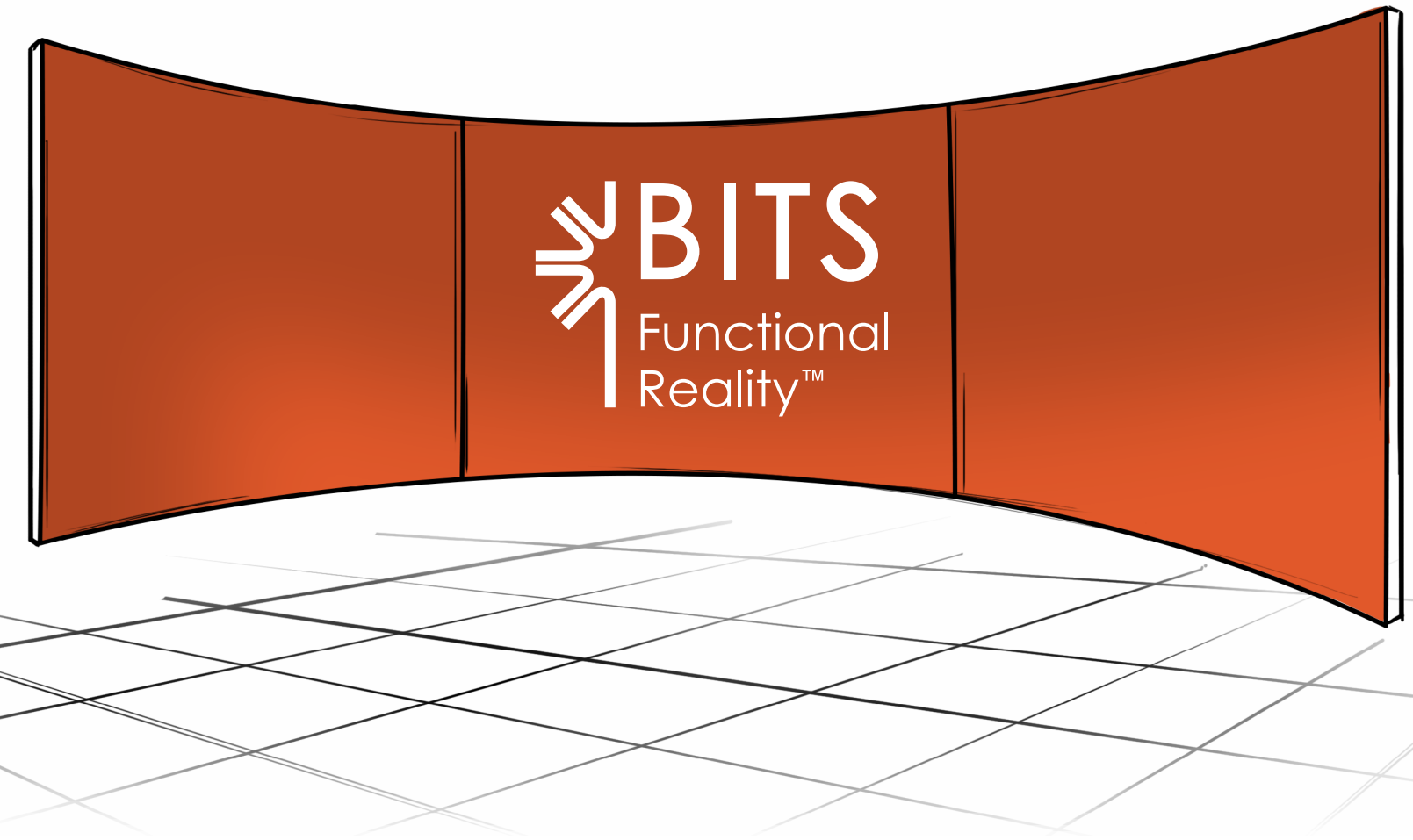
Bioness Medical, Inc.
25103 Rye Canyon Loop
Valencia, CA 91355 USA
Telephone: (800) 211-9136
Email: info@bionessmedical.com
Website: BionessMedical.com

Rx Only

602-00748-001 Rev. A
09/2025



CLINICIAN'S GUIDE

bioness®

List of Symbols

	Caution
	Warning
	Date of Manufacture
	Manufacturer
	Refer to Instruction Manual/Booklet
REF	Re-Order Number
SN	Serial Number
Rx Only	Prescription Only

Contents

CHAPTER 1: **Introduction**

The Bioness Integrated Therapy System (BITS) Functional Reality (FR) is a software device platform using off-the-shelf immersive technology that allows for client interaction with exercise programs that focus on BITS programs, Real-World Experiences, Virtual Reality and Mixed Reality activities. The BITS FR System consists of BITS FR Software (**Figure 1-2**) available on an Off-The-Shelf (OTS) Headset (**Figure 1-1**), and BITS FR Clinician Software (**Figure 1-3**) available on an Off-The Shelf (OTS) Clinician Tablet (**Figure 1-4**). Additional OTS hardware accessories include a router, accessories for charging the OTS Headset and OTS Tablet, as well as disposable hygiene face masks.

Figure 1-1 OTS Headset

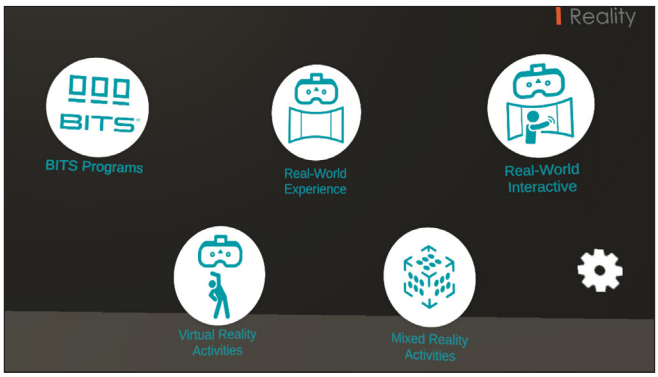


Figure 1-2 BITS FR Software

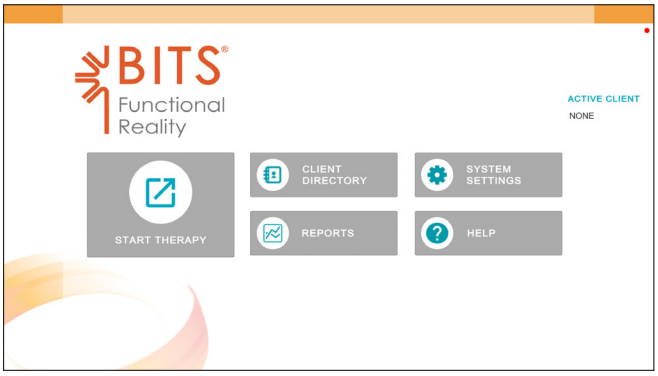


Figure 1-3 BITS FR Clinician Software

Figure 1-4 OTS Clincian Tablet

Be sure to review this guide, including all safety information, before using the Bioness Integrated Therapy System Functional Reality (BITS FR). If you have questions or need technical support, contact the Bioness Product Support Department at 800-211-9136. You can also visit the Bioness website at: BionessMedical.com.

⚠ **Caution:** Do not use the Bioness Integrated Therapy System Functional Reality until you have been properly trained by a Bioness Representative.

CHAPTER 2: **Safety Information**

Indications for Use

The BITS Functional Reality (BITS FR) is a software-only device designed to be used with commercially available Head-Mounted Displays (HMDs) which are compatible with the software application. BITS FR is an immersive virtual reality and display system that interactively displays and tracks upper-extremity rehabilitation exercises for adult patients using a combination of virtual environments and full presence tracked avatars for visual feedback. These rehabilitation exercises are intended to be conducted in a clinical environment and prescribed and supervised by a medical professional trained in rehabilitation therapy.

Warnings

- If a client complains of motion sickness, dizziness, headache, eye strain, or fatigue when using the device, stop use of device immediately.
- Patients may experience discomfort (e.g., visual strain, dizziness, nausea) during use of the device. At the discretion of the clinician, to reduce the risk of adverse effects, patients should be instructed to limit initial exposure duration and gradually increase session length as tolerated.
- Some patients may acclimate more effectively when initiating therapy with passthrough experiences prior to engagement in fully immersive environments.
- The time required for individual patients to acclimate to and obtain therapeutic benefit from extended reality (XR) interventions may vary. Clinicians should monitor patient response and adjust exposure parameters accordingly.
- For further information regarding regulatory considerations for augmented reality and virtual reality medical devices, refer to FDA guidance: https://www.fda.gov/medical-devices/digital-health-center-excellence/augmented-reality-and-virtual-reality-medical-devices-questions-consider.
- Users of the system should exercise caution to prevent tripping hazards during therapy.
- The BITS FR system software programs utilize moving and rotating graphics that may cause dizziness, vertigo, or nausea in sensitive clients.

- Do not use unapproved devices with the BITS FR software system.
- Do not use unapproved accessories with the BITS FR software system.
- Refer to HTC Vive Focus Vision User Manual included with the Headset for warnings/ precautions related to the Headset.
- Refer to Android G10 Tablet User Manual included with the Tablet for warnings/precautions related to the Tablet.

Precautions

- Ensure a safe environment for the client while performing activities with the device (i.e. remove any surrounding obstacles and ensure that the client is unlikely to trip or fall).
- Ensure a medical professional is with the client at all times to prevent any injury.
- Improper shut-down of the BITS FR software may result in the loss of client data. Please follow proper instructions for the shutdown process.
- BITS FR software system is not intended to act as a diagnostic device and does not identify the presence or absence of clinical diagnoses.
- Do not attempt to modify the BITS FR software system (e.g., by installing or uninstalling software or changing system settings). Unauthorized modifications may compromise system security and increase the risk of cybersecurity threats.
- Do not connect the BITS FR software system to the internet or local intranet. Network access may expose the system to cybersecurity threats and is not required for normal operation.
- Make sure to follow the correct procedures from OTS Headset manufacturer when donning, doffing and calibrating the OTS Headset.
- System should only be used in a stationary environment (seated or standing).
- Be aware of the client's limitations in range of motion and avoid program use that could lead to excessive gestures that could injure a client.
- Supervision and assistance for the client should be provided during use of the BITS FR software system.
- Keep area around the user clear of other objects.
- For clients with limited mobility, exercise precaution and remain within a safe distance when client is performing activities.
- Do not use any tool or object that could damage the system or pose a safety risk when

operating the BITS FR software.
- Use caution with clients diagnosed with, or suspected to have, dizziness, nausea, etc.
- Prolonged use of the BITS FR Software, OTS headset and OTS controllers can cause discomfort, eye fatigue, or strain.
- Disposable Face Masks provided are single use only and should not be transferred between clients.
- Do not use any chemical solvents that are acidic or alkaline cleaning agents. Follow manufacturer guidelines for cleaning procedures.
- Always exercise universal precautions and wear gloves when cleaning any component of the system.
- Only use OTS hardware that is compatible with BITS FR Software System (**See Chapter 17**).

Potential Adverse Events

Visual stimulation through head-mounted displays has a small possibility of provoking an adverse reaction. Possible complications include, but are not limited to, the following:

- Claustrophobia
- Discomfort or pain in the head or eyes
- Disorientation/vertigo/dizziness
- Drowsiness
- Eye strain
- Falls or fractures
- Headache/migraine
- Insomnia
- Light-headedness
- Motion sickness
- Nausea
- Pain
- Seizure
- Repetitive strain injury
- Vision problems

Should any of the above occur, stop using the device immediately. At the discretion of the clinician, to reduce the risk of adverse effects, patients should be instructed to limit initial exposure duration and gradually increase session length as tolerated.

Some patients may acclimate more effectively when initiating therapy with passthrough experiences prior to engagement in fully immersive environments.

The time required for individual patients to acclimate to and obtain therapeutic benefit from extended reality (XR) interventions may vary. Clinicians should monitor patient response and adjust exposure parameters accordingly.

For further information regarding regulatory considerations for augmented reality and virtual reality medical devices, refer to FDA guidance:
https://www.fda.gov/medical-devices/digital-health-center-excellence/augmented-reality-and-virtual-reality-medical-devices-questions-consider.

Incident Reporting

Any serious incident that has occurred in relation to the device should be reported to Bioness Medical. If you have questions or need technical support, contact the Bioness Product Support Department at 800-211-9136. You can also visit the Bioness website at: BionessMedical.com.

For the latest information on BITS FR compatibility with OTS Hardware go to:
www.bionessmedical.com/bitsfr/support

CHAPTER 3: **Setting up for Therapy Session**

⚠ **Caution:** Do not use the Bioness Integrated Therapy System Functional Reality until you have been properly trained by a Bioness Representative.

To start a session, ensure the following steps are completed in the order listed below.

1. Plug in the router provided into a wall outlet
2. Power on the Clinician Tablet and ensure tablet is connected to router.
3. Launch BITS FR Clinician Software
4. Don the headset on the client, ensuring client is seated or standing in a clear area free of objects (recommend a 1.5 meter (5-foot) radius around the client)
5. Power on the headset
6. Ensure a green dot can be seen in the top right corner of the tablet
7. Launch a BITS FR Program for client from the Clinician Tablet

STEP 1

1. Plug in the router provided into a wall outlet
2. Confirm the first three lights are solid green before proceeding to the next step. (**Figure 3-1**)
3. If no lights are turning on, confirm the power button on the back of the router is pressed

Figure 3-1 OTS Router Front

in (**Figure 3-2**)

Note: *illustration may not be representative of actual product

Figure 3-2 OTS Router Back

STEP 2

To turn on the tablet, press and hold the power button located on the side of the tablet for a few seconds (**Figure 3-3**). Let go off the power button once “Powered by Android” splash screen appears

Once on the lock screen, swipe up from the bottom of the tablet to unlock it.

Figure 3-3 Tablet Power Button

Then swipe down from the top of the tablet and confirm if “TP Link” network is connected. If not, select ‘Internet’ and select “TP Link” router name. Select ‘Done’ once router states “Connected/ No internet access” Ensure wi-fi symbol appears solid filled with an exclamation mark. Select the circle icon on the bottom of the tablet screen to go back to tablet home page.

Then select the “BITS FR Clinician Software” icon located on the home screen. (**Figure 3-4**)

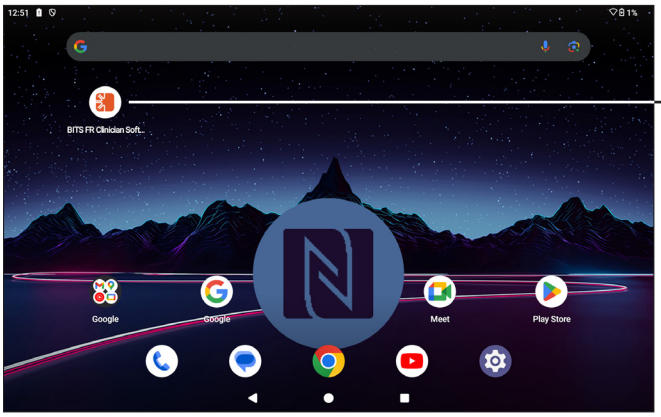


Figure 3-4 Tablet Home Screen

STEP 3

For multi-user/clinical environments, have client don the provided hygiene masks before donning the headset.

Donning the headset

(The following instructions and images are sourced from the headset manufacturer's user guide. A copy of the Headset user guide is also included with the system.)

1. Undo the velcro fastener on the top strap.
2. Press and hold the Quick-Release Button, and then gently pull until fully extended (**Figure 3-6**).

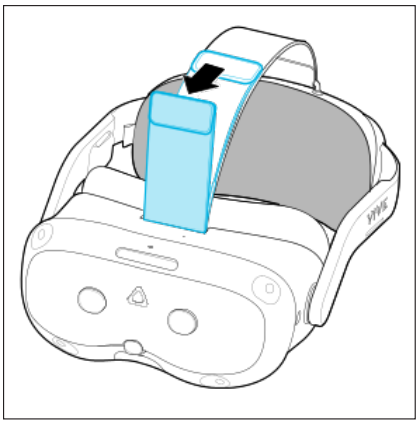


Figure 3-5 Undo Velcro Fastener

Note: If you feel resistance when pulling, turn the adjustment dial counterclockwise a bit first.

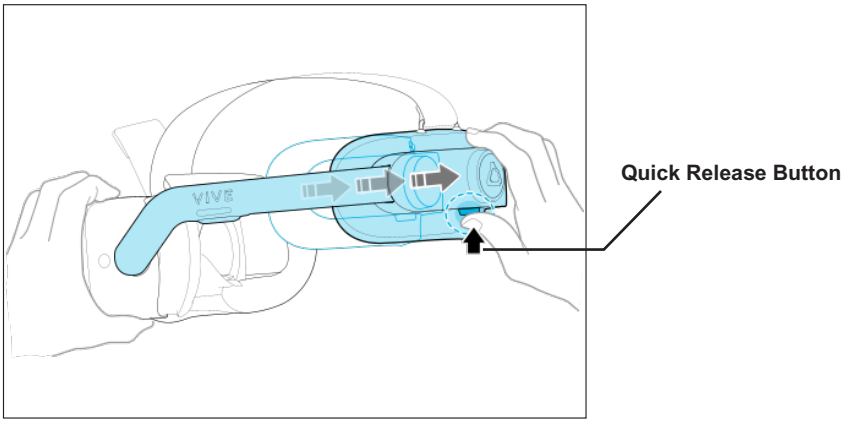


Figure 3-6 Quick Release Button

3. Position the headset over the eyes. While holding the Quick-Release Button, slide the headset band until snug with the back of the head (**Figure 3-7**).

