



**Bioness Inc.**

25103 Rye Canyon Loop  
Valencia, CA 91355 USA  
Telephone: 800.211.9136  
Email: [info@bioness.com](mailto:info@bioness.com)  
Website: [www.bioness.com](http://www.bioness.com)



**Bioness Europe B.V.**

Stationsweg 41  
3331 LR Zwijndrecht, The Netherlands  
Telephone: +31.78.625.6088  
Email: [international@nl.bioness.com](mailto:international@nl.bioness.com)  
Website: [www.bioness.com](http://www.bioness.com)

**Rx Only**



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**BITS**<sup>®</sup>

Bioness | Integrated | Therapy | System

# INSTALLATION GUIDE





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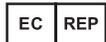


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## List of Symbols

	Caution
	Warning
	Class II Equipment (Double Insulated)
	Type BF Applied Part(s)
	Non-Ionizing Radiation
	Date of Manufacture
	Manufacturer
	This Product Must Not Be Disposed of with Other Household Waste
	Refer to Instruction Manual/Booklet
	FCC ID: RYYEYSHSN
	Re-Order Number
	Lot Number
	Serial Number
	Warning Electricity
	Medical Device
	MR Unsafe
	Quantity 48
	Single Use Only
	European Authorized Representative
	Storage Temperature
	Humidity Limitation
	Atmospheric Pressure Limitation
<b>IP68</b>	Protection Against Ingress of Water
	Keep Dry
	Fragile
<b>Rx Only</b>	Prescription Only
	Complies with the European Union Medical Device Directive

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## Introduction

This document outlines the installation process for the Bioness Integrated Therapy System (BITS). This guide includes a part list, safety information, and installation instructions. Please read this installation guide including all safety information, before starting the installation process.

## Precautions and Warnings

### Precautions

- Unauthorized modifications to the Bioness Integrated Therapy System, such as installing or uninstalling software, will void the warranty.
- Accessing the internet or local intranet with the Bioness Integrated Therapy System will void the warranty.
- Do not alter the Windows 10 Operating System settings by adding Windows user accounts or adjusting the screen saver and sleep timer as this may interfere with the functioning of the software.
- Contact Bioness Product Support Department if any component of the system is malfunctioning. Attempts to modify the hardware will void the warranty.
- Make sure to follow the correct procedures when moving the portable stand, adjusting the height of the display screen, moving or adjusting the Balance Platform, using or storing the Sensor and using or storing the Chest Strap.
- Supervision and assistance for the patient should be provided during use of the Balance Platform.
- Ensure Balance Platform is on level ground prior to instructing clients to step on Platform.
- Keep area around the Balance Platform clear of other objects. Do not stack objects on the Balance Platform.
- Keep Balance Platform at a safe distance from portable stand and display screen when in use.
- Utilize Stabilizing Blocks to assist clients in getting on and off the Balance Platform.
- For clients with limited mobility, exercise precaution and remain within a safe distance when client is performing balance exercises.
- Always lock the wheel casters on the stand when the system is in a stationary position.
- Ensure the wheels on the portable stand are in the locked position before starting a therapy session with a client. Do not unlock wheel casters during therapy.
- Supervision should be provided during use of the system.
- Clients should not use an object that may damage, or is unsafe when interacting with the touchscreen.
- Use caution with clients diagnosed with, or suspected to have, epilepsy.
- Adhesive Patches provided are single use only and should not be transferred between patients.
- Do not use any chemical solvents that are acidic or alkaline cleaning agents.
- Always exercise universal precautions and wear gloves when cleaning any component of the system.

### **Warnings**

- Do not move the Bioness Integrated Therapy System over obstacles on the floor or over uneven or soft surfaces. Doing so could cause the equipment to fall causing damage and/or injury.
- Ensure Sensors are charged prior to performing Balance Therapy.
- Do not charge the Sensors while it is in use by client or user.
- Sensors must be charged using the charging block and cable provided by Bioness.
- Do not use the Bioness Integrated Therapy System near strong electromagnetic fields (e.g. MRI).
- To avoid the potential of electrical shock do not use the Bioness Integrated Therapy System near water.



