

Bertec[®] Balance Advantage[®] Spark Systems User Manual

2 Spark Systems User Manual 80P-0091 2023-09 For customer support or sales, please contact:

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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 Versions 1.0.0, 2.0.0, 2.1.0, and 2.3.0

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Instructions for Use

This manual covers standard operating procedures for the following products:

- Bertec[®] Balance Advantage[®] CDP Spark System
- Bertec[®] Balance Advantage[®] Essential Spark System



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

Read Carefully Before Proceeding

Intended Use:

Balance Evaluation and Rehabilitation

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

BBA systems should only be operated by qualified personnel.



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

- The successful use of the Bertec[®] technology requires an appropriate level of professional expertise to develop proper treatment programs that are specific to the patient and their individual cases. The user should be confident they understand the operation of the system, can properly administer test protocols, and interpret results.
- All Bertec CDP Spark systems are intended to remain in place after installation. Bertec[®] Corporation must be contacted if, for any reason, the Bertec CDP Spark system must be moved. Bertec Essential Spark units 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 reference Bertec Support contact information.

General Maintenance

Bertec[®] balance systems require only basic maintenance, performed on an as-needed basis. For more in-depth cleaning instructions see the Bertec Maintenance Manual.

CDP Spark 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 your support representative when this occurs.
- For good hygiene, patients should wear footies.

Essential Spark Systems

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

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 your support representative for more information on how to schedule your preventative maintenance service this year.

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Welcome

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

Assessments	CDP Spark	Essential Spark
Sensory Organization Test	\checkmark	
Motor Control Test	\checkmark	
Adaptation Test	\checkmark	
Limits of Stability	\checkmark	\checkmark
mCTSIB		\checkmark
Rhythmic Weight Shift		
Unilateral Stance		
Weight Bearing Squat		
COBALT		•
Head Shake SOT	•	
Trainings		
Quick Training	\checkmark	\checkmark
Vision Training	▼	
Mobility Training		
Weight Shifting Training		
Closed Chain Training		
Other Features		
Extra Visual Training Scenes	▼	•
Raw Data Export		
Separate User Accounts		
Data Merge & Sync		

- ✓ Features automatically come with product
- Assessment purchasable with product
- Visual Flow Package: purchasable with product to unlock additional training scenes and related features
- Enterprise Package: purchasable with product to unlock additional data analysis and user features

Bertec[®] Balance Advantage[®] CDP Spark

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

Optional

- Head Shake SOT
- Pediatric safety harness
- Bariatric safety harness
- Extended Warranty

- Height adjustable clinician workstation
- Dedicated computer
- Touchscreen monitor
- Wireless keyboard
- Wireless pointing device/mouse



Included Accessories

 Foam balance pad (18" x 20"x4")

SPECIFICATIONS

Features

- Immersive virtual environments
- Essential assessment and treatment protocols
- Low 4" step height onto an 18" x 20" dual-balance force plate
- High-sensitivity dual-balance plate
- Clinician touchscreen display

Assessments

- Sensory Organization Test
- Motor Control Test
- Adaptation Test
- Limits of Stability

Training

- Quick Training

Solution

- Intuitive software
- Configured to meet your needs
- Unsurpassed classroom education
- Ongoing support
- 500 lb load capacity
- One year parts and labor warranty

Specifiations	
Balance Plate Fz (Vertical Force)	Sensitivity 0.05 lb
Balance Plate COP Accuracy	±0.08 in (forboth COP x and y)
Motion Base Rotation (AP)	±10 deg rotational displacement
Motion Base Rotation (AP)	±50 deg/sec max rotational velocity
Motion Base Translation (AP)	±2.5 in translational displacement
Motion base franslation (AP)	± 6 in/sec max translational velocity
Bilateral Balance Plate COP	Each subject foot independently
Immersive Visual Surround	Computer generated VR based graphics are displayed on a projection screen which remains stationary
Fully Assembled System	76" x 67" x 102" (W x L x H)
Minimum Ceiling Height	102″
System Weight	575 lb
Step Height	4"
Dual Balance Plate	20" x 18" x 1.5" (W x L x H)
Height Adjustable Clinician Workstation	20" x 28.8" x 68.5" (W x L x H)
Touchscreen Display for Clinician	22″ 1080p optical touch monitor
Color Screen Display for Patient	22" 1080p LED monitor
Maximum Patient Weight	500 lb
Maximum Patient Height	80"
Electrical Requirements	Dedicated 100 V 20 Amp NEMA5-20R outlet/power source

Safety

350 lb)

- Easily accessible E-stop control/ switch
 Sturdy safety harness structure
 Standard adjustable safety harness (max weight capacity
 Integrated medical grade power
 - Integrated medical grade power isolation transformer

Bertec[®] Balance Advantage[®] Essential Spark

BERTEC[®] BALANCE ADVANTAGE[®] PACKAGES

Standard Package

- Bertec[®] Balance Advantage[®] software
- Dual-balance force plate
- Laptop computer
- Power cable and USB cable
- Wireless pointing device/mouse
- Foam balance pad (18" x 20" x 4")

Optional Components

- Carrying case
- COBALT™ powered by Bertec[®]



SPECIFICATIONS

Features	Assessments	Solution
Standardized protocols with normalized data	mCTSIB	Intuitive software
Low 1.5" profile in an 18" x 20"	Limits of Stability	Ongoing support
configuration	Training	500lb load capacity
High-sensitivity dual-balance force plate	Quick Training	One-year parts and labor warranty

Fundamental Operations

Turning on the CDP Spark System



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

The Dynamic CDP Spark's base needs to be initialized so that the computer and system can be turned on.

Step 1: Initialize the Base of the CDP Spark System

Flip the green switch by pushing it on the side marked with a "|" symbol. After several seconds, the Emergency Stop button on the base and the remote pendant will flash.



Note: The base, turned on, is shown in Figure 4. To turn off the entire base, press the opposite end of the switch marked with an "O". 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.

Step 2: Respond to the Flashing Light

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



Note: The white Enable button is highlighted in Figure 5.

The last piece of equipment to initialize is the projector.

Step 3: Initialize the Projector

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). Press the remote's power button once and wait 10-15 seconds for the bulb to illuminate.



Note: The remote's power button is highlighted in Figure 2A and 2B (depending on your projector model). 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.



Note: 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 1a: Base Switch



Figure 1b: Estop



Figures 2a and 2b: Projector Remotes

Initial Startup and Login



All Bertec® Balance Advantage® systems include either a dedicated tower computer attached to a cart or a laptop. Be cognizant of the system's wires when testing a patient.

Dedicated Tower System

- 1. Press the power button on the top of the computer tower.
- 2. The power button will illuminate once the system is turned on.
- 3. Log in to the desktop.
- 4. On the desktop, click on the Bertec[®] Balance Advantage[®] logo to load the software.
- 5. If prompted for a password, enter "password" in all lower-case letters, then press the Enter key on the keyboard (or click the "Login" button).

Portable Laptop System

- 1. Press the power button on the side of the laptop
- 2. Log in to the desktop.
- 3. On the desktop, double click 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).



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).

Logging out of Balance Advantage

- 1. Click on the log out button, located in the upper right corner of the screen (shown in Figure 4).
- 2. Click on the exit button (shown in Figure 5).

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



Figure 3: Laptop Power



Figure 4: Logout



Figure 5: Exit

Routine Startup and Login

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

Starting the System

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

Logging in to the Program

- 1. Open Bertec[®] Balance Advantage[®]. Arrive at the login screen, shown in Figure 6.
- 2. Click on the correct username within the Operator box.
- 3. Make sure the desired operator is highlighted in blue.
- 4. Type in the password that was set for the selected operator.
- 5. Click the "Login" button or press the Enter key to arrive at the clinician home screen. Refer to the following page for information regarding the clinician home screen.