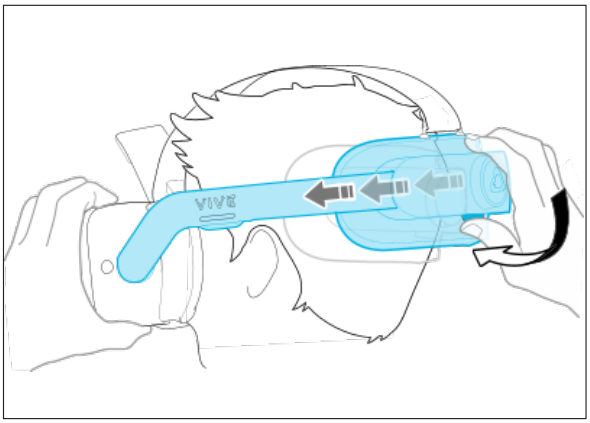


Figure 3-7 Tightening Headset with Quick Release Button

4. Turn the adjustment dial to fine-tune the fit (**Figure 3-8**).

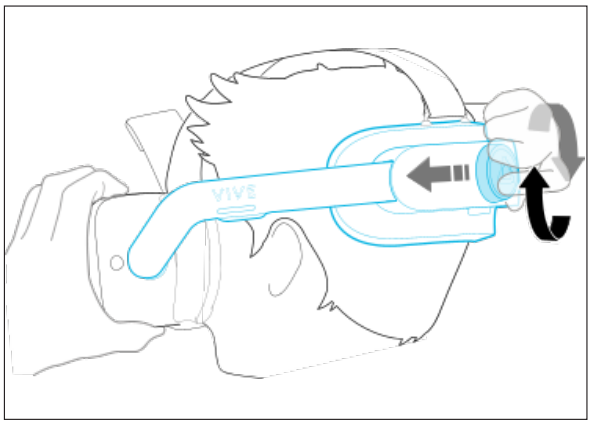


Figure 3-8 Adjustment Dial

5. Adjust the top strap until snug, and then attach the velcro fastener (**Figure 3-9**).

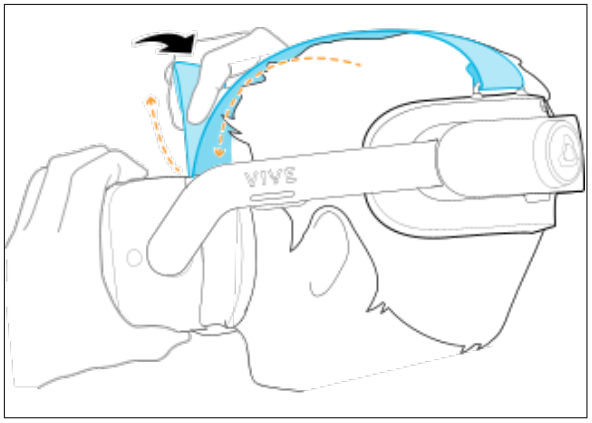


Figure 3-9 Reattach Velcro Fastener

Tip: When ready to take off the headset, press the Quick-Release Button to instantly release the headset band.

Wearing the headset with glasses

(The following instructions and images are sourced from the headset manufacturer's user guide. A copy of the Headset user guide is also included with the system.)

Most glasses fit inside the headset. If Client has wider glasses, the face cushion frame can flex to allow the glasses to fit. Here's how:

- While putting the headset on, gently press on either side of the face cushion frame to make room for the glasses (**Figure 3-10**).

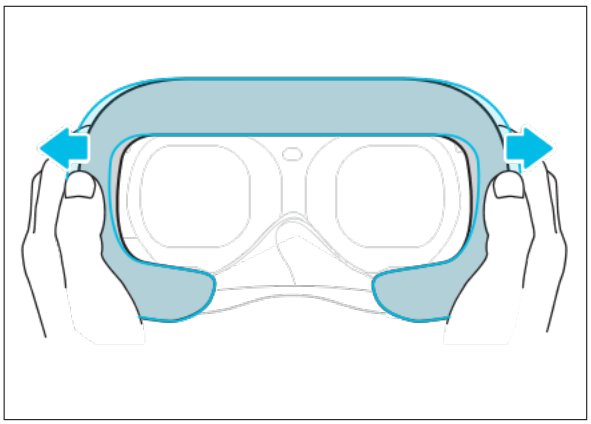


Figure 3-10 Expand Face Cushion

- When taking off the headset, gently press the frame in the same way to release the glasses.

Important:

- If you wear glasses, make sure that no part of your glasses touches the lenses, and that the glasses fit comfortably within the headset. If needed, the Gasket Spacer can be used.
- Make sure the size of the glasses doesn't exceed 150 × 55 mm (5.9 in × 2.1 in). The size reference card (shown below in **Figure 3-11**) included in the box can used to check if the glasses can be used with the headset.

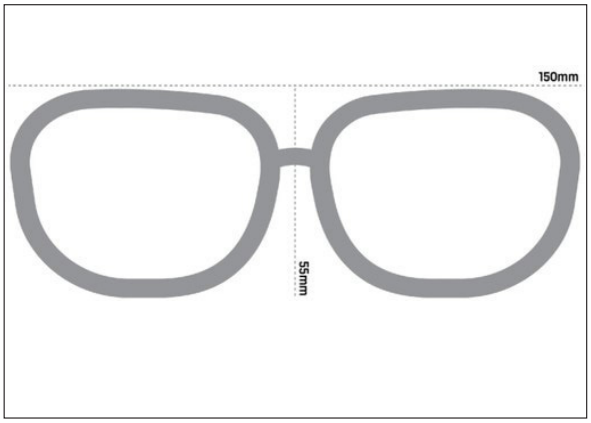


Figure 3-11 Glasses size reference card

Using the Gasket Spacer

(The following instructions and images are sourced from the headset manufacturer's user guide. A copy of the Headset user guide is also included with the system.)

The Gasket Spacer can be used to increase the distance between the eyes and the headset lenses. This accessory accommodates users with different facial structures and users who wear glasses (**Figure 3-12**)

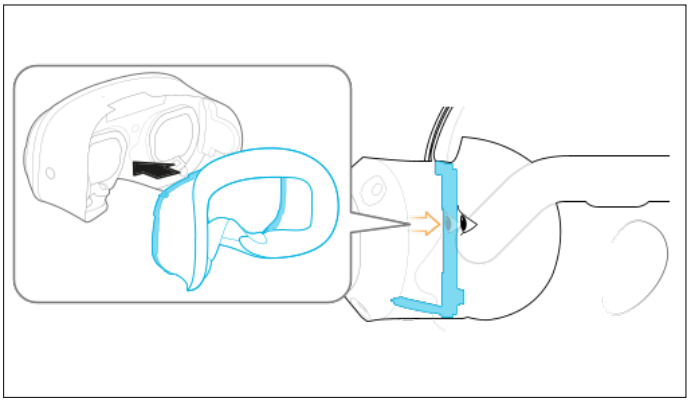


Figure 3-12 Attaching Gasket Spacer

Attach the Gasket Spacer to the face cushion with the tabs fully locked in place (**Figure 3-13**).

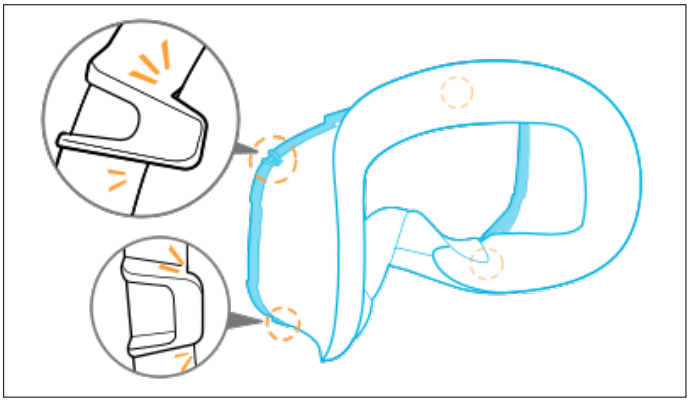


Figure 3-13 Face Gasket Tabs

Note: Attaching the Gasket Spacer is optional. Use it only if any discomfort is felt while wearing the headset (**Figure 3-14**).

To turn on the headset, press and hold the power button for around three seconds.

Figure 3-14 Headset Power Button

Calibrating the headset for optimal display

(The following instructions and images are sourced from the headset manufacturer's user guide. A copy of the Headset user guide is also included with the system.)

Adjusting the IPD on the headset

Interpupillary distance (IPD) is the distance between the centers of the eyes. Setting the right IPD helps in getting a crisp and clear image in VR. The Headset is set to automatically adjust the IPD in BITS Functional Reality Software. Once headset is donned, focus eyes on the blue dot that appears and allow headset to adjust the focus (**See Figure 3-15 to 3-17**). For troubleshooting refer to Chapter 15.

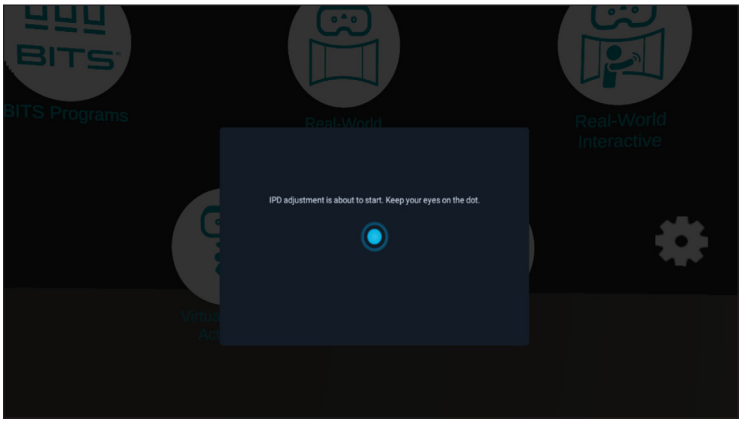


Figure 3-15 IPD Adjustment Start

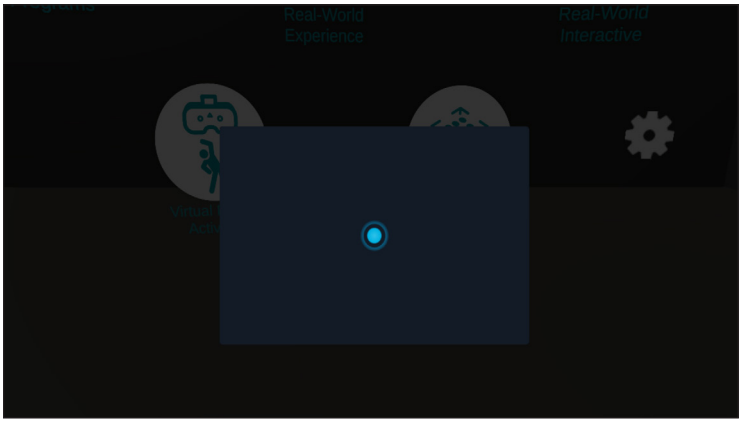


Figure 3-16 IPD Adjustment Active

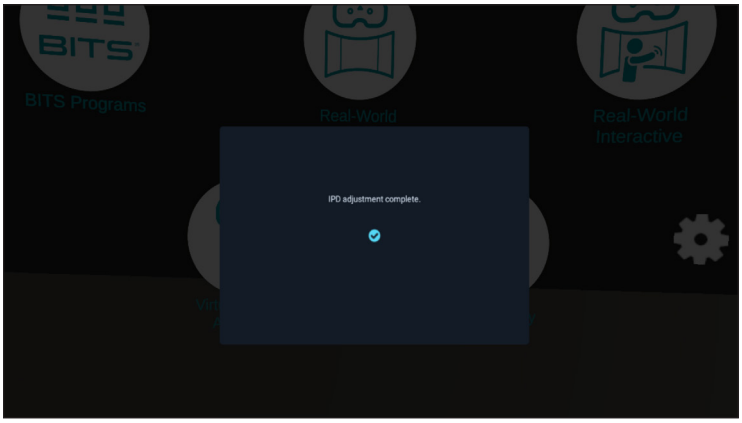


Figure 3-17 IPD Adjustment Complete

Ensure a green light is seen in the top right corner on the tablet (**Figure 3-18**). This indicates that the tablet and headset are paired and in communication. Headset must be donned and in active mode for light to appear green. For troubleshooting, refer to Chapter 15.

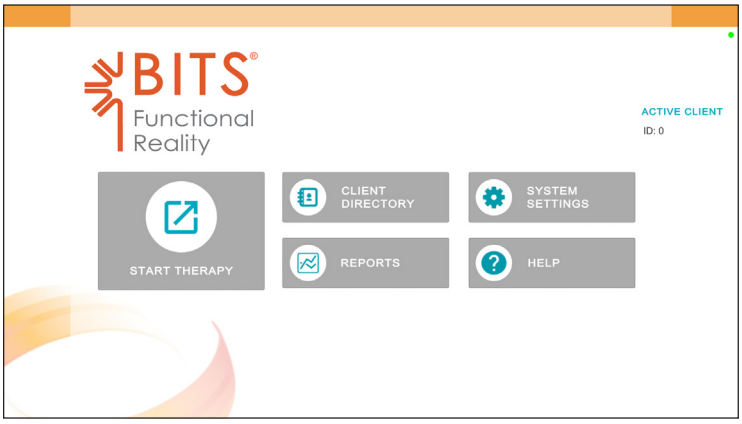


Figure 3-18 Green Light Connection

Understanding Control Inputs

BITS Functional Reality Software allows three modes of input for the client to use for interacting and selecting target stimuli within the BITS FR exercise programs.

MODE 1: Controllers

Hand the client the controllers. Controllers are labelled with “R” for right hand controller and “L” for left hand controller (**Figure 3-20**) and loop wrist strap around the client’s wrist (**Figure 3-19**).

Controllers are automatically paired and a green status light on the controllers indicates successful pairing. See Chapter 15 for troubleshooting.

Client will point the controllers to the target stimuli and press the trigger button to select the target. (**See Figure 3-19 & 3-21**)

(Figure 3-19 and 3-20 are sourced from the headset manufacturer’s user guide. A copy of the Headset user guide is also included with the system.)

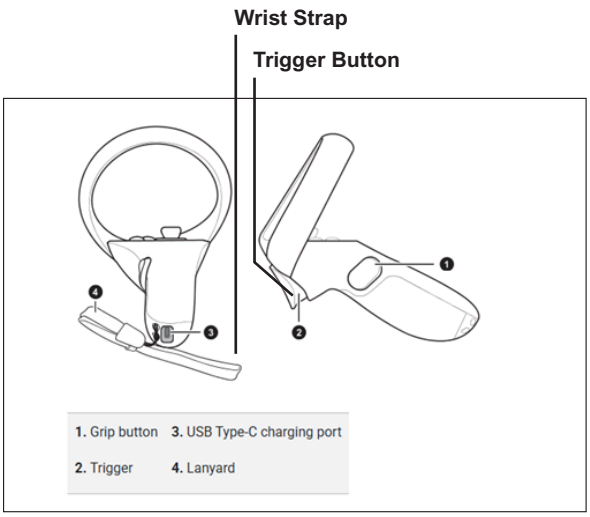


Figure 3-19 Controller Trigger Button and Wrist Strap

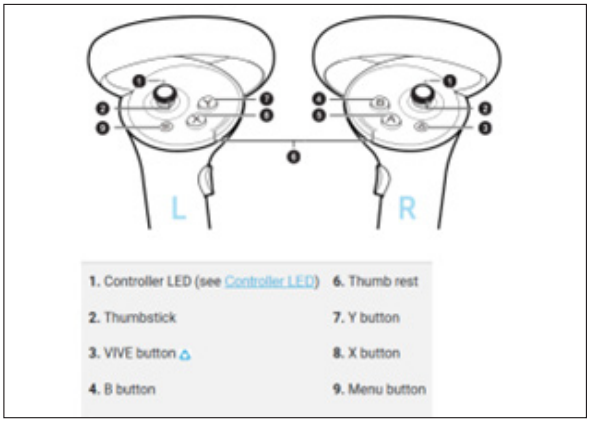


Figure 3-20 Back and Vive Button

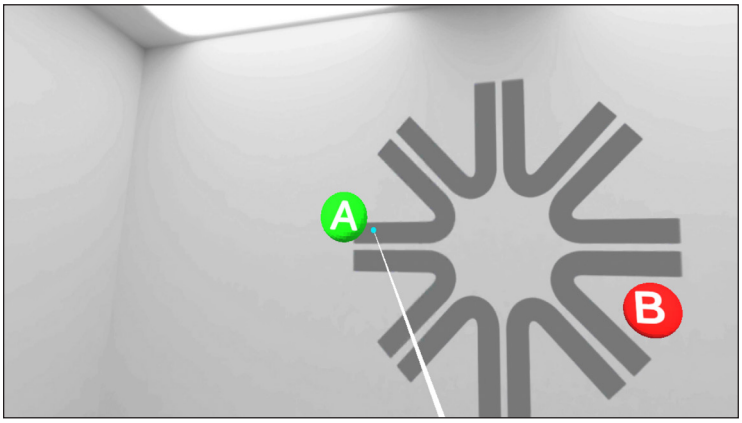


Figure 3-21 Controller Control Input

MODE 2: Touch

Client can use hand gestures to interact with and select stimuli within the BITS FR Software. To activate 'Touch' Mode, place the controllers on the side and have the client raise their hands to the front of the headset. Client will see a blue hand avatar for both right and left hands (**Figure 3-22**). Client can then reach for the targets using either right or left hand.

