

# Bertec<sup>®</sup> Vision Advantage<sup>™</sup>

## User Manual

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

**Bertec® Vision Advantage™**  
**A Division of Bertec® Corporation**

Software Versions 1.0.0, 2.0.0, 2.1.0, 2.3.0, and 2.4.0

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## Bertec Balance Advantage Privacy Policy

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

### Data Security and Privacy:

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

### Why We Collect Your Data:

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

### Data We Collect from You:

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

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

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

### How We Collect Your Data:

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

### Opt-In and Consent:

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

### Data Access and Control:

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

### Benefit to You:

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

### Changes to Our Privacy Policy

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

### Privacy Questions:

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

# Instructions for Use

This manual covers standard operating procedures for the following products:

- Bertec Vision Advantage



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

## Description of the Product

The Bertec Vision Advantage (BVA) is a clinical system to measure changes in vision that result from head movement. It includes a touch-screen laptop computer, head-mounted transducer (head tracker) to measure head velocity in any plane of rotation, a receiver unit for the computer, and a wireless remote control for entering patient responses. The system is designed to administer several assessment protocols in which a visual stimulus is presented on the computer screen. The stimulus is a block letter "E" (called an optotype) that is rotated at random and presented very briefly by the computer, comprising a four alternative, forced-choice test design. The patient watches the screen and identifies which direction the legs of the E are pointing: left, right, up or down. The clinician enters the patient responses with the remote control. By measuring head velocity during patient movement, the computer controls when the stimulus is presented and keeps track of patient responses. Using the pattern of accuracy of patient responses, the computer determines when to stop the assessment and score the test. Test results are displayed on the computer screen and can be printed in color.

## Training Statement

Additional online training can be requested from Bertec support by emailing [support@bertec.com](mailto:support@bertec.com).



# Read Carefully Before Proceeding

## Intended Use:

The Bertec Vision Advantage (BVA) System assesses visual acuity during head movements to provide an objective platform for the monitoring and evaluating the function of vestibulo-ocular reflex (VOR). The clinician can use the assessment results to determine the most effective therapy parameters.

BVA systems should only be operated by qualified personnel.



**WARNING:** To avoid risk of electrical shock, BBA systems must only be connected to properly grounded power sources.

- The successful use of the Bertec<sup>®</sup> 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.

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



All protocols should be performed with hygienic hair covers.



**WARNING:** Do not modify Bertec<sup>®</sup> systems in any way. Modifications will void the warranty.



For additional product service or support, please contact: Bertec<sup>®</sup> Corporation 2500 Citygate Drive Columbus, OH 43219 U.S.A. phone: 614-450-0331 or [balancesupport@bertec.com](mailto:balancesupport@bertec.com)

## Indications for Use

The Type 1003, Bertec Vision Advantage (BVA) System assesses visual acuity during head movements to provide an objective platform for the monitoring and evaluating the function of vestibulo-ocular reflex (VOR). The clinician can use the assessment results to determine the most effective therapy parameters.

## Contraindications

Patients with severe neck pain or neck injuries should be excluded. Also, patients who develop severe motion sensitivity during or after head movements are not suitable for BVA testing. Otherwise, there are no other known contraindications.

## Potential Adverse Effects

In rare cases, the patient may experience transient dizziness or motion sensitivity. In that case, the test can be discontinued immediately.

## General Maintenance

The Head Tracker requires minimal maintenance, performed on an as-needed basis.

### Cleaning

- The band can be put in the washing machine on gentle cycle and air-dried.
- The tracker can be gently wiped down (once turned off) with a very small amount of general cleaning product, taking care to avoid excessive moisture or ANY liquid entering the casing.
- It is recommended that the Head Tracker is cleaned with the charging cable attached to the unit, as the cord works to protect the micro-usb port from moisture. Refer to Figure 1.



Figure 1: Recommended Cleaning Setup



Caution: The head tracker system will be permanently damaged if liquid or moisture enters the casing. Clean with care.



If moisture or liquid enters the casing, keep the head tracker turned off. Do not attempt to turn on the head tracker, charge it, or plug it into the computer. As soon as possible, submerge the unit into a bowl of dry rice or silica gel packets for 24 hours.



Do not place the head tracker into a damp headband.

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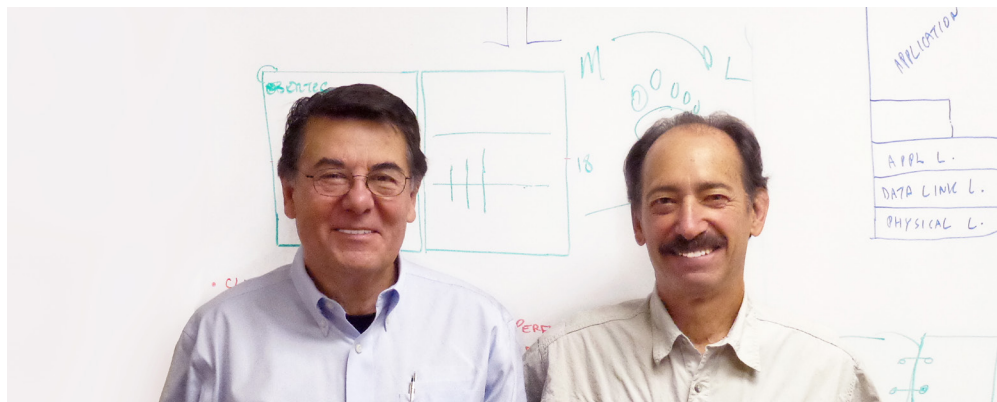
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## Company Overview



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

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

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



# Fundamental Operations

## Bertec Vision Advantage Contents

1. Laptop
2. Motion sensor or Head Tracker
3. Wireless receiver for the Head Tracker.
4. USB cable(s) to charge the Head Tracker, also used to connect the receiver to the laptop for wireless operation
5. USB wall charger for the Head Tracker
6. Headband with a pouch for the placement of Head Tracker
7. Wireless Remote and its dedicated USB dongle to connect remote to the laptop
8. Paper surgical caps (not pictured)



The following items are optional and can be ordered separately

- a. Extra Head Tracker
- b. Extra Bertec Headband
- c. Additional surgical caps
- d. 4 port USB hub
- e. Additional wall charger or USB cables

## Charging the Head Tracker

For wireless operation, the Head Tracker must be charged. When not testing, use the following steps to charge the Head Tracker.

1. Plug the Head Tracker's charging port to the wall charger.
2. The approximate charge time is 1 hour. **The charge level needed to perform a full assessment is at least 25%.**
3. Please do not keep the Balance Advantage software running while charging the Head Tracker. Instead, start the software after placing the Head Tracker on the patient, as described below.

Note: We do not recommend charging the Head Tracker through the laptop. Charging this way will take longer and relies on the charge of the laptop.



Figure 2. Head Tracker charging port & power switch

## Using the Head Tracker

For wireless operation, the Head Tracker must be charged. When not testing, use the following steps to charge the Head Tracker.







1. When ready to test, unplug the Head Tracker from the wall charger and plug the wireless receiver into the laptop using a USB cable.
  - a. (Make sure the LED light on the receiver is on)
2. If the Head Tracker is not on, turn it on by sliding the on/off switch towards the LED light (Figure 2).
  - a. The LED light should be blinking rapidly when the unit is on and paired.
3. Launch the Bertec Balance Advantage software and log in.
4. Verify that the Head Tracker is detected by the software by examining the battery level indicator at the top right corner of the screen.
  - a. **The battery level indicator is an estimate of the remaining charge on the Head Tracker.**
  - b. **It is best to plug the Head Tracker into the wall charger when the unit is not being used for testing.**



Figure 3. Head Tracker battery level



# Head Tracker LED Status Lights

LED Color & Condition	Head Tracker	Receiver
Slow Green flashing 	First received and activated	Successful pairing
Green-Blue flashing 	Fully charged	Paired and communicating with the Head Tracker
Yellow-Blue flashing 	Plugged in and charging	
Red-Blue flashing 	Low on battery. <i>Note: this will not occur when paired and communicating with the receiver</i>	Not paired
Blue flashing 	Communicating with Receiver	Communicating with Head Tracker
Blue solid 	Unit is on and unpaired	Unit is plugged in and unpaired

## Pairing Multiple Head Trackers

To use more than one Head Tracker, use the same procedure as above, with the following changes:

- Keep the second Head Tracker powered off and unplugged while pairing the Head Tracker in use.
- Once the Head Tracker and Receiver have been paired, keep the second Head Tracker off and plug it in to a separate computer or wall outlet to charge
- Each time you switch to a different Head Tracker, repeat the pairing procedure to make sure the system is functioning normally.

## Proper Head Tracker Placement

1. Insert the Head Tracker in the front pouch of the headband so that the LED status light is visible.
2. Place the headband on the patient so that the Head Tracker is in the center of the forehead and the Bertec lettering is upright (Figure 4).
3. Tighten the headband so that the band does not slip when the head is moving.
4. The patient should wear a paper surgical cap under the head band for hygienic reasons.

Note: Proper placement of the Head Tracker is critical to the success of the test.



Figure 4. Correct Head Tracker placement

## Keyboard Instructions and Hotkeys

Many of the buttons and functions inside the Balance Advantage software can be accessed through “hotkeys”. They are defined as follows:

Arrow Right = Start and Stop

Arrow Left= Response input: “I don’t know”

F12 = Switch between Patient/Clinician Screens

(may require holding down the fn key and simultaneously pressing F12)

1 = Response input: Up

2= Response input: Down

3= Response input: Left

4= Response input: Right

For Pediatric Optotypes, the following buttons represent the different optotype shapes:

1= Response Input: Hand

2 = Response Input: Cake

3 = Response Input: Bird

4 = Response Input: Car

# Remote Control Operations



Button 1:  
Up

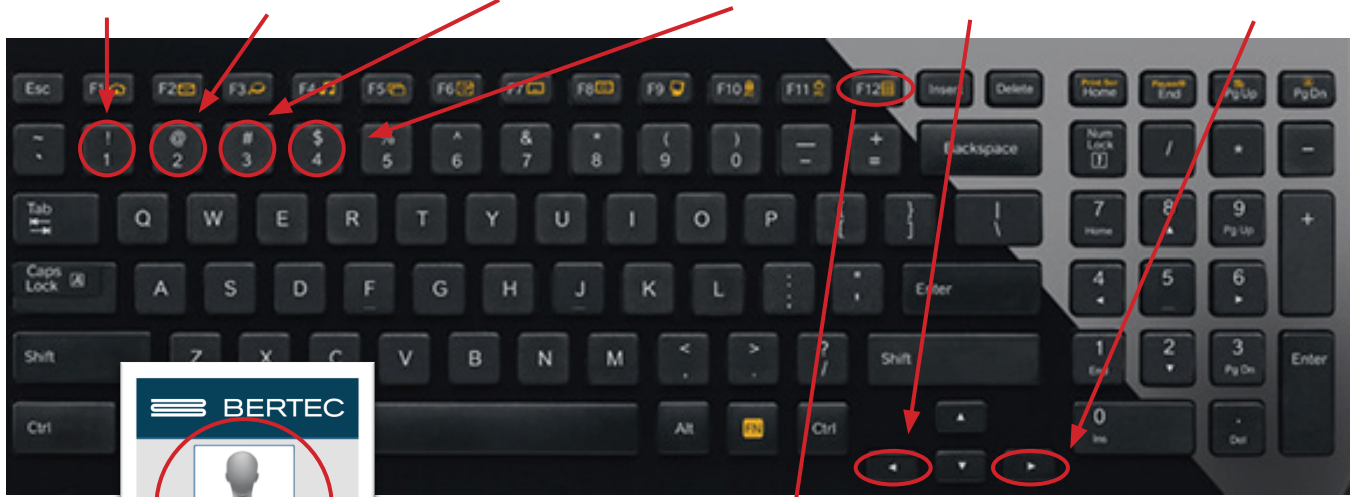
Button 2:  
Down

Button 3:  
Left

Button 4:  
Right

Left Button:  
Don't Know

Right Button:  
Start/Stop



F12/Patient Profile:  
Switch Patient/Clinician Screen

# Routine Startup and Login

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

To Start the System:

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

To Log in to the Program:

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

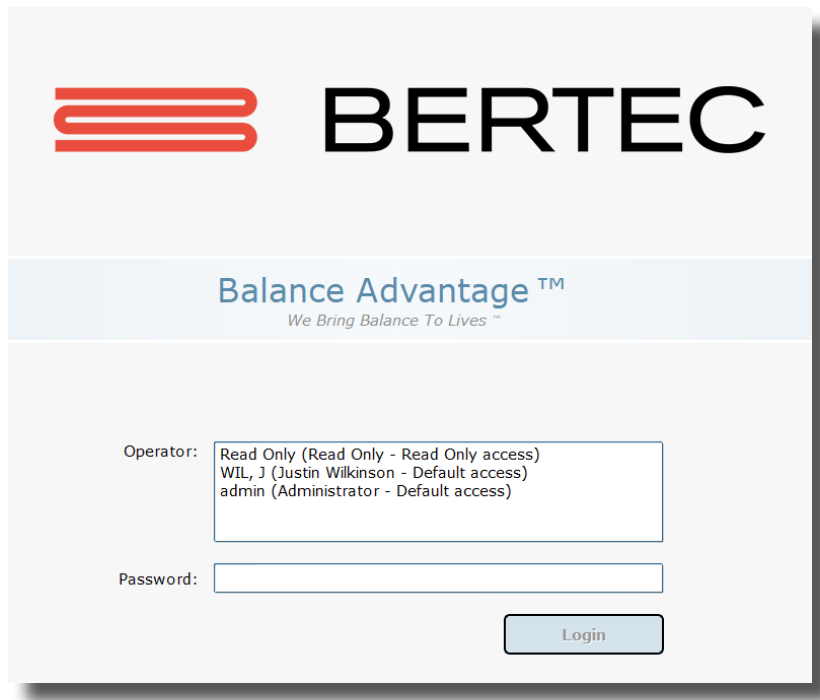


Figure 5: Software Login Screen

## Clinician Home Screen



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

1. Patient Information: Patient information is displayed within the Patients tab. This is the primary interface for loading a patient, creating a patient, and viewing a patient's history.
2. Assessments: All of the 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 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 6: the top bar highlights the tabs, whereas the bar on the left shows where patient information is stored.