 DESERTES

 BERRETES

 BERRETES

Figure 6: Login

Clinician Home Screen

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



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

- 1. Patient Information: Patient information is displayed within the Patients tab. This is the primary interface for loading a patient, creating a patient, and viewing a patient's history.
- 2. Assessments: All of the balance protocols available with the system are located within the Assessments tab. Each protocol is represented by an easily identifiable icon that can be dragged and dropped into a test series.
- 3. Training: A wide range of options are available to help rehabilitate a patient in the Training tab.



Once a patient is selected, an operator may complete assessments or training by clicking on the Assessments or Training tabs. The clinician home screen is illustrated in Figure 7: the top bar highlights the tabs, whereas the bar on the left shows where patient information is stored.

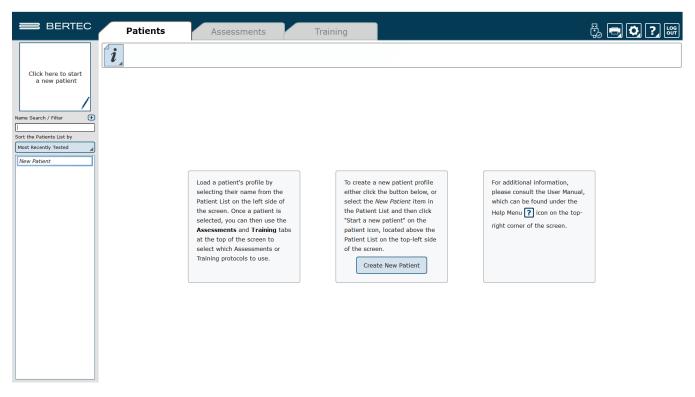


Figure 7: Clinician Home Screen.

Facility Setup and System Configuration



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

Options Setup

The operator must select the gear icon in the upper right corner of the screen and then click on Configuration. In doing so, the operator will load the configuration options screen in a new window where General Settings, Test Settings, Additional Fields, Test Series, and the Database can be configured (Figure 8).

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), in addition to other options, such as the requirement that patients must have a valid identifier, if the program should zero the plate when the system starts or the plate is connected (so that there is no need to click the Zero Plate Load menu item), and what Report Header will be contained at the top of each report page.

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.

Configuration (Options	×
General Settings Test Settings	These settings are used to control how Bertec Balance Advantage behaves overall. Units: Imperial (inches, pounds) Require Patients to have a valid identifier (otherwise, can be blank) Zero the plate whenever the program starts or the plate is connected (otherwise, use the menu item)	
Additional Fields	The Report Header is shown just before the Patient Information on the first page of any patient report.	
Database	The Report Footer is shown at the end of the last page of any patient report, after the test results.	
	ОК Cancel	

Figure 8: Configuration General Settings

Test Settings

The Test Settings configuration options, shown in Figure 9, 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.

General Settings Settings	
	n't require it (more disk storage used)
	OK Cancel

Figure 9: Configuration Test Settings

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.

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 10 shows the 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 12 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 11. 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 0k to save the new field/update.

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.

🚍 Edit Additional Field	×
Additional Field Name: Treating Physician	
Description:	
Type: Any Text Values List:	
Sort Order: 1	
Required: 🦳	
	OK Cancel

Figure 10: Edit Additional Field

Allow Multiple Selections: () Yes () No

Figure 11: Allow Multiple Selections Box.

💳 Edit Additional Fields	×
Symptoms	Name <pre> Rename</pre>
Do you feel depressed?	Allow Multiple Selections: 🔵 Yes 💽 No
<new entry=""></new>	Type List Contents Here
Add New List	Delete List OK Cancel

Figure 12: Values Editor Window

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 Figures 13a and 13b.
- 2. After clicking, a popup window will appear with empty patient information fields. The popup window is illustrated in Figure 14.
- 3. Fill in all required fields. These fields are colored yellow. Afterwards, fill out relevant (but optional) information fields.
- 4. (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.
- 5. Click on the Save Changes button to establish the new patient profile.

To create a new patient profile, either click the button below, or select the New Patient item and click "Start a new patient" on the top-left of the screen.

New Patient

Figures 13a and 13b: Creating New Patients.

New Pat	ient					×
Name:	First Name		Last Name			
dentifier:		Sex:	Male 🖌	Date of Birth:	MM / DD / YYYY	
Height:	feet' inch	nes"				
Phone:		Alt:]		
E-Mail:]	
Address:						
						Turn on Camera
					Additional Fields	Notes
	Field			v	'alue	<u>*</u>
Treating	9 Physician					
Complai	nts					
Diagnos	is					
Goals						•
					Save Cha	nges Don't Save Changes

Figure 14: The New Patient Window.

Recalling Existing Patients

To Select a Patient who is Already in the System

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

Filtering by Additional Fields

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

For example, if a list has been created for Physical Therapist containing John, April and Joanne, the patient list can be filtered to show only Joanne's patients. To do this, click on the + sign (shown in Figure 15a) next to Name Search / Filter, then click on Physical Therapist, then on the box next to Joanne. This screen is shown in Figure 15. 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 15a: Patient Sorting

Select Filter Field		?	×
Field:	Treating Physician value(s) to filter with:		
Treating Physician			
Referring Physician			
Physical Therapist			
Complaints			
Diagnosis			
Goals			
ICD9			
Assessments			
Trainings			
	ОК	Cance	

Figure 15: Select Filter Field - Patient List.

New Plate Configuration

When an unrecognized plate is connected to the system, a pop-up window will appear immediately after the operator logs into the software, as shown in Figure 16. The operator should click on the image matching the plate that has just been plugged in and select OK. It is critical the correct plate is selected; an incorrectly identified plate will result in skewed test calculations.

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

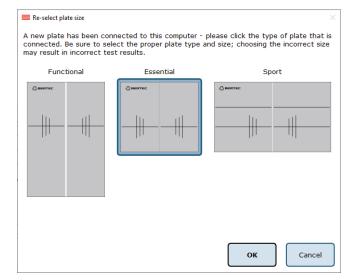


Figure 16: Pop-up Window.

Patient Assessment

To Start a Patient Assessment

- 1. Create a New Patient or access an Existing Patient.
- 2. To perform new assessments, click the Assessments tab, shown in Figure 17, then drag and drop the desired assessment(s) into the Test Series List, located on the left.



Note: Assessments can be re-ordered within the test series by clicking and dragging the test name to a new position. For a description of an assessment, refer to the appropriate chapter devoted to that assessment further in this manual.

- 3. After setting up the order to perform the assessments, select Start the Test Series, located directly below the patient's name in the top left corner.
- 4. Properly position the patient's feet on the balance plate. For most assessments, a patient will position their feet such that their medial malleoli are aligned with the line running from left to right and the lateral calcanei are aligned with the small, medium, or large lines. This will be indicated on the clinician screen. In general, the patient is allowed to splay their feet equilaterally so that they are standing comfortably. Proper foot placement is illustrated in Figure 18.
- 5. Perform the assessments as directed on the computer screen. At any point during an assessment, the clinician may input notes by clicking in the Test Notes area, located on the bottom left corner of the screen. Figure 19 shows this screen.



Figure 17: Assessments Tab

	Eyes Open	Eyes Closed	Eyes Open - Foam	Eyes Closed - Foam
atient One	4.0	4.0	4.0	4.0
Stop	3.0	3.0	3.0	3.0
Egit Testing	2.0	2.0	2.0	2.0
SIB of Stability				
t Bearing Squat ^f Tests Report	1.0	1.0	1.0	1.0
	Trial 1 Trial 2 Tri	al 3 Trial 1 Trial 2 Trial 3	Trial 1 Trial 2 Trial 3	Trial 1 Trial 2 Trial 3
			42%	
		-	42%	
		Timer Bar		

Figure 19: Example Clinician Screen During Assessment.