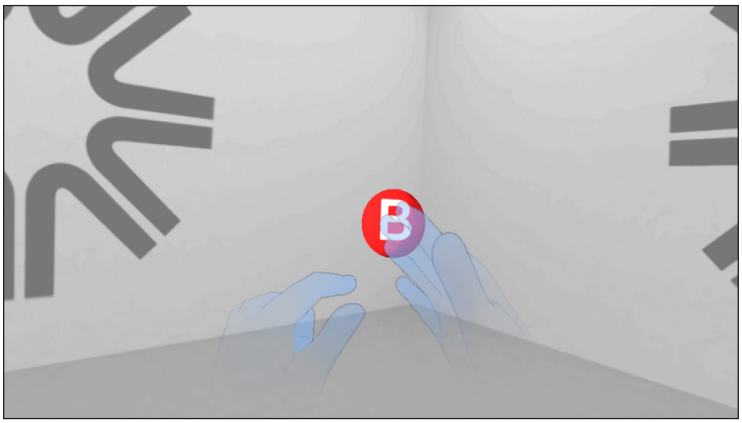


Figure 3-22 Touch Control Input

MODE 3: Head Track

For Head tracking, simply instruct client to turn their head and align the white reticle target to the object/stimuli that needs to be selected. Wait for the loading circle to complete before moving to the next target. The loading circle will turn green for the duration selected in the BITS FR Clinician Software. See Chapters 8-12 for parameter descriptions per program (**Figure 3-23**).

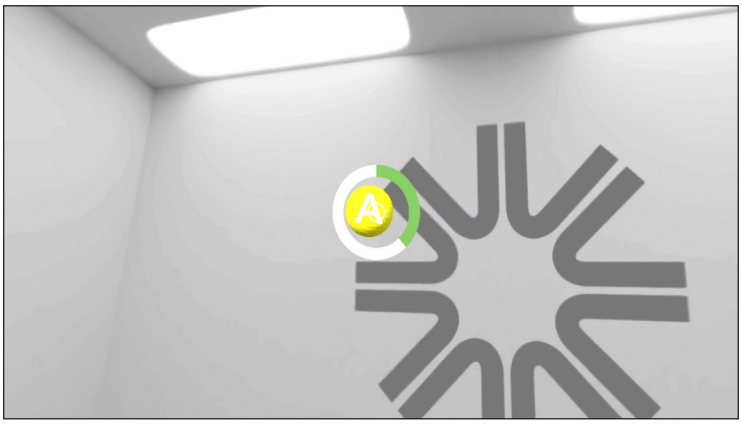


Figure 3-23 Head Track Control Input

MODE 4: Head Track with Controllers

The Head Track with Controller mode requires client to look and align the white reticle target icon with the target stimuli. To select/eliminate the target stimuli, client will need to press the trigger button on either the left or right controller (**Figure 3-24**).

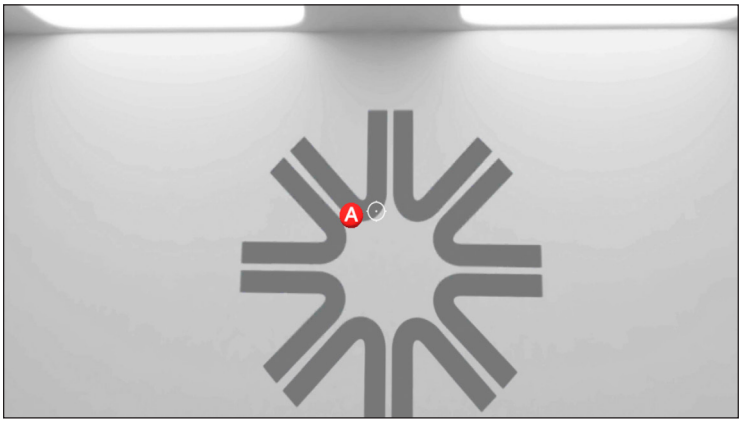


Figure 3-24 Head Track with Controller Input

If you have questions or need technical support, contact the Bioness Product Support Department at 800-211-9136. You can also visit the Bioness website at: BionessMedical.com.

CHAPTER 4: **Introduction to BITS FR Clinician Software Navigation**

The BITS FR Software System consists of BITS FR Software on the OTS Headset and BITS FR Clinician Software on the OTS Clinician Tablet. When using the system, clinician should drive the client experience through the BITS FR Clinician Software on the Clinician Tablet.

Home Screen

The Home Screen is the first screen that will appear when launching the BITS FR Clinician Software application. The Home Screen consists of four menu options, which appear as icon buttons. **See Figure 4-1**.

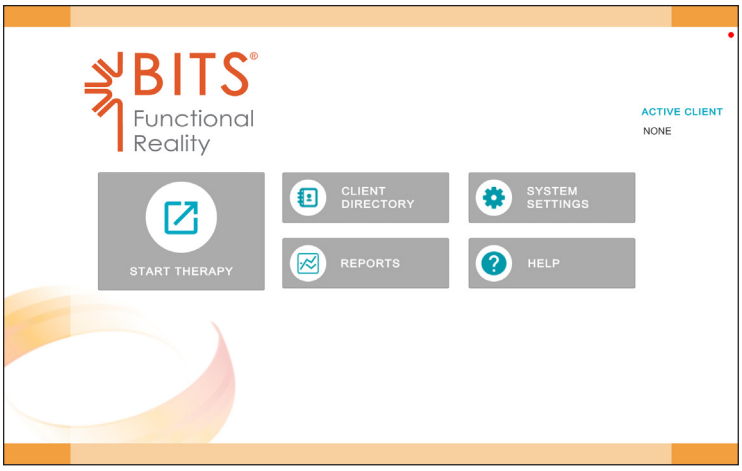


Figure 4-1 BITS FR Clinician Software Home Screen

Start Therapy

The Start Therapy Module allows the user to select a client and program and launch a session. **See Figure 4-1**. For more information see the “Start Therapy” section of this guide.

Client Directory

The Client Directory allows the user to access the client directory, view client information, add a new client and select an existing client and delete a client. **See Figure 4-1**. For more information see the “Client Directory” section of this guide.

Reports

The Reports Module allows the user to view a client’s session results. **See Figure 4-1**. For more information see the “Reports” section of this guide.

System Settings

The System Settings Module allows a user to select the correct channel for tablet and headset connection. **See Figure 4-1**.

Program Categories

Within the Start Therapy Module, the Category Menu divides the BITS FR Programs into modules for a particular application. **See Figure 4-2**. Selecting a Category Menu Button opens a screen displaying the available programs found in the selected category.

The Program Category can be accessed after the Start Therapy Button has been selected and a client has been added or selected from the Client List. Refer to the “Client Directory” and “Start Therapy” sections of this guide for more information.

Figure 4-2 Category Menu

The BITS Programs Module, features the programs listed below. To access the BITS Programs Module, press the BITS Programs Button. **See Figure 4-2**.

- User Paced
- Sequence
- Smooth Pursuit

The Real-World Experience Module, features the programs listed below. To access the Real-World Experience Module, press the Real-World Experience Button. **See Figure 4-2**.

- Grocery Store
- Restaurant
- Living Room
- Mall Escalator
- Football Game
- Kayak
- Concert
- Ferris Wheel
- Basketball Game
- Coaster Ride
- Rooftop
- Hockey Game
- Fashion Show
- Car Front Seat
- Functional Journey
- Daytime Driving
  - Journey
  - Highway
  - Residential
  - City
  - Downtown
  - Drive-Thru
  - School
  - Tourist Attraction
- Nighttime Driving
  - Journey
  - Highway
  - Residential
  - City
  - Downtown

The Real-World Interactive Module, features the programs listed below. To access the Real-World Interactive Module, press the Real-World Interactive Button. **See Figure 4-2**.

- Grocery Store 3 Aisle
- Grocery Store 5 Aisle
- Driving Sequence
- Functional Journey

The Virtual Reality Activities Module, features the programs listed below. To access the Virtual Reality Activities Module, press the Virtual Reality Activities Button. **See Figure 4-2**.

- Tennis 1
- Tennis 2
- Football
- Soccer

The Mixed Reality Activities Module, features the programs listed below. To access the Mixed Reality Activities Module, press the Mixed Reality Activities Button. **See Figure 4-2**.

- 360 Cube

Program Categories and Programs

The BITS FR software application consists of 5 program modules, which are divided into 40 different programs. The programs are a mix of client interactive or client experiences and provide visual and/or auditory feedback. The programs also generate records on client performance for each session.

To access the Program Categories and Programs:

1. From the Category Menu, select the appropriate category. **See Figure 4-2**.
2. The Program Menu will open displaying the available programs found in the selected category. **See Figure 4-3**.
3. To select a program, press one of the program buttons. For programs that contain parameters, a parameter screen will open first. **See Figure 4-4**. For programs that do not require parameter options, selecting the program name will launch the program.

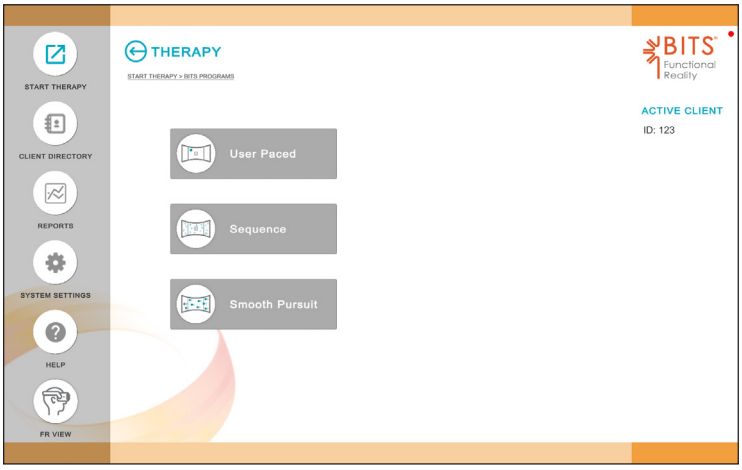


Figure 4-3 Program Options Per Category

Figure 4-4 Program Start Screen

Quick Access without Clinician Tablet

For quick access to programs without the clinician tablet, a user can navigate programs directly in the BITS FR Software on the headset. Using controllers or hand gestures, a user can select a category from the main menu (**See Figure 4-5**). Categories include:

- BITS Programs
- Real-World Experience
- Real-World Interactive
- Virtual Reality Activities
- Mixed Reality Activities

Figure 4-5 BITS FR Categories in Headset

Using controllers or hand gestures, user can select the following programs within each category. Unlike the BITS FR Clinician Software on the tablet, the BITS FR Software on the headset does not allow for customization or personalization of parameters. Programs are set with default parameters. Default settings are noted per program below.

BITS Programs

User Paced Program: Select between Controllers, Touch or Head Track. **See Figure 4-6**.
Sequence Program: Select between Controllers, Touch or Head Track. **See Figure 4-6**.
Smooth Pursuit Program: Select between Controllers, Touch or Head Track. **See Figure 4-6**.

Figure 4-6 BITS Programs in Headset

Real-World Experience

Launch any Real-World Experience program from the headset by selecting program name. **See Figure 4-7**.

Figure 4-7 Real-World Experience in Headset

Real-World Interactive

Launch any Real-World Interactive program from the headset by selecting program name. Control input is defaulted to Touch for all programs in this category. **See Figure 4-8**.

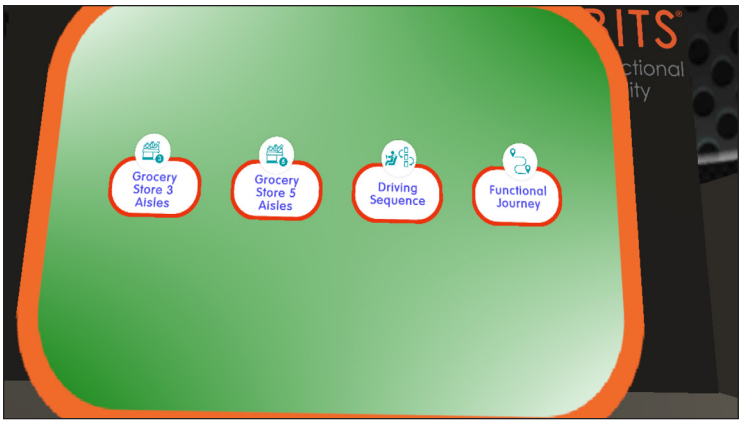


Figure 4-8 Real-World Interactive in Headset

Virtual Reality Activities

Launch any Virtual Reality Activities program from the headset by selecting program name. Default control input is Head Track for Tennis 1 and Tennis 2 programs, and Head Track with Controllers for Soccer and Football programs. **See Figure 4-9**.

Figure 4-9 Virtual Reality Activites in Headset

Mixed Reality Activities

Launch the Mixed Reality Activities program from the headset by selecting program name. Control input is defaulted to Touch for program in this category. **See Figure 4-10**.

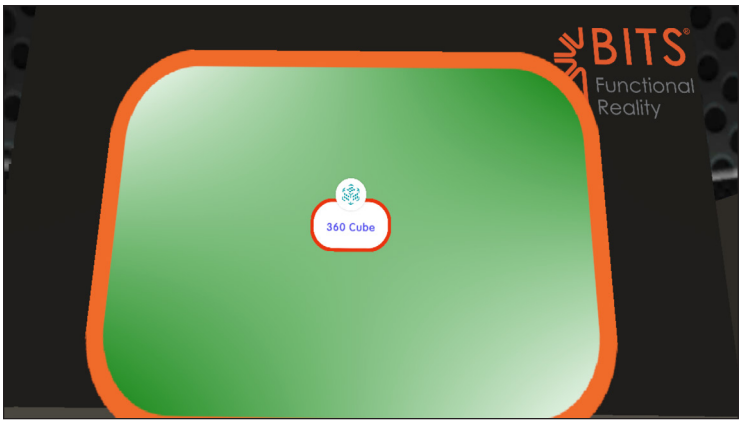


Figure 4-10 Mixed Reality Activites in Headset

To exit out of a program using hand tracking, hold up both of your hands, in a thumbs up position, with the palms facing towards you. **See Figure 4-11**. Then pinch the index and thumb finger together to select “Main Menu”.

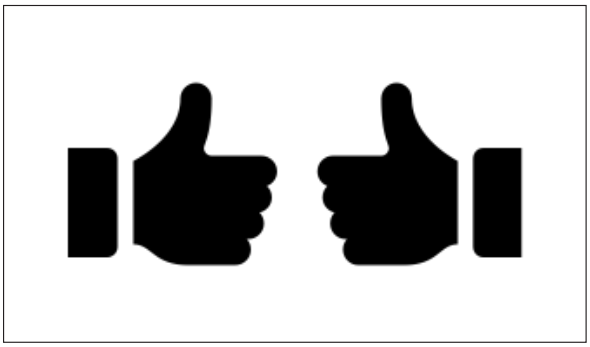


Figure 4-11 Exit Hand Gesture and Selection Hand Gesture

To exit out of a program using the controllers, select the ‘B’ button on the right controller and select “Main Menu” using the trigger button on either controller. **See Figure 4-12 and 4-13**.

To make any selections in the BITS FR Software using the controllers, press the trigger button on either left or right controller.

(Figure 4-12 and 4-13 are sourced from the headset manufacturer's user guide. A copy of the Headset user guide is also included with the system.)

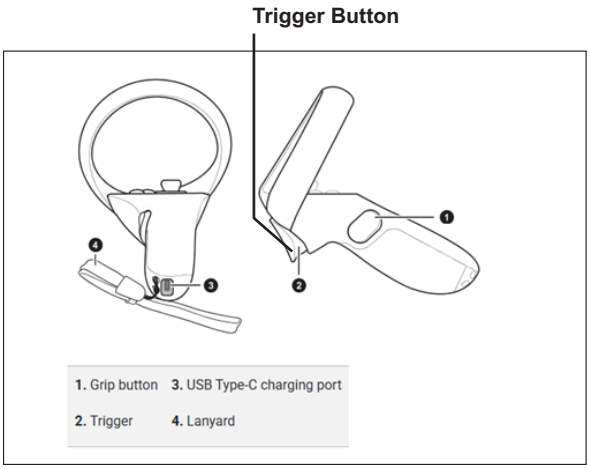


Figure 4-12 Controller Trigger Button and Wrist Strap

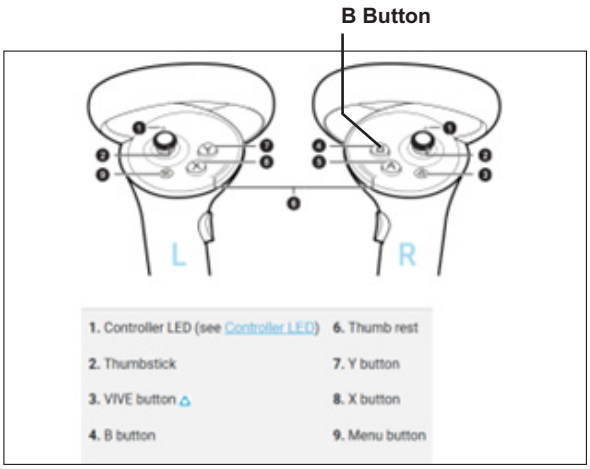


Figure 4-13 Back and Vive Button

User Controls for Headset

On the front-left side of the headset, the headset button allows you to control several basic functions. **See Figure 4-14**.

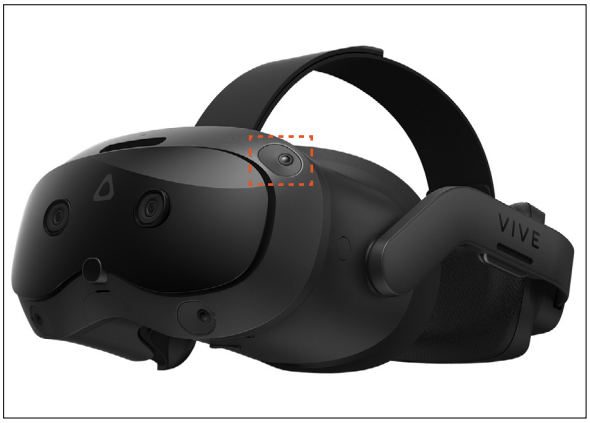


Figure 4-14 Headset Button

(The following instructions are sourced from the headset manufacturer's user guide. A copy of the Headset user guide is also included with the system.))