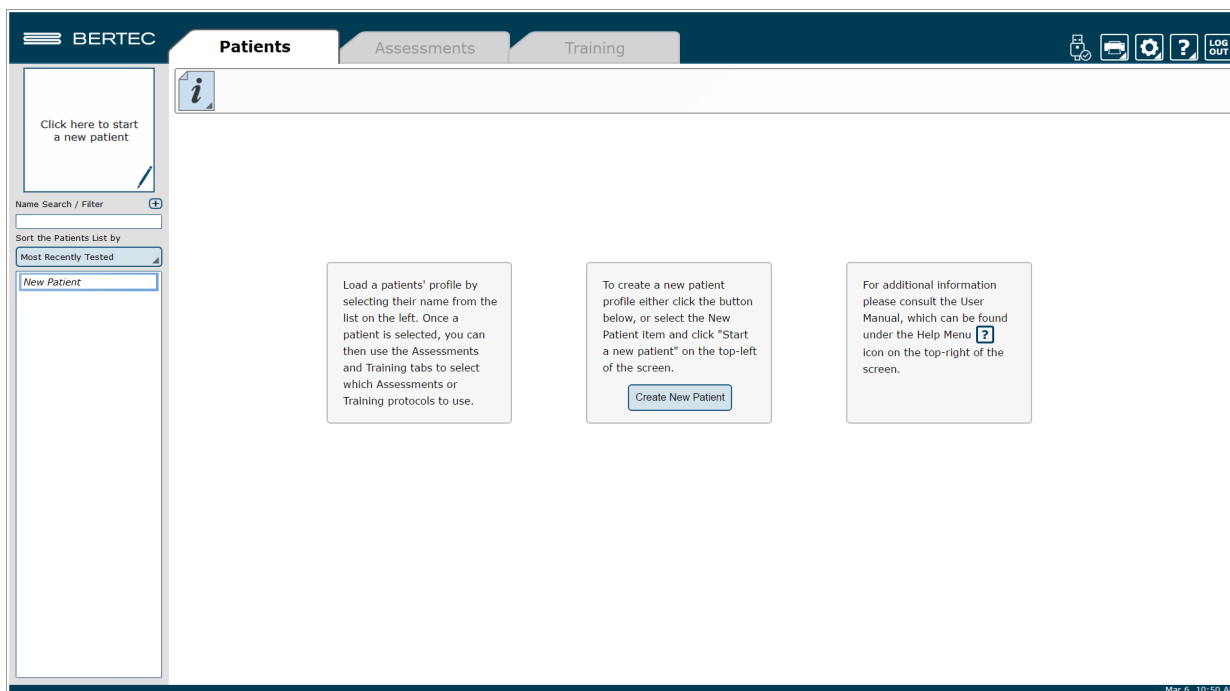


Figure 6: Clinician Home Screen

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

# Facility Setup and System Configuration




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



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

## Options Setup

The operator must select the gear icon  in the upper right corner of the screen and then click on Configuration. In doing so, the operator will load the configuration options screen in a new window where General Settings, Test Settings, Additional Fields, Test Series, Operators, Security Roles, and the Database can be configured (Figure 7).

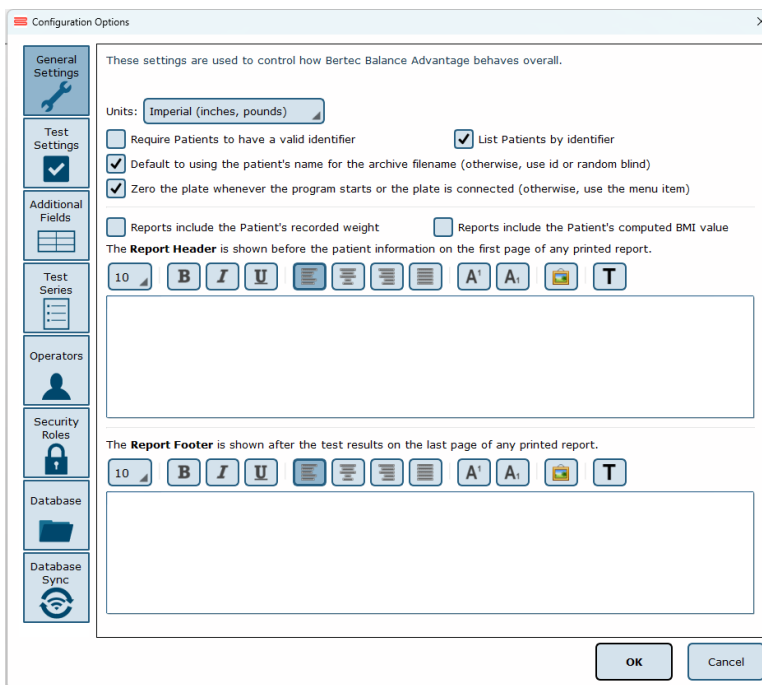


Figure 7: Configuration Options Screen. The General Settings Field is Currently Selected

## General Settings

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

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

# Balance Advantage Software Updates

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

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

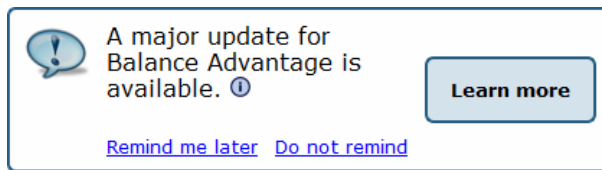


Figure 8: Update Notifications

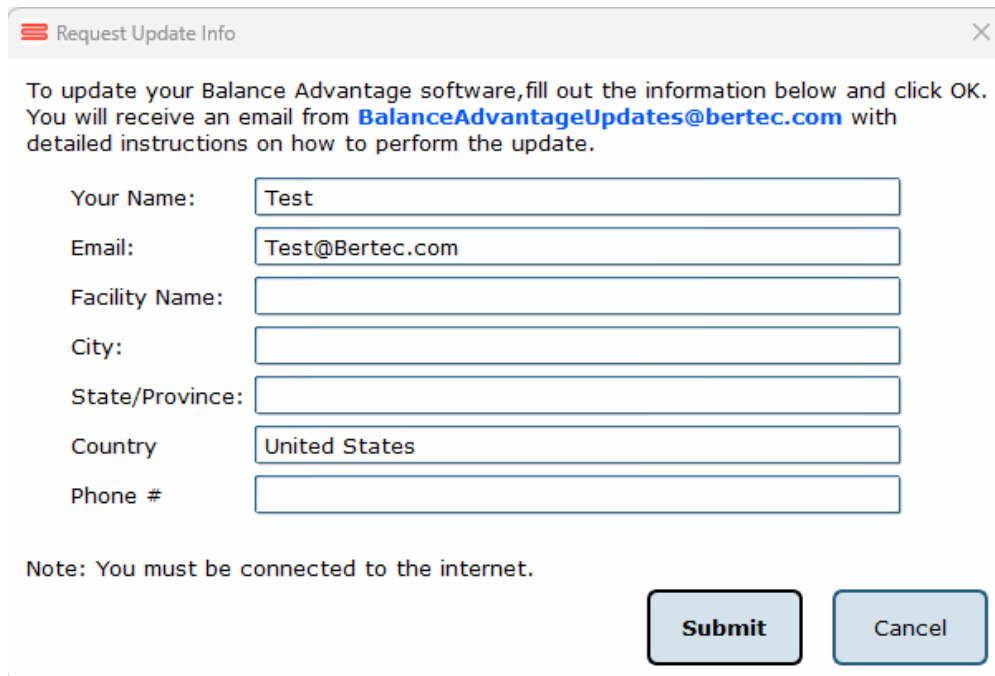


Figure 9: Request Update Info

## Test Settings

The Test Settings configuration options, shown in Figure 8, 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.

The screen DPI for the Vision Tracker can be changed in this window from their corresponding options, as seen in Figure 8.

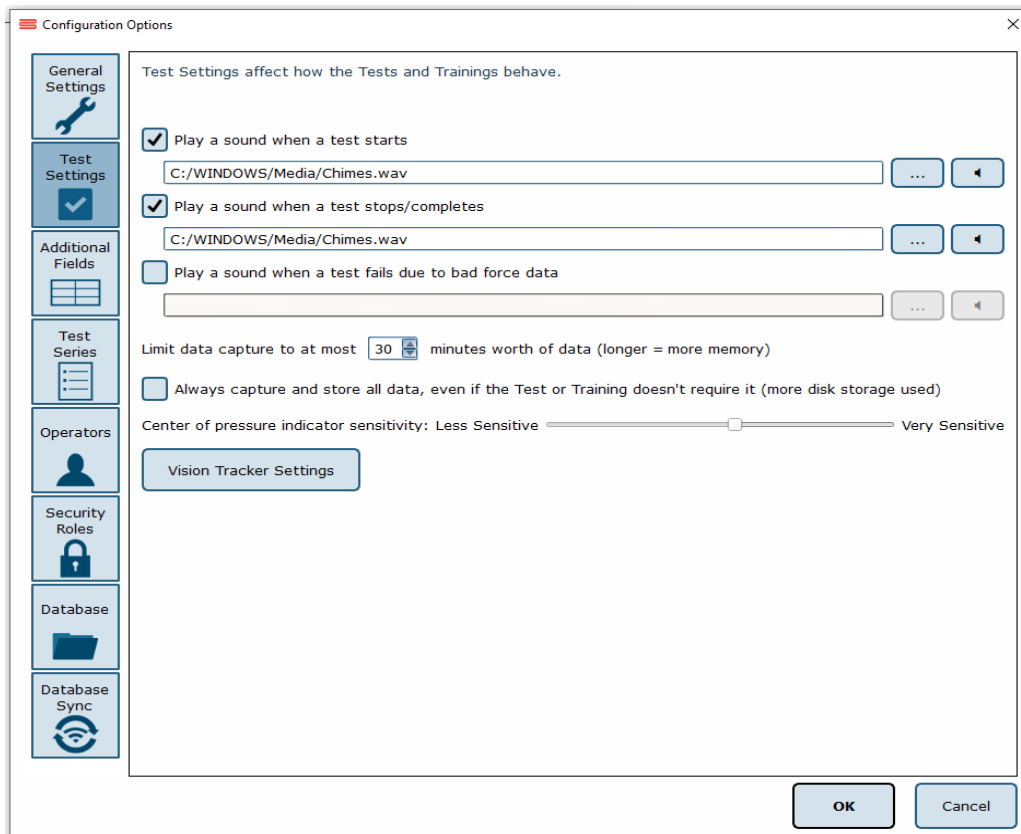


Figure 10: Data Size Notification





## Additional Fields

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

**Edit Field:** Selecting a current field in the system list (at the top of the box) will activate the Edit Field button. This allows the operator to set the type of text that appears in the box (either operator-input text or text from user-created lists), set where in the list the field will appear, and check whether or not it is a required field. Figure 9 shows the Edit Field options menu.

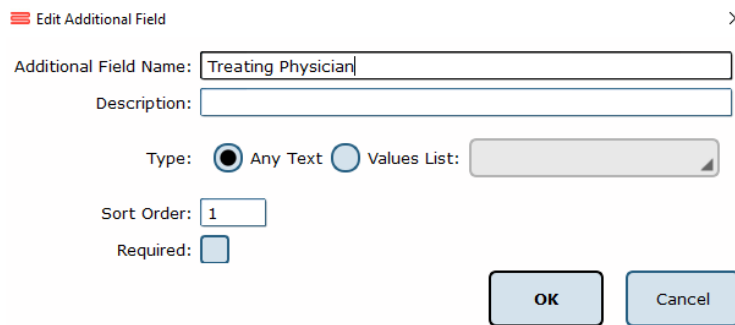


Figure 11: Edit Field Options Menu

**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 11 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 10. If selected, the operator can begin typing in the contents of the list in the text box, as every new line would then coincide with a new possible selection (by default the information is only for one field). When finished, select Ok to save the new field/update.

Allow Multiple Selections:  Yes  No

Figure 12: Allow Multiple Selections Box

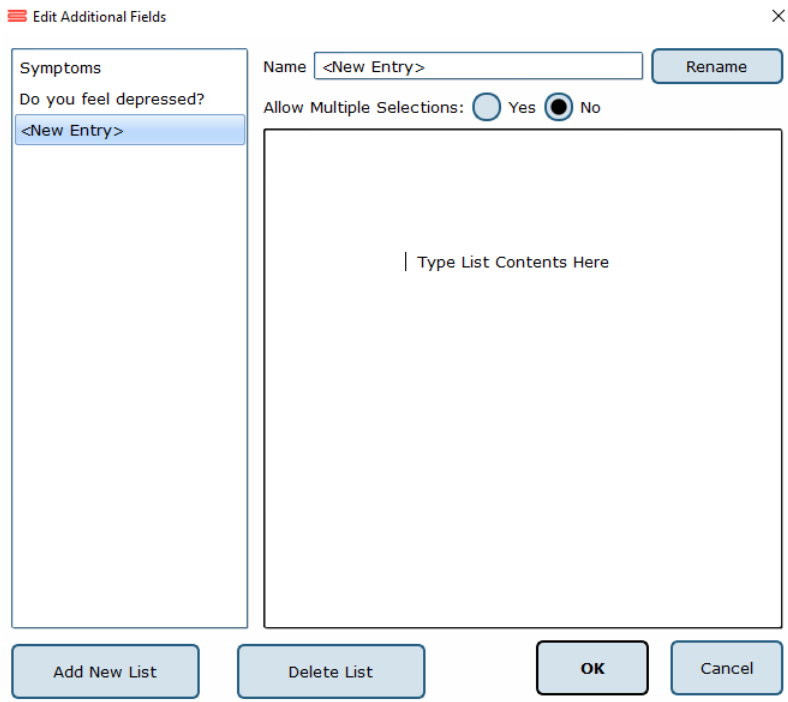


Figure 13: Values Editor Window

## Test Series

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



## Operators

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

To edit or delete an operator, the current operator can click on an entry and then click either Edit Operator or Delete Operator. To create a new operator, the operator can click New Operator. Clicking on edit Operator or New Operator will open the window link shown in Figure 12.