To View and Print Reports of Completed Assessments

- 1. Navigate to the patient tab and confirm the correct patient is selected.
- 2. Above the patient information is a timeline that displays a date for each day a record has been recorded for the patient. Click on the date and the assessment to select the proper report.
- 3. Once the desired assessment report is pulled up, click on the print icon located in the upper right corner of the screen.
- 4. Progress reports can be viewed by returning to the Patients tab, shown in Figure 20.

BERTEC Pati	ents Assessments	Training		2
42012	(2013) (2013)	Indining		
	May May May 24 23 21			
Patient Informa				
Name: Patient	Quick Training 4:01 pm		Height: , Weight: BMI:	
Identifier:	Quick Training 4:16 pm	Sex:	Date of Birth:	
ch / Filter				
2h / Filter			Phone:	
tients List by			Email:	
ently Tested				
nty Tested A Patient Notes				
ntty Tested A Patient Notes				
nti Dine Additional Infor				
ntly Tested Patient Notes at Additional Infor Treating Physicia				
ntty Tested Additional Infor Treating Physici Referring Physici	6			
ntty Tested Anton	6			
ndty Tested nd Dine Additional Infor Treating Physicia Referring Physicia Referring Physicia Complaints	6			
ntty Tested A nt One Additional Infor Treating Physical Referring Physical Physical Therapis	6			

Figure 20: Return to Patient Screen to View Test Reports

Re-collecting Trials



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

To Repeat a Trial

- 1. Hold down the Control (Ctrl) button and press the Delete (Del) button.
- 2. In the popup window that appears, shown in Figure 21, choose either Yes, I want to delete the last collected trial, or No, I do not want to delete the last collected trial.
- 3. Only the most recently collected trial will be deleted.

🚍 Delete I	Results X
2	Are you sure that you want to delete the last collected trial results for Limits of Stability? This cannot be undone!
	<u>Y</u> es <u>N</u> o

Figure 21: Delete Trial Verification

Saving and Loading a List of Assessments

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

To Save the List

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

Selecting an Existing Test Series

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

Figure 22 illustrates the menu for saving and selecting saved lists. Both assessments and trainings can be combined to a comprehensive list. Simply select the assessments that are to be performed, switch to the Training tab to select the trainings to perform, and then save the list.

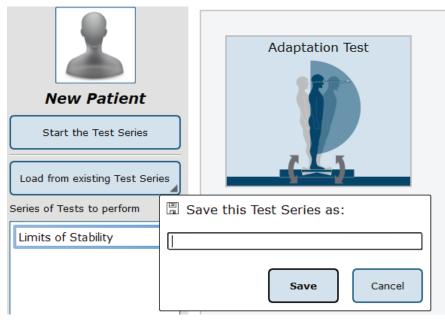


Figure 22: List Interface. Note that the bar to save tests is open.

Assessment Reports

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

Individual Test Reports

Individual Test Reports present the results from a single assessment performed on a specific day. An individual test report may be generated for any single assessment or training. Figure 23 is an example of a Limits of Stability Individual Test Report.

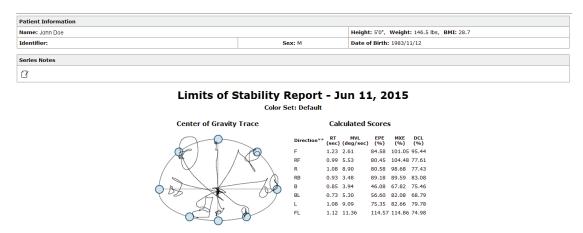


Figure 23: Limits of Stability Individual Test Report

Combined Reports

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

Patient Information						
Name: John Doe		Height: 7'3", Weight: N/A, BMI: N/A				
Identifier:	Sex: M	Date of Birth: 1925/01/30				
Series Notes						
a						
Visual Processing Time Report - Jan 29, 2016 13:31:42						
Visual	Processing Time (VPT) ≤ 30	ms				
Patient Pro	cessing Time Outcome Within accen	table levels				

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

Figure 24: 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 25 is an example Leftward VMS Daily Training Report.

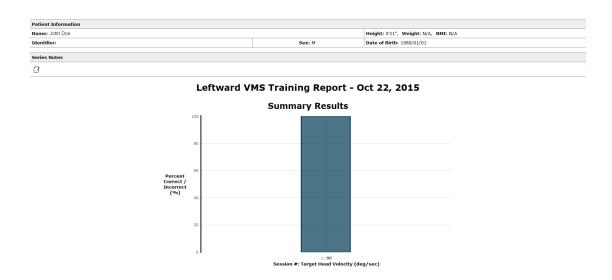


Figure 25: Leftward VMS Daily Training Report.

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 26.

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 outside of the 5th percentile) of the age-matched normative range. A sample report legend is shown in Figure 27.

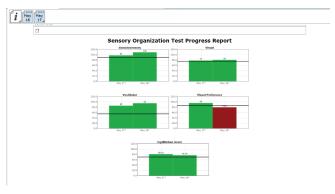


Figure 26: Sensory Organization Test Progress Report.

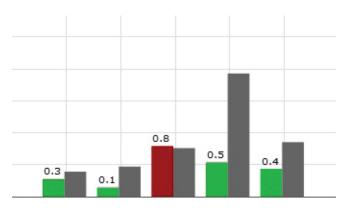


Figure 27: Report Legend.

Patient Screen Layout

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



Figure 28: "Hold Still" Message before the Patient Moves.

Figure 29: "Begin" Message Indicating to Begin Movement.



Figure 30: "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.
- If the database section is disabled, exit the Balance Advantage[®] program. 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 31, is where the Current Database Statistics, Schedule Automatic Backups, Manually Backup and Restore the Database, and Configure and Perform Database Merge operations can be accessed.



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

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

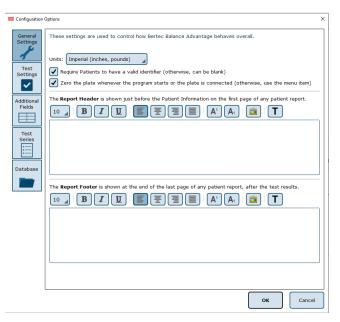


Figure 31: Configurations Options: General Settings

Turning this off is not recommended!

— 🗹 Enable Automatic database backups. —
Backup storage folder: C:\ProgramData\Bertec\BalanceAdvantage\Backups
Backups will be made every 3 曼 days, and will be kept for 🔞 🖨 days.
At most, 45 🖶 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 32: 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 33.
- 4. As a safety feature, the restoration function will default to creating a backup of the current database before it starts overwriting the current database. To skip the backup step, uncheck the "Create an archive backup..." option.
- 5. Click Ok. A confirmation message will be displayed.
- 6. Read the message to be sure the right option was selected.
- 7. Click Yes to logout while the database is restored.

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 lose all of current database's records - forever.

Figure 33: Overwrite Option.



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.

Merge Options

A merge can be performed through a one-way (from a database archive) operation. The Database Configuration page is used for one-way merging.

Merging from an Archive

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

To Conduct a One-Way Merge

- 1. Click on the Merge or Restore Databases from Archive button in the bottom right-hand corner of the Database Configuration page to select an archive to merge.
- 2. Navigate to the file. Click on the file to select it, then click on the Open button.
- 3. The program should default to merging, not restoring, an archive. Even so, ensure that the Merge circle is selected. (Figure 34)
- 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.

Restore Database Options	?	×
You can merge the archive database with your current database, or else restore and replace you database with the archive database.	ur curre	ent
Merge the database from the archive into your current one.		
This will result in you having patients, test results, operators, etc., from both your current da and the archive database combined into your current database. Any newer records in the arc overwrite older ones in your current database.		
Overwrite and replace your current database with the archive.		
Warning! All current patients, test results, operators, etc, will be replaced with the contents archive. Only do this if you are sure you want to lose all of current database's records - forev		:he
Make a backup archive of the current database before the merge or restore operation (reco	mmeno	led)
ОК	Cance	



Turning the System Off



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

To Turn off the Computer

- If signed into a Bertec[®] operator account, click the Logout button (Figure 35). It is located on the upper right corner of the screen. If a popup window ap- pears, click Yes to confirm the logout.
- 2. From the Bertec[®] login screen, click on the [X] button in the upper right cor- ner of the screen (Figure 36).
- 3. Select the power button (or power options button, depending on the version of Windows), and click on the option to Shut Down.
- 4. Prime IVR Systems: Refer to page 10 to turn off the dome's projector.