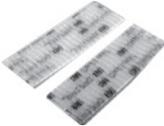
- Users of the Bioness Integrated Therapy System should exercise caution to prevent tripping hazards during the course of therapy. Sources of such tripping hazards include power cables and the legs of the Portable Stand. Please note that some additional falling hazards may result from use of the larger touchscreen display monitor, as clients may be required to stretch farther to complete exercises.
- Stored Energy Hazard: The lift mechanism in the Stand Tower is under tension and will move rapidly, on its own, as soon as attached equipment is removed. For this reason, do not remove equipment or make adjustments to lift tension unless the touchscreen display monitor has been moved to the highest position on the stand tower. Failure to follow these instructions may result in personal injury and/or equipment damage.
- The equipment must only be connected to an earthed MAINS socket-outlet (i.e. Only plug the Bioness Integrated Therapy System into 3 pronged grounded wall outlets.). Not doing so may result in an increased risk of electric shock.
- Misuse of the system could cause the unit to fall and result in injury and/or damage.
- Do not climb, sit, or lean on any part of the portable stand, doing so could cause the equipment to fall causing damage and/or injury.
- Remove the Sensor before undergoing any diagnostic or therapeutic medical procedure such as X-ray examination, ultrasound, MRI, etc.
- Users of the Balance Platform should exercise caution when stepping on or off the Balance Platform to prevent tipping hazards during the course of the therapy. Please note that some additional tipping hazards may result when performing Static Balance activities while on Platform as reaching could result in Platform tipping, loss of balance and subsequent fall hazard.
- The Bioness Integrated Therapy System software programs utilize moving and rotating graphics that may cause dizziness, vertigo, or nausea in sensitive patients. Individuals experiencing dizziness, vertigo, or nausea while using BITS should discontinue use immediately.
- The BITS Balance Adhesive Patch can be attached to patient's clothing or directly applied to the skin. It is normal for the skin under the Adhesive Patch to become red. The redness should disappear in approximately one hour once the patch is removed. However, some patients may experience skin irritation, an allergic reaction, or hypersensitivity to the the gel pads on the back of the Adhesive Patch. Persistent redness, lesions or blisters are signs of irritation. Use of the Adhesive Patch should be temporarily halted until the irritation is resolved. Patients should consult their physician if irritation persists.
- Do not apply the Adhesive Patch over skin folds, scarred tissue, irritated skin, uneven skin surfaces, or broken skin.
- Always inspect the gel pads on the back of the Adhesive Patch before use. Do not apply the Adhesive Patch if the gel pads appear dried out, worn, dirty, or irregular.
- Make sure the Adhesive Patch liner is removed before adhering to the clothing or skin.
- Do not use the Adhesive Patch with an expired "Use by" date.
- Do not use unapproved devices/hardware with the Bioness Integrated Therapy System.
- Do not use unapproved accessories with the Bioness Integrated Therapy System.
- Improper shut-down of the BITS software may result in the loss of client data. Please follow proper instructions for the shut down process.
- Refer to the manufacturer's instructions provided with the touchscreen display for additional warnings and safety information.
- Bioness Integrated Therapy System is not intended to act as a diagnostic device and does not identify the presence or absence of clinical diagnoses.
- Make sure the computer is shut down and turned off before moving the stand.
- Make sure the Balance Platform is placed in a secured location when not in use to avoid tripping hazards.

## BITS Installation Component List

The components for the BITS product consists of three different kits: Hardware Kit, Software Kit, and Computer Kit. Do not start the installation process until all three kits have been received.

BITS Hardware Kit: BIT-2055 (55" Display)		
Description	Illustration (Reference Only)	Quantity
Touchscreen Display Monitor (with Attached CPU Mount) Mounted on Assembled Ergotron Display Stand with Attached Keyboard Tray		1
Magnetic Stylus		2
Touchscreen Display Monitor Remote Control		1
Mounting Plate Screws		4
Touchscreen Cleaning Kit		1
Literature	BITS Clinician's Guide can be accessed through the 'Help' Menu in the Software Application.	

BITS Software Kit: BIT-2055		
Description	Illustration (Reference Only)	Quantity
BITS License Key (contained in a box)		1
USB Hub		1
Encrypted Backup Drive (contained in a box)		1

BITS Software Kit: BIT-2055		
Description	Illustration (Reference Only)	Quantity
Extension USB Cord		1
Wire Loom		1
Zip Ties		10
Mounting Bases		10
Fasteners		2 packages
Round Cord Clips		1 package
Literature	BITS Installation Guide	1

BITS Computer Kit: BIT-2055		
Description	Illustration (Reference Only)	Quantity
Computer with Mounting Bracket, Hardware, and Power Adapter with Cord		1
Multi-country AC Plugs		1
Wireless Keyboard		1
Power Strip		1
HDMI Cable		1

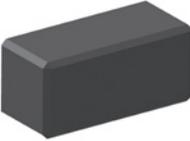
## BITS Balance Installation Component List

The components for the BITS Balance product consists of two different kits: BITS Balance Accessory Kit and BITS Balance Platform Kit. Do not start the installation process until both kits have been received.