Figure 14: Edit Operator Profile Window

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

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

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



## Security Roles

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

To edit or delete a security role, first click on an entry and then either click Edit Security Role or Delete Security Role. To create a new security role, click New Security Role. Clicking Edit Security Role or New Security Role will open a new window, as shown in Figure 13.

**Edit Security Role**

Role Name:

Description:

Access Rights:

- Can Login
- Is Super Operator / System Admin
- Is Manager Operator
- Can View Operators
- Can Add Operators
- Can Delete Operators
- Can Edit Operators
- Can View Patients
- Can Add Patients

Figure 15: New Window for Security Role Edits

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

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

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

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

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



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

# Establishing New Patients

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

To Create a New Patient:

1. Click on the New Patient button in the center of the screen immediately after logging into the system and arriving at the clinician home screen. Alternatively, select New Patient from the patient list and then click on the Click here to Start a New Patient square (located in the upper left corner of the screen). Both options are shown in Figure 14.
2. After clicking, a popup window will appear with empty patient information fields. Illustrated in Figure 15.
3. Fill in all required fields. These fields are colored yellow. Afterwards, fill out any desired optional fields.
4. (Optional): Take the patient's photo by clicking on the Turn on Camera button, wait for the live camera image to appear, and then clicking on the Take Picture button.
5. Click on the Save Changes button to establish the new patient profile.

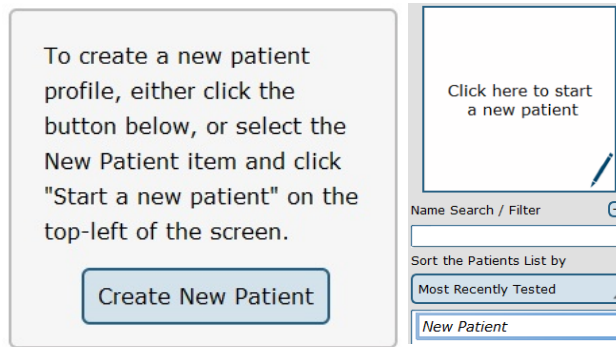


Figure 16: Creating New Patients

New Patient

Name:

Identifier:  Sex:  Date of Birth:  /  /

Height:  feet' inches"

Phone:  Alt:

E-Mail:

Address:

Field	Value
Treating Physician	<input type="text"/>
Complaints	<input type="text"/>
Diagnosis	<input type="text"/>
Goals	<input type="text"/>

Figure 17: 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 15) next to Name Search / Filter, then click on Physical Therapist, then on the box next to Joanne. This screen is shown in Figure 16. 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.

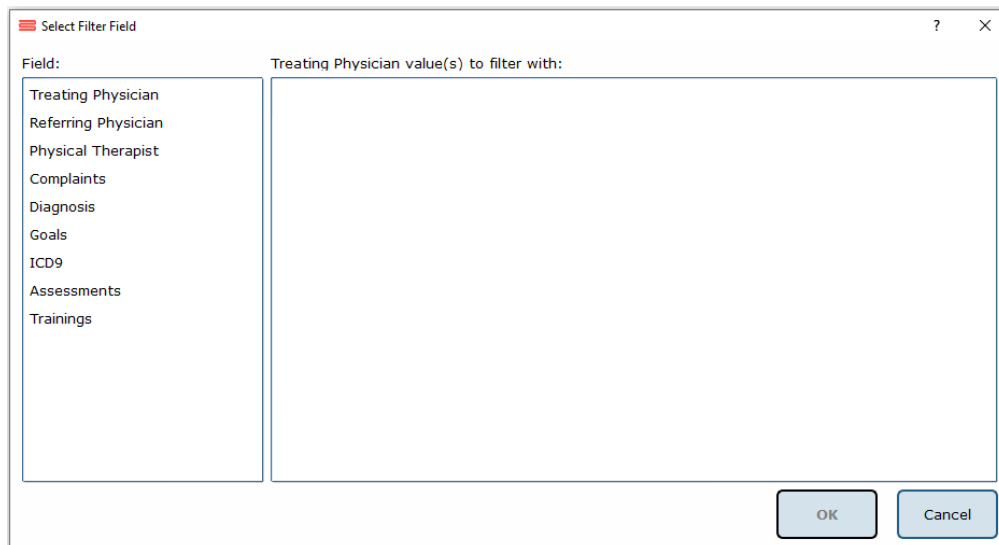


Figure 18: Select Filter Field - Patient List

# Patient Assessment

## Test Setup

Once a patient file has been created, click on the Assessments tab. You can create a test profile by dragging each test to the Series of Tests to Perform window or by clicking on Load from existing Test Series. (Figure 17a.)

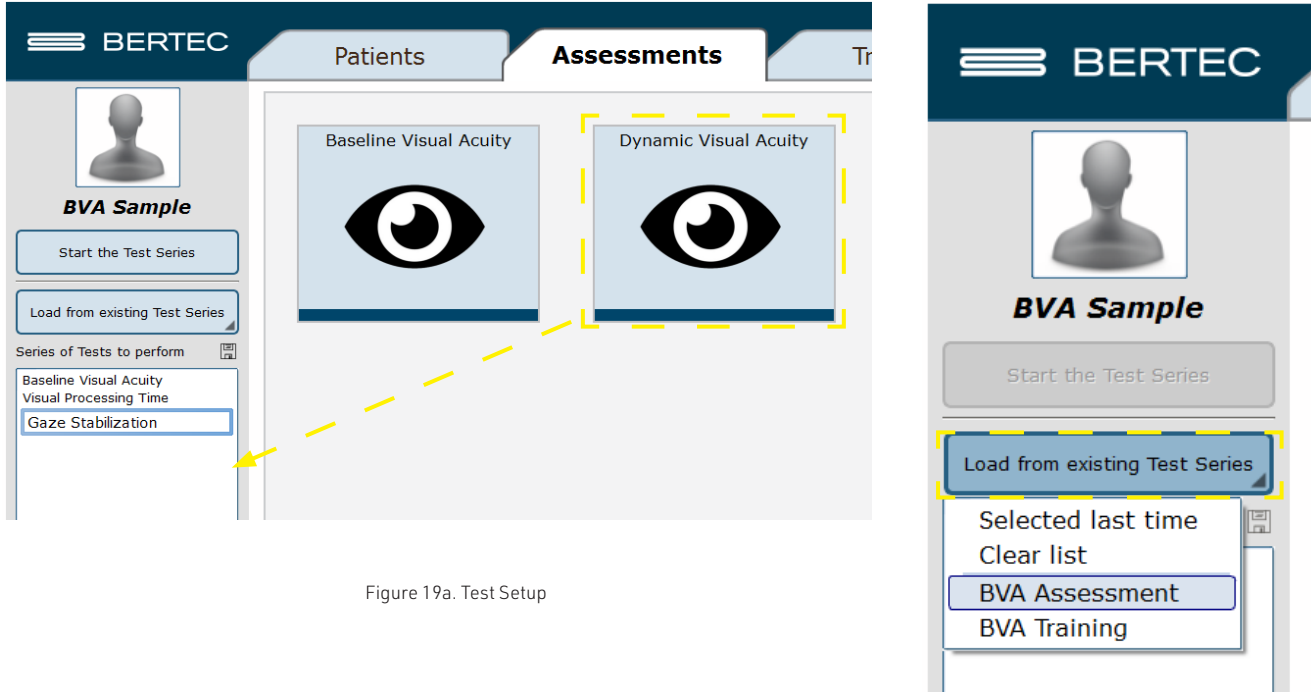


Figure 19a. Test Setup

A typical test series includes the Baseline Visual Acuity (BLVA), Visual Processing Time (VPT), Gaze Stabilization (GST), Dynamic Visual Acuity (DVA) tests and or Impulse DVA (iDVA).

The first two tests, BLVA and VPT, provide baseline information and **must be performed at least once** before GST, DVA, and iDVA can be performed. However, there is no need to repeat BLVA and VPT for the same patient if the tests were performed on the same day.

Test series can also be saved by selecting the icon next to the test series window, then assigning a name to the series (Figure 17b.).

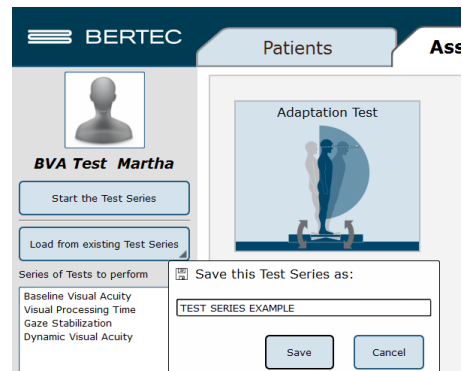


Figure 19b. Test Setup



## Test Options

### Baseline Visual Acuity (BLVA)

- Distance (5-16 feet)
- Patient Position (Sitting, Standing, Standing on Foam)
- Max No. of Trials (15, 20, 30, 40) – Maximum number of trials to be performed before deciding that the threshold for the test cannot be established.
- Optotype (E, C, Pediatric)
- Progressive Lenses (check if the patient is wearing progressive lenses)

Note: Once the Optotype and patient position is chosen for BLVA, you will not be able to change it for VPT, GST, DVA or iDVA, unless the patient repeats the BLVA assessment.

Note: this option will only keep record of whether or not the patient is wearing progressive lenses. This will not alter any features of the test itself.

### Visual Processing Time (VPT)

### Gaze Stabilization Test (GST)

- Head Rotation (Yaw, Pitch, Roll)
- Starting Side (Random, Left, Right) – allows you to choose which direction to test first. The software chooses the side to test first if Random is selected.
- Metronome (Head Turn, Head Rotation, Off) – the metronome can be turned on to chime once per head turn to each side or once per each head rotation from one side back to the same side.
- Head Angle (Progressive, Fixed) – Increased head velocity can be achieved by two methods: (1) Fixed: Moving the head at a fixed amplitude with increased frequency or (2) Progressive: Moving the head with increased amplitude and frequency with a natural head rotation.
- Velocity Feedback (check to provide visual velocity feedback)
- Gaze High Performance (check to test head velocities higher than 150 deg/sec)

Note: this mode of testing can also be triggered during regular Gaze Stabilization testing if the patient correctly identifies the optotype at 150 deg/sec. A dialogue box will indicate when this occurs.

### Dynamic Visual Acuity (DVA)

- Same as options for GST but without the Gaze High Performance option

### Impulse DVA (iDVA)

- Total Impulse Count (6-40 in increments of 2)
- Head Rotation (Yaw, Pitch RALP, Pitch LARP)

Once all of the settings have been chosen, click on Start the Test Series (Figure 18).



Figure 20. Start the Test

## Performing an Assessment

The recommended test procedure is to first perform BLVA and VPT. GST, DVA and iDVA can be performed in any order after completion of BLVA and VPT. BLVA and VPT do not have to be repeated if they have been performed at least once on the same day.

1. Place the screen 5-16 feet away from the patient.
2. Set the distance from the screen to the patient in the software before starting the tests.
  - a. Although this software parameter should be as close to the actual distance as possible, extreme accuracy is not needed.
  - b. The height and the angle of the screen should be adjusted so that it is directly in front of the patient and approximately at their eye level.
3. Once all options have been set, click on Start the Test Series.
  - a. Set test options to match patient's needs.
4. The Clinician Screen (Figure 19) for the first test in the list should now appear.
5. The Guidelines can be used to prepare the patient for the test.
6. Start the test by clicking the right arrow on the wireless remote.
  - a. Starting the test will immediately switch to the Patient Screen.
  - b. If the patient screen does not appear, click F12 on the keyboard, or click on the patient picture on the top left of the screen (see Figure 19)

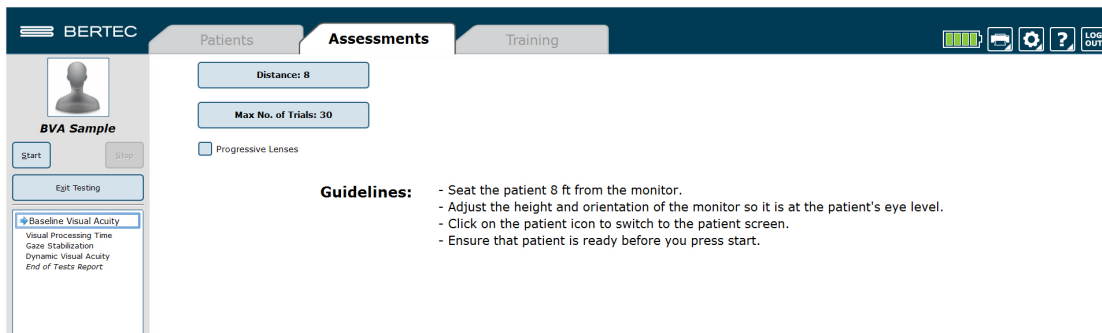


Figure 21. Clinician Screen

7. Ask the patient to sit still and focus on the center of the circle.
  - a. Although this software parameter should be as close to the actual distance as possible, extreme accuracy is not needed.
8. Once the optotype appears, the patient must verbally indicate its direction or shape (up, down, left, right or car, bird, cake, phone).
  - a. The response is recorded by the clinician in one of two ways; using the wireless remote controller, or the laptop keyboard.
9. If the patient is unsure of the direction or shape, you can enter an "I don't know" response, which assigns an incorrect response for that trial.
  - a. Trials where the patient is unsure of the letter orientation or shape are identified in the report by the letter U.
  - b. As a general rule, it is best not to encourage the patient to guess the direction or shape of the optotype, if they are unsure. Excessive guessing may affect the statistical performance of the threshold search algorithm.

**Table 1. Patient response input chart**

Remote Control Button	Keyboard Key	Patient Response	Pediatric Patient Response
Left Arrow (Toggle)	Left Arrow	I don't Know	I don't know
Button 1	1	Up	Hand
Button 2	2	Down	Cake
Button 3	3	Left	Bird
Button 4	4	Right	Car

Note: This part of the protocol is the same for all tests.