Figure 35: Software Logout Button



Figure 36: Exit Button

Essential Spark Assessments

Each assessment is described in-depth and contains the following:

- 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

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

- Modified Clinical Test of Sensory Interaction on Balance (mCTSIB)
- Limits of Stability (LOS)



Figure 37: Essential Spark

Modified Clinical Test of Sensory Interaction on Balance (mCTSIB)



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

Goal

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

Protocol

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

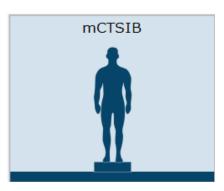
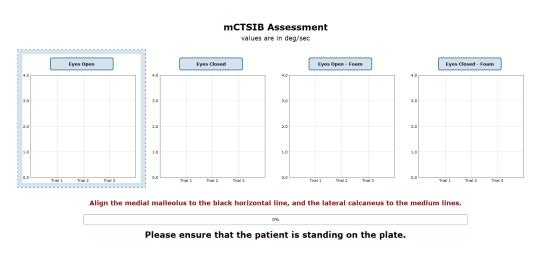


Figure 38: mCTSIB icon

Patient Instructions

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



Protocol Performance

Figure 39: mCTSIB Main Clinician Screen.

Eyes Open on Firm Surface

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

Eyes Closed on Firm Surface

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

Eyes Open on Foam Surface

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

Eyes Closed on Firm Surface

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

Caution/General Assessment Information

Trials may be interrupted at any time by selecting the Stop button on the clinician screen or the third button on the wireless remote (see 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 patient instructions.

When the trial is stopped, the clinician will be prompted to choose Fall or Discard.

If FALL is selected:

- The trial is then saved as a FALL with the time of the event captured.
- If a fall has taken place, the maximum value for sway velocity will be included in the numerical data allowing for the sway velocity to be averaged (6 deg/sec).
- The patient will then need to be repositioned to insure proper foot placement for additional trials.

If DISCARD is selected:

- The trial will not be saved.
- The patient will then need to be repositioned to insure proper foot placement for additional trials. Assessment notes may be created at any time in the Notes text box (lower left corner).

If trial is marked STEP or PULL:

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

Test Completion Protocol

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

Test Analysis

Generated Reports will Include:

- Center of Gravity (COG): Indicates the sway velocity in degrees per second.
- Mean Center of Gravity Sway Velocity for each condition.
- Composite Sway Score: Average over the trials.
- Center of Gravity Alignment: Indicates the patient's Center of Gravity position in relation to the center of the base of support at the start of each of the trials.
- Red/Green Bars: Results falling outside of the normal values will be represented by solid red bars, whereas results falling inside of the normal values will be represented by solid green bars.

Reports

- Summary Reports: Summary of the patient's performance during one trial or trial series.
- Center of Gravity sway tracings are shown with the average COG sway velocity and time duration of each trial.
- The Mean Center of Gravity Sway Velocity is given with a comparison to the normative data.
- The Center of Gravity Alignment Scores are placed on a graph.
- Test comments, if entered, are included at the end of the report.

Progress Reports: Summary of the patient's performance for a series of trials conducted at different times.

- To view progress reports, click the information icon i in the patient's timeline.
- A drop-down menu will appear and list the available progress reports.

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

Printing/Saving

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

Practical Considerations

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

mCTSIB Report - Jun 26, 2013

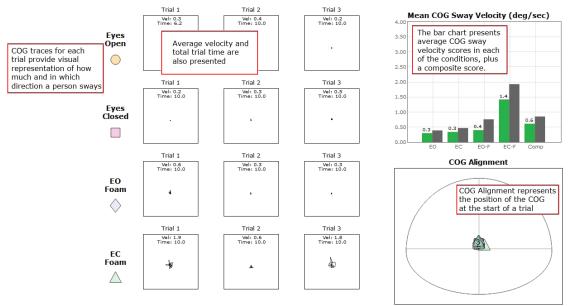


Figure 40: mCTSIB Report Information

Limits of Stability (LOS)



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

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.

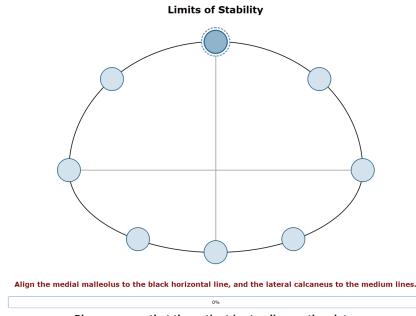
Protocol

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

Patient Instructions

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

Protocol Performance



Please ensure that the patient is standing on the plate.

Figure 42: LOS Main Clinician Screen.

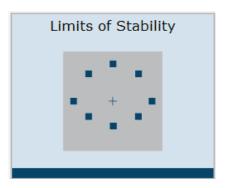


Figure 41: LOS icon

Test Sequences

A total of 8 different directions are tested during the assessment.

- Trial 1: Forward
- Trial 2: Forward Right
- Trial 3: Right
- Trial 4: Backward Right
- Trial 5: Backward
- Trial 6: Backward Left
- Trial 7: Left
- Trial 8: Forward Left

Test Performance

For each test direction, the patient is instructed where to place their feet and how to perform the assessment.

The patient should practice this test several times before data is collected. This is to ensure that the patient clearly understands how to perform the test.

The clinician should repeat for each direction until all eight trials are complete.

General Assessment Information:

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

If trial is marked STEP or PULL:

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

Test Completion Protocol

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

Test Analysis

Generated Reports Will Include:

- Directional Control (DCL): A measurement of how much of the patient's movement was in the target direction.
- End Point Excursion (EPE): A measurement of how far the patient leans towards the target on his or her first attempt.
- Maximum Excursion (MXE): A measurement of the maximum amount the patient leaned during the trial.
- Reaction Time (RT): A measurement, in seconds, of the time taken by the patient to respond to the command to move towards the target.
- Mean COG Velocity (MV): A measurement, in degrees/second, of the speed at which the patient moved towards the target.
- Red/Green Bars: Results falling outside of the normal values will be represented by solid red bars, whereas results falling inside of the normal values will be represented by solid green bars.

Reports

Summary Reports: Summary of the patient's performance during one trial or trial series.

- Center of Gravity sway tracings are shown for each of the directions.
- Results from each trial are displayed in a table to the right of the COG sway tracings.
- Calculated scores for each of the primary directions (Forward, Backward, Left, Right), as well as the Composite score, are given in bar graphs for each of the measures. The Composite score is the average of the trials, whereas the Calculated scores factor and weigh data from each trial.
- Test comments, if entered, are included at the end of the report.

Progress Reports: Summary of the patient's performance for a series of trials conducted at different times.

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

Printing/Saving

- Select the desired protocol report from the patient's timeline.
- While viewing the report, select the printer icon to either save a PDF file or print to a regular printer.
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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 musculoskel- etal 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 unwill- ing or fearful of approaching limits of stability. Also consider aphysiological causes, such as not providing the best effort (or exaggeration).