**Note: BITS Balance components are only shipped if BITS Balance Module has been purchased.**

BITS Balance Accessory Kit: BIT-3655		
Description	Illustration (Reference Only)	Quantity
Motion Sensors BIT-3355		2
Charging Block and Cable		2
XS/S Chest Strap BIT-3420		1
M/XL Chest Strap BIT-3452		3
2XL/3XL Chest Strap BIT-3477		1
Single Use Adhesive Patches BIT-3555		48
Literature	BITS Balance Activation Guide	1

**Note: BITS Balance Accessory Kit Components come in re-usable packaging which contains trays for storing all balance related equipment and wireless keyboard.**

BITS Balance Platform Kit: BIT-3255		
Description	Illustration (Reference Only)	Quantity
Balance Platform		1
Stabilizing Blocks		2

BITS Power Supply Kit (UK): BIT-A001 (Only Included with UK Installations)		
Description	Illustration (Reference Only)	Quantity
UK Power Strip		1
UK Power Cord		1

BITS Power Supply Kit (UK): BIT-A001 (Only Included with UK Installations)		
Description	Illustration (Reference Only)	Quantity
EU Power Strip		1
EU Power Cord		1

**Note:** Verify that all components have been received. Do not start the installation process if any of the listed components are missing. For technical support contact Bioness Product Support Department at 800.211.9136, Option 3 or your Bioness Sales Representative.

## Tools Needed for Installation

The list below includes items needed to install the BITS. The tools are not provided with the system.

- 14mm Wrench
- 14mm Socket Driver (optional)
- Phillips Screw Driver
- Scissors
- Safety Gloves
- Box Cutter with Safety Guard

## Unpacking and Setting Up the Hardware Kit

1. The BITS Hardware Kit is a large package that is delivered on top of a wooden pallet. The package consists of a pallet with ramp, layered cardboard, foam inserts, shipping straps, and plastic shipping wrap. See Figure 1.
2. Remove all plastic shipping wrap by cutting it from the top with a box cutter.
3. Cut all green shipping straps. Start with the straps located above the wooden ramp, see Figure 1.
4. Lower the wooden pallet ramp.
5. Cut the tape around the box lid and lift to remove the lid.
6. On the bottom box lip, cut the tape and completely unfold the bottom lip on all four sides.
7. Cut the outer layer of cardboard down the middle to remove.
8. Open the side cardboard flaps and remove the front and back cardboard panels. See Figure 2.
9. Carefully remove the side cardboard panels with attached foam inserts that are supporting the Touchscreen Display Monitor. See Figure 2.
10. Cut the green shipping straps that are attached to the anchors on the bottom of the box.
11. Remove the foam wrap and the foam blocks that are located under the BITS display stand.
12. Carefully roll the BITS System down the wooden ramp.
13. Cut the green shipping straps from the cardboard in front of the Touchscreen Display Monitor. Remove the cardboard, foam blocks, and foam cover from the Touchscreen Display Monitor.
14. The box attached to the back of the system will contain the display screen remote control, stylus, Touchscreen Cleaning Kit, display screen literature, and a small bag of screws. Remove the contents and set aside.
15. The Touchscreen Display Monitor was intentionally left loose to allow for rotation. Position the monitor so that it is level, and hand tighten the knob found in the back of the mounting bracket by turning it clockwise. See Figure 3.



Figure 1: Hardware Kit Packaging

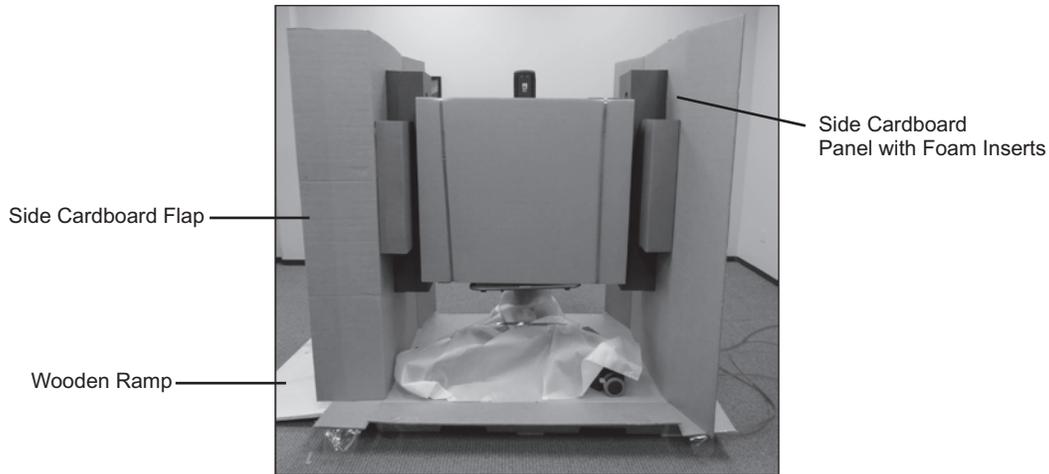


Figure 2: Side Cardboard Flaps and Front Panel



Figure 3: Knob, Back of Mounting Bracket

## Adjusting Display Stand Lift Tension

The display monitor should be able to move smoothly and easily on the tower of the portable display stand and stay in place. If movement is difficult or the display monitor does not stay in the desired position, then adjustment to the tension in the tower is needed. Depending on the display monitor and the adjustment it may take several turns to notice a difference in tension.