## Assessment Layout

The layout for the patient screen for all tests incorporates a central target area where the optotypes will appear. For BLVA, VPT tests and iDVA tests, the target area is circled by a single black ring, which remains unchanged throughout these two tests (Figure 22).

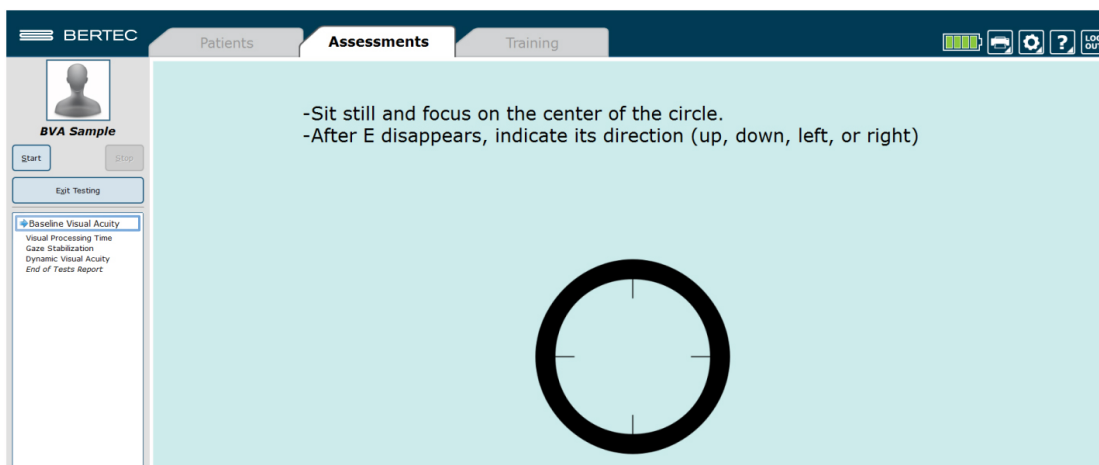


Figure 22. Patient Screen

For the GST and DVA tests, the color of the inner ring changes to grey (Figure 23). Whenever the Visual Feedback box is checked, an outer ring appears to provide an indication of how the head velocity matches the target velocity. A black ring indicates that the head velocity is below target velocity and a white ring indicates that the head velocity is over target velocity. When the head velocity is within the acceptable range, the color of the outer ring matches the gray color of the inner ring.

Note: The optotype appears only when the head velocity is within an acceptable range of the target velocity.

Clinicians will also notice numbers appear in the lower right corner of the screen while a trial is being performed. For the GST, the first number is the current target velocity and the second number is the head velocity of the most recent head rotation (this number will change after each head rotation). A picture of the patient screen during the GST protocol is shown in Figure 24, as well as in the GST portion of this manual.

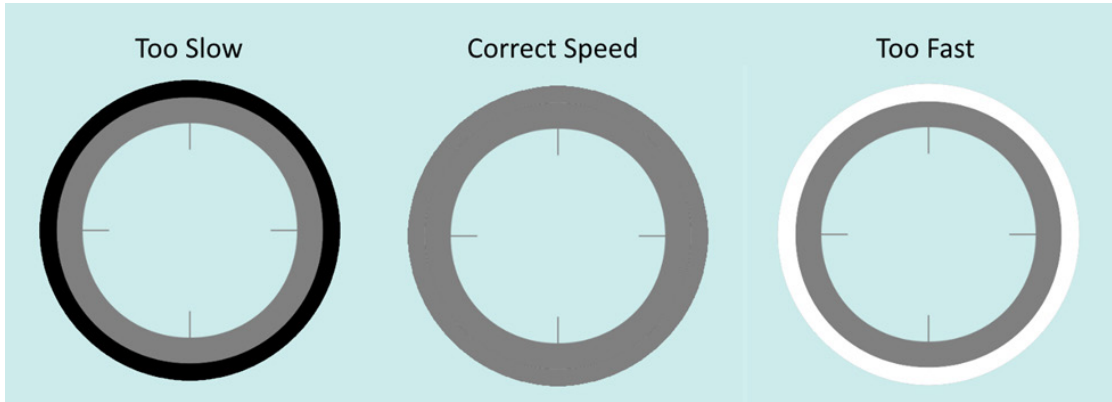


Figure 23. Velocity feedback on Patient Screen

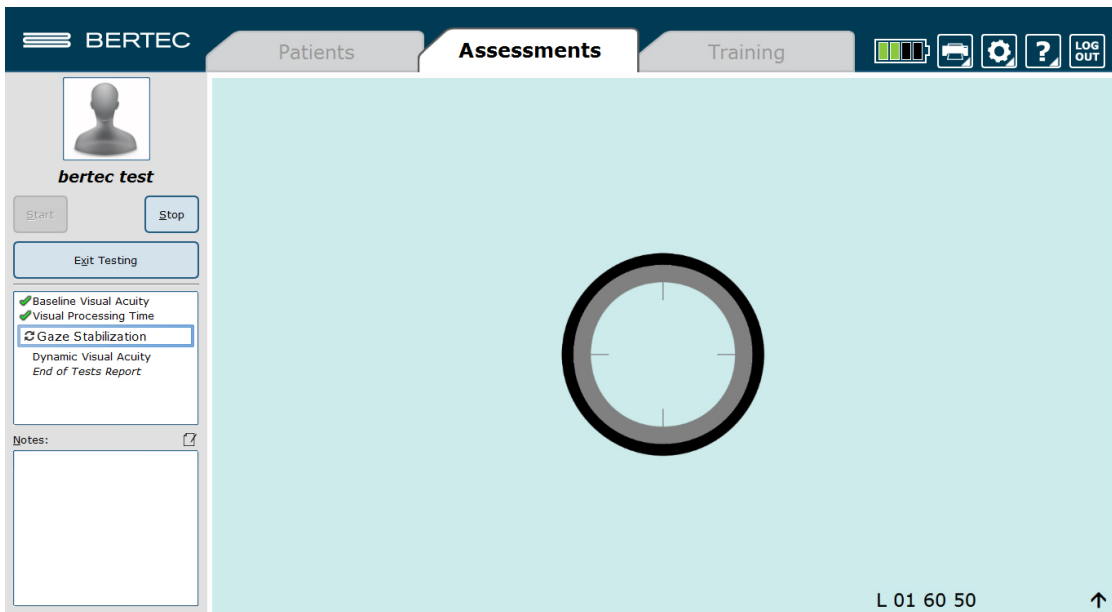


Figure 24. Head Turn Amplitude Increase

The arrow that occasionally appears on the bottom right corner of the screen (Figure 24) is an indication that the patient's head turning amplitude should increase.

# System Troubleshooting

## The Head Tracker is not recognized by the software

1. While on the Patient tab, click on the Gear icon in the top right hand corner of the screen and choose to "Pair Wireless Head Tracker."
  - a. Unplug the receiver from the computer and exit out of the Bertec Balance Advantage completely. Plug the receiver back in and restart the software. You may want to use a different USB port if the procedure is not successful.
  - b. Make sure the Head Tracker is charged. If the charge is low, the LEDs on the Head Tracker and receiver will flash red. Charge the Head Tracker and try again.
  - c. Check to make sure there is a valid license key attached to the software. Click on the "?" at the top right corner and select "About Bertec Balance Advantage". A valid license key should appear next to the License Registration information.

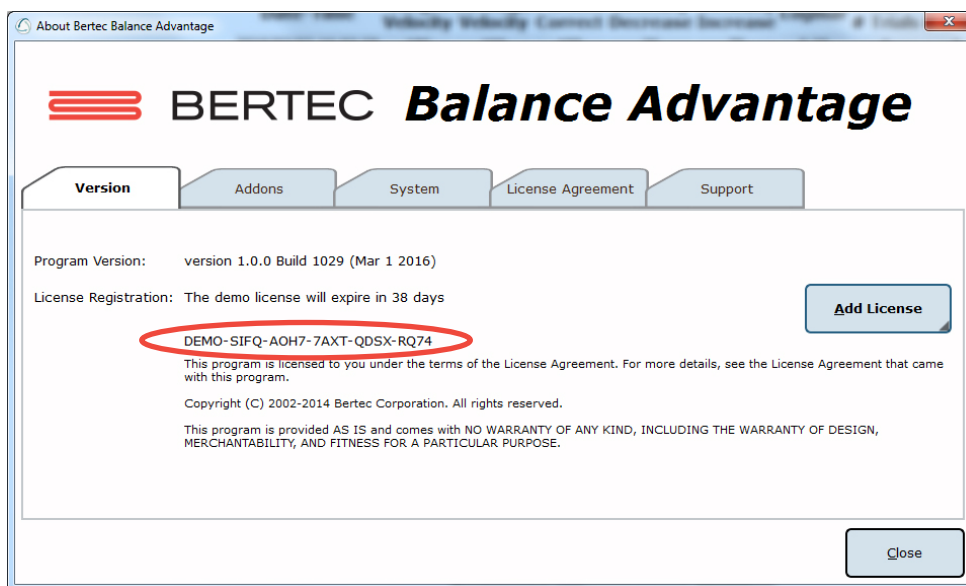


Figure 25. Checking the License

- d. Click on the "System" tab above and scroll all the way down. Check Device Information to verify that the Head Tracker is listed (Figure 24).

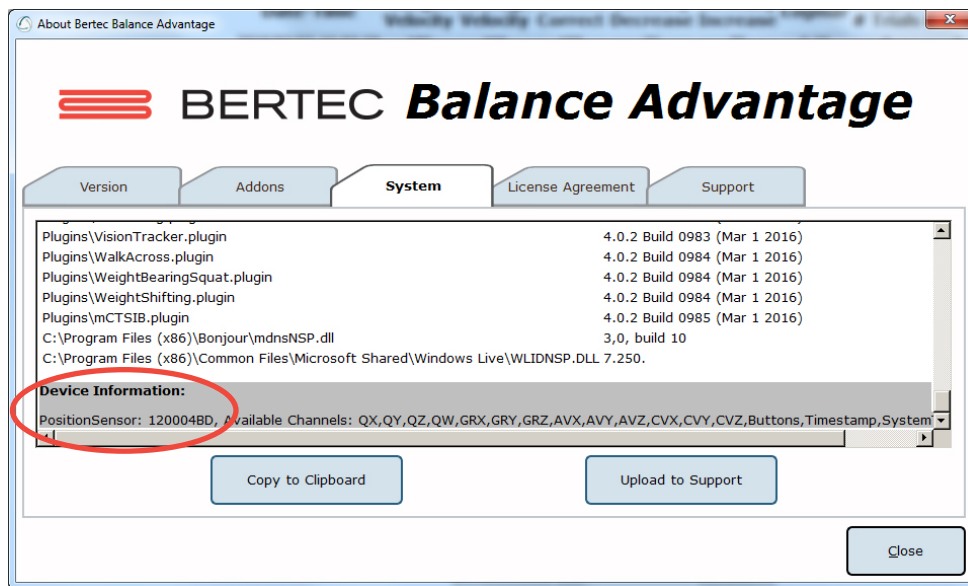


Figure 26. Checking the Head Tracker Connection

If the above procedures do not resolve the issue, please contact Bertec Support.  
t: 614-450-0331  
e: support@bertec.com

## BVA Assessments

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

The following five assessments are designed to assess a patient's capacity to process visual cues during different head movements.

- Baseline Visual Acuity
- Visual Processing Time
- Gaze Stabilization Test
- Dynamic Visual Acuity
- Impulse DVA



## Baseline Visual Acuity (BLVA)

The patient sits while looking straight ahead at the center of the laptop screen. The patient screen will be made available when the trial is initiated. A trial can be initiated using the right arrow on the wireless remote or by selecting Start on the screen.

When the test starts, the optotype will flash in the center of the screen. Once the optotype disappears, the patient should identify the direction of optotype by indicating the direction (for letter optotypes) or the shape (for pediatric optotypes) or "I don't know". The clinician should record the response by using the numbers 1 through 4, respectively, on the wireless remote or laptop keyboard, or the left arrow if the response is "I don't know".

(Table 1). The next trial will begin immediately after the clinician records the response.

It is important for the patient to continue to look straight ahead and focus on the center of the circle. Once a baseline visual acuity is determined, a notification window will appear asking if you want to continue to the next test (Figure 25). If the test needs to be repeated for any reason, answer "No" and stay on that assessment. Otherwise, select "Yes" to proceed to the next assessment.

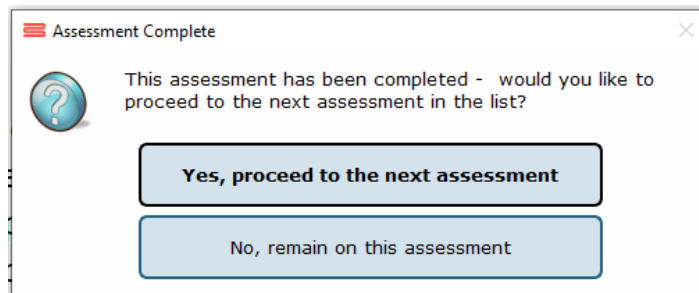


Figure 27. Prompt indicating end of test

## BLVA Reports

The BLVA test report is selected from the Patient tab in Balance Advantage. Each test will be associated with the date and time that it was performed (Figure 26).

