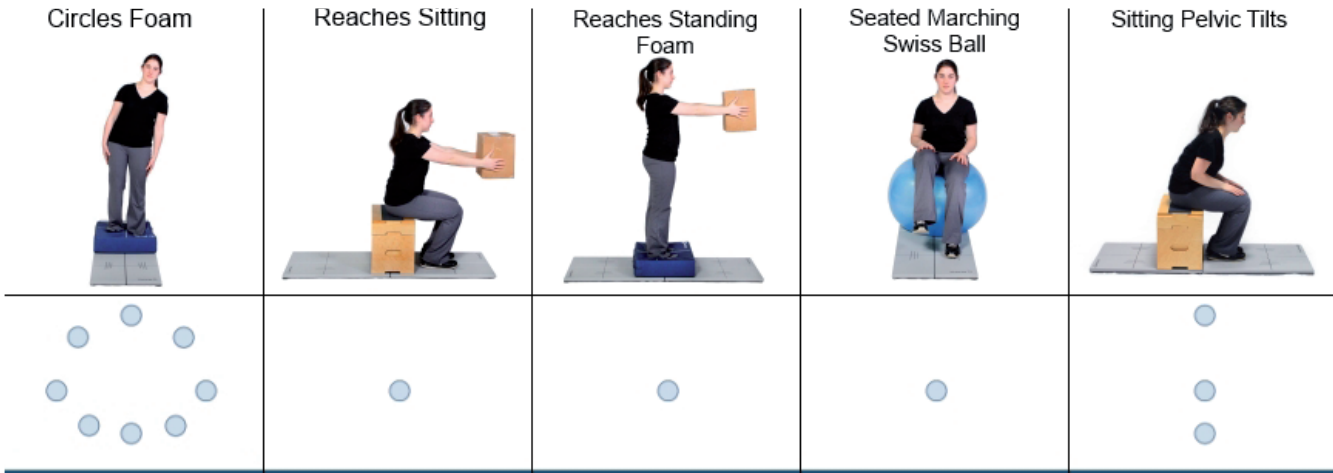


Figure 107: Examples of Back Training

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

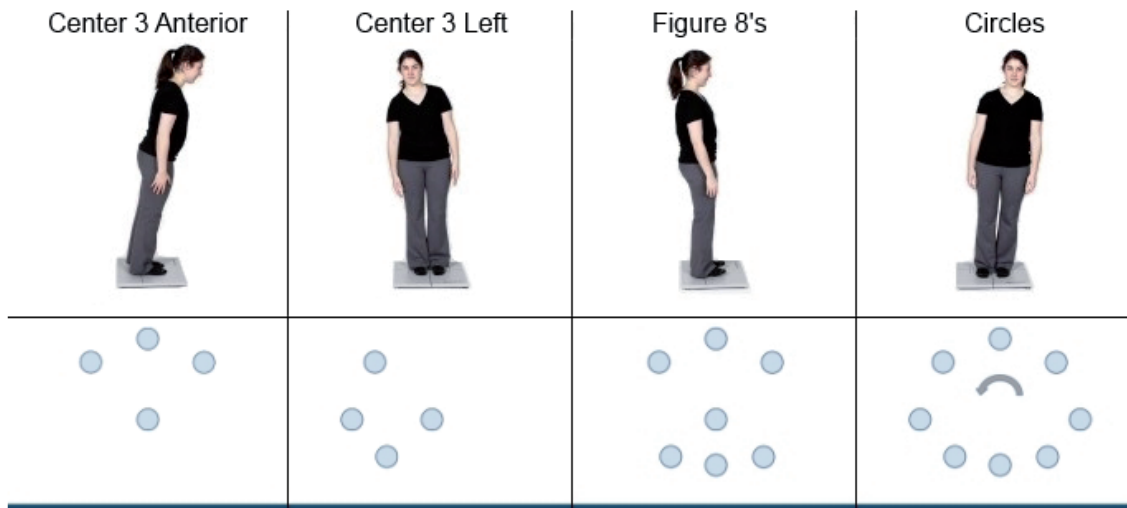


Figure 108: Examples of Quick Training

Additional Training Protocols

The following protocols are available for purchase to add on to your Bertec system and assist in the evaluation of patients:

- Perturbation Training

To add an option to your CDP/IVR system, speak with a Bertec® Sales Representative.