### To adjust the display stand tower tension:

1. Make sure the touchscreen display monitor has been moved to the highest position on the stand tower.
2. Remove the cover on the top of the portable stand tower. See Figure 4.
3. To tighten the tension, use a 14 mm wrench to turn the nut clockwise (turn toward the plus symbol). See Figure 4.
4. To loosen the tension, use a 14 mm wrench to turn the nut counter-clockwise (turn toward the minus symbol). See Figure 4.
5. Put the cover back on the portable stand tower.

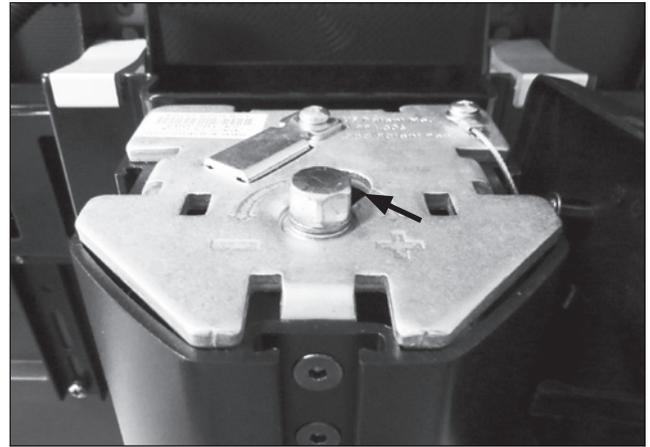
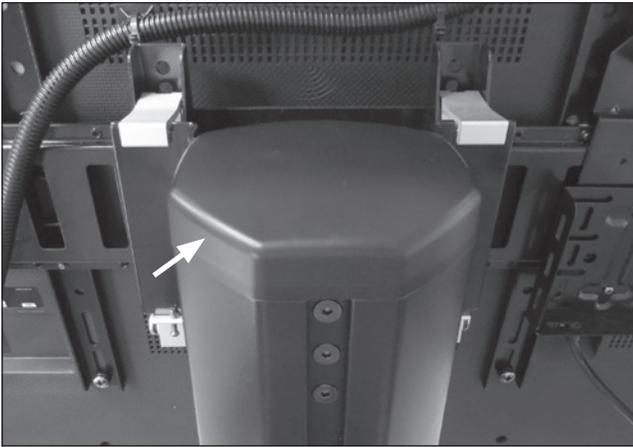


Figure 4: Portable Stand Tower Cover (Left), Adjustment Nut on Portable Stand Tower (Right)

## Computer Installation

1. Open the computer package and verify that the computer, mounting bracket, hardware, and power adapter are present.
2. Attach the computer mounting bracket to the CPU Mount. See Figure 5. Secure with the four screws provided in the Hardware Kit. The screws are located in a small bag in the box containing the remote control, Touchscreen Cleaning Kit, stylus, and literature.

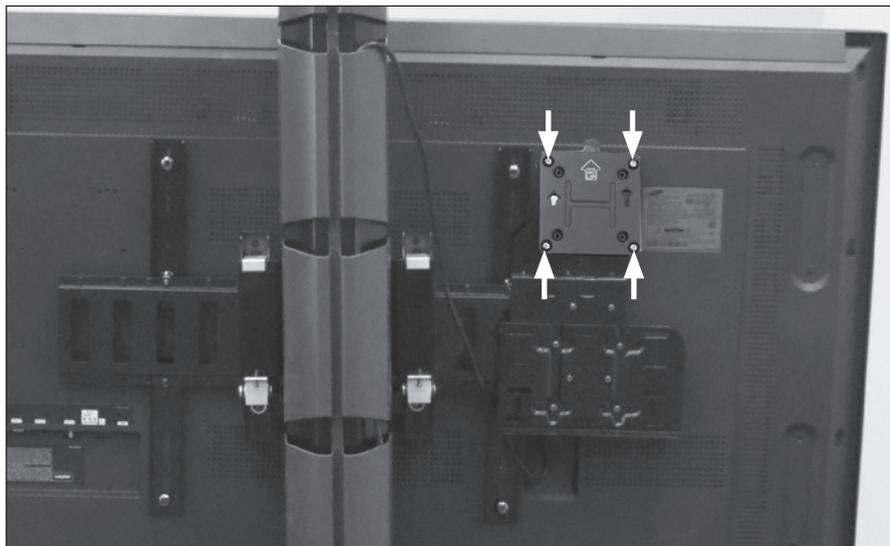


Figure 5: Attaching Computer Mounting Bracket

3. Remove the computer from the plastic bag and attach 2 screws (provided with the computer) to the back of the computer. See Figure 6. Do not over tighten the screws. The screws will be used to slide the computer into the computer mounting bracket.
4. Slide the computer, with attached screws, into the computer mounting bracket. See Figure 6. The computer should fit snugly into place and should be able to be easily removed.