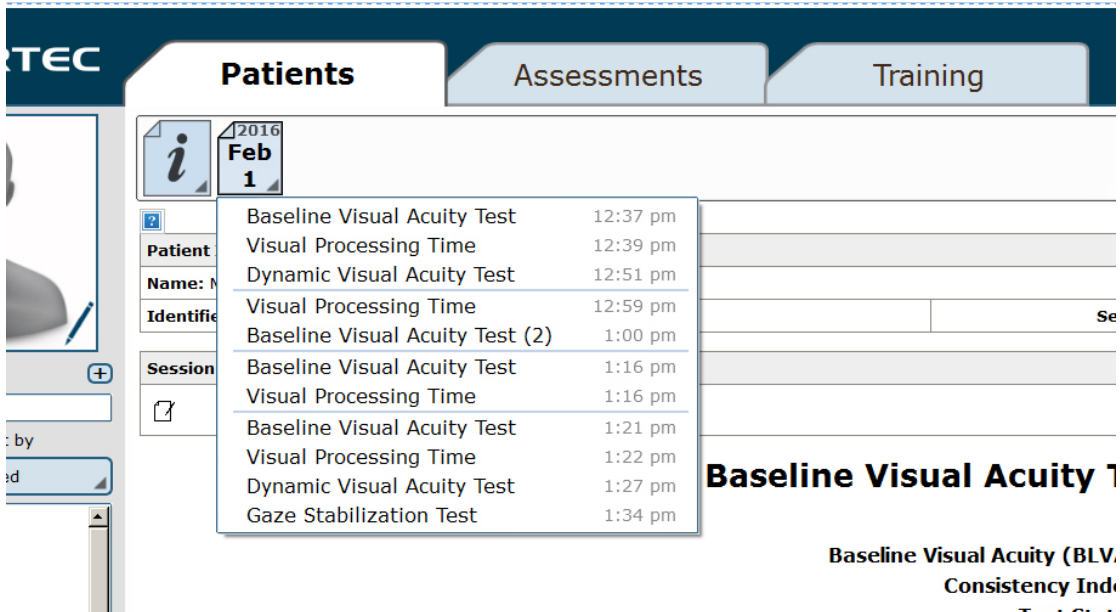


Figure 28. Showing the test report date/time selections for multiple tests

The report indicates if the test was successfully completed and that the threshold has been established. A parameter called the "Consistency Index (CI)" represents the consistency of the patient's responses. The CI is related to how often the actual response matches the expected response for the estimated threshold. For example, a patient who answered every trial with a response that points the algorithm towards the correct threshold is considered "consistent." If all responses are considered "consistent" then the test will be assigned a value of 4 out of 4.

The CI can be used as a quality measure that takes into account the complexity of the convergence algorithm, and the reliability of the patient's responses. The CI is calculated by first finding the percentage of trials with the expected (consistent) responses. This percentage is then converted to an index number between 1 and 4. Index points are subtracted if a test is terminated early, or if many patient responses are inconsistent with the final threshold. Low CI values may indicate guessing or lapse of attention by the patient, so the validity of the threshold should be considered by the clinician and the test may need to be repeated.

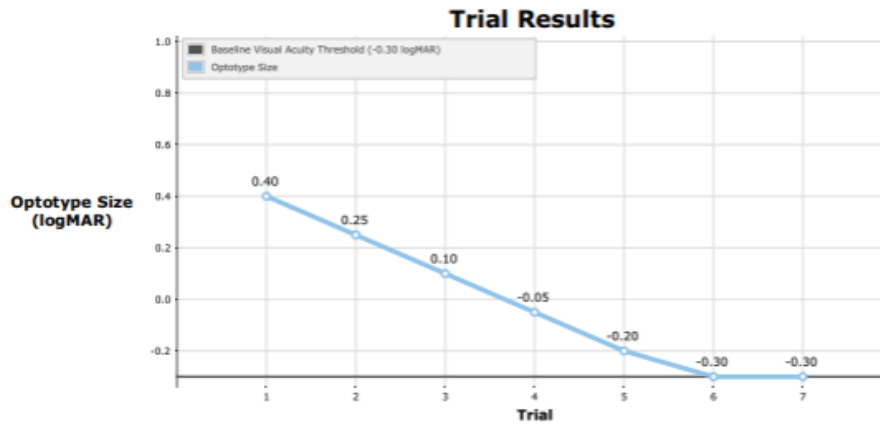
The progression of the test is illustrated in the Trial Results graph of the optotype size versus the trial number. A trial summary table summarizes the optotype size and the patient response for each trial. The trials in which the patient response was "I do not know" are marked by (U). The BLVA report shows the Test Parameters used for the current test. The only parameters applicable for BLVA are the distance, the range of possible optotype (letter) sizes, and whether the patient is wearing progressive lenses.

A sample test report is shown below in Figure 27 for reference.

Patient Information		
Name: Test VMS		Height: 5'2"
Identifier:	Sex: F	Date of Birth: 2000/03/03

## Baseline Visual Acuity Report January 12 2024

Baseline Visual Acuity (BLVA)	≤ -0.30 logMAR
Consistency Index	4 of 4
Test Status	Successfully completed



Trial	Optotype Size (logMar)	Response
1	0.40	correct
2	0.25	correct
3	0.10	correct
4	-0.05	correct
5	-0.20	correct
6	-0.30	correct
7	-0.30	correct

Baseline Visual Acuity (BLVA)	≤ -0.30 logMAR
Consistency Index	4 of 4

### Test Parameters

Optotype Size	-0.30 to 1.00 logMAR
Distance	5 ft
Patient Position	Sitting
Progressive Lenses	No
Optotype	E

Figure 29. BLVA Report

## Visual Processing Time (VPT)

The patient sits while looking straight ahead at the center of the laptop screen. The patient screen will be made available when the trial is initiated. A trial can be initiated using the right arrow on the wireless remote or by selecting Start on the screen.

When the test starts, the optotype will flash in the center of the screen. Once the optotype disappears, the patient should identify the direction or shape by indicating "up", "down", "left", "right" (for letter optotypes), or "hand", "cake", "bird", "car" (for pediatric optotypes), or "I don't know". The clinician should record the response by using the numbers 1 through 4, respectively, on the wireless remote or laptop keyboard, or the left arrow if the response is "I don't know" (Table 1). The next trial will begin immediately after the clinician records the response.

It is important for the patient to continue to look straight ahead and focus on the center of the circle. Again, once the visual processing time is determined, a notification window will appear asking if it should continue to the next test. If the test needs to be repeated for any reason, answer "No" and stay on that assessment. Otherwise, click "Yes" to proceed to the next assessment.

**If the visual processing time (VPT) exceeds 70 ms, a warning message will be displayed to indicate that proceeding with the GST and DVA tests may result in inaccurate results.** High VPT may also increase the time for each trial because it is more difficult to maintain constant head velocity during the optotype display.

## VPT Reports

The VPT test report is selected from the Patient tab in Balance Advantage. Each test will be associated with the date and time that it was performed (Figure 26).

The report indicates if the test was successfully completed and that the threshold has been established. If a patient reaches the maximum number of trials, then the report determines an estimated threshold. A parameter called the "Consistency Index (CI)" represents the consistency of the patient's responses. The CI is related to how often the actual response matches the expected response for the estimated threshold. For example, a patient who answered every trial with a response that points the algorithm towards the correct threshold is considered "consistent." If all responses are considered "consistent" then the test will be assigned a value of 4 out of 4.

The CI can be used as a quality measure that takes into account the complexity of the convergence algorithm, and the reliability of the patient's responses. The CI is calculated by first finding the percentage of trials with the expected (consistent) responses. This percentage is then converted to an index number between 1 and 4. Index points are subtracted if a test is terminated early, or if many patient responses are inconsistent with the final threshold. Low CI values may indicate guessing or lapse of attention by the patient, so the validity of the threshold should be considered by the clinician and the test may need to be repeated.

The progression of the test is illustrated in the Trial Results graph of the display time in milliseconds (ms) versus the trial number. A trial summary table summarizes the optotype size and the patient response for each trial. The trials in which the patient response was "I do not know" are marked by (U).

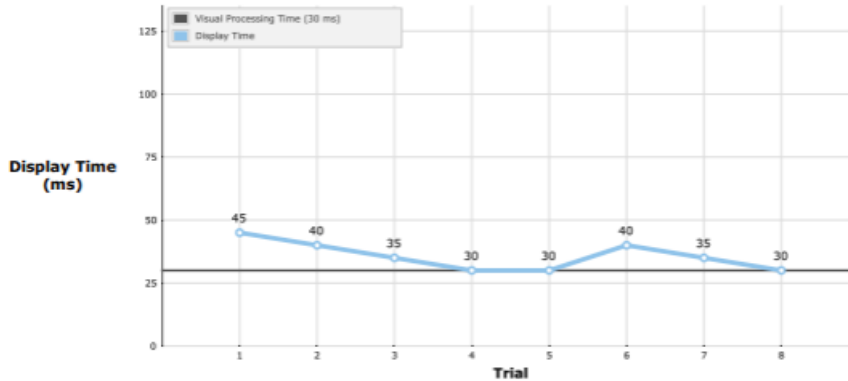
The VPT report shows the Test Parameters used for the current test. The only parameters applicable for VPT are the distance, the optotype (letter) size, and whether the patient is wearing progressive lenses. A sample test report is shown opposite in Figure 28 for reference.

Patient Information		
Name: Test VMS		Height: 5'2"
Identifier:	Sex: F	Date of Birth: 2000/03/03

## Visual Processing Time Report January 12 2024

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

### Trial Results



Trial	Display Time (ms)	Response
1	45	correct
2	40	correct
3	35	correct
4	30	correct
5	30	incorrect
6	40	correct
7	35	correct
8	30	correct

Visual Processing Time (VPT)	≤ 30 ms
Consistency Index	4 of 4

### Test Parameters

Optotype Size	-0.10 logMAR
Distance	5 ft
Patient Position	Sitting
Progressive Lenses	No
Optotype	E

Figure 30. VPT Report

## Gaze Stabilization Test (GST)

The patient sits or stands while looking straight ahead at the center of the laptop screen. The patient screen will be made available when the trial is initiated. A trial can be initiated using the right arrow on the wireless remote or by selecting Start on the screen.

**If the patient's BLVA and VPT tests are not found for that day, the start button will be grayed out and GST cannot be started.**

The layout for the GST patient screen incorporates a central target area where the optotype will appear. This is shown as a gray ring. Whenever the Visual Feedback box is checked, an outer ring appears to provide an indication of how the head velocity matches the target velocity. A black ring indicates that the head velocity is below the target velocity and the white ring indicates that the head velocity is over the target velocity. When the head velocity is within the acceptable range, the color of the outer ring matches the gray color of the inner ring. The letter appears only when the head velocity is within the acceptable range (Figure 21).

In GST, the patient is required to move the head at different velocities. This is traditionally done with fixing the head angle (usually at 20 deg.) and then changing the frequency of the head movements to achieve the desired velocity. This approach causes the frequency to be very low for low head velocities and very high for high head velocities. For high head velocities, the required frequency may be so high that during the optotype display, the velocity may not remain constant as required. This is especially true if VPT is relatively high.

BVA offers an alternative method in which the frequency and head angle are progressively increased for increasing head velocities. In addition to addressing the above issues with the fixed head angle approach, the progressive option is a more natural way of changing the head velocity.

For example, if the fixed setting is selected for GST testing, a patient with VPT of 60 ms can be properly tested up to the head velocity of 230 deg/sec. For higher head velocities, if the patient attempts to maintain the fixed amplitude of 20 degrees, the head velocity will no longer be within acceptable limits and the optotype will not be displayed. By contrast, if the progressive setting is selected, the same patient can be properly tested with no such issues at head velocity of up to 300 deg/sec.

Regardless of whether the fixed or progressive head angle is selected, the metronome works properly. For the progressive option, the metronome can help the patient or the clinician to adjust the head angle in order to achieve the target head velocity.

If the test is performed actively (patient moving his or her own head) and the velocity feedback setting is turned on, the patient should be instructed to match the color of the two rings (Figure 9). The metronome (see page 7) may be used to help with the frequency and amplitude of head movements. Alternatively, the test can be performed without the velocity feedback (colored rings). In this scenario, the clinician should cue the patient to move their head faster or slower.

If the test is performed passively (clinician moving the patient's head), the patient should be instructed to concentrate just on determining the direction and shape of the optotype and not pay attention to anything else on the screen. The clinician can use the visual feedback to move the patient's head at the desired velocity.

In addition to the visual feedback, the patient screen for GST provides the clinician with information about the current trial. The bottom right corner shows the direction being tested (L for leftward, R for rightward), the target head velocity, and the head velocity during the last cycle before the optotype is displayed. The latter number will change after each head rotation.

When the head reaches the desired velocity, the optotype will flash in the center of the screen. Once the optotype disappears, the patient should stop moving their head and identify the direction or shape of the optotype by indicating "up", "down", "left", "right" (for letter optotypes), or "hand", "cake", "bird", "car" (for pediatric optotypes) or "I don't know". The clinician should record the response by using the numbers 1 through 4, respectively, on the wireless remote or laptop keyboard, or the left arrow if the response is "I don't know" (Table 1).

At the top of the screen, the achieved head velocity during the display of optotype is shown. If this velocity is not within the acceptable range, a warning is displayed and the trial is discarded. In some cases, the clinician has the option of discarding and repeating the trial or keeping it and using it for calculation of the GST threshold. The next trial will begin immediately after the clinician records the response.

If a starting side is selected in the options, the GST will begin with testing for head movement toward the specified side and then switches to the movements in the opposite direction. When Random is selected, the starting side is chosen randomly by the software.

It is important for the patient to continue to look straight ahead and focus on the center of the circle. Once the GST threshold is determined, a notification window will appear asking if it should continue to the next test. If the test needs to be repeated for any reason, answer "No" and stay on that assessment. Otherwise, click "Yes" to proceed to the next assessment.

## **GST Reports**

The report indicates if the test was successfully completed and the threshold has been established. A parameter called the "Consistency Index (CI)" represents the consistency of the patient's responses. The CI is related to how often the actual response matches the expected response for the estimated threshold. For example, a patient who answered every trial with a response that points the algorithm towards the correct threshold is considered "consistent." If all responses are considered "consistent" then the test will be assigned a value of 4 out of 4.

The CI can be used as a quality measure that takes into account the complexity of the convergence algorithm, and the reliability of the patient's responses. The CI is calculated by first finding the percentage of trials with the expected (consistent) responses. This percentage is then converted to an index number between 1 and 4. Index points are subtracted if a test is terminated early, or if many patient responses are inconsistent with the final threshold. Low CI values may indicate guessing or lapse of attention by the patient, so the validity of the threshold should be considered by the clinician and the test may need to be repeated.