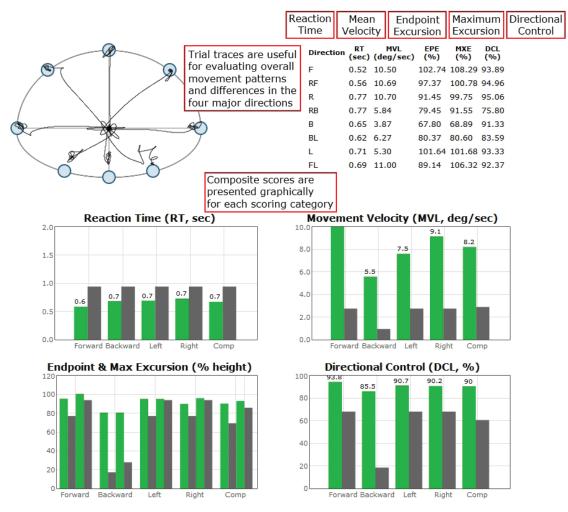


Figure 43: LOS Report Information.

CDP Spark Assessments



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

Information regarding dynamic plate assessments can be found on the following pages. 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 44: CDP Spark

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.

Patient Instruction

"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."

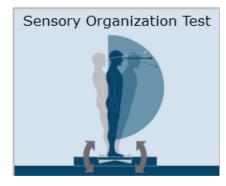


Figure 45: SOT Icon

Protocol Performance

- 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.

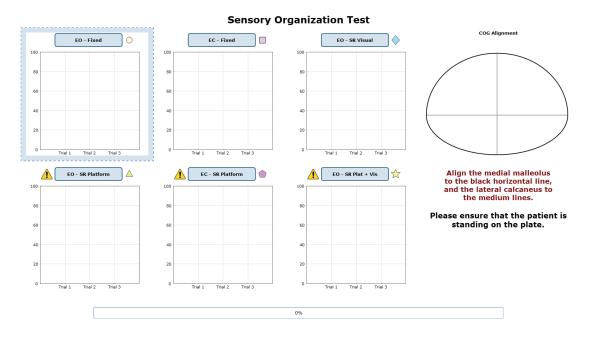


Figure 46: SOT Clinician Screen

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

Printing/Saving

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

Practical Considerations:

Abnormal sway or fall	Implications
None	Normal individuals have minimal sway on the firm surface either with eyes open or closed. Also, normal individuals have increased sway on the 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 infor- mation 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.

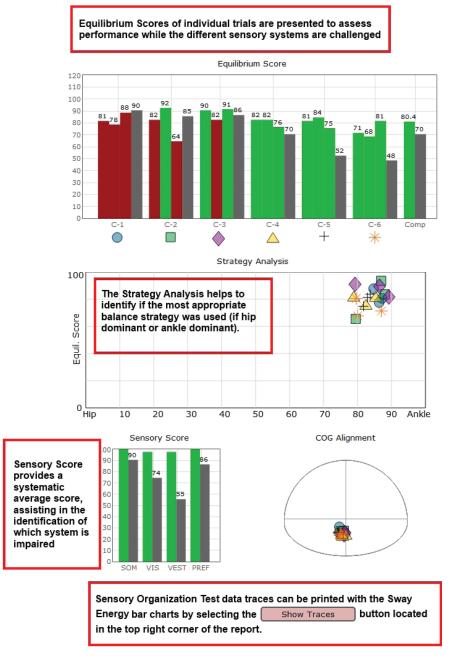


Figure 47: SOT Report Information.

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 preprogrammed automatic responses with minimal voluntary intervention. Patients with abnormal MCT results are considered to be at higher risk of falling.

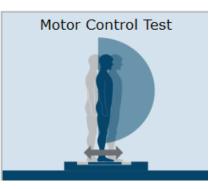


Figure 49: MCT Clinician Screen

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.

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

- 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.

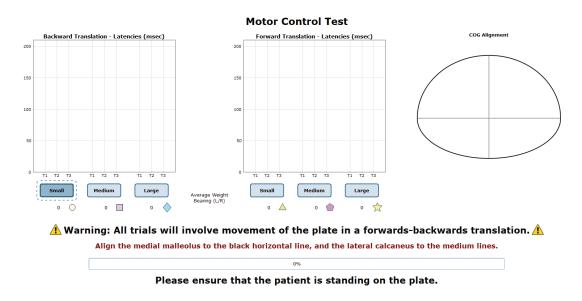


Figure 49: MCT Clinician Screen

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.

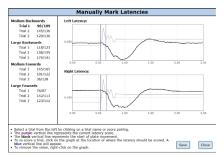


Figure 50: Manually Mark Latencies Utility.

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 neu- ral pathways. The cause is usually central abnormalities but they can also occur in musculoskeletal problems.
Abnormal Amplitude Scaling	Abnormal Amplitude Scaling indicates inadequate, inap- propriate, or asymmetrical level of force exerted during the recovery from the support disturbance. It indicates non-spe- cific neuromuscular or musculoskeletal impairment.

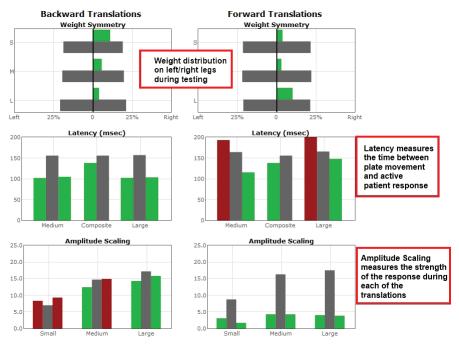


Figure 51: MCT Report Information.

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.

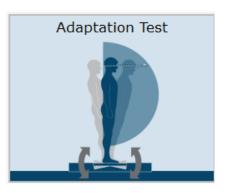


Figure 52: ADT Icon

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

- 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.

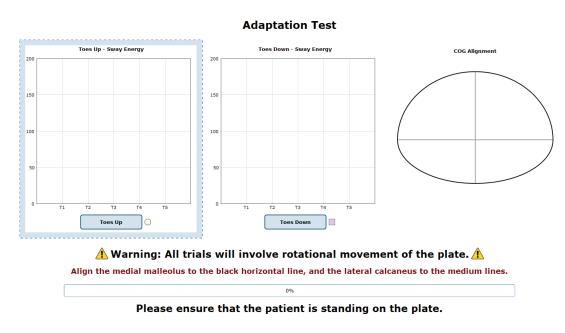


Figure 53: ADT Clinician Screen.

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.

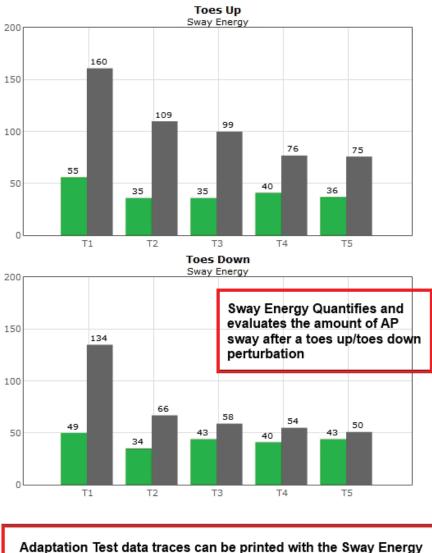
- To view progress reports, click the information icon i in the patient's timeline.
- A drop-down menu will appear and list the available progress reports.
- The progress a patient makes on a report is given with progress reports that chart their performance scores over time.

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.



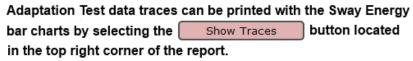


Figure 54: ADT Report Info.

Additional Assessment Protocols

Additional protocols are available on each system which can assist in the evaluation of highly athletic patients or those with head injury.

Protocols available on the Essential Spark include:

- COBALT

Protocols available on the CDP Spark include:

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

To add one of the above assessments onto a system, speak with your sales representative.

COBALT™

 \triangle

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

COBALT is a trademarked protocol for functional balance testing related to head injury. This protocol is designed to stimulate the visual, vestibular, and somatosensory systems. The patient is to stand as still as possible during each condition while the balance plate measures their degree of sway as each of the balance systems are stimulated.