Figure 6: Attaching Screws to Back of the Computer (Left)  
Attaching Computer to the Computer Mounting Bracket (Right)

**Note: When attached, the connection ports on the computer will be on the right hand side.**

## USB Hub

1. Remove the USB Hub from its packaging.
2. Connect 2 strips of fastener together. Remove the protective cover from one side and affix it to the bottom of the USB Hub.
3. Plug the USB Hub into the yellow USB port on the left side of the computer.
4. Remove the protective cover from the fastener and affix the USB Hub directly to the back of the Touchscreen Display positioned to the left of the mounting bracket. See Figure 7.

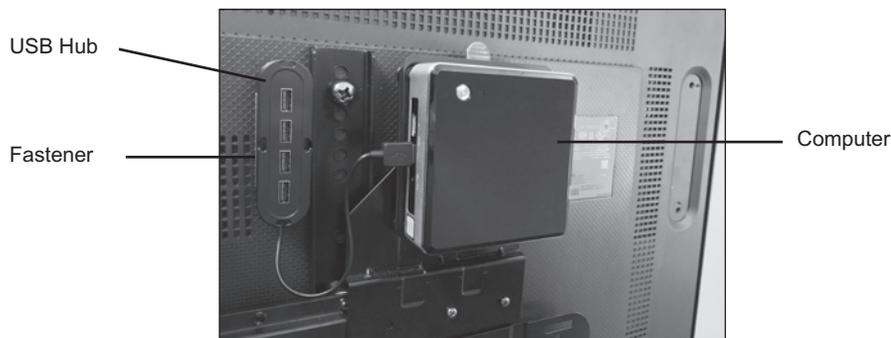


Figure 7: Securing the USB Hub

## BITS License Key

1. Remove the BITS License Key from the box located in the Software Kit package.
2. Remove the protective cover from the BITS License Key.
3. Plug the BITS License Key into the USB Hub. See Figure 8.

## Encrypted Backup USB

1. Remove the Encrypted Backup USB from the box located in the Software Kit package.
2. Remove the protective cover from the Encrypted Backup USB.
3. Plug the Encrypted Backup USB into the USB hub. See Figure 8.

## Wireless Keyboard

1. Remove the Wireless Keyboard with integrated touch pad and small USB from package.
2. Plug the small USB into the USB Hub. See Figure 8.
3. Remove the battery protection strip(s) from the bottom of the keyboard. Turn the keyboard on by sliding the switch located on the front panel of the keyboard to the ON position.

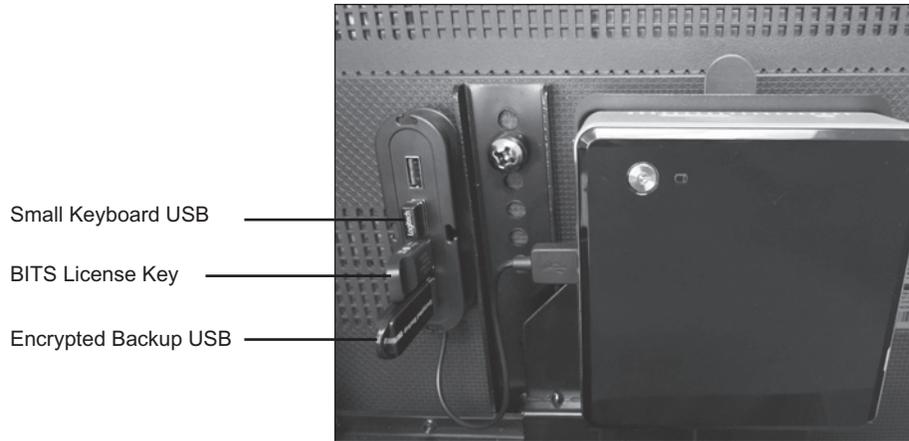


Figure 8: Connection Locations of BITS License Key, Encrypted Backup USB, and Small Keyboard USB

## Touchscreen USB

1. Remove the tape securing the Touchscreen USB cable in the lower left corner of the Display Monitor.
2. Plug the Touchscreen USB cable directly into one of the USB ports located on the right side of the computer.

**Note: The Touchscreen USB must be plugged directly into the computer and not the USB Hub in order for the Touchscreen to function properly.**

## USB Extension Cable

1. Remove the USB Extension Cable from its packaging.
2. Attach one of the Cord Clips to the right side of the Touchscreen bezel about six inches from the bottom of the Touchscreen Monitor. See Figure 9.
3. Insert the USB Extension Cable into the available USB port on the right side of the computer.
4. Secure the USB Extension Cable into the Cord Clip.
5. Remove the slack from the USB Extension Cable by looping the cable with two loops, and secure the USB Extension Cable to the Mounting Base by feeding a zip tie through the opening in the Mounting Base and tightening it around the loops.