The progression of the test is illustrated in two line graphs of leftward and rightward head velocities versus the trial number. Finally, two tables summarize the target head velocity, achieved head velocity, and the patient response for each trial for each direction of head movement. The trials in which the patient response was "I do not know" are marked by (U). If there is more than one GST test for the current date, click on the Test time dropdown icon to select which test is used for the report.

The GST report shows the Test Parameters used for the current test. The GST parameters include the VPT value (calculated in the baseline test), test direction, distance, the optotype size (0.2 logMAR above BLVA), range of possible head velocities, and whether the patient is wearing progressive lenses. A sample test report is shown below in Figure 29 for reference.

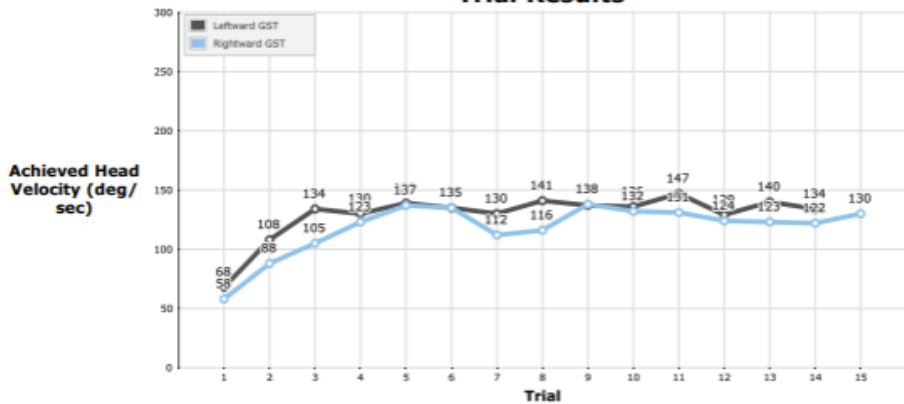


Patient Information		
Name: Test VMS		Height: 5'2"
Identifier:	Sex: F	Date of Birth: 2000/03/03

## Gaze Stabilization Report January 12 2024

	Leftward	Rightward
Gaze Stabilization Test (GST)	140 deg/sec	125 deg/sec
Consistency Index	3 of 4	1 of 4
Test Status	Successfully completed	Reached maximum # of trials
Visual Processing Time	30 ms	

### Trial Results



Leftward GST				Rightward GST			
Trial	Target Vel	Achieved Vel	Response	Trial	Target Vel	Achieved Vel	Response
1	60	68	correct	1	60	58	correct
2	100	108	correct	2	90	88	correct
3	140	134	correct	3	120	105	correct
4	150	130	correct	4	130	123	correct
5	150	139	correct	5	150	137	correct
6	150	135	incorrect	6	150	135	incorrect
7	150	130	correct	7	110	112	correct
8	150	141	correct	8	120	116	correct
9	150	137	correct	9	130	138	correct
10	150	136	correct	10	150	132	correct
11	150	147	correct	11	140	131	correct
12	150	129	correct	12	140	124	correct
13	150	140	correct	13	130	123	correct
14	150	134	correct	14	130	122	correct
--	--	--	--	15	140	130	correct

<b>Leftward GST</b>	140 deg/sec	<b>Rightward GST</b>	125 deg/sec
<b>Consistency Index</b>	3 of 4	<b>Consistency Index</b>	1 of 4

### Test Parameters

Optotype Size	-0.10 logMAR
Visual Processing Time	30 ms
Gaze High Performance	No
Target Head Velocity	60-150 deg/sec
First Test Direction	Rightward (Random)
Test Axis	yaw
Distance	5 ft
Patient Position	Sitting
Progressive Lenses	No
Optotype	E

Figure 31. GST Report

## Dynamic Visual Acuity (DVA)

The patient sits or stands while looking straight ahead at the center of the laptop screen. The patient screen will be made available when the trial is initiated. A trial can be initiated using the right arrow on the wireless remote or by selecting Start on the screen.

If the patient's BLVA and VPT tests are not found for that day, the start button will be grayed out and DVA cannot be started.

The layout for the DVA patient screen incorporates a central target area where the optotype will appear. This is shown as a gray ring. Whenever the Visual Feedback box is checked, an outer ring appears to provide an indication of how the head velocity matches the target velocity. For DVA, the target velocity is set at 100 deg/sec. A black ring indicates that the head velocity is below the target velocity and the white ring indicates that the head velocity is higher than the target velocity. When the head velocity is within the acceptable range, the color of the outer ring matches the gray color of the inner ring. The optotype appears only when the head velocity is within the acceptable range (Figure 9).

If the test is performed actively (patient moving his or her own head) and the velocity feedback setting is turned on, the patient should be instructed to match the color of the two rings (Figure 9). The metronome (see page 7) may be used to help with the frequency and amplitude of head movements. Alternatively, the test can be performed without the velocity feedback (colored rings). In this scenario, the clinician should cue the patient to move their head faster or slower.

If the test is performed passively (clinician moving the patient's head), the patient should be instructed to concentrate just on determining the direction or shape of the optotype and not pay attention to anything else on the screen. The clinician can use the visual feedback to move the patient's head at the desired velocity. In addition to the visual feedback, the patient screen for DVA provides the clinician with information about the current trial. The bottom right corner shows the direction being tested (L for leftward, R for rightward), optotype size, the target head velocity, and the head velocity during the last cycle before the optotype is displayed. The latter number will change after each head rotation.

When the head reaches the desired velocity, the optotype will flash in the center of the screen. Once the optotype disappears, the patient should stop moving his or her head and identify the direction or shape of the optotype by indicating "up", "down", "left", "right" (for letter optotypes), or "hand", "cake", "bird", "car" (for pediatric optotypes) or "I don't know". The clinician should record the response by using the numbers 1 through 4, respectively, on the wireless remote or laptop keyboard, or the left arrow if the response is "I don't know" (Table 1). At the top of the screen, the achieved head velocity during the display of the optotype is shown. If this velocity is not within the acceptable range, a warning is displayed, and the trial is discarded. In some cases, the clinician has the option of discarding and repeating the trial or keeping it and using it for calculation of the DVA threshold. The next trial will begin immediately after the clinician records the response.

If a starting side is selected in the options, the DVA will begin with testing for head movement toward the specified side and then switches to the movements in the opposite direction. When Random is selected, the starting side is chosen randomly by the software.

It is important for the patient to continue to look straight ahead and focus on the center of the circle. Once the DVA threshold is determined, a notification window will appear asking if it should continue to the next test. If the test needs to be repeated for any reason, answer "No" and stay on that assessment. Otherwise, click "Yes" to proceed to the next assessment.

## DVA Reports

The report indicates if the test was successfully completed and the threshold has been established. A parameter called the "Consistency Index (CI)" represents the consistency of the patient's responses. The CI is related to how often the actual response matches the expected response for the estimated threshold. For example in DVA testing, the patient is expected to respond correctly for trials where the optotype size is larger than the threshold and to respond incorrectly for trials where the optotype size is smaller than the threshold. If all responses are considered "consistent" then the test will be assigned a value of 4 out of 4.

The CI can be used as a quality measure that takes into account the complexity of the convergence algorithm, and the reliability of the patient's responses. The CI is calculated by first finding the percentage of trials with the expected (consistent) responses. This percentage is then converted to an index number between 1 and 4. Index points are subtracted if a test is terminated early, or if many patient responses are inconsistent with the final threshold. Low CI values may indicate guessing or lapse of attention by the patient, so the validity of the threshold should be considered by the clinician and the test may need to be repeated.

The DVA thresholds are illustrated in a bar graph with one bar each for leftward and rightward head movements, and for the BLVA established during baseline testing. The progression of the test is also illustrated in a line graphs of optotype size versus the trial number for leftward and rightward head movements. Finally, two tables summarize the optotype size, the achieved head velocity, and the patient response for each trial for each direction of head movement. The trials in which the patient response was "I do not know" are marked by (U). If there is more than one DVA test for the current date, click on the Test time icon to select which test is used for the report.

The DVA report shows the Test Parameters used for the current test. The DVA parameters include the VPT value (calculated in the baseline test), test direction, distance, the target head velocity (~100 deg/sec), the range of possible optotype sizes, and whether the patient is wearing progressive lenses.

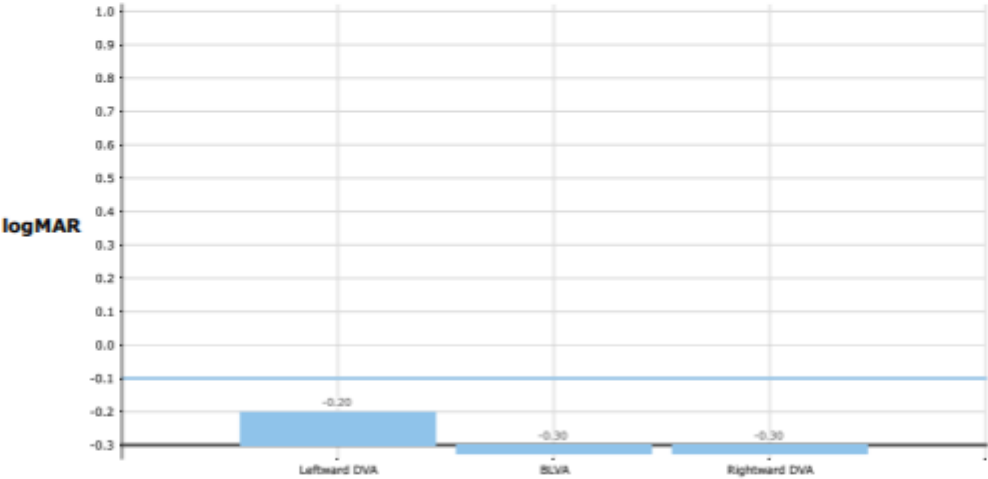
A sample test report is shown below in Figure 30a-b for reference.

Patient Information		
Name: Test VMS		Height: 5'2"
Identifier:	Sex: F	Date of Birth: 2000/03/03

## Dynamic Visual Acuity Report January 12 2024

	Leftward	Rightward
Dynamic Visual Acuity (DVA)	-0.20 logMAR	≤ -0.30 logMAR
Consistency Index	4 of 4	4 of 4
Test Status	Successfully completed	Successfully completed
Visual Processing Time	30 ms	

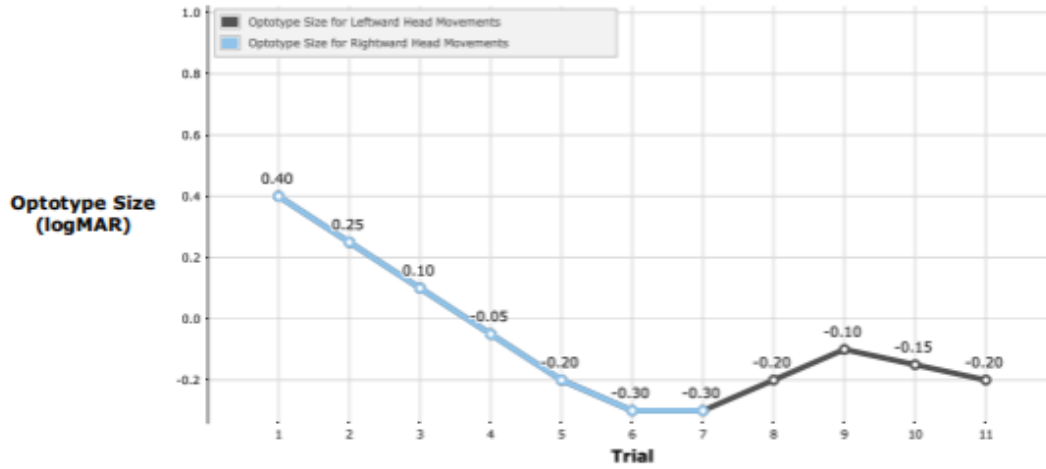
### Summary Results



	Leftward DVA	BLVA	Rightward DVA
logMAR	-0.20	-0.30	-0.30
Approximate Acuity	20 / 13	20 / 10	20 / 10
Average Achieved Head Velocity	109	--	104
Lines Lost	1.0	--	0.0

Figure 32a. DVA Report

### Trial Results



Leftward DVA			
Trial	Optotype Size	Achieved Vel	Response
1	0.40	117	correct
2	0.25	115	correct
3	0.10	116	correct
4	-0.05	112	correct
5	-0.20	101	correct
6	-0.30	116	correct
7	-0.30	102	incorrect
8	-0.20	108	incorrect (U)
9	-0.10	98	correct
10	-0.15	106	correct
11	-0.20	104	correct

**Leftward DVA** -0.20 logMAR  
**Consistency Index** 4 of 4

Rightward DVA			
Trial	Optotype Size	Achieved Vel	Response
1	0.40	104	correct
2	0.25	110	correct
3	0.10	103	correct
4	-0.05	96	correct
5	-0.20	103	correct
6	-0.30	106	correct
7	-0.30	106	correct
--	--	--	--
--	--	--	--
--	--	--	--
--	--	--	--

**Rightward DVA** ≤ -0.30 logMAR  
**Consistency Index** 4 of 4

### Test Parameters

<b>Optotype Size</b>	-0.30 to 1.00 logMAR
<b>Visual Processing Time</b>	30 ms
<b>Target Head Velocity</b>	~100 deg/sec
<b>First Test Direction</b>	Leftward
<b>Test Axis</b>	yaw
<b>Distance</b>	5 ft
<b>Patient Position</b>	Sitting
<b>Progressive Lenses</b>	No
<b>Optotype</b>	E

Figure 32b. DVA Report, continued

## Impulse DVA (iDVA)

The patient sits or stands while looking straight ahead at the center of the laptop screen. The patient screen will be made available when the trial is initiated. A trial can be initiated using the right arrow on the wireless remote or by selecting Start on the screen.

If the patient's BLVA and VPT tests are not found for that day, the start button will be grayed out and Impulse DVA cannot be started.

The layout for the Impulse patient screen incorporates a central target area where the optotype will appear. This is shown as a gray ring.