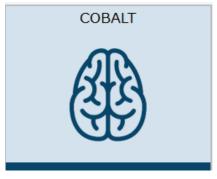


Figure 55: COBALT Icon

Protocol

Patients will be asked to stand directly on the balance plate for half of the conditions and on top of foam surface for the remaining conditions. A total of eight conditions are available for testing; each condition consists of two

20 second trials. Baseline tests should utilize four conditions, whereas it is recommended that post-injury tests should utilize all eight conditions. Data collection for each trial is initiated at the discretion of the operator.

Test Setup

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

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

After placing COBALT in the Series of Tests to perform list, determine if the patient has had a prior head injury. If the patient has, enter the date of patient's last injury by selecting the Injury Date on the bottom left of the screen (Figure 56). Clicking on the date will open a calendar menu. If the patient has not had a head injury before, ignore the previous step. Once a date has been entered for an injury (or no date has been selected for a baseline test), click on the Visit Type on the bottom left of the screen. Select the visit type. Afterwards, click Ok to enter the test screen.

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



Figure 56: COBALT Remote Functions.

Additional Assessment Protocols: COBALT™

		COBALT		
			Bas	seline
Firm Surface	Eyes Open Firm Surface	Eyes Closed Firm Surface	Head Shake (EC) Firm Surface	VMS Feet Together Firm Surface
Trial 1 Score:		0	0	0
Trial 2 Score:	0	0	0	0
Foam Surface	Eyes Open Foam Surface	Eyes Closed Foam Surface	Head Shake (EC) Foam Surface	VMS Feet Together Foam Surface
Trial 1 Score:	0	0	0	0
Trial 2 Score:	0	0	0	0
Align the medial r	malleolus to the black		the lateral calcaneus	to the medium lin
Pi	ease ensure that		tanding on the p	late.
	Trial 1 Score: Trial 2 Score: Foam Surface Trial 1 Score: Trial 2 Score: Align the medial of	Film Surface Film Surface Trial 1 Score: 0 Trial 2 Score: 0 Foam Surface Even Open Foam Surface Trial 1 Score: 0 Trial 2 Score: 0 Align the medial malleolus to the black	Firm Surface Free Open From Surface Pres Surface Trial 1 Score: 0 0 Trial 2 Score: 0 0 Foam Surface Eyee Closed Foam Surface Eyee Closed Foam Surface Trial 1 Score: 0 0 Trial 2 Score: 0 0 Trial 2 Score: 0 0 Align the medial malleolus to the black horizontal line, and to 0	Firm Surface Eyes Open Firm Surface Eyes Closed Firm Surface Head Stuke (C) Firm Surface Trial 1 Score: 0 0 0 Total 2 Score: 0 0 0 Foam Surface Eyes Open Foam Surface Eyes Closed Fram Surface Head Stuke (C) Fram Surface Trial 2 Score: 0 0 0 Trial 2 Score: 0 0 0 Align the medial malleolus to the black horizontal line, and the lateral calcaneus Align the medial malleolus to the black horizontal line, and the lateral calcaneus

Patient Instructions

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

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

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

Condition 1: Normal Stance Eyes Open

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

Condition 2: Normal Stance Eyes Closed

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

Condition 3: Normal Stance Head Shake + Eyes Closed

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

Condition 4: Narrow Stance Visual Motor Sensitivity (VMS)

- Patient is instructed to stand at the center of the balance plate with feet together, both arms extended out in front of them with hands clasped together and thumbs straight up. (The clinician should demonstrate the correct position)
- While focusing on their thumbs, the patient rotates their entire body 30 degrees right/left (total excursion of 60 degrees) in sync with a metronome set to 40 beats/min.
- At the conclusion of the trial, allow for 10-20 seconds of rest before starting the next trial.
- Errors are recorded by the clinician as before.

Condition 5: Normal Stance Eyes Open on Foam

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

Condition 6: Normal Stance Eyes Closed on Foam

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

Condition 7: Normal Stance Head Shake + Eyes Closed on Foam

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

Condition 8: Narrow Stance Visual Motor Sensitivity (VMS) on Foam

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

Test Completion Protocol

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

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

Test Analysis

The report will present the following:

- Sway Score: An objective assessment of COP movement during the trial.
- # of errors: How many times the patient moved out of the test position.
- Center of Pressure trace

Reports

Summary Reports: Summary of patient's performance during one trial or trial series.

- Report containing the COP traces, sway score, number of errors, and time until the first error for each trial.
- Viewed from the patient's timeline. An example Single Day Summary Report is included on the following page.

Progress Reports: Summary of patient's performance for a series of trials conducted at different times.

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

Printing/Saving

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

Errors		Conditions						
	1	2	3	4	5	6	7	8
Trial 1	-	-	0	0	-	-	0	1
Trial 2	-	-	0	1	-	-	0	0
Total	-	-	0	1	-	-	0	1
Sway Scores				Cond	tions			
	1	2	3	4	5	6	7	8
Trial 1	-	-	0.70	1.54	-	-	1.20	1.30
Trial 2	-	-	0.45	1.20	-	-	0.70	1.28
Average	-	-	0.57	1.37	-	-	0.95	1.29
Patient Age Sway Scon Percentile:	e: 0.95 78th	25th Percentile	dition 7: data is for	Soth Percentile	h 1 error o	75th Percentile		95th Percentile
Sway Scor Percentile:	e: 0.95 78th		dition 7: data is for		Sway So th 1 error of			95th Percentile
Sway Scor Percentile:	e: 0.95 78th		dition 7:		Sway So th 1 error of	75th Percentile	<	95th Percentile
Sway Scor Percentile: 5th Percentile	e: 0.95 78th 	25th Percentile	dition 7: data is for dition 8: data is for	50th Percentile		0.99	<	
Sway Scor Percentile 5th Percentile 1.82 1 Patient Ag Sway Scor	e: 0.95 78th 	25th Percentile		50th Percentile		0.99	〈	0.81 0.65
Sway Scor Percentile Sth Percentile	e: 0.95 78th 	1.37		50th Percentile		0.99	〈	

Cobalt Baseline Report - February 4 2021

Figure 59: COBALT Report Information

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.

Goal

Protocol

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 headshake. 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.

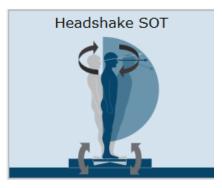


Figure 60: HS-SOT Icon

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

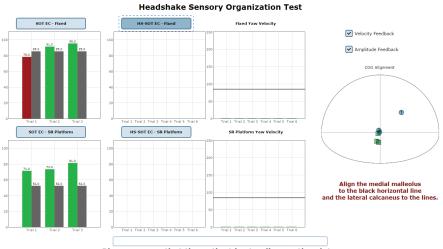
- 1. Turn on the Head Tracking system by pushing the small switch in the corner. Use a pen (if necessary). Once on, the system's light will glow blue.
- 2. From the settings icon, click Pair Wireless Head Tracker.
- 3. Follow the instructions in the new window that appears.

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."



Please ensure that the patient is standing on the plate.

Figure 61: HS-SOT Clinician Screen.

Protocol Performance

- 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.
- 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:

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.

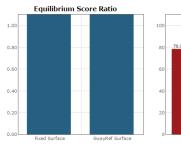


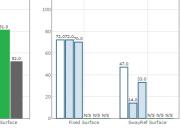
Hygienic Bouffant Cap should be worn underneath the headband when performing this protocol.

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.

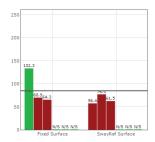






HS-SOT Equilibrium Scores

HSSOT Yaw Velocity





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Figure 62: HS-SOT Report.

Training Fundamentals

A wide variety of balance training exercises are available on each balance package. All of the systems implement versions of Quick 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. 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.
- 4. The specified training will then appear in the list.
- 5. Any available options for the selected trainings will appear in the box titled "Test Options," located immediately below the list of trainings to perform.
- 6. All trainings require the appropriate level to be selected, based on the capabilities of the patient.