Function	Steps
Turn passthrough mode on and off (to see real surroundings)	Press twice. The VIVE button on the right controller can also be pressed twice to activate passthrough mode.
Force quit unresponsive app	Press and hold for 10 seconds.
Open the Power menu (to choose whether to power off or restart)	Press and hold for 3 seconds.

Headset control modes:

1. **Controller**
2. **Hand Tracking**
   - The hand tracking feature allows use of hands as controllers
   - The following hand gestures are available:

- *Pinch to select:* With palm facing outward, move hand to position the cursor, and then pinch the thumb and index finger together to select.
- *Pinch and drag to scroll:* With palm facing outward, pinch and drag to scroll pages or move sliders.

If you have questions or need technical support, contact the Bioness Product Support Department at 800-211-9136. You can also visit the Bioness website at: BionessMedical.com.

CHAPTER 5: **Start Therapy**

Before initiating BITS FR program with a client to start therapy, ensure that the following steps have been completed. Refer to Chapter 4 for detailed steps.

1. Ensure that there are no objects, equipment, or obstacles within a 1.5-meter (5-foot) radius around the patient during use. This helps prevent tripping hazards, interference with movement, and ensures patient safety throughout the session.
2. Plug in the router provided into a wall outlet.
3. Power on the Clinician Tablet and ensure tablet is connected to router.
4. Launch BITS FR Clinician Software.
5. Don the headset on the client, ensuring client is seated or standing in a clear area free of objects (recommend a 1.5 meter (5-foot) radius around the client).
6. Power on the headset.
7. Ensure a green dot can be seen in the top right corner of the tablet.
8. Launch a BITS FR Program for client from the Clinician Tablet.

Follow the steps below to navigate to the program modules:

Step 1:
Select ‘Start Therapy’ on the BITS FR Clinician Software Main Menu (**See Figure 5-1**)

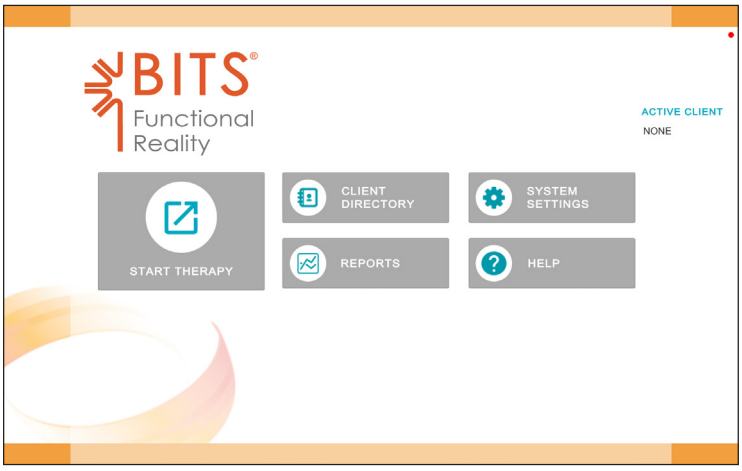


Figure 5-1 Start Therapy

Step 2:

Select existing client or create a new client. (**See Figure 5-2**). Refer to Chapter 6 for more details.

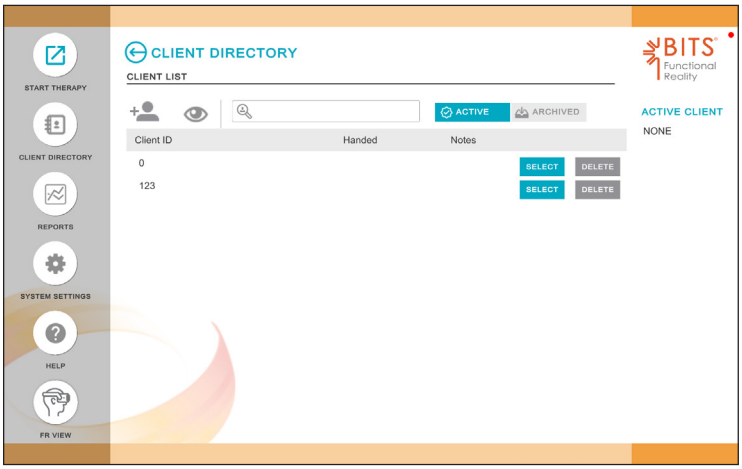


Figure 5-2 Add or Select a Client

Step 3:

Select program category to choose a program (**See Figure 5-3**). Refer to Chapters 7-12 for details on each program.

Figure 5-3 Category Menu

CHAPTER 6: **Client Directory**

The Client Directory Module allows the user to access the Client Directory and add a new client, select an existing client or delete a client.

Creating a New Client Record

1. From the Home Screen, press the Client Directory Button. **See Figure 6-1**.

Figure 6-1 BITS FR Clinician Software Home Screen

2. The Client List Screen will open. Press the New Client Icon, **see Figure 6-2**.

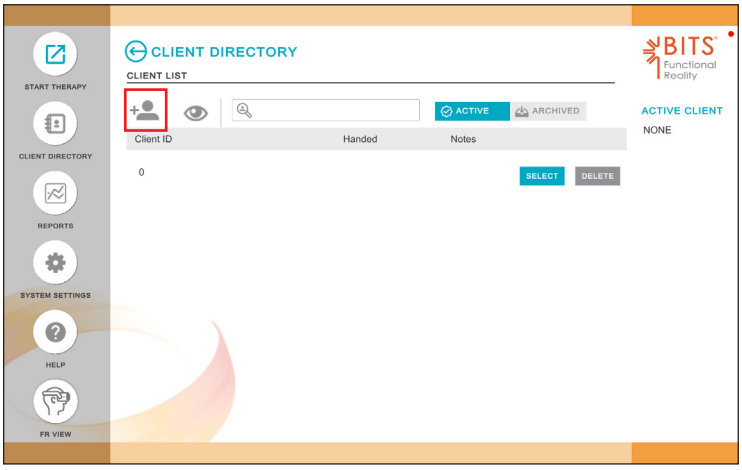


Figure 6-2 Client Directory Screen

3. The New Client Screen will open. Enter the required information into the data fields using the touchscreen keyboard. Verify that all information has been correctly entered and select the Add Button. **See Figure 6-3**.

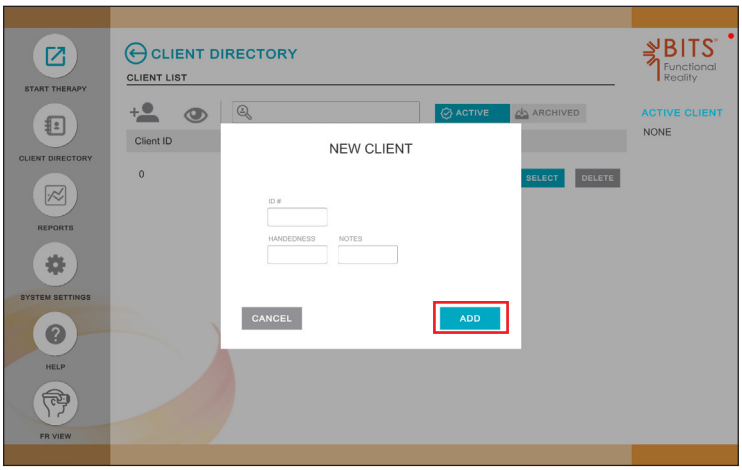


Figure 6-3 Add a Client

4. Select the Select icon in the row of the client ID listed to start session for that client. **See Figure 6-4**.

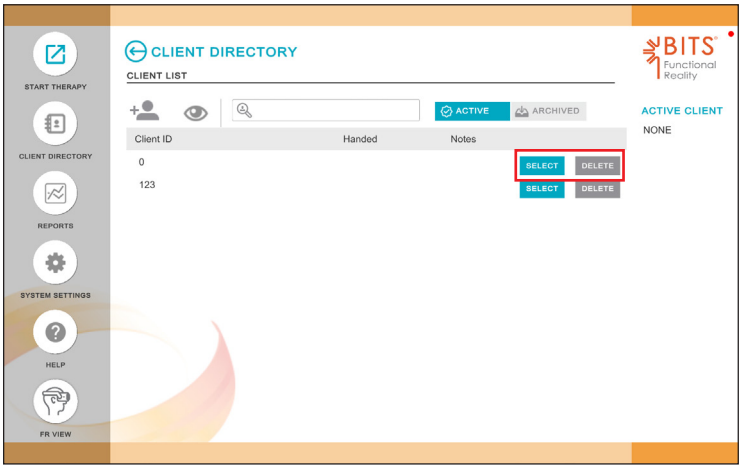


Figure 6-4 Select or Delete a Client

Deleting an Existing Client Record

1. From the Home Screen or Navigation Bar, select Client Directory. **See Figure 6-1**.
2. The Client List Screen will open. **See Figure 6-2**.
3. Delete the desired client from the Client List by selecting the Delete icon in the client ID row. **See Figure 6-4**.

If you have questions or need technical support, contact the Bioness Product Support Department at 800-211-9136. You can also visit the Bioness website at: BionessMedical.com.

CHAPTER 7: **Therapy Categories**

⚠ **Caution:** Ensure that there are no objects, equipment, or obstacles within a 1.5-meter (5-foot) radius around the patient during use. This helps prevent tripping hazards, interference with movement, and ensures patient safety throughout the session.

BITS Programs

The programs in the BITS Programs category are designed to exercise vision, motor and cognition abilities. The programs provide practice for visuomotor coordination, visual attention, peripheral awareness, reaction time, and cognitive training. The BITS Programs Category contains 3 programs – User Paced, Sequence and Smooth Pursuit.

Real-World Experiences

The Real-World Experience category is designed to help bridge the gap between structured therapy and real-life functional outcomes. Set in familiar and real-world environments like a grocery store, mall escalator etc., this module provides immersive scenarios to practice cognition, visual perception and spatial awareness among others. By simulating everyday challenges in a controlled format, this module supports personalized session planning and encourages real-world skill transfer. The Real-World Experience category contains 27 programs:

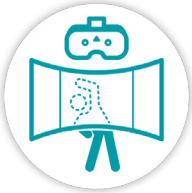
- Grocery Store
- Restaurant
- Living Room
- Mall Escalator
- Football Game
- Kayak
- Concert
- Ferris Wheel
- Basketball Game
- Coaster Ride
- Rooftop
- Hockey Game
- Fashion Show
- Car Front Seat
- Functional Journey
- Daytime Driving
  - Journey
  - Highway
  - Residential
  - City
  - Commercial
  - Drive-Thru
  - School
- Nighttime Driving
  - Journey
  - Highway
  - City

Real-World Interactive

The Real-World Interactive category allows immersive, task-oriented exercises in environments that reflect everyday life. Designed to show real-world settings such as navigating a grocery store, driving etc., this module integrates cognitive, visual, and motor challenges. Utilize goal-oriented scenarios that exercise multiple domains simultaneously making it ideal for targeted involvement. The Real-World Interactive category contains 4 programs: Grocery Store 3 Aisles, Grocery Store 5 Aisles, Driving Sequence and Functional Journey.

Virtual Reality Activities

The Virtual Reality Activities category is designed to exercise visuomotor coordination, peripheral awareness and attention. These programs provide practice for smooth pursuit, saccadic eye movements, accurate timing, target anticipation and motor planning. Virtual reality training can help exercise sustained, selective, and divided attention. The virtual reality activities category contains 4 programs: Tennis 1, Tennis 2, Football and Soccer.



Mixed Reality Activities

The Mixed Reality Activities category is designed to immerse clients in interactive 360° environments that exercise cognitive, motor, and perceptual skills. By using stimuli across a full spatial field, these activities encourage visual scanning, tracking, and responding dynamically with the surroundings. By overlaying virtual cues onto the physical environment, this category can provide practice for visual perception and spatial awareness in naturalistic settings. The Mixed Reality Activities category contains 1 program: 360 Cube.

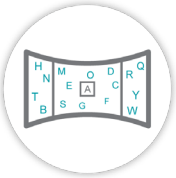
If you have questions or need technical support, contact the Bioness Product Support Department at 800-211-9136. You can also visit the Bioness website at: BionessMedical.com.

CHAPTER 8: **BITS Module Programs**

⚠ **Caution:** Ensure that there are no objects, equipment, or obstacles within a 1.5-meter (5-foot) radius around the patient during use. This helps prevent tripping hazards, interference with movement, and ensures patient safety throughout the session.

User Paced Program

Stimuli targets appear on the screen one at a time. Client is instructed to visually scan their surrounding and eliminate each stimulus as it appears at their own pace. The objective is to correctly eliminate as many stimuli as possible. With Target Time Parameter, stimuli targets appear on the screen one at a time and remain on screen for the duration selection. Client is instructed to visually scan the screen to identify the stimulus and eliminate it before it disappears.



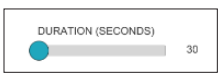
Sequence Program

All target stimuli will appear on the display at once, depending on the quantity chosen. Targets must be eliminated in the correct sequence.

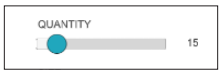
Smooth Pursuit

Guides clients to follow moving stimuli by looking and holding the white reticle on the moving target. Only 3 parameters from the list below apply for Smooth Pursuit Program: Background, Speed and Size.

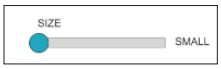
Parameters



Duration: The Duration Parameter controls the length of time the therapy program will run. Drag the blue indicator to change the value.

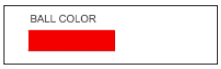


Quantity: The Quantity Parameter controls the number of target stimuli displayed during the therapy session. Drag the blue indicator to change the value.

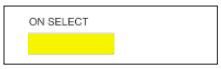


Size: The Size Parameter is used to change the size of the target stimuli. Drag the blue indicator to change the value.

Character Type: The Character Type Parameter is used to change the type of character displayed during the program session. The Character Type Parameter options include Letters, Numbers, Letters & Numbers and Circles. To change the type of target stimuli displayed, select the drop down menu to make your selection.



Ball Color: The Ball Color Parameter is used to change the color of the main target stimuli. Select the default red rectangle, and a menu pop-up will appear. Select any color and select ok.



On Select: The On Select Parameter is used to identify if a target stimuli was attended to. If attended to successfully, the target stimuli will change to the color selected here. Select the default yellow rectangle, and a menu pop-up will appear. Select any color and select ok.

Target Time: The Target Time Parameter controls the length of the time the target stimulus will remain in one location, before disappearing and reappearing in a new location on the display. Drag the blue indicator to change the value.

Sequence Mode: The Sequence Mode Parameter controls the order in which the target stimuli need to be attended to. This parameter is only available in the Sequence Program.

> *In Order:* The In Order Parameter, if selected, will require client to select target stimuli in order. For example, if a quantity of 10 was selected with character type of letters, the client must select targets in order of A, B C. etc.

Random: The Random Parameter, if selected, does not require client to select targets in order. For example, if a quantity of 10 was selected with character type of letters, the client can select targets in any order such as C, A, B. etc.

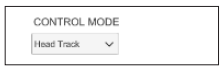
Contrast: The Contrast Parameter is used to increase or decrease the contrast of the background. Drag the blue indicator to change the value.

Audio Volume: The Audio Volume Parameters controls the level of volume for the program. Drag the blue indicator to change value.

Persistence: The Persistence Parameter provides an added visual scanning exercise. With Persistence Off, targets disappear once selected.

Change Color: If Change Color is selected, once a target is selected, it remains on the screen but in a different color than the original target.

Flash: If Flash is selected, once a target is selected, it remains on the screen and flashes for a short duration before disappearing.



Control Mode: The Control Mode Parameter controls which input control the client will utilize to complete the program. To change the mode, select the drop down menu and select from any of the following:

Controller: The Controller Parameter requires the client to use the controllers provided with the system to attend to target stimuli. Client will be shown a line of where the controller is pointed towards, and must press the trigger button on the back of the controller. Can be achieved with right or left controller.

Touch: The Touch Parameter requires the client to use hands to select target stimuli. Client must keep hands in front of the headset and a blue avatar of the hands will be seen in the headset display. Using either left or right hand, client can select the target stimuli.

Head Track: The Head Track Parameter requires the client to look and align the white reticle on the target stimuli in order to select it. Once Head Track mode is selected, a second parameter appears of Head Track Hold Time.

Head Track Hold Time: The Head Track Hold Time Parameter sets a total time a client must look and hold head position at the target stimuli before the system recognizes correct input. For example, if 0.50 is selected, a client must turn head and align the white target icon on the target stimuli. The client then holds that position for 0.50 seconds before moving on to the next target. A loading circle appears around the target stimuli to let the client know of correct or incorrect selection.

Track w/ Controller: The Track with Controller Parameter requires client to look and align the white target icon with the target stimuli. To select the target stimuli, client will need to press the trigger button on either the left or right controller.

Grid: The Grid Parameter when enabled places a grid on the display during the therapy program session. To turn the Grid Parameter On select the box. The box will turn blue and a checkmark will appear.

Background: The Background Parameter shows the room or background the client will see behind the target stimuli.

Default: The Default background is a white room with entryways, floor, ceiling and walls.

Stadium: The Stadium background is a soccer stadium setting with field and bench seats

Optokinetic: The Optokinetic background controls the type of pattern available for optokinetic stimulation. Once selected, optokinetic options will include:

Type: The Type Parameters controls the type of pattern available. Options include checkered, horizontal stripes or vertical stripes. Select the dropdown to select type of pattern.

Speed: The Speed Parameter controls how fast the optokinetic screen will move. Select the dropdown to select None, Slow, Medium or Fast

Direction: The Direction Parameter controls the direction of movement for the optokinetic visual display. Options include “L to R” which is Left to Right, “R to L” which is Right to Left, “U to D” which is Up to Down and “D to U” which is Down to Up. Select the dropdown to select the direction.