In Impulse DVA, the clinician is required to place their hands on the sides of the patient's head and move the head in one quick motion to complete an impulse. The direction of the impulse is determined by the pre-selected Head Rotation option. If YAW head impulse is chosen, the head will be rotated quickly in the left or right direction. If RALP or LARP head impulse is chosen, the head will be move quickly up or down, in the vertical plane.

When the RALP head rotation is selected, the clinician will first turn the patient's head 45 degrees to the left. After the head is positioned, the test can begin. Once the test begins, the clinician will move the patient's head in a quick up or down motion in the pitch plane (relative to the ground).

When LARP head rotation is selected, the clinician will first turn the patient's head 45 degrees to the right. After the head is positioned, the test can begin. Once the test begins, the clinician will move the patient's head in a quick up or down motion in the pitch plane (relative to the ground).

During the impulse, the patient should be instructed to concentrate on determining the direction of the optotype and to not pay attention to anything else on the screen. When the head reaches the desired velocity and acceleration, the optotype will display on the screen. Once the optotype is displayed, the patient is to instructed to identify the direction or shape of the optotype, and the clinician is to input their response using the clinician remote.

The software records each impulse's velocity and acceleration. For a successful YAW impulse, head velocity must be greater than 75 deg/sec and the acceleration must be greater than 1000 deg/sec<sup>2</sup>. For successful LARP and RALP impulses, head velocity must be greater than 50 deg/sec and the acceleration must be greater than 1000 deg/sec<sup>2</sup>. It is recommended that the head velocity not to exceed 300 deg/sec. The patient screen provides information about the current and previous trial in the right-hand corner, including impulse count in each direction and the previous trial's peak head velocity.

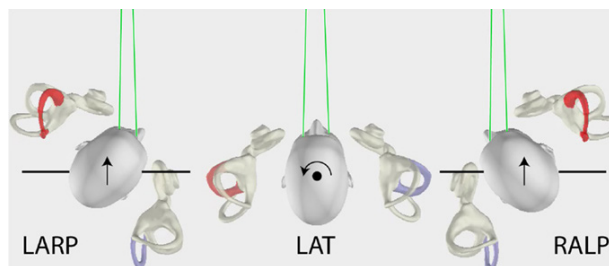


Figure 33. Semicircular Canal Orientation for YAW rotation and Vertical RALP and LARP

Note: The head movements for LARP (left anterior-right posterior) and RALP (right anterior-left posterior) and lateral semicircular canal stimulation (arrows), as viewed from above. Adapted from "The video head impulse test (vHIT) of semicircular canal function - age-dependent normative values of VOR gain in healthy subjects" by L. McGarvie, H. MacDougall, G. Halmagyi, A. Burgess, K. Weber, and I. Curthoys, 2015, *Frontiers in Neurology* 6:154. Copyright © 2015 McGarvie, MacDougall, Halmagyi, Burgess, Weber and Curthoys.

## Impulse DVA Reports

The report indicates the total number of head impulses that were completed along with the number of optotype directions the patient identified correctly. The graphs displayed on the report provide a visual summary of the velocity and acceleration profiles of each head impulse, as well as the number of incorrect and correct responses.

The line plots show the velocity of the head for each impulse (top graph) and the acceleration of the head of each impulse for each impulse (bottom graph). Additionally, dots displayed on the line plot indicate the display period of the optotype. Solid black dots indicate that the optotype response was correct during that impulse. White dots with the black outline indicate that the optotype response was incorrect.

The bar graph displaying correct answers versus average head velocity encompasses five velocity buckets (75-125, 125-175, 175-225, 225-275, 275-325). The ratio depicted on each bar represents the number of correct answers relative to the total head impulses within the corresponding Average Head Velocity bucket. The height of the bar indicates the percentage of correct answers for that specific Average Head Velocity Bucket.

The correct answers vs Peak Head Acceleration graph includes different acceleration buckets (1000-1500, 1500-2500, 2500-3500, 3500-4500, 4500-5500, 5500-6500, 6500-7500). The ratio depicted on each bar represents the number of correct answers vs the total number of head impulses in that Peak Acceleration bucket. The height of the bar displays the percentage of correct answers for that Average Head Velocity Bucket.

The legend for the graphs is shown below the graphs. It provides information about the color of the line tracings and their associated direction along with the color of the bars and their corresponding head direction.

The two tables summarize the average velocity, peak velocity, average acceleration, and the patient response for each trial for each impulse in each direction. The trials in which the patient response was "I do not know" are marked by (U). Finally, below the two tables is an additional table that displays the Test Parameters.

Patient Information		
Name: Patient Test		Height: 1.73 m
Identifier:	Sex: M	Date of Birth: 1999/10/18

## Impulse DVA Report January 8 2024

	Leftward Impulses	Rightward Impulses
Total Head Impulses	6	6
Correct Answers	6	6
Baseline Visual Acuity (BLVA)	≤ -0.30 logMAR	
Visual Processing Time (VPT)	≤ 30 ms	

### Yaw Summary Results

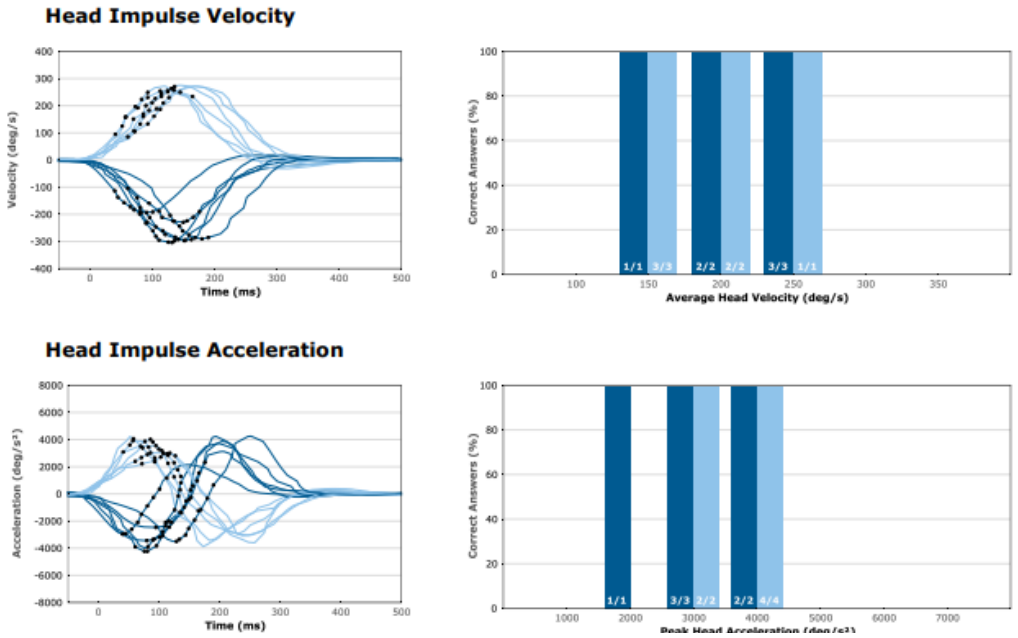


Figure 34. Impulse DVA Report

Right Anterior						Left Posterior					
Trial	Average Vel	Peak Vel	Average Accel	Peak Accel	Response	Trial	Average Vel	Peak Vel	Average Accel	Peak Accel	Response
1	191	284	1174	3642	correct	1	302	326	1599	3334	correct
2	179	201	255	2285	correct	2	152	246	1807	2929	correct
3	139	179	2197	2464	correct	3	250	282	1523	4853	incorrect
4	242	262	1275	3521	correct	4	283	321	922	3866	correct
5	262	283	1130	2502	correct	5	350	374	2019	5201	correct
6	207	234	1801	2533	correct	6	205	249	892	2351	correct

### Test Parameters

Distance	5 ft
Patient Position	Sitting
Progressive Lenses	No
Optotype	E

Figure 35. Impulse DVA Report



# Balance Performance Evaluation

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

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

Patient Information		
Name: Meghan L Short		Height: 5'4"
Identifier:	Sex: M	Date of Birth: 1997/09/28


## Balance Performance Evaluation May 15 2023

### Limits of Stability (LOS)

Limits of Stability quantifies impairments in the ability to intentionally and accurately move the patient's center of gravity (COG) to its limits without losing balance. It combines the ability to move with the willingness to do so. LOS helps to determine if there is a voluntary motor problem, and if there is, it helps determine whether the problem stems from movement timing, movement control, limits of safe actual movement, limits of perceived movement, or reaction times. Results of LOS can be used to inform training, using the LOS protocol, to increase the patient's ability to move outside their base of support, which is required for activities of daily living.

Time	LOS Results	Explanation
1:15 PM	<b>Abnormal</b>	The patient's overall <b>Reaction Time</b> was 1.3, which is above normal limits
	Normal	The patient's overall <b>Movement Velocity</b> was 7.0, which is within normal limits
	Normal	The patient's overall <b>Endpoint Excursion</b> was 71, which is within normal limits
	Normal	The patient's overall <b>Maximum Excursion</b> was 92, which is within normal limits
	<b>Abnormal</b>	The patient's overall <b>Directional Control</b> was 42.9, which is below normal limits

### Analysis and Recommendation to Care Plan:

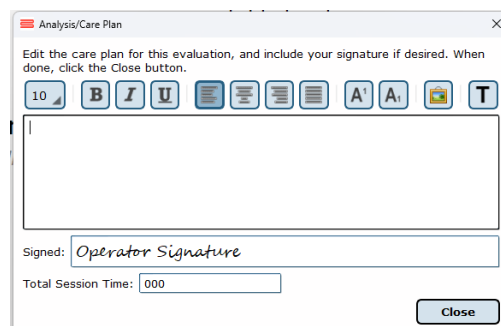
 Right-click to create/edit the Care Plan and Signature Testing

Signature: Operator Signature Date: 2024-01-18

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

Total Session Time: 1 minute, 20 seconds

Figure 36. Balance Evaluation Note



Analysis/Care Plan

Edit the care plan for this evaluation, and include your signature if desired. When done, click the Close button.

10 B I U [List Icon] [List Icon] [List Icon] A<sup>1</sup> A<sub>1</sub> [Image Icon] T

Signed: Operator Signature

Total Session Time:

Close

Figure 37. Edit Analysis/Care Plan

# Training

## Visual Motion Sensitivity (VMS)

Training BVA Training protocols provide a method for improving the gaze stabilization of patients that have deficits in this area. They are intended to gradually improve the patient's head-eye coordination. The protocol is similar to the GST but instead of determining a threshold, the patient is presented repeatedly with the same size optotype at the same target head velocity. If the patient can correctly identify the direction of the optotype in a sufficient number of trials, the velocity is increased to the next level. However, if the ratio of correct to incorrect answers is below a certain level, the head velocity Figure 31. VMS Training Options for the next training is decreased. The training can be selected to display the optotype only during leftward or rightward head movements.

Distance: 8	5	11	16
Patient Position: Sitting	Sitting	Standing	On Foam
Initial Head Velocity: 60	30	120	200
Optotype Size: 0.40	-0.30	0.40	1.00
Visual Processing Time: ...	30	70	100
Minimum Number Of Tri...	4	13	20
Maximum Number Of Tri...	5	25	40
Difficulty Increase %: 75	60	85	100
Difficulty Decrease %: 35	10	35	50
Optotype: E	E	C	Pediatrics
Scene: Standard	Standard	Starfield	Tunnel
Metronome: Head Turn	Head Turn	Head Rotation	Off
Head Angle: Progressive	Progressive	Fixed	
<input checked="" type="checkbox"/> Velocity Feedback			

Figure 38. VMS Training Options

Click on the Training tab to access the VMS training protocols. Similar to the assessment protocols, you can create a training profile by dragging each module to the Series of Tests to Perform window or by clicking on Load from existing Test Series. If the patient has completed the DVA and GST assessments, the software will select the optimized options (see below) based on the results from those tests. This feature is not available when the training profile is loaded from the existing profiles.

The following options can be selected for the VMS training modules. If the patient has undergone GST and DVA assessments, some of the options will be set based on the results from those tests. These options are identified by an asterisk.

### \*Distance

\*Initial Head Velocity - The initial head velocity for VMS training. If available, the initial head velocity is set at 20 deg/sec below the GST threshold.

\*Optotype Size - If available, the optotype is set at the size specified in GST.

\*Visual Processing Time - If available, the display time is set at 30 ms above VPT.

Minimum Number of Trials - Minimum number of trials performed at each target head velocity. The default is 4.

Patient Position - The standard is sitting, but to increase the difficulty of training, the operator directs their patient to stand or stand on foam.

Optotype - Select from the tumbling E, Landolt C or pediatrics.

Scene - Select from different optokinetic scene options that will display behind the concentric circle.

Maximum Number of Trials – Maximum number of trials performed at each target head velocity. The default is 30.

Difficulty Increase % –The minimum ratio of correct to incorrect answers required to increase the head velocity to the next level. The default is 75% (3/4 correct answers)

Difficulty Decrease % –The maximum ratio of correct to incorrect answers required to decrease the head velocity to the previous level. The default is 35%.

Metronome – Same as in GST and DVA.

Velocity Feedback – Same as in GST and DVA.

The clinician has the ability to override the default values and set the options according to his or her training plans. Once the options are selected, click on Start the Test Series. Follow the same steps as described for GST to perform VMS training. Once the percent for increasing or decreasing the difficulty is reached, a message is displayed. The options include proceeding to the next target velocity, to change the options, or to end the training.

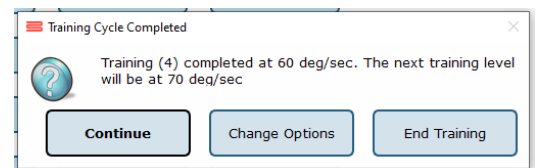


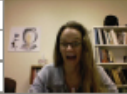
Figure 39. Options after Completion of VMS Training for one Head Velocity

## VMS Training Reports

The VMS Training report shows the above options used for the training. The report shows bar graphs of the ratio of correct to incorrect answers for each head velocity. A table for each head session shows the achieved head velocity and the patient response for each trial.