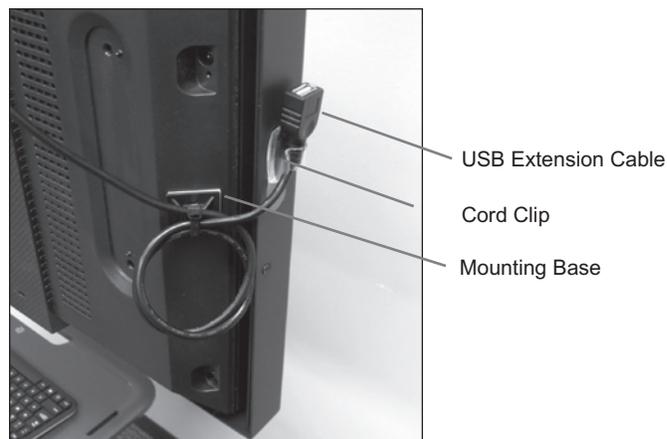


Figure 9: USB Extension Cable

## Power and HDMI Cable Installation

1. Remove the Touchscreen Display Monitor Power Cord from package and insert into the back of the monitor.
2. Connect the PC Power Adapter to the PC Power Cord and plug it into the PC power port on the right side of the computer.
3. Remove the HDMI cable from its packaging. Plug one end of the cable into the HDMI output on the right side of the computer. Plug the other end into the "HDMI IN 1" input on the back of the display monitor.

**Note: For Installations in the UK use the appropriate blades with the AC power adapter supplied with the computer and the power cord supplied in the BITS Power Supply Kit, UK (BIT-A001). Discard the Touchscreen Display Monitor Power Cord from the BITS Hardware Kit (117-00154-000 or 117-00154-001). Replace this power cord with the one supplied in the BITS Power Supply Kit, UK (BIT-A001).**

## Securing the Power Strip

**Note: For Installations in the UK use the Power Strip supplied in the BITS Power Supply Kit, UK (BIT-A001). Discard the Power Strip from the BITS Computer Kit (117-00160-001) and replace it with the Power Strip supplied in the BITS Power Supply Kit, UK (BIT-A001).**

1. Connect 2 strips of fastener together. Remove the protective cover from one side and affix it to one end of the bottom of the Power Strip.
2. Connect 2 more strips of fastener together. Remove the protective cover from one side and affix it to the other end of the bottom of the Power Strip.
3. Remove the protective covers from the other side of both fasteners and mount the Power Strip to the Mounting Platform on the back of the display stand. See Figure 10.

**Note: Secure the power strip toward the rear of the Mounting Platform.**



Figure 10: Mounted PC Power Adapter and Power Strip

## Cable Management

The wire loom, zip ties, mounting bases, and fasteners are used for cable management.

1. Measure the length needed for the specific monitor size.
2. Remove the wire loom from packaging and cut two 4-foot long sections with scissors

**Note: The length of wire loom needed will differ depending on the Monitor Display size.**

3. Using one of the wire loom pieces, open the split seam on the wire loom and insert in the HDMI Cable and Touchscreen USB Cables. See Figure 11.



Figure 11: Inserting Cables into the Wire Loom

4. Remove the protective covers from five mounting bases and attach the bases to the back of the Display Monitor. See Figure 12 for suggested attachment locations. The number of mounting bases used and the attachment position will vary depending on the Display Monitor size.
5. Feed the zip ties through the openings in the mounting bases. See Figure 13.
6. Secure the zip ties around the wire loom and tighten. See Figure 13. Cut off the excess zip tie material with scissors.
7. Create a loop with the HDMI cable, and secure it to the mounting base and tighten. Cut off the excess zip tie material with scissors

 **Caution:** Be careful when cutting the zip tie material near electrical cables.

8. With the second piece of wire loom, open the split seam on the wire loom and insert in the PC Power Cord and Touchscreen Display Monitor Power Cord. See Figure 14.