If you have questions or need technical support, contact the Bioness Product Support Department at 800-211-9136. You can also visit the Bioness website at: BionessMedical.com.

CHAPTER 9: **Real-World Experience Module Programs**

⚠ **Caution:** Ensure that there are no objects, equipment, or obstacles within a 1.5-meter (5-foot) radius around the patient during use. This helps prevent tripping hazards, interference with movement, and ensures patient safety throughout the session.

The Real-World Experience Module features programs that immerse the client in different settings. Guide the client to stand or sit and view the experience. The client can also be guided to find and verbalize key points of interest. Find below summary of each experience, sample instructions and key points of focus that the client can focus on, as well as the focus areas that can be exercised with each experience.

Grocery Store (5:50 Min Video) – with audio

Immerse the client in a real supermarket setting. Instruct them to visually scan shelves, locate specific items, and navigate the aisle.

Sample Instruction:
Find and name produce items while avoiding obstacles and responding to distractions.

Sample Key points of interests/questions:

1. Price of celery
2. How many organic products are available today
3. Which fruit is on the sign on the wall
4. How many cabbage options do you see
5. Where would you weigh and price your produce

Focus Areas: Visual scanning, sustained attention, peripheral awareness, cognitive flexibility, daily living skills

Living Room (2 Min Video) – with audio

Immerse in a familiar home environment in an easy setting to determine a basic level of tolerance in this low-level environment.

Sample Instruction:

Identify specific household objects while maintaining awareness of your surroundings.

Sample Key points of interests/questions:

1. What is the blue object on your left
2. Is this is a 1 story or 2 story apartment
3. Where is the door
4. What is playing on the TV
5. How many candles are above your head

Focus Areas: Spatial awareness, object recognition, stimuli tolerance

Restaurant (3 Min Video) – with audio

Observe a dining setting with ambient noise and multitasking requirements.

Sample Instruction:

Scan the restaurant scene to locate your seat and respond to social or environmental cues.

Sample Key point of interests/questions:

1. Are you dining with anyone
2. How many plates with napkins do you see
3. Where do you think the restroom would be
4. If there was an emergency, where would you go to exit the restaurant
5. Who would you place your food order with

Focus Areas: Selective attention, auditory-visual integration, stimuli tolerance, social awareness

Car Front Seat (2 Min Video) – with audio

Simulates being seated in the driver seat in a moving vehicle driving on different roads.

Sample Instruction:
As the car is moving scan for objects, signage, people, cars etc. that you would need to be aware of while driving. Verbalize things you see as you scan.

Sample Key point of interests/questions:

1. Are you on a one way or two way street
2. What car are you driving
3. Do you see what the road sign is before you enter the round-about
4. Are you alone in the car
5. Did you see any pedestrian cross your path, what is the speed limit at that time

Focus Areas: Visual attention, divided attention, spatial orientation, foreground vs. background discernment, tolerance of visual stimulus

Escalator (2 Min Video) – with audio

Expose the client to vertical movement and dynamic environment. Moving in a space looking at stationary objects.

Sample Instruction:
Visually explore storefronts and areas above and below the escalators, maintaining balance while observing surrounding objects.

Sample Key points of interests/questions:

1. Is there anyone on the escalator with you as you are going up
2. What city are you in
3. How many floors does this mall have
4. Is there someone on the escalator with you on the way down. Where did they go shopping
5. What coffee store do you see

Focus Areas: Balance, depth perception, visual-motor integration, body awareness

Ferris Wheel (1:30 Min Video) – no audio

Replicate elevation and slow rotation on a Ferris wheel.

Sample Instruction:
Focus on maintaining visual stability while observing changing views and moving stimuli.

Sample Key points of interests/questions:

1. What time of day is it when you start on the Ferris wheel
2. What time of day does it look like when you are at the top of the wheel
3. What is the name of the hotel

Focus Areas: Vestibular adaptation, visual tracking, spatial orientation, anxiety tolerance

Rooftop (3 Min Video) – no audio

High-elevation urban setting with various visual depths and objects of interest.

Sample Instruction:
Explore the rooftop environment and acknowledge distant and peripheral stimuli.

Sample Key points of interests/questions:

1. How many cross-walks can you count
2. What are you standing on
3. How many levels are there in the parking garage
4. What color is the awning on the parking garage building
5. What type of a road are you looking at

Focus Areas: Peripheral awareness, depth perception, postural control, visual exploration

Football game (3 Min Video) – with audio

A crowded stadium scene with high intensity audio and visual stimuli.

Sample Instruction:
Observe people, screens in the environment and, react to sounds and movements.

Sample Key points of interests/questions:

1. What car logo do you see
2. Name who is coming out to the field as they appear (mascot, cheerleaders, players)
3. Which football team is this
4. Which player number is practicing next to you
5. Who are the security people, how many are there, identify them

Focus Areas: Motion tracking, selective attention, auditory-visual integration, tolerance to environment

Hockey game (40 Sec Video) - no audio

Fast-paced arena with different experiences and visual change in point-of-views.

Sample Instruction:
Follow the puck and players across the ice while maintaining situational awareness and then enjoy Zamboni ride.

Sample Key points of interests/questions:

1. Which brand names do you see on the jumbotron
2. What player number is sitting next to you
3. How many bowling pins are on the field
4. What is the current jackpot amount
5. What year is this game happening in

Focus Areas: Rapid eye movements, visual anticipation, peripheral vision, visual contrast

Kayak (3 Min Video) - no audio

Simulates water motion and coordination in a natural setting.

Sample Instruction:
Observe paddle motions to steer and avoid obstacles while visually tracking environmental elements. Observe for elements on the shoreline.

Sample Key points of interests/questions:

1. What state are you in
2. What is the color of your kayak
3. How many other rafts are with you, and what color are they
4. Is there anyone camping, point them out
5. How many dogs do you see

Focus Areas: environmental scanning, peripheral vision, visual scanning, motion tracking

Coaster ride (1:40 Min Video) - no audio

High-intensity motion with fast moving visuals.

Sample Instruction:
Stay visually engaged while experiencing rapid directional changes and speed variations.

Sample Key points of interests/questions:

1. Do you see any body of water
2. What direction are you turning on the first turn
3. Is there anyone else with you on the coaster
4. Call out when you see someone standing by the coaster
5. What is the name of the coaster you are on

Focus Areas: Vestibular training, visual stability, sensory integration, anxiety modulation

Concert (4:00 Min Video) - no audio

Busy environment with “harsh”/” Strobe” effect lighting.

Instruction:
Scan the crowd and respond to changes in light and surrounding from the performance.

Sample Key points of interests/questions:

1. Where is the DJ booth
2. What brand is listed on the DJ booth
3. How many people are holding a microphone

Focus Areas: Environmental awareness, tolerance to visual, attention shifting

Fashion show (2 Min Video) - with audio

Backstage at a crowded fashion show in dim lighting.

Sample Instruction:
Observe the people and attire while filtering out distractions and identifying target details.

Sample Key points of interests/questions:

1. Point to where the lady with the red hair is
2. Point out when you see a red backpack
3. What object is the model handed

Focus Areas: Visual detail discrimination, selective attention, low-light discrimination

Basketball game (2 Min Video) - no audio

Interactive sports environment with low intensity arena environment.

Sample Instruction:
Enjoy the basketball game, paying attention to players and crowd.

Sample Key points of interests/questions:

1. What color are the player jerseys
2. Countdown with the timer
3. Count how many times you see the basket scored from both teams

Focus Areas: Motion tracking, sustained attention

Functional Journey (15 Min Video) - with audio

Multi-scene experience simulating transitions across environments. Experiences gradually become more involved over 7 settings. Each setting lasts for 2 minutes. Clients journey through Living Room, Lobby, Park, Atrium, Escalator, Boat Ride and Football Game.

Client can look down to skip to the next scenario at any time during the program.

Sample Instruction:
Move through a sequence of real-world settings, observing tasks and adapting to advancing stimuli at each stage.

Sample Key points of interests/questions:

1. Describe what type if setting you are in each new setting
2. What is the name of the building when you are standing in the atrium
3. Are you sitting outside the east or west tower in the park

Focus Areas: Cognitive flexibility, decision-making, attention switching, spatial awareness

Daytime Driving

Journey (18 Min Video) - no audio
Drive through various environments with and without passengers.

Sample Instruction:
Drive through varied environments, maintaining speed, lane position, and awareness of road signs.

Sample Key points of interests/questions:

1. What are about to drive through
2. Without turning your head, can you tell if there is anyone in the back seat as you go through the tunnel
3. What is your speed limit as you pull into the school
4. What is the speed limit in the residential area
5. Which lane are you in when you first get on the highway

Focus Areas: Divided attention, reaction time, visual scanning, situational awareness

Highway (9 Min Video) - no audio
Drive through varying traffic on the highway and observing cars and lane changes.

Sample Instruction: Maintain speed and spacing in high-traffic flow. React to lane changes and merge instructions.

Sample Key points of interests/questions:

1. Note when you see there is someone in your blind spot
2. What type of a car is it, and its color
3. What speed are you going when the car passes you

Focus Areas: Anticipation, lane control, sustained attention, hazard awareness

Residential (3:45 Min Video) - no audio
Drive through a quitter neighborhood at slower speeds.

Sample Instruction: Drive cautiously through a neighborhood setting, responding to pedestrians, parked cars, and children playing.

Sample Key points of interests/questions:

1. What is the name of the community you are entering
2. Is there a pedestrian on the side walk as you enter, what color shirt are they wearing
3. Who is in the car with you

Focus Areas: Peripheral awareness, selective attention, braking response, vigilance

City (7 Min Video) - no audio
Driving through a city setting with varying speed, road signs and traffic levels.

Sample Instruction: Navigate busy intersections, traffic lights, and jaywalking pedestrians in an urban setting.

Sample Key points of interests/question:

1. What is the name of the tunnel you are entering
2. Verbalize when you are coming to a red traffic light
3. What direction are you wanting to turn after the bus passes

Focus Areas: Executive functioning, visual tracking, multitasking, distraction management

Drive-Thru (2:30 Min Video) - no audio
Drive through a fast-food drive-thru lane, placing and retrieving order.

Sample Instruction:
Navigate to the drive-thru, place your order, and respond to auditory prompts while maintaining vehicle control.

Sample Key points of interests/question:

1. Is there a car behind you in the lane
2. How many bags does the person in front of you receive
3. Which restaurant drive-thru are you in

Focus Areas: Task sequencing, auditory memory, spatial awareness, divided attention

School (3:30 Min Video) - no audio
Drive through school zone to drop off and pick-up kids observing rules for school zone.

Sample Instruction: Observe school zone speed limits, watch for crossing guards, and respond to sudden child movement.

Sample Key points of interests/question:

1. What's your speed as you enter the school zone
2. What is the speed limit in the school zone
3. Should the car be moving once the kids are picked up at school

Focus Areas: Rule adherence, reaction control, peripheral vision, hazard detection

Commercial (4:30 Min Video) - no audio
Drive through a tight spaced commercial area with pedestrian traffic and car parking areas.

Sample Instruction:
Drive carefully in an area with unpredictable pedestrian movement.

Sample Key points of interests/question:

1. What is the speed limit in this area
2. What type of a commercial area are you in
3. Name any storefront you see

Focus Areas: Distraction filtering, visual memory, navigation skills, sustained focus

Nighttime Driving

Journey (19 Min Video) - no audio
Drive through various environments with and without passengers.

Sample Instructions: Maintain focus and visual tracking in low-light conditions while adapting to headlight glare and road signs.

Sample Key points of interests/questions:

1. Turn your head appropriately to watch as you are reversing
2. Identify when you are on a highway
3. What is your speed when on the highway

Focus Areas: Contrast sensitivity, visual scanning, glare adaptation, night-driving confidence

Highway (10 Min Video) - no audio
Drive through varying traffic on the highway and observing cars and lane changes.

Sample Instructions: Drive at safe speeds, identify distant taillights, and adjust to reduced visibility and occasional hazards.

Sample Key points of interests/questions:

1. Look towards the truck with hazard lights
2. What lane are you driving in
3. What is your speed limit

Focus Areas: Anticipation, depth perception, hazard avoidance, visual processing under low light

City (6:40 Min Video) - no audio
Driving through a city setting with varying speed, road signs and traffic levels.

Sample Instruction: Navigate dimly lit, busy intersections, traffic lights, and jaywalking pedestrians in an urban setting.

Sample Key points of interests/question:

1. What is the name of the tunnel you are entering
2. Verbalize when you are coming to a red traffic light
3. What direction are you wanting to turn after the bus passes

Focus Areas: Executive functioning, visual tracking, multitasking, distraction management

If you have questions or need technical support, contact the Bioness Product Support Department at 800-211-9136. You can also visit the Bioness website at: BionessMedical.com.

CHAPTER 10: **Real-World Interactive Programs**

⚠ **Caution:** Ensure that there are no objects, equipment, or obstacles within a 1.5-meter (5-foot) radius around the patient during use. This helps prevent tripping hazards, interference with movement, and ensures patient safety throughout the session.

The Real-World Interactive Programs are Immersive, task-oriented exercise programs in real-life environments (e.g., grocery store, driving etc.). These programs integrate cognitive, visual, and motor exercises to support goal-oriented, functional outcomes across multiple domains.

Grocery Store 3 Aisles

The Grocery Store 3 aisles program features real-world grocery store aisles. Client is instructed to listen to the list of items to be selected. Client can always view shopping list with hints during this program. Client can also hear and be challenged with ambient noise that can be heard in grocery store as well as an audio narration of the shopping list.

The program progresses through 3 aisles, each aisle having some items to shop for. Only 'Touch' control mode can be used in this program. Client is required to reach and select the item on the grocery shelf.

Aisle 1	Client is to find and select: "Ramen" – Right, Second from the top shelf and "Tortillas" – Left, second from the top shelf.
Aisle 2	Client is to find and select: "Nature Valley Minis" –Left, third from the top shelf and "Wheaties" – right, bottom shelf.
Aisle 3	Client is to find and select: "Trix" – Right, Middle shelves

If client is not able to locate the item, “next item” button can be selected and the video will progress to the next item on the list.

No parameters for customization are available for Grocery Store 3 Aisles Program.

Grocery Store 5 Aisles

The Grocery Store 5 Aisles program is a more interactive and customizable real-world grocery store experience. Instruct the client to go to Aisles 2 through 6 in any order. Each aisle contains 3 items the client must select. Shopping list is displayed at all time for the client to view. Client can select “repeat list” which will provide an audio narration of the list again. Client can also select “return to start” which will bring them back to the front of the grocery store.

Brightness, Audio Announcement and Ambient Audio parameters are only applicable for Grocery Store 5 Aisles Program.

Driving Sequence

The Driving Sequence program features a parked car, where the client is required to identify the sequence of checking mirrors and putting the car in reverse to back out of the parking spot. Instructions are provided after 30 seconds have elapsed to allow client to acclimate to the setting being experienced.

Client must select the sequence in order of:

1. Rear View mirror
2. Right Side Mirror
3. Left Side Mirror
4. Gear Shift Box

Functional Journey

Functional Journey enables graded reeducation in a safe environment, where client is asked to complete increasingly complex sequenced task. An audio narration prompt is given to the client at the start of each level in the program, and repeated per step after the first step. No visual cues are provided.

Level 1	Laundry Room is a 2 step command. Client will be verbally instructed to: “Clean the lint trap on the dryer and use the knob to turn on the dryer’ Client is required to select the dryer lint trap and dryer knob.
Level 2	Grocery Store is a 3 step command. Client will be verbally instructed to: ‘Grab the Zapps Regular Chips, Nacho Cheese Chips and Spudsy Hot Fries’ Client is required to find 3 grocery items in the aisle. These include: • Zapps Regular Chips – Left, middle shelf • Nacho Cheese Chips – Left, top shelf • Spudsy Hot fries – Right, second from the top shelf
Level 3	Kitchen Setting is a 4 step command. Client will be verbally instructed to: ‘Assemble the sandwich, turn on the stove, cook the sandwich and plate the sandwich’ Client must select the correct order of items to cook a grilled cheese sandwich. • Select bread and cheese on the counter • Select the first stove knob • Select the cooking pan • Select the assembled and plated sandwich

Level 4	Washroom setting for medication management is a 6 step command. Client will be verbally instructed to: 'Open the cabinet, remove 2 medications, read the labels, & place pills into the organizer' Client must select the correct order of items to sort medication. • Open drawer to the bottom right • Select the first medication • Select the second medication • Turn and read the first medication label • Turn and read the second medical label • Turn back and select the pill organizer

Parameters

Brightness Level: The Brightness Level Parameter controls the brightness intensity of the grocery store program. Select the drop-down box and choose from Dim, Medium or Bright brightness levels.

Audio Announcements: The Audio Announcement Parameter can be turned on or off. Blue check mark indicates audio announcements are turned on. Audio announcement refers to the audio narration of the grocery list.

Ambient Audio: The Ambient Audio Parameter can be turned on or off. Blue check mark indicates ambient audio is turned on. Ambient audio refers to the natural sounds heard in a grocery store.

Control Mode: The Control Mode Parameter controls which input control the client will utilize to complete the program. To change the mode, press the drop down menu and select from any of the following:

Controller: The Controller Parameter requires user to use the controllers provided with the system to attend to target stimuli. User will be shown a line of where the controller is pointed towards, and must press the trigger button on the back of the controller. Can be achieved with right or left controller.

Touch: The Touch Parameter requires the user to use hands to select target stimuli. User must keep hands in front of the headset and a blue avatar of the hands will be seen in the headset display. Using either left or right hand, user can select the target stimuli.

Head Track: The Head Track Parameter requires the user to look and align the white reticle on the target stimuli in order to select it. Once Head Track mode is selected, a second parameter appears of Head Track Hold Time.