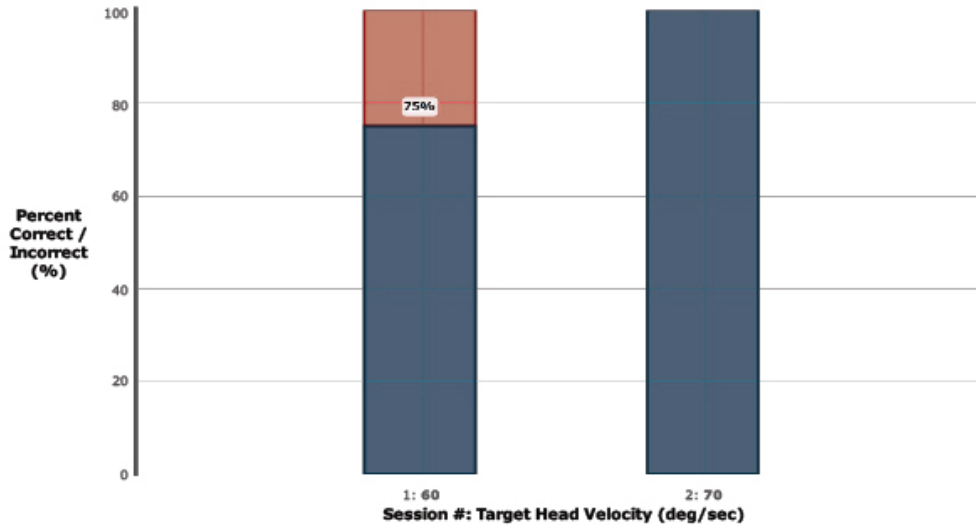
Figure 33 below shows an example of with two training sessions made up of multiple trials each.

Patient Information		
Name: VMS Testing Martha		Height: 5'7", Weight: N/A, BMI: N/A
Identifier:	Sex: F	Date of Birth: 1991/01/01



## VMS Training Right Report - May 23, 2016

### Summary Results



### Trial Results Per Session

#### Session# 1 @ 12:55:27

Optotype Size	-0.10 logmar
Target Velocity	60 deg/sec
Average Velocity	55 deg/sec
Percent Correct	75%

Trial	Achieved Velocity (deg/sec)	Response
1	54	incorrect (U)
2	56	incorrect (U)
3	54	correct
4	51	correct
5	58	correct
6	58	correct
7	54	correct
8	56	correct

#### Session# 2 @ 12:57:26

Optotype Size	-0.10 logmar
Target Velocity	70 deg/sec
Average Velocity	78 deg/sec
Percent Correct	100%

Trial	Achieved Velocity (deg/sec)	Response
1	79	correct
2	63	correct
3	101	correct
4	68	correct












Figure 40. VMS Training Report














# Bertec Vision Advantage System Safety

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

## Symbols Used

Symbol	Description
	Carefully read these instructions prior to use
	Caution
	Mandatory action
	High Voltage
	Power on
	Power off
	Earth (Ground)
	Alternating current
	Fuse
	Complies with Type B requirements of IEC 60601-1
	Complies with Medical Devices Regulation (EU) 2017/745 and RoHS Directive (2011/65/EC)

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

## 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 BVA system should only be used as specified in the user manual.
- Note 4**      Only use approved power supplies.
- Note 5**      WARNING: To avoid risk of electrical shock, BVA systems must only be connected to properly grounded mains.
- Note 6**      Use biocompatible bouffant cap with the system. Bouffant caps are single use and should be discarded after each patient.
- Note 7**      Ensure children are supervised around equipment and that unused receptacles are covered in pediatric environments.
- Note 8**      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 9**      Keep Bertec Vision Advantage systems away from liquids. Do not allow moisture inside the device.
- Note 10**     Do not use the device in the presence of flammable anaesthetics (gases).
- Note 11**     No parts may be eaten, burnt, or in any way used for purposes other than posturography and balance test-ing.
- Note 12**     Bertec Vision Advantage Systems can be disposed of as normal electronic waste, according to local regulations.
- Note 13**     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 14** The device is disconnected from the mains by pulling the plug from the wall outlet.
- Note 15** The BVA System 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 BVA System may be interfered with by other equipment with CISPR emission requirements.
- Note 16** 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 17** The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals. If it is used in a residential environment (for which CISPR II class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- Note 18** WARNING: No additional networking/data coupling is to be made outside of what has been designed for the Bertec Vision Advantage 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 environment and conditions so that we may provide the best solution for syncing databases.
- Note 19** Bertec Vision Advantage is intended to only be connected to the specified computer, which has been tested as part of the ME Equipment.

## Responsibility of the Manufacturer

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

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

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

# 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

## USB Wall Charger

Input Voltage: 100-240 VAC - 50/60Hz

Input Current: 0.3A

Output Voltage: 5V

Output Current: 2.4A max

## Operating Mode

Warm-up time: <5 minutes

Mode of Operation: Continuous

## Storage and Handling

Temperature: -20° C (-4° F) to +60° C (+140° F)

Rel. Humidity: <90% R.H. 35 °C non-condensing

Air Pressure: 500 hPa to 1060 hPa

## Standards

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

System: IEC 60601-1


EMC: IEC 60601-1-2

# Guidance and Manufacturer's Declaration Tables

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

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

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

Guidance and manufacturer's declaration - electromagnetic immunity - for equipment and systems that are NOT life-supporting			
Bertec Vision Advantage System is 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 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of Static Systems, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.17 \sqrt{P}$ $d = .5 \sqrt{P}$ (80 MHz to 800 MHz) $d = 1 \sqrt{P}$ (80 MHz to 2.5 GHz) where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with this symbol: 
<p><b>Note 1:</b> At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.</p> <p><b>Note 2:</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.</p>			

Recommended separation distances between portable and mobile RF communications equipment and Bertec Vision Advantage Static Systems			
Bertec Vision Advantage System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of BVA System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and BVA 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)	$d = 1.17 \sqrt{P}$ (V1=3)	$d = 1.17 \sqrt{P}$ (E1=7)	$d = 1 \sqrt{P}$ (E1=7)
0.01	0.117	0.050	0.10
0.1	0.369	0.158	.316
1	1.167	0.50	1.00
10	3.689	1.58	3.16
100	11.667	5.00	10.00
For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ 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.			
<p><b>Note 1:</b> At 80 MHz and 800 MHz the separation distance for the higher frequency range applies.</p> <p><b>Note 2:</b> 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.</p> <p><b>Note 3:</b> 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.</p> <p><b>Note 4:</b> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

## Accessories and Cables

Item	Origin	Termination	No.
Black USB Cable 1 ft 6" Cable Length, A/Male to 5 Pin B Mini Male	Laptop	3-Space Sensor Wireless Dongle	1
Black USB Cable 3 ft Cable Length, A/Male to 5 Pin B Mini Male	Wall Charger	3-Space Sensor Wireless 2.0	1

Part Number	Part Name
37P-0012	Bertec Balance Advantage Laptop
30P-0238	3-Space Sensor Wireless 2.0
30P-0239	3-Space Sensor Wireless Dongle
37P-0029	Wireless Remote
37P-0060	2 Port USB Wall Charger
97P-0051	Elastic Head Band with Pocket for Sensor
97P-0053	Poly Hairnet - 100 Count
97P-0054	BVA Custom Carrying Case
30S-0712	Black USB Cable 1 ft. 6" Cable Length, A/Male to 5 Pin B Mini Male

## Appendix A: Frequently Asked Questions

### **Should patients be encouraged to guess the orientation of the letter when they are unsure?**

As a general rule, no. Excessive guessing may affect the statistical performance of the threshold search algorithm. It is best to tell patients to acknowledge when they cannot clearly identify the direction of the letter.

### **What does the message *Resetting the sensor* mean?**

BVA is designed not to require an initial calibration of the Head Tracker. Instead, the orientation of the Head Tracker is reset before each trial. The message about resetting the sensor is displayed if the patient is moving his or her head prematurely before the trial begins. Once the message is displayed, ask the patient to stop moving their head, click on OK and continue with the test.

### **Is it better to ask patients to move their own head (active testing) or move their head for them (passive testing) in GST and DVA?**

Different clinicians have different preferences on this issue. The premise of this question is that these methods may produce different results because in active testing, the head movements are more predictable, which may allow the patient to use other sensory mechanisms (e.g., neck receptors) to augment vestibular responses. However, large-scale studies have not yet examined this question in different patient groups. However, research has shown that there is no clinically significant difference between active and passive testing.

### **Why does it occasionally take a long time for the software to establish a threshold during GST?**

This situation usually occurs when the patient's head velocities are within the acceptable range but they are consistently below the target velocity. In these cases, an accurate threshold cannot be established if the patient repeatedly identifies the orientation of the letter correctly. A similar situation occurs if the head velocities are consistently higher than the target velocity and the patient repeatedly identifies the orientation of the letter incorrectly. When the clinician notices one of these patterns, it is best to pause between trials (by not entering the patient response immediately) and ask the patient to begin the head movements faster or slower than before and adjust as necessary. This may break the cycle of repeating the same head velocities and lead to the convergence of the threshold search algorithm.

### **Sometimes the patient is moving his or her head for a long time and no letter appears even though the head velocity seems to be within the acceptable range. Why?**

There may be several reasons for this issue. First, if VPT is larger than 70 ms, it will be difficult to maintain a relatively constant head velocity that is needed for the display of the optotype. This can be particularly problematic in high head velocities. This is one of the reasons for the warning in the VPT report. If VPT is larger than 70 ms, reconsider testing the patient at high head velocities.

Another possibility is that the Head Tracker may need to be reset. One can pause the test and select the Reset Sensor option by clicking on the gear icon.



**When the patient stops moving their head during a test, why doesn't the velocity value in the bottom right-hand corner of the patient screen update to zero? Instead it freezes at the last value. Is this supposed to happen?**

Yes, the value at the bottom of the screen represents the last peak velocity before the optotype is displayed. Once the patient's head resumes turning, the display will be updated again.

**What do I do if my patient becomes symptomatic during testing?**

make a mental note of their response, but do not enter it until the patient feels better. At that point, enter their response and continue with testing. Delaying the entry of their response effectively becomes a pause in the test.

**How do I view results when I'm finished testing?**

Select the patient tab, then select the icon that resembles a piece of paper with the date. Select the test you want to review in the dropdown menu. If only one test was performed on that date, the report will automatically be loaded.

## Appendix B: Passwords and Security

### Security Concerns

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

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




Figure B1: Settings Button.

### Forgotten Passwords

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

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

## Appendix C: License and Support Features

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

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

**About Bertec® Balance Advantage®:** This option will open a new window, shown in Figure C1. The new window contains six different tabs: Version, Addons, System, License Agreement, Privacy Policy and Support. These tabs are underlined/described below and on the following page.

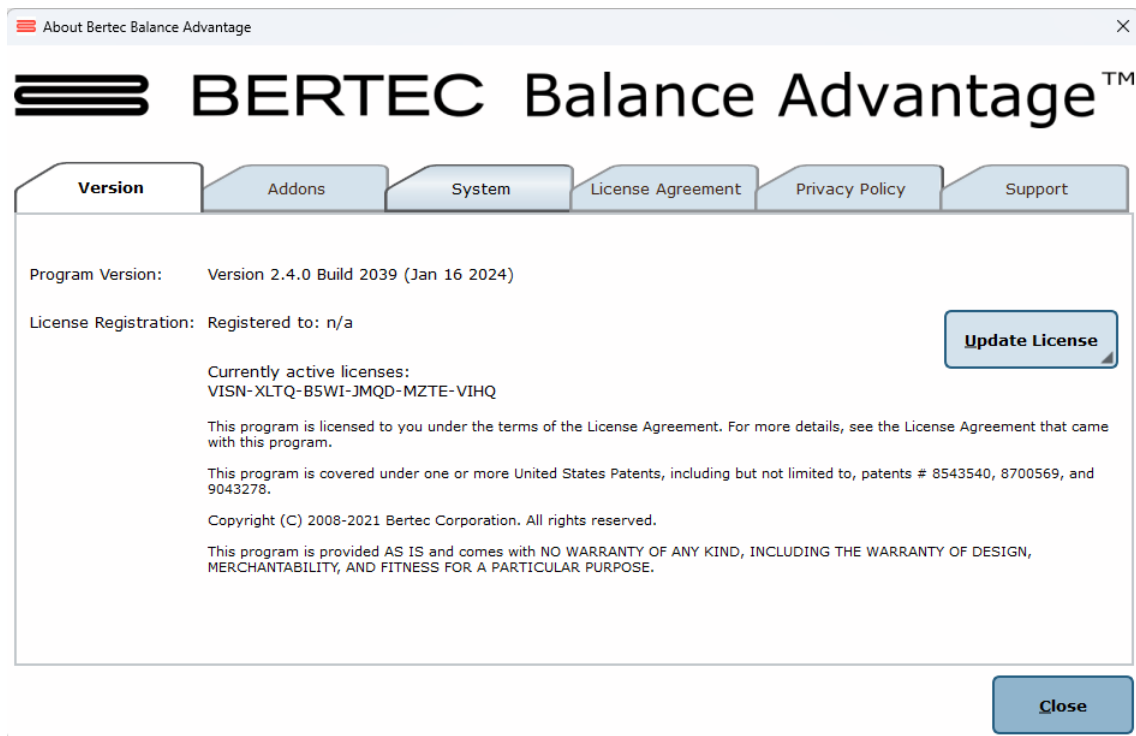


Figure C1: About Balance Advantage.

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

To register or update a license:

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



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

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

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

### To copy/paste this information from the clipboard

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

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

### To directly upload this information to support

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

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

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

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

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

### To opt out of sending anonymous program reports to Bertec®

1. In the Support Tab, click on the box to the left of the phrase "Collect and report screenshots during application faults" so that no check-mark shows.
2. Close the window by clicking the Close button.



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



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

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



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

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



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



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

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

#### **If the operator does not have a remote session scheduled**

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

#### **If the operator does have a remote session scheduled**

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



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



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

## Appendix D: Error Messages – Balance Advantage Software

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

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

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



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

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

## Appendix E: 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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Fax: +1 (614) 430-5425

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Support: [support@bertec.com](mailto:support@bertec.com)

## Appendix F: References

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