Perturbation Training

Goal

This training is designed based on Motor Control Test and Adaptation Test Assessments to help the patient adapt to a quick visual and/or proprioceptive stimulus during balance training exercises.

Protocol

During this training, the platform movement direction, speed, and distance can be selected. At the same time as the platform movement, the scene movement direction and type can also be selected. At any point during the training, the selected perturbation options can be just visual or just proprioceptive, however the training difficulty can be changed by allowing for simultaneous visual and proprioceptive perturbations as well as increasing speed and reducing predictability by using the "Random" options.

Patient Instructions

"Maintain balance with as little movement as possible during and after the perturbation."

Figure 109: Perturbation Clinician Screen

Training Options

Scene:

- Blank
- Rock Wall
- Checkered Room
- Airport
- Fountain

Delay Start: The time between the start of the trial and the start of the Perturbation. This feature allows for data to be collected prior to the perturbation.

Hold Time: The time between the end of the perturbation and the end of the trial. The platform and/or the scene will re-home its position after this time has elapsed.

Scene Movement:

- Static: No scene movement
- Plate Referenced: The movement of the scene will mimic the movement of the platform during the trial
- Sway Referenced: The movement of the scene is based on the patient's sway during the trial
- Roll Rotation: The movement of the scene will be 15 degrees clockwise or counterclockwise during the trial

Plate Movement: The way in which the platform will move during the perturbation. The user can select None, Rotation, Translation, or Random (a random selection between None, Rotation, and Translation)

Plate Direction: The direction of platform movement during the perturbation. The user can select Forward, Backward, or Random (random selection between Forward and Backward)

Movement Level: The amount of movement from the platform or the scene chosen between a selection of Small, Medium, and Large, or Random (a random selection between Small, Medium, or Large)

Movement Speed: The speed of platform or scene movement can be selected between Slow and Fast.

End of Test Report

The end-of-test report is compiled after completion of a test. This report will include the patient information, the settings from the test, and any data/metrics pertaining to the test. The Perturbation training includes a Movement Score for all trials. Any trials which are translations will also include a Latency score.

Scoring Components

Movement Score: This score is the average patient movement velocity divided by the stimulus velocity. Higher scores indicate more patient movement. Scores can be compared to each other; however rotation movement scores are generally lower than translation movement scores.



Figure 110: Fountain Scene



Figure 111: Airport Scene

Perturbation Report - April 27 2022

Trial	Scene Movement	Plate Movement	Movement Direction	Movement Level	Movement Speed	Movement Score	Latency
1	Static	Rotation (R)	Forward (R)	Large (R)	Slow	45	--
2	Static	Rotation (R)	Forward (R)	Medium (R)	Slow	31	--
3	Plate Referenced (R)	Rotation (R)	Forward (R)	Large (R)	Slow	35	--
4	Static (R)	Rotation (R)	Forward (R)	Medium (R)	Slow	34	--
5	Sway Referenced (R)	Rotation (R)	Backward (R)	Large (R)	Slow	20	--
6	Roll Rotation	Translation (R)	Forward (R)	Medium (R)	Slow	94	139
7	Roll Rotation	Rotation (R)	Forward (R)	Small (R)	Slow	44	--
8	Roll Rotation	Rotation (R)	Forward (R)	Small (R)	Slow	31	--
Delay: None		Hold Time: 2 secs			Scene: Airport		
Trial	Scene Movement	Plate Movement	Movement Direction	Movement Level	Movement Speed	Movement Score	Latency
9	Roll Rotation	Translation (R)	Forward (R)	Large (R)	Slow	127	123
10	Roll Rotation	Translation (R)	Forward (R)	Large (R)	Slow	77	121
11	Roll Rotation	Translation (R)	Forward (R)	Large (R)	Slow	98	125
12	Roll Rotation	Rotation (R)	Forward (R)	Small (R)	Slow	42	--
Delay: None		Hold Time: 2 secs			Scene: Fountain		