Head Track Hold Time: The Head Track Hold Time Parameter allows a total time a user must look and hold head position at the target stimuli before the system recognizes correct input. For example, if 0.50 is selected, a user must turn head and align the white target icon on the target stimuli. The user then holds that position for 0.50 seconds before moving on to the next target. A loading circle appears around the target stimuli to let the user know of correct or incorrect selection.

Track w/ Controller: The Track with Controller Parameter requires user to look and align the white target icon with the target stimuli. To select the target stimuli, user will need to press the trigger button on either the left or right controller.

If you have questions or need technical support, contact the Bioness Product Support Department at 800-211-9136. You can also visit the Bioness website at: BionessMedical.com.

CHAPTER 11: **Virtual Reality Activities Module Programs**

⚠ **Caution:** Ensure that there are no objects, equipment, or obstacles within a 1.5-meter (5-foot) radius around the patient during use. This helps prevent tripping hazards, interference with movement, and ensures patient safety throughout the session.

Tennis 1

Train visual tracking and sustained attention by following a moving tennis ball across the court using coordinated eye and head movements. The ball's speed and direction change, challenging smooth pursuit skills. User will be instructed to: "Follow the green tennis ball with the target sight by moving your head". Program will run for 20 seconds.

Client will align the white target reticle in the middle of the visual field to the green tennis ball and use eye and head movements to keep the reticle aligned to the green tennis ball and track the ball's path. Client will have to stay focused as the speed and direction change.

Focus Areas: Smooth pursuit, visual tracking, sustained attention

Tennis 2

Continue training smooth pursuit and visual tracking by following the green tennis ball with both the eyes and head movements. This version features a different background environment, providing more distractions. Client will be instructed to: "Follow the green tennis ball with the target sight by moving your head". Program will run for 20 seconds.

Client will align the white target reticle in the middle of the visual field to the green tennis ball and use eye and head movements to keep the reticle aligned to the green tennis ball and track the ball's path. Client will have to stay focused as the speed and direction change.

Focus Areas: Smooth pursuit, visual tracking, sustained attention

Football

Boost hand-eye coordination and reaction time by striking incoming footballs using controller. React quickly as balls approach from various directions, demanding rapid motor planning and peripheral awareness. Client will be instructed to: “Shoot all the balls until they turn green and drop to the ground”. Program will run for 30 seconds.

Client will align the white target reticle in the middle of the visual field to any of the footballs on screen and press the trigger button on either controller to select the target.

Focus Areas: Hand-eye coordination, reaction time, motor planning, peripheral awareness

Soccer

Assist visuomotor coordination and selective attention by visually tracking and hitting soccer balls approaching from different angles and distances. Aim and respond with precision using the controller while staying visually alert. Client will be instructed to: “Shoot all the balls until they turn green and drop to the ground”. Program will run for 30 seconds.

Client will align the white target reticle in the middle of the visual field to any of the soccer balls on screen and press the trigger button on either controller to select the target.

Focus Areas: Hand-eye coordination, reaction time, motor planning, peripheral awareness

If you have questions or need technical support, contact the Bioness Product Support Department at 800-211-9136. You can also visit the Bioness website at: BionessMedical.com.

CHAPTER 12: **Mixed Reality Activities Module Program**

⚠ **Caution:** Ensure that there are no objects, equipment, or obstacles within a 1.5-meter (5-foot) radius around the patient during use. This helps prevent tripping hazards, interference with movement, and ensures patient safety throughout the session.

Mixed Reality Activities immerse user in 360° environment that engage cognitive, motor, and perceptual skills. These activities promote visual scanning, tracking, and spatial awareness by overlaying virtual cues onto the real world.

360 Cube Program:

Stimuli targets (such as circles, letters, numbers, and triangles) appear on the virtual walls of a transparent 360° cube surrounding the user. While seeing their real environment, the client visually scans the space to locate and eliminate each target. The goal is to select all the correct targets while engaging full-range visual scanning and spatial awareness.

Parameters:

Sequence Type: The Sequence Type Parameter is used to instruct the client which stimuli to select. Options include: Circles, Triangles, Letters, Numbers, Number in Order, Letters in Order and Manual. Manual Mode refers to therapist guided, where the clinician can verbally instruct the user to select a particular stimuli.

Control Mode: The Control Mode Parameter controls which input control the client will utilize to complete the program. To change the mode, press the drop down menu and select from any of the following:

Controller: The Controller Parameter requires user to use the controllers provided with the system to attend to target stimuli. Client will be shown a line of where the controller is pointed towards, and must press the trigger button on the back of the controller. Can be achieved with right or left controller.

Touch: The Touch Parameter requires the client to use hands to select target stimuli. Client must keep hands in front of the headset and a blue avatar of the hands will be seen in the headset display. Using either left or right hand, client can select the target stimuli.

Head Track: The Head Track Parameter requires the client to look and align the white reticle on the target stimuli in order to select it. Once Head Track mode is selected, a second parameter appears of Head Track Hold Time.

Head Track Hold Time: The Head Track Hold Time Parameter allows a total time a client must look and hold head position at the target stimuli before the system recognizes correct input. For example, if 0.50 is selected, a client must turn head and align the white target icon on the target stimuli. The client then holds that position for 0.50 seconds before moving on to the next target. A loading circle appears around the target stimuli to let the client know of correct or incorrect selection.

Track w/ Controller: The Track with Controller Parameter requires client to look and align the white target icon with the target stimuli. To select the target stimuli, client will need to press the trigger button on either the left or right controller.

If you have questions or need technical support, contact the Bioness Product Support Department at 800-211-9136. You can also visit the Bioness website at: BionessMedical.com.

CHAPTER 13: **Reports and Results**

Reports

The Reports feature allows the user to view a client's session results. To access reports per client, follow the steps below:

1. Confirm Client ID that is currently 'Active'. If 'None' or a different Client ID is selected, go to Client Directory. **See Figure 13-1**.
2. Select Client ID and select Reports from side navigation. **See Figure 13-2**.
3. Select View Reports for the session. **See Figure 13-3**.

Figure 13-1 Active Client

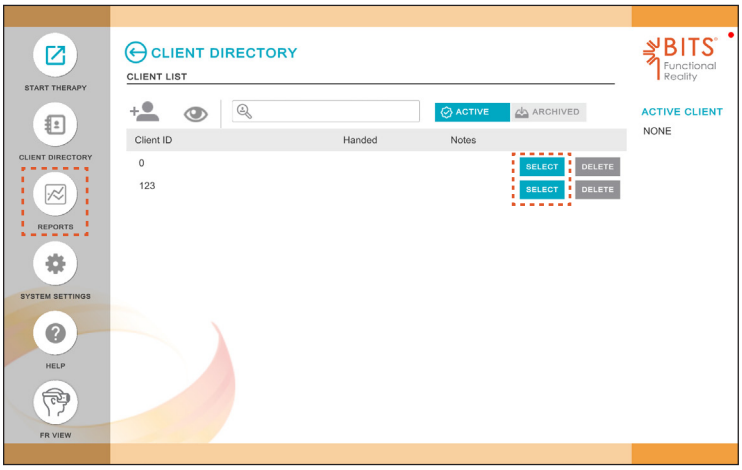


Figure 13-2 Select a Client

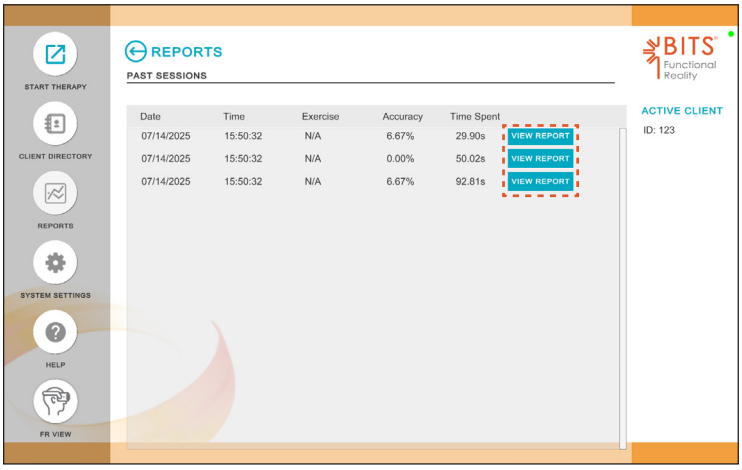


Figure 13-3 Select View Report

Results

Results for applicable BITS FR programs are divided into session metrics and therapy parameters. Session metrics note the results per client, per program. Therapy parameters note the parameters that were set for that program.

User Paced Program:

SESSION METRICS	
Session Duration (seconds)	Total time program was active
Accuracy (percent)	The accuracy is a measure of how precisely a target stimuli was eliminated
Time to Complete (seconds)	Time period used to complete the program beginning when the program was started
Reaction Time (seconds)	The average time period between the initial appearance of the stimulus and the moment the stimulus is hit
Stimuli (number)	Total number of stimuli displayed during the program
Hits (number)	Number of on target interactions
Misses (number)	Number of off target interactions
Total Time on Incorrect Targets (seconds)	Total time on incorrect target
Total Time on Target (seconds)	Total time on correct target
Longest Time on Target (seconds)	Longest time spent on a given target
Average Reaction Time (seconds)	The average time period between the initial appearance of the stimulus and the moment the stimulus is hit

Sequence Program:

SESSION METRICS	
Session Duration (seconds)	Total time program was active
Accuracy (percent)	The accuracy is a measure of how precisely a target stimuli was eliminated
Time to Complete (seconds)	Time period used to complete the program beginning when the program was started
Reaction Time (seconds)	The average time period between the initial appearance of the stimulus and the moment the stimulus is hit
Stimuli (number)	Total number of stimuli displayed during the program
Hits (number)	Number of on target interactions
Misses (number)	Number of off target interactions
Total Time on Incorrect Targets (seconds)	Total time on incorrect target
Total Time on Target (seconds)	Total time on correct target
Longest Time on Target (seconds)	Longest time spent on a given target
Average Reaction Time (seconds)	The average time period between the initial appearance of the stimulus and the moment the stimulus is hit

Smooth Pursuit Program:

SESSION METRICS	
Session Duration (seconds)	Total time program was active
Time to Complete (seconds)	Time period used to complete the program beginning when the program was started
Time on Target (seconds)	Total time on correct target
Final Score (number)	Percentage of total time on target for the session duration
Number of Targets (number)	The total number of distractors present along with the target

Grocery Store 5 Aisles:

SESSION METRICS	
Total Time (seconds)	Total time program was active
Items Selected (number)	Total number of items selected
Per Item Durations (seconds)	Amount of time taken to find each item during program. Listed per aisle and item.

Driving Sequence:

SESSION METRICS	
Total Time (seconds)	Total time program was active
Items Selection Times (number)	Amount of time taken to find each item during program. Listed per action required.

Functional Journey:

SESSION METRICS	
Total Time (seconds)	Total time program was active
Levels Completed (number)	Total number of levels completed
Per Level Details (seconds and number)	Amount of time taken to find each level and number of tasks completed per level. Listed per level.

360 Cube:

SESSION METRICS	
Total Time (seconds)	Total time program was active
Total Selections (number)	Total number of selections available
Correct Selections (number)	Total number of correct selections made
Accuracy (percent)	The accuracy is a measure of how precisely a target stimuli was eliminated
Selection History (seconds)	Amount of time taken to select each target

If you have questions or need technical support, contact the Bioness Product Support Department at 800-211-9136. You can also visit the Bioness website at: BionessMedical.com.

CHAPTER 14: **System Battery Levels, Shutdown and Charging**

Battery Levels

Headset

(The following instructions and images are sourced from the headset manufacturer's user guide. A copy of the Headset user guide is also included with the system.)

There are two ways to determine headset battery level. One way is with the battery indicator lights on the back of the headset, the other is within the software.

When charging the battery, the battery LEDs will continuously display the current power level. **Figure 14-1**.

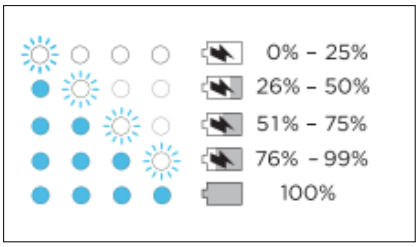


Figure 14-1 Battery Level While Charging

When using the headset, press the power button to show the power level when the headset is idle. **Figure 14-2**.

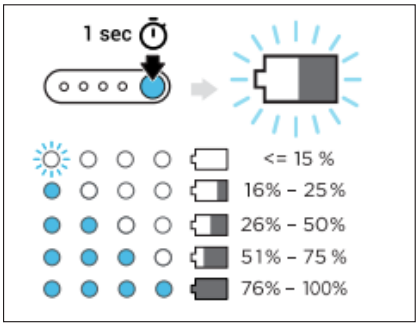


Figure 14-2 Battery Level While Idle

Tablet

Tablet battery level can be determined by swiping down once from the top to the middle of the screen. Battery level is indicated in the top right corner on the screen. **See Figure 14-3.**

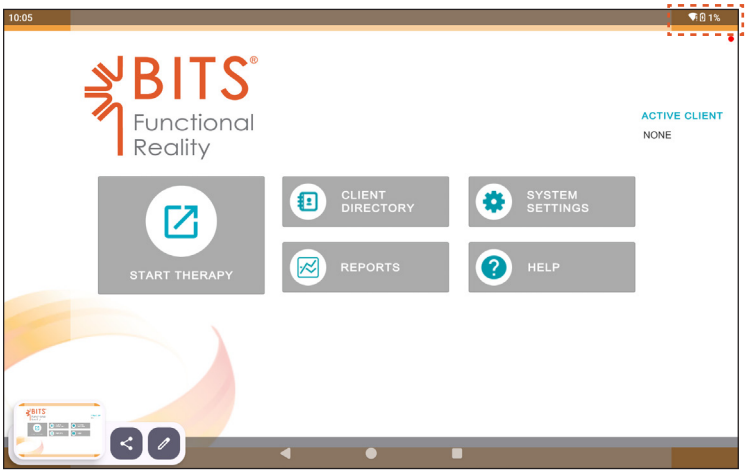


Figure 14-3 Tablet Battery Level

Shutdown

Headset

(The following instructions and images are sourced from the headset manufacturer's user guide. A copy of the Headset user guide is also included with the system.)

To turn off the headset, do either of the following:

Option 1:

Whether the headset is currently active or in standby mode, press and hold the power button until the battery LEDs start flashing one after the other. Wait for all the battery LEDs to completely turn off. **See Figure 14-4**.

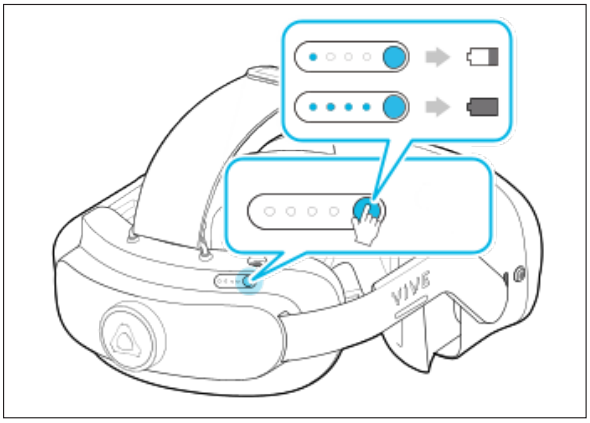


Figure 14-4 Headset Power Button

Option 2:

Press and hold the headset button until the Power menu appears and then select Shutdown with either hand controls or controllers. **See Figure 14-5 and 14-6**.

Figure 14-5 Side Button on Headset

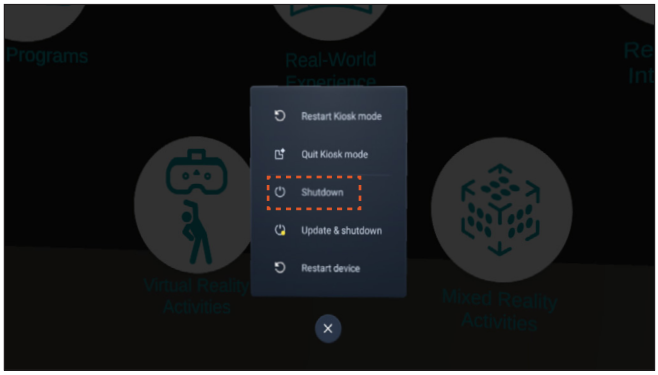


Figure 14-6 Selecting Shutdown in Headset

Tablet

To turn off the tablet, swipe down from the top to the middle of the tablet screen twice. On the menu, near the bottom of the screen, select the power icon, and then select “power off”. **Figure 14-7**.

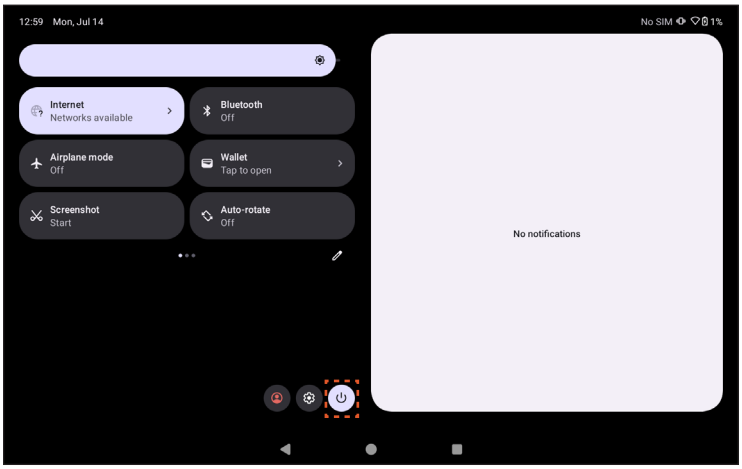


Figure 14-7 Shutdown Tablet

Charging

Headset

(The following instructions and images are sourced from the headset manufacturer’s user guide. A copy of the Headset user guide is also included with the system.)