Training/Test Options:

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

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.

Visual Training Options

The training types listed below are only available on the CDP Spark 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 Figures 92, 93, and 94.



Figure 63: Rock Wall. Figure 64: Checkered Room.

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.

Viewing a Saved List

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

Compliance Score

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

- Specified Pacing exercises: a representation of the percentage of targets that were successfully reached during the training exercise. Example: if the pacing was set to 2 seconds and the training time is set to 1 minute, the target switches a total of 30 times. If the patient reaches the target 19 times within the 1 minute, the score of 63.3% is attained.
- No Pacing:
 - Single Target: The compliance score is given as a percentage of how long the patient is able to stay within the target.
 - Multiple targets: No compliance score is available.
- On Demand: As there is no pacing time selected and the movement from target to target is patient initiated the information, the transition time is averaged and compiled as the compliance score.

System Safety

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

Symbols Used

Symbol	Description
(Carefully read these instructions prior to use
	Indicates CAUTION unless used with one of the following other captions:
\wedge	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
4	Electrical Shock, High Voltage
	Power on
\bigcirc	Power off
	Earth (Ground)
\sim	Alternating current
	Fuse
	Type B Applied Part
	Applied Part: CDP/IVR Balance Plate, Head Tracker
Λ	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.
CE	Complies with Medical Devices Directive 93/42/EEC and RoHS Directive (2011/65/EC)
	Electronic equipment covered by the Directive 2002/96/EC on waste electrical and electronic equipment (WEEE).
X	All electrical and electrical products, batteries, and accumulators must be taken to separate collection at the end of their working life. The requirement applies in the European Union. Do not dispose of these products as unsorted municipal waste.
	You can return your device to Bertec or to any Bertec supplier. you can also contact you local authorities for advice on disposal.

Symbol	Description
STA	Your remote has been programmed to work with a static system.
DYN	Your remote has been programmed to work with a dynamic system.
VIS	Your remote has been programmed to work with Bertec Vision Advantage (BVA).
REF	Catalog Number
NEF	(used in compliance with ISO 15223-1)
	Serial Number
SN	(used in accordance with ISO 15223-1)
	Authorized EC Representative in the European Community
EC REP	(used in accordance with ISO 15223-1)
	Consult Instructions For Use
i	(used in accordance with IEC 60601-1)
	Indicates device manufacturer
	Includes name and address of the manufacturer
	(used in accordance with ISO 15223-1)
	Manufacturer build date
	(used in accordance with ISO 15223-1)
	Direct Current
	(used in accordance with IEC 60601-1)
	ON/OFF (Power/Stand-by)
U U	(used in accordance with IEC 60601-1)
<u> </u>	Equipment Safe Working Load
kg lb	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 prescribed 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 BBACDP/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 enviornments.
- Note 9 None of the Bertec system parts are user servicable. For the sake of safety, and in order not to void the warranty, the system should only be serviced by authorized service personel. In case of defects, please make a detailed description of the defect(s) and contact your supplier. Do not use a defective device.
- Note 10 Keep Bertec Balance Advantage systems away from liquids. Do not allow moisture inside the device.
- Note 11 Do not use the device in the presence of flammable anaesthetics (gases).
- Note 12 No parts may be eaten, burnt, or in any way used for purposes other than posturography and balance 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. Extenstion cords or power strips (MSPO) other than those provided with the system, should notbe 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 enviornment (for which CISPR II class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as reloacting or re-orienting the equipment.
- Note 23 WARNING: No additional networking/data coupling is to be made outside of what has been designed for the Bertec Balance Advantage Dynamic System. According to IEC 60601-1 standards, this system will only be connected wirelessly to the internet. If your facility is a hospital or university setting, please contact Bertec support to discuss your specific enviornment and conditions so that we may provide the best solution for syncing databases.
- Note 24 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 personel authorized by the manufacturer.
- The electrical installation to which the equipment is connected complies with EN/IEC requirements.
- The equipment is used in accordance with the instructions for use.

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

Operating Environment

These systems are suitable for use in the patient 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

Isolation Transformer

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

Operating Mode

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

Storage and Handling

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

Standards

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

Input Voltage Configuration

Configured at factory

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

Warning: Check input voltage before starting system

Guidance and Manufacturer's Declaration Tables

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

Guidance and manufacturer's declaration - electromagnetic emissions for all equipment and systems

Bertec Balance Advantage Static Systems are intended for use in the electromagnetic environment specified below. The user of Static Systems should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic enviornment - guidance	
RF emissions CISPR 11	Group 1	Bertec Balance Advantage Dynamic Systems use RF energy only for internal functions. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class A		
Harmonic emissions IEC 61000-3-2	Class A	Bertec Balance Advantage Dynamic Systems are suitable for use in industrial areas and hospitals. If it is used in a residential enviornment (for which CISPR II class B is normally required) this equipment might	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	not offer adequate protection to radio-frequency communication services. The user might need to ta mitigation measures, such as reloacting or re-orienting the equipment.	

Guidance and manufacturer's declaration - electromagnetic immunity for all equipment and systems

Bertec Balance Advantage Static Systems are intended for use in the electromagnetic environment specified below. The user of Static Systems should ensure that it is used in such an environment.

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

Guidance and manufacturer's declaration - electromagnetic immunity - for equipment and systems that are NOT life-supporting

Bertec Balance Advantage Static Systems are intended for use in the electromagnetic environment specified below. The user of Static Systems should ensure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic envivonment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of Static Systems, including cables, than the recommended separation distance calculated from the equation ap- plicable 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 dis- tance 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 struc- tures, objects and people. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

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

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

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

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.

Note 2: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

Note 3: An additional factor of 10/3 has been incorporated into the formula used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Accessories and Cables

Item	Origin	Termination	No.
Shielded HDMI Cable (15 ft)	Projector	Tower PC	1
AC Power Cable with Ferrite (15 ft)	Projector	Base/Isolation Transformer	1
USB A to B Cable (10 ft)	Inkjet Printer	Tower PC	1
USB A to B Cable (10 ft)	Balance Plate	Laptop	1
AC Power Cable (5 ft)	Inkjet Printer	Power Strip	1
AC Power Cable (10 ft)	Wall Mains	Base/Isolation Transformer	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 Activity - up to 300 lbs	
97P-0034	Bariatric Activity - up to 450 lbs	
97P-0035	Pediatric Activity - 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	Ergotron Power Strip, 6 Outlet 125 VAC 15A	
37P-0003	Voyageur Complete System PC, Dynamic System	
37P-0022	HP Envy 4520 e-All-in-One Printer	
37P-0023	Corded Keyboard and Mouse, Logitech	
37P-0024	Webcam 500 5MP Camera	
80P-0002	Balance Advantage Dynamic System User Manual	
80P-0009	Balance Advantage Static System User Manual	
80P-1091	Balance Advantage Spark Systems User Manual	
30P-0238	Head Tracker for HS-SOT Protocol	
30P-0239	Receiver for HS-SOT Protocol	
97P-0051	Headband for HS-SOT Protocol	
37P-0060	Wall Charger for Head Tracker for HS-SOT Protocol	
97P-0053	Poly Hairnet/Bouffant Caps - 100 Count, blue	
97P-0079	Hygienic Foot Covers - 100 Count	
37P-0029	SMKlink Wireless Remote	
97P-0076	Standard balance Advantage foam block with cover	
BP5046	Essential Balance Plate	

Appendix A: Abbreviations and Glossary

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

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.

Ataxia: Incoordination.

Auditory: Having to do with hearing.

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

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

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

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

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

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

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

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

Diplopia: Double vision.

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

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

End Point Excursion: A measurement of how far the patient leans towards the target on his or her first attempt. End Sway: Measured for Tandem Walk, the amount of sway of the COG at the end of the Tandem Walk trial.