Figure 112: Perturbation Report Information













For more detailed design information about this training, please email info@bertec.com and ask to see the Bertec Perturbation White Paper.




Bertec Balance Advantage CDP/IVR™ Safety

This guide contains information, cautions, and warnings which must be followed 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
	Indicates CAUTION unless used with one of the following other captions: DANGER: indicates a hazardous situation which, if not avoided, will result in death or serious injury WARNING: indicates a hazardous situation which, if not avoided, could result in death or serious injury CAUTION: indicates a hazardous situation which, if not avoided, could result in minor or moderate injury
	Mandatory action
	Electrical Shock, High Voltage
	Power on
	Power off
	Earth (Ground)
	Alternating current
	Fuse
	Type B Applied Part Applied Part: CDP/IVR Balance Plate, Head Tracker Note: Subclause 7.2.10 requires that, for clear differentiation, this symbol is not to be applied in such a way as to give the impression of being inscribed within a square.
	Complies with Medical Devices Regulation (EU) 2017/745 and RoHS Directive (2011/65/EC)

Symbol	Description
	<p>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.</p> <p>You can return your device to Bertec or to any Bertec supplier. you can also contact you local authorities for advice on disposal.</p>
	<p>Your remote has been programmed to work with a static system.</p>
	<p>Your remote has been programmed to work with a CDP/IVR™.</p>
	<p>Your remote has been programmed to work with Bertec Vision Advantage (BVA).</p>
	<p>Catalog Number (used in compliance with ISO 15223-1)</p>
	<p>Serial Number (used in accordance with ISO 15223-1)</p>
	<p>Authorized EC Representative in the European Community (used in accordance with ISO 15223-1)</p>
	<p>Consult Instructions For Use (used in accordance with IEC 60601-1)</p>
	<p>Indicates device manufacturer Includes name and address of the manufacturer (used in accordance with ISO 15223-1)</p>
	<p>Manufacturer build date (used in accordance with ISO 15223-1)</p>
	<p>Direct Current (used in accordance with IEC 60601-1)</p>
	<p>Single Use Only</p>

Symbol	Description
	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)
	General Warning

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 safety harness must be worn by the subject at all times when they are completing a protocol on the BBA CDP/IVR system. Proper use of the harness should be achieved using the guidance outlines in this manual. Do not exceed the maximum weight limit of the harness
- 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 appropriate for your product. Only items that have been specified as part of the system, or compatible with the system, shall be connected. The disconnection device shall be positioned for easy access by the clinician at all times during use.
- 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 environments.
- 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 personnel. 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 testing.
- 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 through the CDP/IVR base.
- 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 CDP/IVR base should be plugged into a dedicated outlet that complies with the required power rating of the system. Extension cords or power strips (MSPO) other than those provided with the system, should not be used with the CDP/IVR base. Multiple-socket outlets that are provided as part of the system shall not be placed on the floor. The maximum 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 CDP/IVR base. Do not connect any other devices to the CDP/IVR base. Connecting other devices to the base can overdrive the isolation transformer resulting in a blown fuse or damage to the system.
- Note 19** Do not connect system components directly to wall outlets. By not using the isolation transformer within the CDP/IVR base, you put the patient and operator at risk to be exposed to power surges or electrical shock.
- Note 20** The CDP/IVR base needs to be installed and put into service according to the EMC information provided in this manual. Portable and mobile RF communications equipment can affect medical electrical equipment. The CDP/IVR system 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 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 relocating 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 CDP/IVR™. 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 environment and conditions so that we may provide the best solution for syncing databases.