Charge the headset with the AC adapter provided. It is recommended to charge the headset’s battery to full charge before each use. Charging the headset while in use is not recommended.

Option 1:

Charge the Headset and Controllers using the Charging Case provided. **See Figure 14-8, 14-9 and 14-10** for location on cables in the charging case.

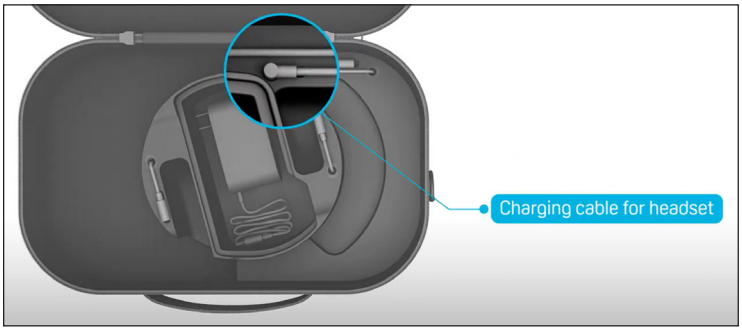


Figure 14-8 USB Cables for Headset in Charging Case

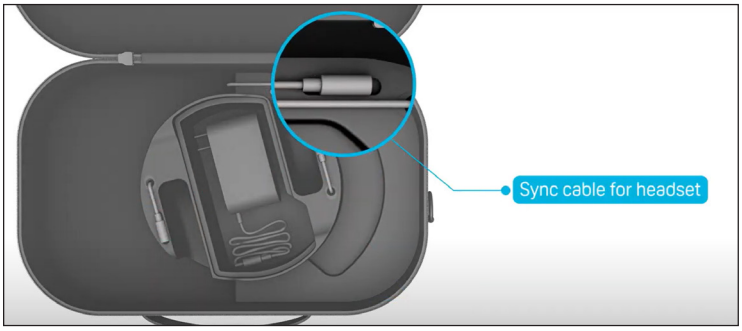


Figure 14-9 Sync Cable for Headset in Charging Case

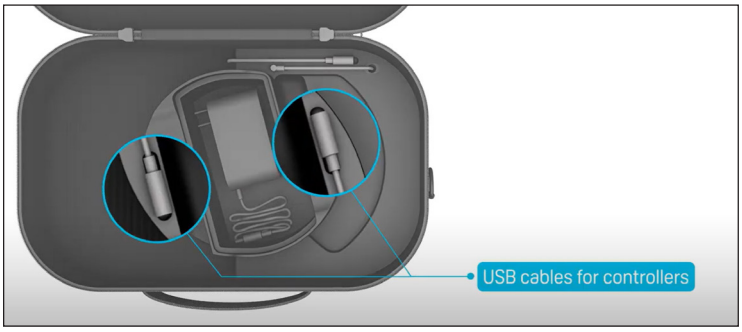


Figure 14-10 Charging Cable for Controllers in Charging Case

Step 1: First place the controllers in the charging case and insert the USB cables for the controllers into the back of each controller. **See Figures 14-11 and 14-12**.

Figure 14-11 Place Controllers in the Charging Case

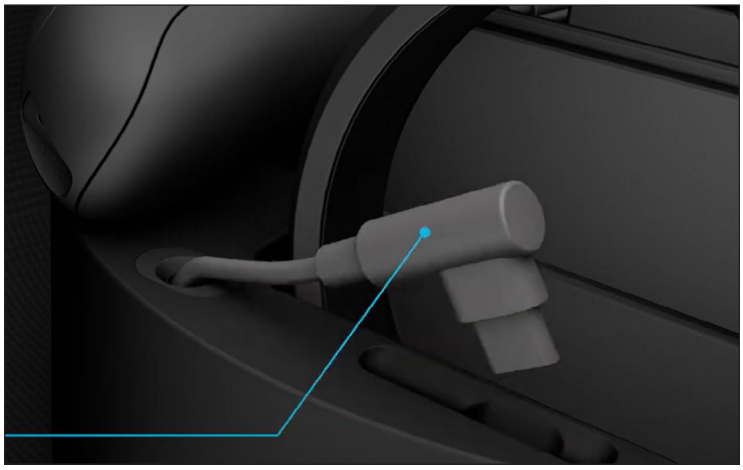


Figure 14-12 Connect the Cable to Controller

Step 2: Expand the Headset and place into the charging case to fit securely above the controllers. Plug the sync cable to the USB port located on the side of the headset at the front. And attach the headset charging cable to the port located on the top, in the back of the headset. **See Figure 14-13, 14-14 and 14-15**.

Figure 14-13 Place the Headset in the Charging Case

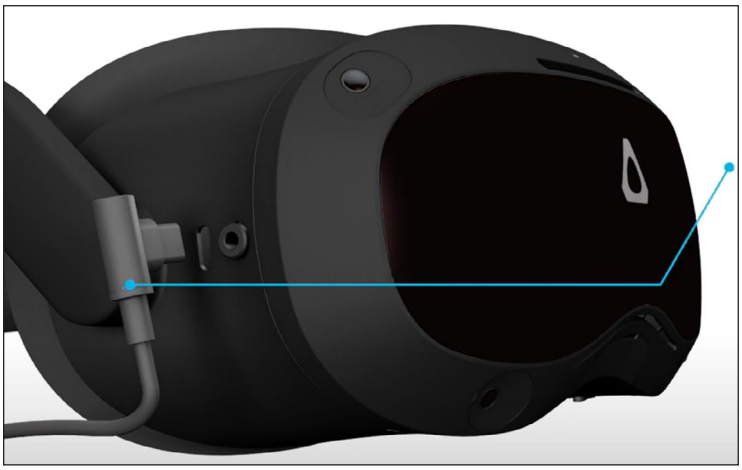


Figure 14-14 Attach the Sync Cable to the Headset Side Port

Figure 14-15 Connect the Charge Cable to Back of Headset

Step 3: Plug the AC adapter charging cable in the bottom corner of the charging case. System is charging when lights appear in the battery indicator on the back of the headset. **See Figure 14-16**.

Figure 14-16 Connect the AC Adapter Cable to the Charging Case

Option 2:

Charge the headset by connecting the AC adapter to a power outlet and then connecting it to the headset. **Figure 14-17**.

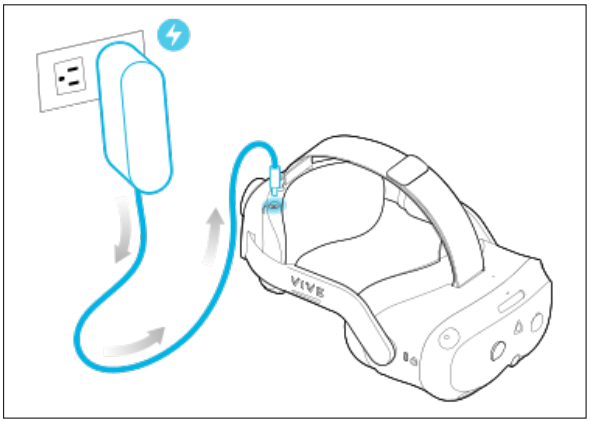


Figure 14-17 Charging Headset with Wall Outlet

You can check the battery level by pressing the power button on the back of the headset. **Figure 14-18**.

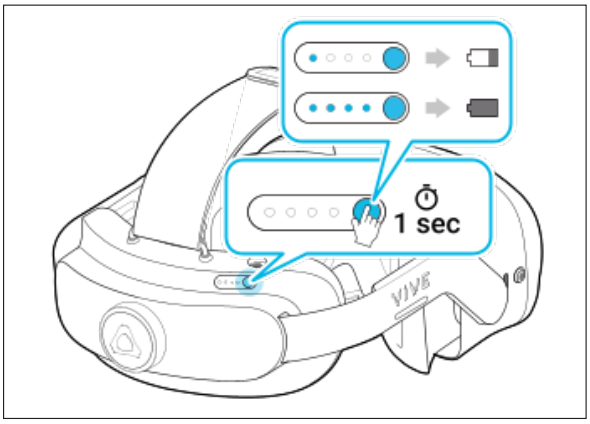


Figure 14-18 Battery level indicator

Charging the controllers

The controllers use built-in rechargeable lithium-ion batteries. Charge them periodically with the splitter cable. Charge the controllers by plugging them into the headset with the included splitter cable. **Figure 14-19**.

Note: • Controllers can be charged even when the headset is in standby mode.
• It is strongly recommended to connect the headset to a power outlet when you're charging the controllers.

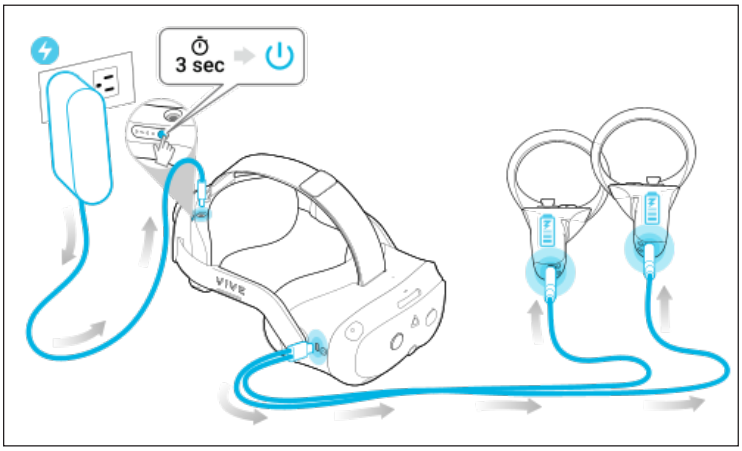


Figure 14-19 Charging Controllers with Headset

Controllers can also be charged independently using any USB charger with an output of at least 10 watts. **Figure 14-20**.

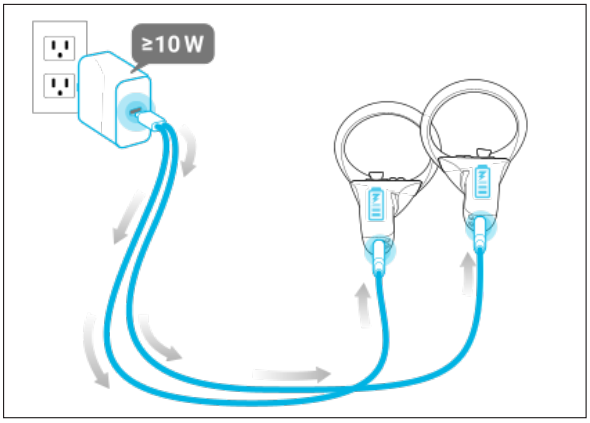


Figure 14-20 Charging Controllers with Wall Outlet

Tablet

Plug the USB-C cable provided with the tablet to charge the tablet. Charge port is located on the side of the tablet.

If you have questions or need technical support, contact the Bioness Product Support Department at 800-211-9136. You can also visit the Bioness website at: BionessMedical.com.

CHAPTER 15: **Troubleshooting**

This Chapter reviews basic troubleshooting and operating tips. If you have questions or need technical support, contact the Bioness Product Support Department at 800-211-9136. You can also visit the Bioness website at: BionessMedical.com.

Unable to Launch Program from Tablet to Headset

For the tablet and headset to communicate, both the Tablet and Headset must be on the same network and channel. Once the connection is successful, a green dot can be seen in the top right corner of the tablet.

Follow the steps below to confirm the components are connected and paired.

Pairing Headset and Tablet

Headset & Tablet are automatically paired. If the tablet is not detecting the headset, first confirm both headset and tablet are on the correct local network.

Network on Tablet

On the tablet, swipe down twice from the top to the middle of the screen. Then on the menu, select the 'Internet' icon (**See Figure 15-1**). Select "TP-Link" network. Enter in the password if required. The exact name and password instructions for the router can be located on the bottom of the router.

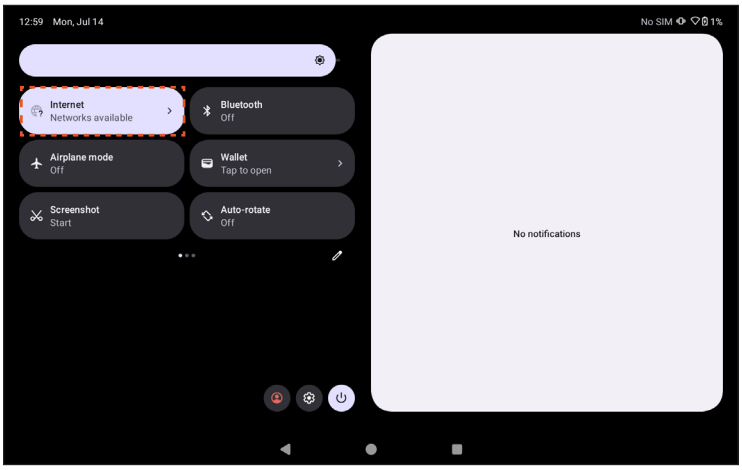


Figure 15-1 Network Selection on Tablet

Launch BITS FR application. Select Settings and note the channel selected (**See Figure 15-2**). Use the '+' or '-' to change the channel number and select 'Save Settings'.

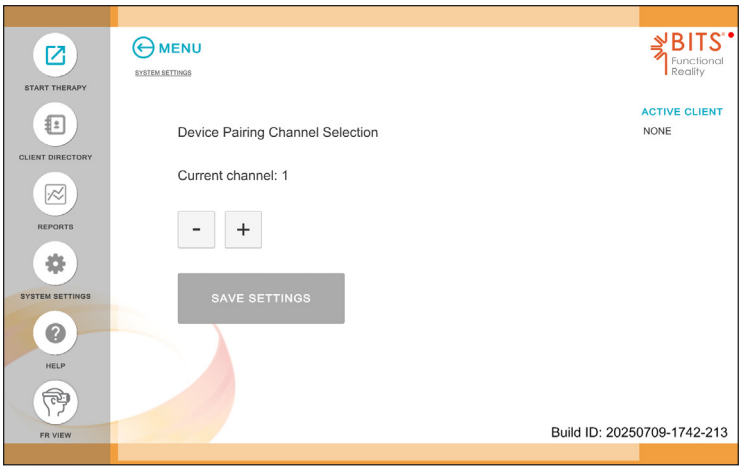


Figure 15-2 Channel Selection on Tablet

Network on Headset

On the headset, using the controllers, navigate to Settings.

To use the controllers, press the "VIVE" icon on the right controller. Then select the wifi icon by

pointing the controller and using the trigger button on the back of the controller, with your index finger. **See Figure 15-3**.

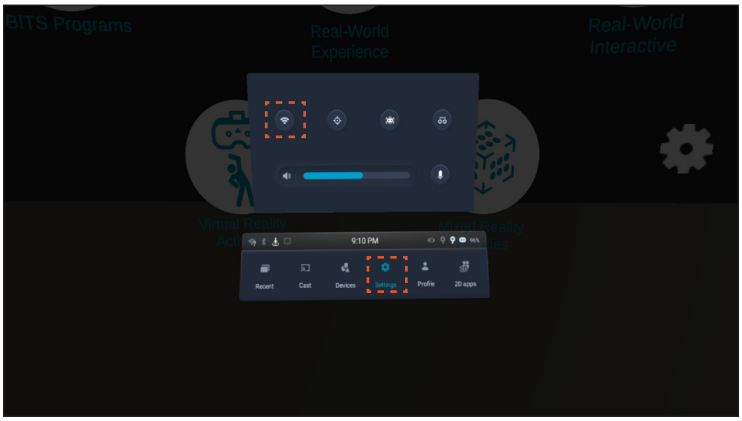


Figure 15-3 Settings Bar in Headset

Then select “TP-Link” network. Enter in the password if required. The exact name and password instructions for the router can be located on the bottom of the router. Network will state ‘Connected, no internet’. Select ‘X’ to close out the screen. Select the “VIVE” icon on the controller to exit out of the menu. See **Figure 15-4**.

Figure 15-4 Select Network

In BITS FR Main Menu, select ‘Settings’ icon in the bottom right corner. Confirm the channel number selected is the same as selected on the tablet. **See Figure 15-5**.

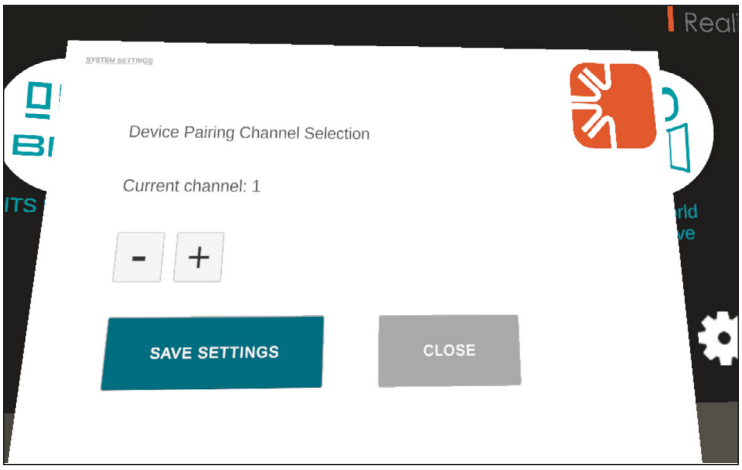


Figure 15-5 Channel Selection on Headset

You have successful connection when you see a green dot on the top right corner in the tablet application (**See Figure 15-2**). Headset must be turned on and within the BITS FR Software application while donned on the head. And the Tablet must be turned on and in the BITS FR Clinician Software application.

Troubleshooting Controllers

The controllers included with the OTS Headset should automatically pair with the system. If a controller is not paired or not responding within the BITS FR Software application, try the steps below:

1. Confirm controllers are on. There should be a green light visible on the controller.
2. If there is no light on the controller, press the “VIVE” icon on the right controller and press the “menu” button on the left controller.
3. If a blue light comes on and not green, press the “VIVE” icon on the right controller and press the “menu” button on the left controller again.
4. If light does not turn green, ensure controllers are paired with the Headset.