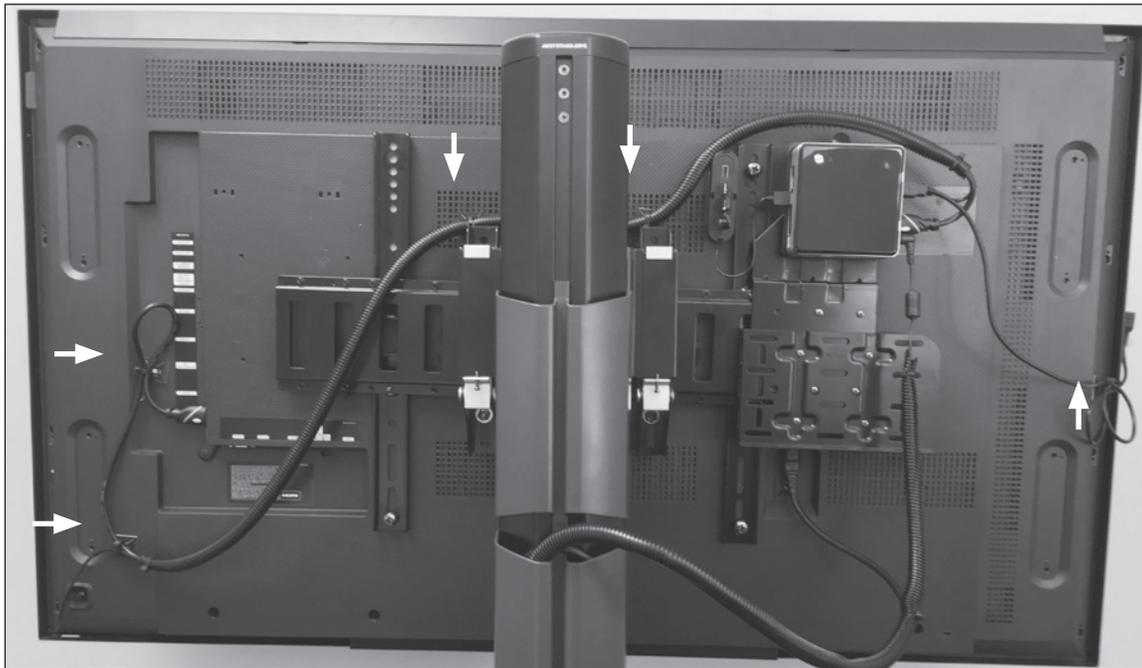


Figure 12: Mounting Bases Attachment Locations for 55" Monitor (example only)

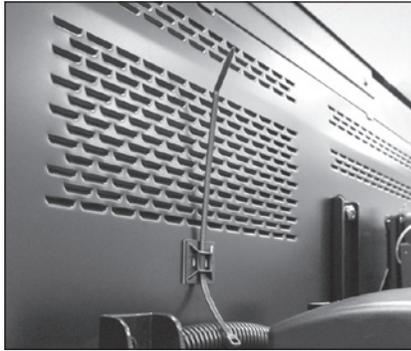


Figure 13: Feeding Zip Tie into Mounting Base (Left), Securing Zip Tie (Right)

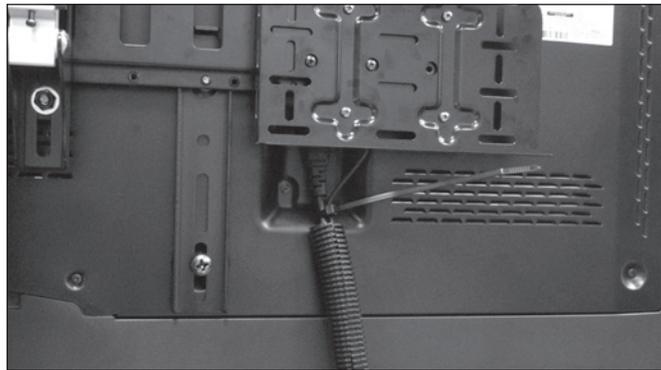


Figure 14: Inserting PC Power Cord and Display Monitor Cord (example only)

9. Carefully push the Touchscreen Display Monitor down to the lowest position on the tower of the display stand.
10. Insert the wire loom (with the PC power and Display Monitor cords) into the left side of the tower covers that are located on the back of the display stand. Start with the cover that is second to the top. Make sure to include enough slack in the wire loom to accommodate the movement of the display stand. See Figure 15. This is needed so the cables do not pull out of their connection points when the Display Monitor is in the highest position on the display stand.
11. Wind the Touchscreen Display Monitor Power Cord up the right side of the display stand tower covers and back down the left side.
12. Plug the PC power cord and Display Monitor power cord into the power strip. Set the power switch on the Power Strip to the ON position.
13. Raise and lower the position of the Display Monitor on the display stand to verify that the wire loom with cables can move freely with the monitor. If the cables cannot move freely, then adjust the length of wire loom that was inserted into the tower covers.
14. Wind the excess cable length of the PC power cord, and wrap it with the attached cable strap.