Note 24 Connection of the CPD to an IT-network that includes other equipment could result in previously unidentified risks to patients, operators or third parties; the responsible organization should identify, analyze, evaluate and control these risks, subsequent changes to the IT-network could introduce new risks and require additional analysis. changes to the IT-network include: changes in the IT-network configuration, connection of additional items to the IT-network, disconnecting items from the IT-network, update of equipment connected to the IT-network, and upgrade of equipment connected to the IT-network.

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 personnel 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.

Guidance and Manufacturer’s Declaration Tables

Bertec Balance Advantage CDP/IVRs™ 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 CDP/IVRs™ are intended for use in the electromagnetic environment specified below. The user of CDP/IVRs™ 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 CDP/IVRs™ 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 CDP/IVRs™ 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 relocating 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 CDP/IVRs™ are intended for use in the electromagnetic environment specified below. The user of CDP/IVRs™ 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 CDP/IVRs™ requires continued operation during very long power mains interruptions, it is recommended that the CDP/IVRs™ 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 CDP/IVRs™ are intended for use in the electromagnetic environment specified below. The user of CDP/IVRs™ 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 CDP/IVRs™, 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 CDP/IVR™			
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 CDP/IVRs™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and CDP/IVRs™ 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 $d = 1.17 \sqrt{P}$ (V1=3)	80 MHz to 800 MHz $d = 1.17 \sqrt{P}$ (E1=7)	800 MHz to 2.5 GHz $d = 1 \sqrt{P}$ (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 <i>d</i> in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where <i>P</i> 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

Part Number	Item	Origin	Termination	No.
	Shielded HDMI Cable (15 ft)	Projector	Tower PC	1
	AC Power Cable with Ferrite (15 ft)	Projector	Base	1
	USB A to B Cable (10 ft)	Inkjet Printer	Tower PC	1
	AC Power Cable (5 ft)	Inkjet Printer	Power Strip	1
30P-0283 Medical Grade	AC Power Cable (10 ft)	Wall Mains	Base	1
	AC Power Cable (6 ft)	Tower PC/Laptop	Power Strip	1
	AC Power Cable (6 ft)	Monitor	Power Strip	1
	Cable Bundle - Audio, USB, DVI (6 ft)	Monitor	Tower PC	1
	Cat-5 Ethernet	Base	Tower PC	1
	Head Tracker Charging Cable (6 ft)	Charger	Head Tracker	1
	Receiver Data Cable (3 ft)	Tower PC/Laptop	Receiver	1

Part Number	Part Name
35P-0048	Pendant Emergency Stop Button Assembly; 25 ft
97P-0033	Single Line Drops For Harness
97P-0041	Standard Harness - up to 300 lbs
97P-0034	Bariatric Harness - up to 450 lbs
97P-0035	Pediatric Harness - up to 100 lbs
37P-0082	Projector Replacement Lamp
36P-0147	Remote Control for Projector
37P-0005	22-inch LED Touch Screen Monitor
37P-0019	Power Strip, 6 Outlet 125 VAC 15A
37P-0003	System PC, Dynamic System
37P-0023	Corded Keyboard and Mouse
37P-0024	Webcam 500 5MP Camera
80P-0002	Balance Advantage CDP/IVR System User Manual
30P-0238	Head Tracker for HS-SOT Protocol
30P-0239	Receiver (HS-SOT Protocol)
97P-0051	Headband (HS-SOT Protocol)
37P-0060	Wall Charger for Head Tracker (HS-SOT Protocol)
97P-0053	Poly Hairnet/Bouffant Caps - 100 Count
97P-0079	Hygienic Foot Covers - 100 Count
37P-0029	Wireless Remote
97P-0076	Standard Balance Advantage foam with cover

Appendix A: Abbreviations and Glossary

Adaptation Test (ADT): The protocol quantifies impairments in the patient's ability to adapt automatic responses to minimize sway when exposed to surface irregularities and unexpected changes in support surface inclinations. The ADT quantifies the patient's ability to systematically reduce their sway energy during repeated exposure to the same surface tilt disturbance.