Pairing Controllers to the Headset:

1. Press the “VIVE” button on the right controller. Point to and select ‘Devices’ from the menu and then select the ‘glasses’ icon. **See Figure 15-6**.

Figure 15-6 Vive Menu

2. Select settings icon on the top right (**See Figure 15-6**) and select ‘Pair New’ (**See Figure 15-7**). Follow the instructions noted in the headset to pair the controller.

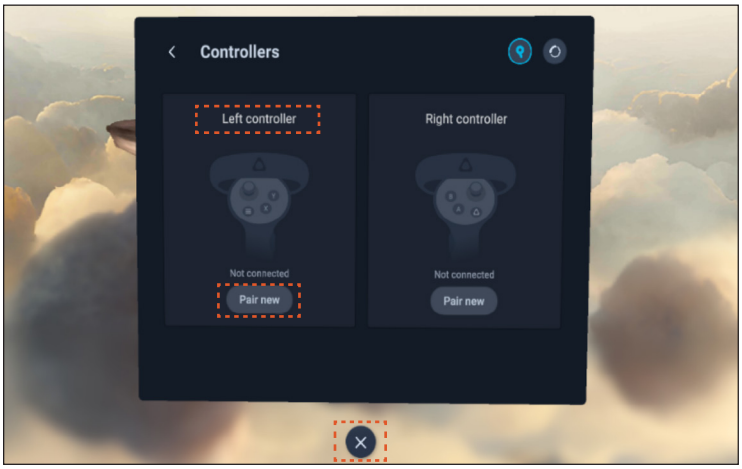


Figure 15-7 Controller Pairing Mode

3. Once paired, controller version number will be noted under the “Left controller” or “Rich controller” heading and battery level will be visible underneath the image of the controller (**See Figure 15-8**). If controller continues to state “Not connected” try step 2 again. Select ‘x’ to close out the menu and return to BITS FR Main Menu. (**Figure 15-8**)

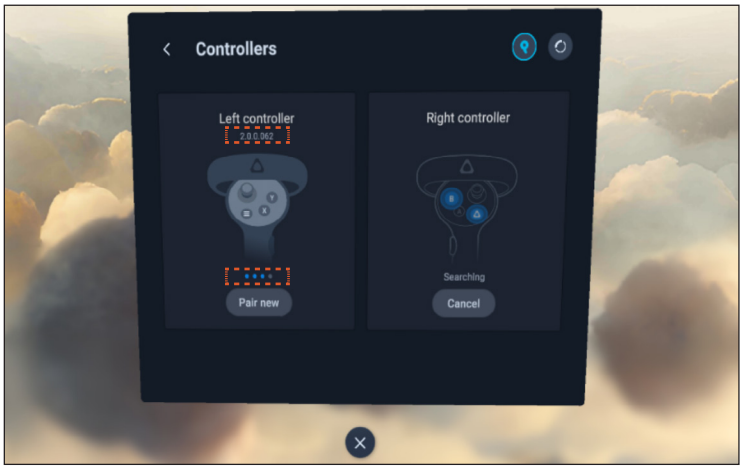


Figure 15-8 Controller Pairing Example

Controllers Interfering with Touch Mode

If the controllers are interfering with the Touch Mode and the system is not recognizing the client’s hand gestures. Or the controllers image is displayed within the software even when not being used, the controllers can be put into standby mode. To do so, press and hold the “VIVE” icon the right controller for 3 seconds and wait for the blue or green light to turn off. For the left controller, press and hold the “Menu” icon for seconds and wait for the blue or green light to turn off. To make the controllers active again, simply pick up the controllers or press the “VIVE” or “Menu” icons on right and left controllers respectively for a brief second.

IPD Calibration Troubleshooting

Once client has donned the headset, and automatic IPD adjustment calibration screen will appear (See Chapter 3 for more details). If IPD is not adjusted correct, client will see a screen stating ‘Unable to adjust IPD’. Select ‘OK’. (**See Figure 15-9**).

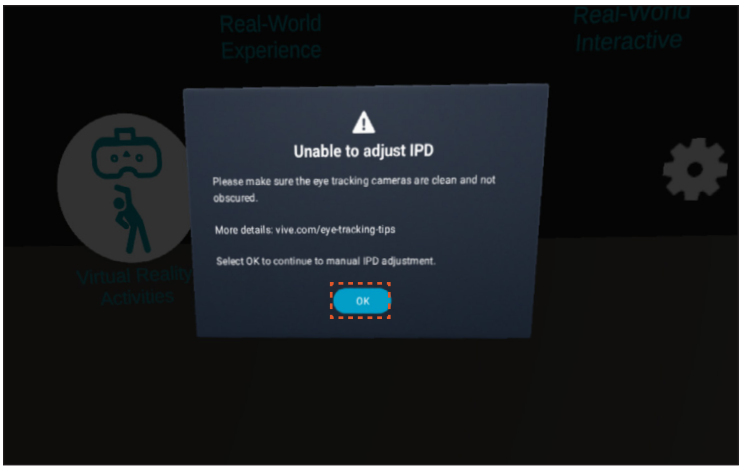


Figure 15-9 Unable to adjust IPD

Client will then see screen to manually adjust IPD. Use the ‘+’ or ‘-’ to adjust IPD manually until the vertical lines are in focus (**See Figure 15-10**). The volume up and down button located on the bottom left on the front of the headset can also be used to adjust the values (**See Figure 15-11**). Select ‘x’ when adjustment is complete (**Figure 15-10**).

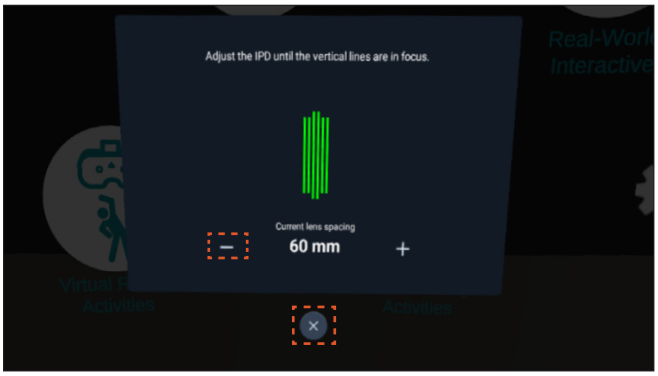


Figure 15-10 Manual IPD Adjustment

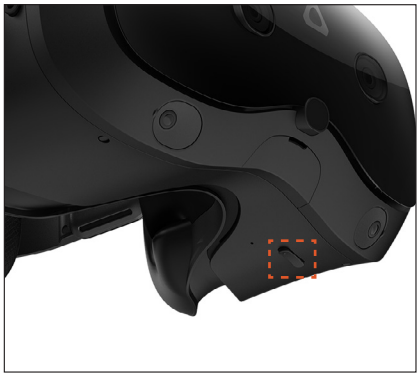


Figure 15-11 Headset Volume Button

Reset View Troubleshooting

If a client has moved outside of the boundary or the headset has been moved, and the ‘front view’ needs to be reset. Press the “VIVE” icon on the right controller and select ‘Settings’ and then select the ‘target’ icon on the screen.

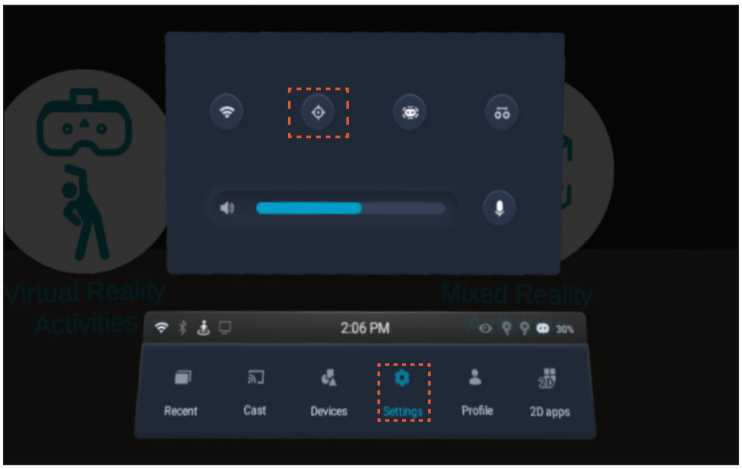


Figure 15-12 Reset View

Then face the direction to reset the forward orientation and press the trigger button on either controller. Or if using hand controls, pinch the index finger and thumb together. **See Figure 15-13**.

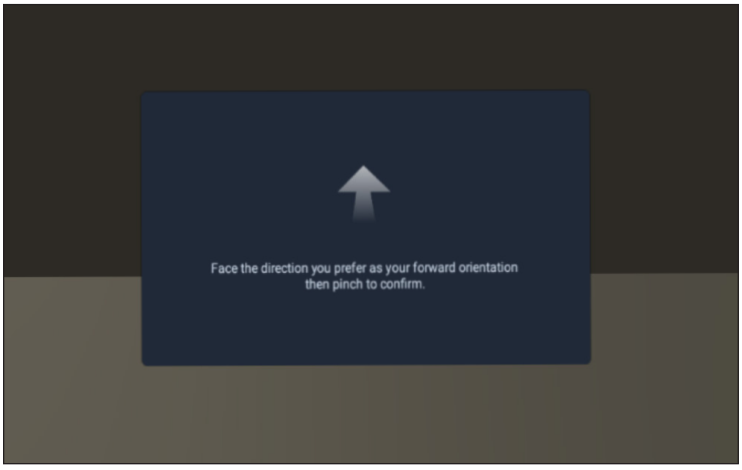


Figure 15-13 Select new forward-facing view

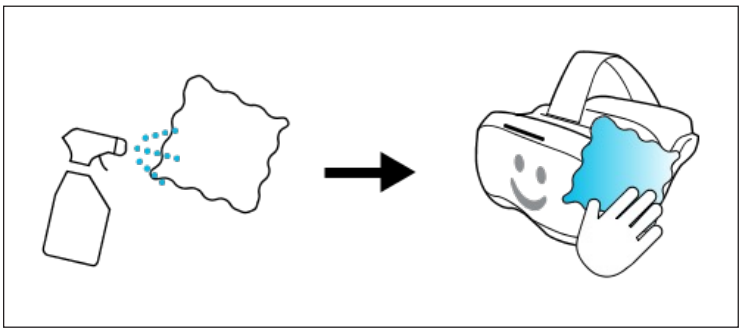
If you have questions or need technical support, contact the Bioness Product Support Department at 800-211-9136. You can also visit the Bioness website at: BionessMedical.com.

CHAPTER 16: **Cleaning and Disinfecting**

The following steps are provided by the headset manufacturer. Reminder: Use provided hygienic masks for multi-user environments

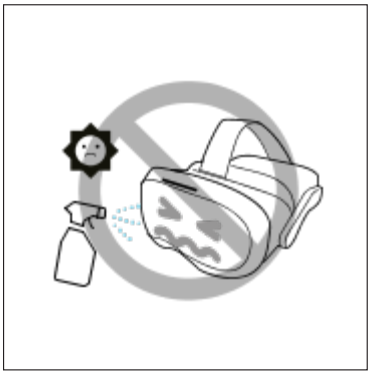
Here are a few tips to help keep VIVE Focus Vision clean and hygienic.

Do's



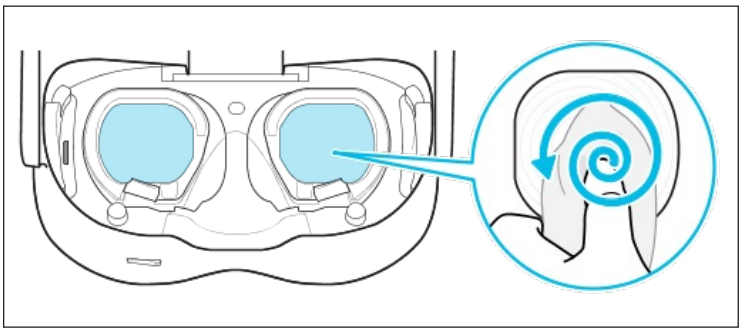
- Dampen a cloth with a diluted alcohol solution containing 70%–75% ethanol (ethyl alcohol) and use it to wipe the hard surfaces of the headset and controllers clean, especially places you frequently touch with your hands.
- PU leather face gaskets can also be wiped clean with a damp cloth.
- To avoid skin irritation, make sure the headset and any accessories are free from disinfectants before using them again.
- Using a UVC cleaner is an effective and recommended way to decontaminate VR headsets and controllers. Before using a UVC cleaner on your VR devices, make sure to properly cover the headset lenses. Discoloration due to UV exposure is not covered by warranty.

Don’ts



- Don’t spray or pour liquid directly on the headset or controllers.
- Don’t use any liquids or cleaning solutions on the lenses.
- Don’t expose the headset or controllers to direct sunlight.
- Don’t machine wash the headset or controllers.

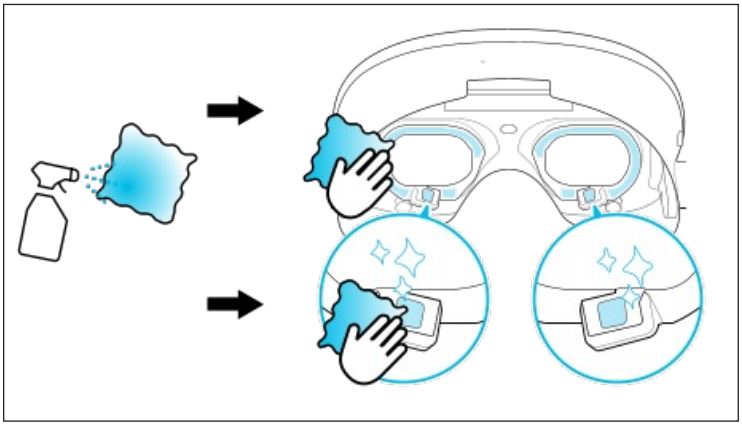
Cleaning the headset lenses



- Use a clean, dry cloth such as the lens cleaning cloth that came in the box to wipe the lenses clean.
- Never use any kind of cleaning solution on the lenses.
- To avoid smudging the lenses while cleaning them, wipe in a circular motion from the center of each lens to its outer edge.

Cleaning the eye tracking cameras

1. Pull to remove the magnetic face cushion.
2. Remove any dust or particulate matter from the eye tracking cameras and delicate parts of the eye frames using a touch-free dust removal tool such as a handheld air blower.
3. Dampen a clean, microfiber cloth with an alcohol-based cleaning solution containing 99.5%–99.9% alcohol.
4. Gently dab the eye tracking cameras and the delicate parts of the eye frames with the cloth.



⚠ **Warning:** Do not rub, wipe, or scrub the eye frames or eye tracking cameras with the microfiber cloth. Doing so could cause irreversible damage to the eye tracking cameras.

If you have questions or need technical support, contact the Bioness Product Support Department at 800-211-9136. You can also visit the Bioness website at: BionessMedical.com.

CHAPTER 17: **Software Specifications**

The BITS Functional Reality Software is currently intended to be used with the following general purpose computing platform which is a commercially available Head-Mounted Display (HMDs) that has been validated as compatible with the software application:

- HTC Vive Focus Vision: Release Version: 2.6
- BITS Functional Reality Software: Version 1.0.0

The BITS Functional Reality Clinician Software is currently intended to be used with the following general purpose computing platform which is an Android Tablet that has been validated as compatible with the software application:

- Android G10 Tablet: Android 14
- BITS Functional Reality Clinician Software: Version 1.0.0

BITS Functional Reality Software and BITS Functional Reality Clinician Software are available on closed general computing platforms: OTS Headset and Tablet. On both OTS hardware device platforms, the internet connectivity and auto-updates have been disabled to prevent inadvertent platform modifications. If any unexpected changes are observed notify Bioness Medical immediately.

If new software releases of OTS hardware are released by the manufacturer, Bioness Medical will complete verification and validation of the changes before release. All updates are reviewed and tested in accordance with FDA regulations to ensure continued safety, effectiveness, and compliance before being released.

For the latest information on BITS FR compatibility with OTS Hardware go to: www.bionessmedical.com/bitsfr/support

If you have questions or need technical support, contact the Bioness Product Support Department at 800-211-9136. You can also visit the Bioness website at: BionessMedical.com.

CHAPTER 18: **Network, Privacy & Security**

The security of Bioness products is an important factor in protecting information and systems from external and internal threats. Therefore, customers must take responsibility for maintaining a secure IT environment that is compliant with general IT standards. Bioness encourages customers to implement the following industry-standard practices:

- Physical Security (e.g. do not allow unauthorized individuals to use the Bioness Integrated Therapy System Functional Reality (BITS FR))
- Operational Security (e.g. do not leave a logged-in BITS FR system unattended, do not connect the system to the Internet, do not connect any external media—such as USB flash drives, SIM cards, or SD cards—to the BITS FR system, unless provided by Bioness Medical for approved software updates, do not alter the BITS FR software or install unauthorized software including Virus scan software
- Risk Management
- Security Policies
- Contingency Planning

The implementation of security practices may vary by site and include many other technologies, such as firewalls, virus scanning, and anti-spyware software, etc. Although internet connectivity is disabled on the BITS FR, a remote possibility remains that the system can be hacked or altered. If such an occurrence is suspected, contact Bioness Product Support at 800-211-9136. Additional information related to security, privacy, and available software upgrade to the system can also be requested from this department.

Data Security

The system is designed to operate on a dedicated, isolated network and does not store or transmit any patient health information (PHI).

If you have questions or need technical support, contact the Bioness Product Support Department at 800-211-9136. You can also visit the Bioness website at: BionessMedical.com.