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

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

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

Imbalance: Observable unsteadiness.

Impact Index: Measured in Step Up/Over as the force of the trailing leg when it strikes the ground on the other side of the block. Labyrinth: Refers to the inner ear which includes the cochlea and vestibular organs.

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

Lateropulsion: Tendency to fall to the side.

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

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

Mal De Debarquement: The sensation of rocking or movement that persists after a sea cruise or other form of travel. Maximum Excursion: A measurement of the maximum amount the patient leaned during the trial.

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

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

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

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

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

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

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

Motor Control Test (MCT): The protocol assesses the ability of the automatic motor system to quickly and effectively recover following unexpected support surface disturbances. 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.

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

Oscillopsia: Subjective illusion of visual motion.

Otoconia: Calcium carbonate crystals embedded within the maculae within the otolith organs (utricle and saccule). Ototoxic: Having a harmful effect on the labyrinthine structures.

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

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

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

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

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

Saccades: Abrupt rapid eye movement of both eyes utilized to change the point of fixation.

Saccule: The saccule is a bed of sensory cells situated in the inner ear. The saccule translates head movements into neural impulses which the brain can interpret. The saccule is sensitive to linear translations of the head, specifically movements up and down (think about moving on an elevator).

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

Sensory Organization Test (SOT): The protocol which objectively identifies abnormalities in the patient's use of the three sensory systems that contribute to postural control: somatosensory, visual and vestibular. Six sensory conditions are present: all available, absent vision, visual referenced, sway reference, eyes closed sway referenced, sway and visual referenced. The result is an equilibrium score, strategy analysis, Sensory analysis, and COG alignment.

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

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

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

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

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

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

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

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

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

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

Vertigo: Dizziness characterized by a sense of spinning.

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

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

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

Walk Across (WA): The assessment quantifies the patient's steady gait while walking across the balance plate. The WA enhances observational testing of gait by measuring the average width and length of the patient's steps on the balance plate, the symmetry of left and right leg step lengths, and the patient's gait speed across the balance plate. Because the length of the balance plate, the test may not be appropriate for highly fit individuals whose stride lengths are greater than five feet.

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

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

Appendix B: References

- 1. Jacobsin GP, et al (1993). "Posturographic Testing." Handbook of Balance Function Testing 259-334.
- 2. Branstater M, DeBruin HA, Sahrmann SA (1983). "Himparetic gait: Analysis of temporal variables." Arch Phys Med Rehab 64: 583-587

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

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

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

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

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

Appendix C: Frequently Asked Questions

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 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 Spark 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 Spark System, Turn on?

The computer is attached to the base of the CDP Spark. 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 Mark Patient Deleted. Click Yes to confirm. Deleted patients cannot be recovered.

Appendix D: Passwords and Security

Security Concerns

It is recommended that operators routinely change their Balance Advantage[®] account's password 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 D.
- 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 D: Settings Button.

Appendix E: 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 Scroller _____ - Right Click ————————————————————— - Next Condition - Previous Condition - Start/End Trial _____ - Switch between Patient and Clinician Screen Note: The USB Dongle is shown to the right of the remote in Figure E1. It needs to be plugged into the computer's USB for the remote to function with the system. Do not attempt to store



Figure E1: Remote and Dongle.

DYN



files on the Dongle.

Note: Refer to the System Safety section for remote labelling and programming information.

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 F1.
- 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.

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.

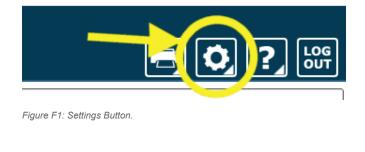


Figure F1: Settings Button.

Appendix G: CDP Spark Alignment

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 F1)
- 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 F2.
- 6. The pattern (Figure F3) will project both on the dome as well as partially on the floor underneath the lens (Figure F4). The image has proper alignment when the bottom alignment square (circled in Figure F4) 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 F5, 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.



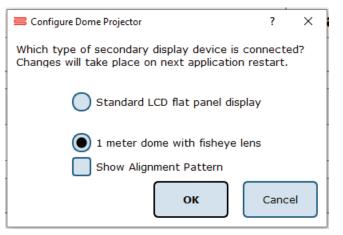


Figure F2: Configure Dome Projector



Figure F3: System Alignment Pattern

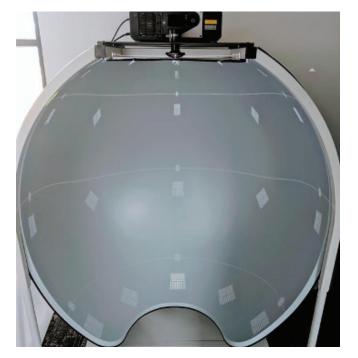




Figure F4: Dome Alignment

Figure F5: 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 **P** symbol (located on the upper right-hand corner of the Clinician Screen, next to the Logout button). Clicking on this symbol will open a list of three to four different options, described in bold on the following pages. Immediately below are the different functions which can be completed from this tab–shown as step-by-step instructions on the following pages.

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

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

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.

	BERTEC Balance Advantage®			
Version	Addons System License Agreement Support			
Program Version:	version 1.0.0 Build 1040 (Jan 25 2017)			
License Registration:	Registered to: n/a Add License			
	AAAA-D6HQ-BUX6-XKDA-ME2Z-BYVY			
	This program is licensed to you under the terms of the License Agreement. For more details, see the License Agreement that came with this program.			
	Copyright (C) 2002-2016 Bertec Corporation. All rights reserved.			
	This program is provided AS IS and comes with NO WARRANTY OF ANY KIND, INCLUDING THE WARRANTY OF DESIGN, MERCHANTABILITY, AND FITNESS FOR A PARTICULAR PURPOSE.			
	Close			
L				

Figure H1: About Window Tabs

- 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.

Support

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

To opt out of sending anonymous program reports to Bertec[®]:

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



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



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

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



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

88 Spark Systems User Manual 80P-0091 2023-09 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.	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.
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 con- tact 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 anyway, 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 per- form 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 un- able 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.

Error Message	Possible Cause/Solution
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 soft- ware. 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 back- ups. 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 at- tempted 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.

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

Error Message	Possible Cause/Solution
The Balance Advantage Database needs to be upgraded. If you do not have a recent backup copy of the database, we recommend that you perform a backup now. Backup the database before performing the database upgrade?	Before upgrading the structure of your database, it is always wise to create a copy of your current database so that no information can be lost. The upgrade should not need the back-up copy, but it is good to have in case.
The License Key that you have entered is invalid. Please check to make sure that you have entered the correct license key. If you believe that you have, then please contact Bertec Corpo- ration at support@bertec.com to obtain a valid License Key.	The license key activation process is multi-step and requires that your key be entered into a specific field. If there is any error in the key entry, this error will occur. If you believe this message is occur- ring in error, please contact Bertec Support for assistance.
It appears that the program is unable to register your information automatically online - would you like to register your license key via phone or email?	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.
If you believe that this message is in error, please check the license key and registration information that you have entered, or %2 for support and resolution with this matter. The Activation Code that you have entered is invalid or empty.	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.
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.	
The operator "XXOperatorXX" cannot be logged in. Please check that the operator name and password are correct, and that operator "XXOperatorXX" has the proper access rights.	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.
Please click OK and re-enter the operator name and password in order to log into the system	
Login Error	
It looks like there is no email client program installed or configured to send email. This is common if you are using some form of web-based email such as Google Mail, Hotmail, Yahoo Email, or similar.	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.
You would like to save the PDF report to your Documents folder so that you can send it yourself using your web-based email?	
Mail send failure	
One or more of the required patient fields are blank or incorrect. Please complete the fields and press Save again.	There is information missing in the Patient Information profile that you are creating. The required fields preventing the commit are highlighted in yellow.
Unable to commit	

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

Appendix J: Contact Bertec®

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

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