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.

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.

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.

Computerized Dynamic Posturography: Postural sway is quantified by measuring sway in conditions in which visual and somatosensory cues are absent or altered.

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.

Forward Lunge (FL): The assessment quantifies the patient's ability to control body weight while lunging forward with one leg.

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.

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.

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).

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.

Motor Control Test (MCT): The protocol assesses the ability of the automatic motor system to quickly and effectively recover after an unexpected support surface disturbance. The MCT isolates and quantifies impairments in timing and strength of the automatic response in each leg, as well as impairments in coordination of responses between the two legs and movement directions.

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.

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

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.

Appendix B: References

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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.

On the CDP/IVR™ System, how do I undo the Emergency Stop?

After pressing the emergency stop button, the red button will need to be released through being twisted to the right. Afterwards, pushing the flashing button will release the safety brakes. If this does not work, contact Bertec® Support.

Why Won't my Computer, attached to the CDP/IVR™ System, Turn on?

The computer is attached to the base of the CDP/IVR™. This base protects against electrical surges and other electrical issues. While protecting the computer and system, the base's breaker probably flipped--keeping the system safe, but turning it off in the process. Contact Bertec® Support for instructions on how to turn the system back on.

How do I Archive One Patient?

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 One Patient?

From the clinician home screen, select the patient to delete. Right-click on the patient. In the dropdown list, select Delete Patient. If a patient archive is needed, leave the check box selected. Select OK. 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 routinely (i.e. every few months) for security measures. 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). Refer to Figure 113.
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 113: 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). Refer to the image above on the right.
3. On the dropdown menu, click on the Configuration option.
4. In the middle left corner of the new window, click on the Operators button.
5. Select the correct 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. If desired, the password can be blank. However, this is not recommended.
7. Click Ok on both windows to finish changing the operator's password.

Appendix E: Using the Wireless Remote

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 specific trials 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 114. It needs to be plugged into the computer's USB for the remote to function with the system. Do not attempt to store files on the Dongle.



Note: Refer to the Bertec Balance Advantage Dynamic System Safety for remote labelling and programming information.

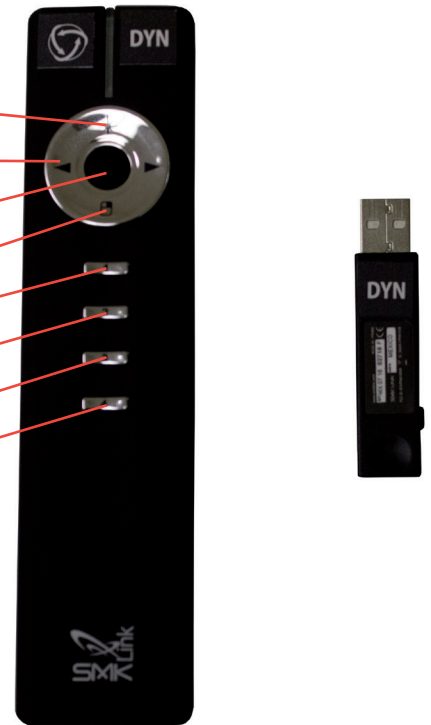


Figure 114: Remote and Dongle

Appendix F: 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 diagnostic process.

1. Click on the settings button, illustrated in Figure 115.
2. In the dropdown menu, click on the Reset Sensors button.
3. If this process does not appear to fix the plate, try again and ensure that the plate is not disturbed.
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 115: Settings Button

Manual Calibration

If the steps above do not work, manual calibration could be necessary. This often occurs because the balance plate becomes damaged (for example, dropped) and is sending error messages or providing erroneous data. In this case, the plate must be returned to Bertec® for repairs. Please call the customer support line for assistance if the plate is not working properly or has been damaged.

Appendix G: Aligning the CDP/IVR System

The CDP/IVR System can be aligned using our built-in alignment pattern found in the Balance Advantage software. This alignment pattern can be used to determine the optimal position of both the image from the projector as well as the balance plate for your system. To find the alignment pattern, follow the steps below.

1. Open the Balance Advantage software
2. Click on the settings button (Figure 116)
3. In the dropdown menu, click on the Configure Dome Projector button.
4. Ensure that the 1-meter dome with fisheye lens option is selected
5. Select the check box that says "Show Alignment Pattern" as seen in Figure 117.
6. The pattern (Figure 118) will project both on the dome as well as partially on the floor underneath the lens (Figure 119). The image has proper alignment when the bottom alignment square (circled in Figure 119) is touching the front edge of the dome and measures 5.5" tall.
7. There is a + symbol which is labeled 90* at the bottom of this alignment pattern and projected on to the floor. As shown in Figure 120, that + symbol should be centered in the middle of the balance plate.
8. Once the alignment is set, click OK for the alignment pattern to close.



Figure 116: Settings Button

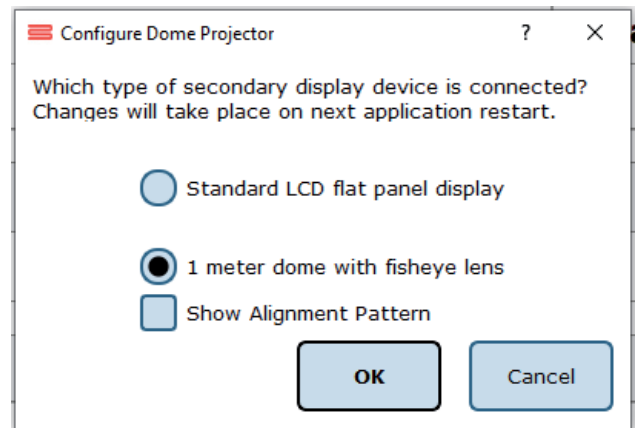


Figure 117: Configure Dome Projector



Figure 118: Alignment Image



Figure 119: Dome Alignment

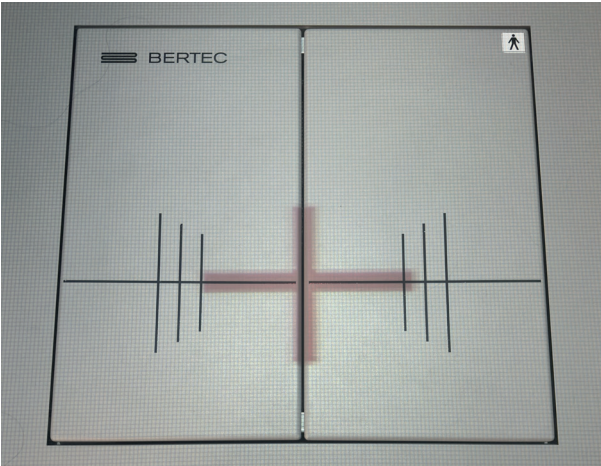



Figure 120: Balance Plate Alignment

Appendix H: 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 or In of Sending Anonymous Program and Performance 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 six different tabs: Version, Addons, System, License Agreement, Privacy Policy and Support. These tabs are underlined/described below and on the following page.

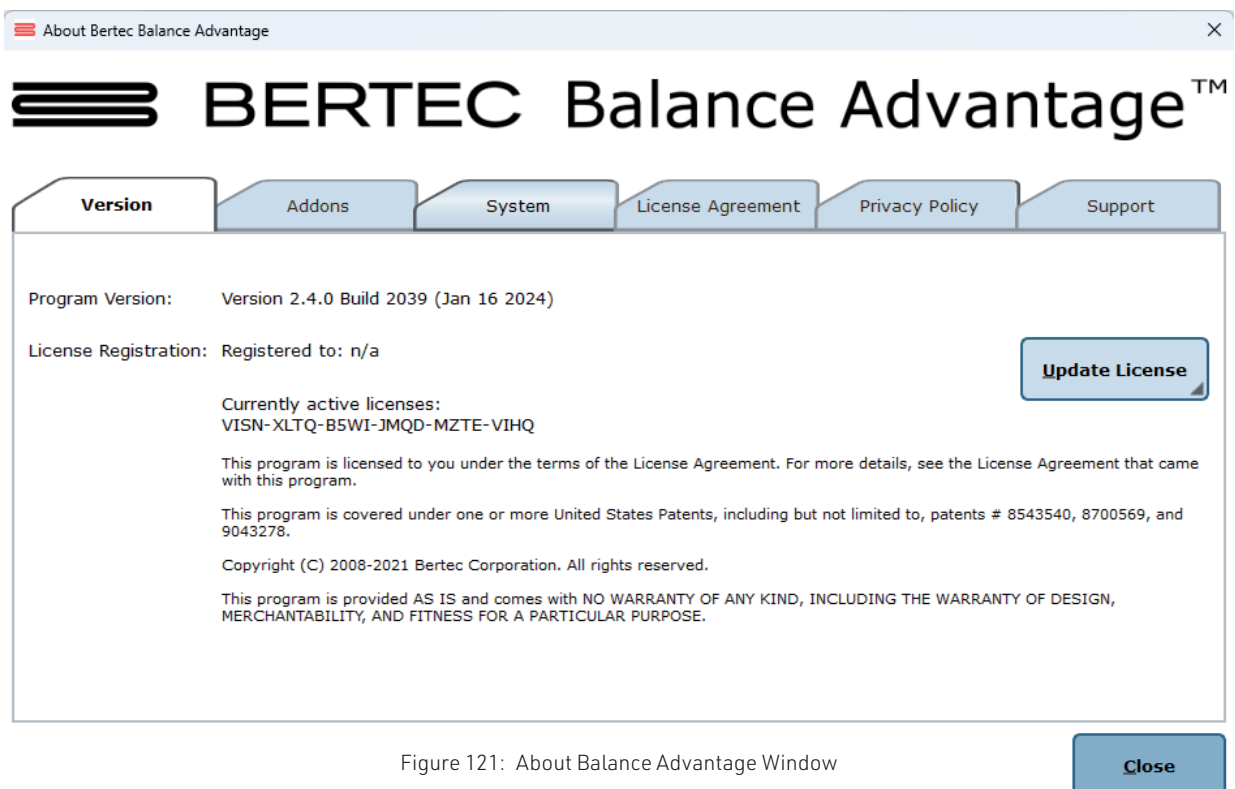


Figure 121: About Balance Advantage Window

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.
4. If the license key is successfully registered, click Ok, then click Yes to exit and restart the software.
5. If the license key is shown to be invalid, click Ok and enter a correct code. If the code is not accepted after a few tries, contact Bertec® support (contact information is included in the Support tab described on the following page).



Note: The computer does not need to be connected to the internet to register a license key.

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. There is no need to upload this information unless support is needed, though. If desired, the operator may write down this information in case of a system crash occurs.

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

Privacy Policy: The Privacy Policy tab displays the Privacy Policy, included in this manual. The option to opt in or out of sharing anonymous program performance and general usage data is available in this tab and can be done at any time.

Support: The Support tab includes information and instructions for contacting support, in addition to Bertec's address and the option to collect and report software failure.

To opt out of sending anonymous software failure reports to Bertec® :

1. In the Support Tab, click on the box to the left of the phrase "Collect and report screenshots during application faults" 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 I: 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 - Long 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.

<p>Attempting to save the Security Role "XXXX" failed. Attempting to save the Security Role "XXXX" failed because the identifier is null.</p>	<p>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.</p>
<p>Attempting to delete the Security Role "XXXX" failed.</p>	<p>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.</p>
<p>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.</p> <p>failed to complete</p> <p>Merge Failed</p>	<p>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.</p>
<p>Restoring the database from XXDatabaseNameXX. The existing database was not replaced. Click OK to continue testing with the current, unchanged, database.</p> <p>Restore Failed</p>	<p>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.</p>
<p>The integrity check did not find any errors with the database.</p>	<p>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.</p>
<p>There appears to be some problem with the database - you may want to restore from a backup copy or use the Rebuild Database feature.</p>	<p>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.</p>
<p>The database was not able to be optimized; this may be due to lack of disk space or memory.</p>	<p>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.</p>
<p>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.</p> <p>Recovery Failed</p>	<p>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 back-ups and then trying the recovery process again.</p>
<p>The additional field "XXAdditionalFieldXX" is already being used. Please enter a new name for this additional field.</p> <p>Name error</p>	<p>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.</p>
<p>The operator name "XXOperatorNameXX" is already being used. Please enter a new name.</p> <p>Name error</p>	<p>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.</p>

<p>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.</p> <p>Backup the database before performing the database upgrade?</p>	<p>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.</p>
<p>The License Key that you have entered is invalid.</p> <p>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.</p>	<p>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.</p>
<p>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?</p> <p>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.</p> <p>The Activation Code that you have entered is invalid or empty.</p> <p>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.</p> <p>Invalid Activation Code</p>	<p>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.</p> <p>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.</p>
<p>The operator "XXOperatorXX" cannot be logged in.</p> <p>Please check that the operator name and password are correct, and that operator "XXOperatorXX" has the proper access rights.</p> <p>Please click OK and re-enter the operator name and password in order to log into the system</p> <p>Login Error</p>	<p>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.</p>
<p>It looks like there is no email client program installed or configured to send email.</p> <p>This is common if you are using some form of web-based email such as Google Mail, Hotmail, Yahoo Email, or similar.</p> <p>You would like to save the PDF report to your Documents folder so that you can send it yourself using your web-based email?</p> <p>Mail send failure</p>	<p>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.</p>
<p>One or more of the required patient fields are blank or incorrect. Please complete the fields and press Save again.</p> <p>Unable to commit</p>	<p>There is information missing in the Patient Information profile that you are creating. The required fields preventing the commit are highlighted in yellow.h</p>

<p>One or more of the required Additional Fields values are blank. Please complete the fields and press Save again.</p> <p>Unable to write patient additional field records to database. Changes have not been saved.</p>	<p>There is information missing in the Patient Information profile that you are creating. The required Additional Fields preventing the commit are highlighted in yellow.</p>
<p>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.</p>	<p>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.</p>
<p>Unable to write the patient picture to database. However, the other changes have been saved.</p>	<p>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.</p>
<p>Do you really want to delete XXPatientNameXX? This operation cannot be undone!</p> <p>Delete Patient</p>	<p>Marking a patient as deleted means that their information will no longer be visible to any operator that logs into the system. The patient information will be deleted from the database and retrieving their data cannot be done.</p>
<p>Are you really sure that you wish to restore the archive from XX-ArchiveNameXX? 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.</p> <p>This operation cannot be undone! Anything you currently have in the database will be gone forever! This is your last chance to change your mind!</p>	<p>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.</p>
<p>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.</p>	<p>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.</p>
<p>This test was completed successfully. Are you sure that you want to redo it and overwrite the data?</p> <p>This cannot be undone!</p>	<p>This message only occurs if a successfully completed test is being overwritten by another test. There are very few protocols that allow this functionality.</p>
<p>Are you sure that you want to delete the last collected %1 results%2? This cannot be undone!</p> <p>Delete Results</p>	<p>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.</p>



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