**Note: Final cable management assembly may differ depending on Display Monitor size.**

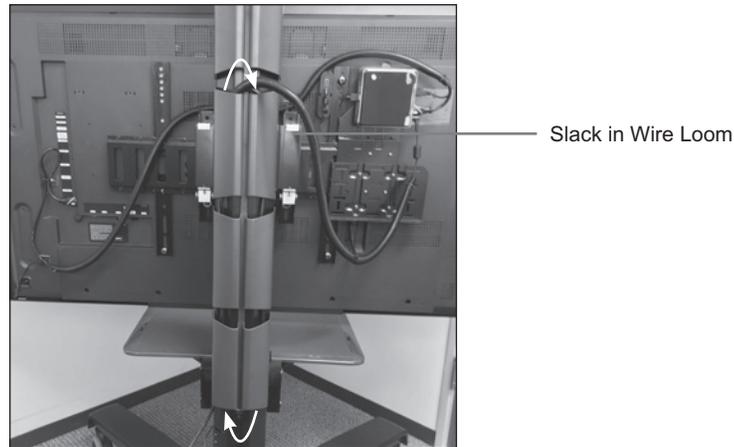


Figure 15: Wire Loom Inserted into Left Side of the Tower Covers

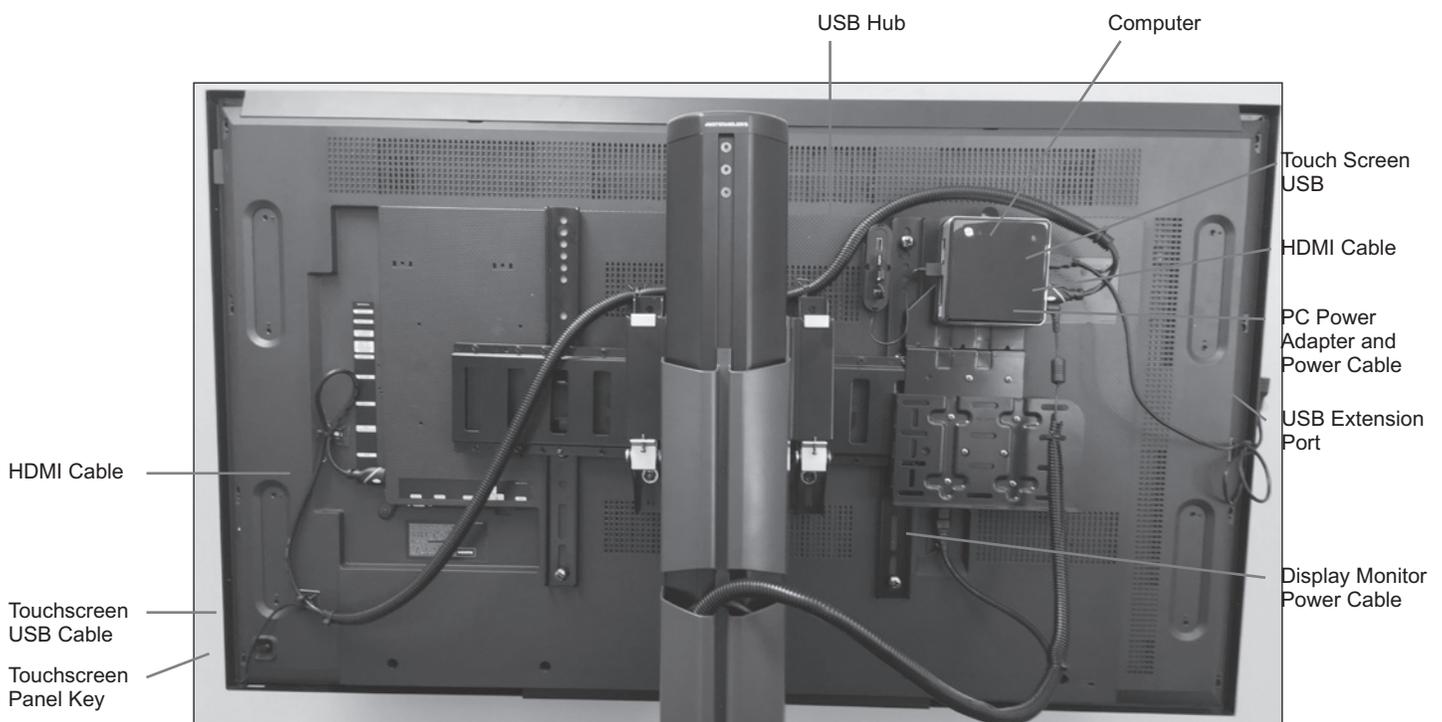


Figure 16: Example of BITS with Completed Cable Management

## Moving the BITS Display Stand

After the BITS hardware has been installed, the system will need to be moved to the location designated for therapy sessions.

### To move the portable display stand:

1. Carefully push the touchscreen display monitor down to the lowest position on the tower of the portable display stand. See Figure 17.
2. Unlock the wheel casters and point the wheels in the direction of travel.
3. Push the portable display stand from the side with both hands on the tower. See Figure 17.
4. Move the display stand to the new location and lock the wheel casters.
5. Position the Display Monitor to the desired height by pushing the bottom of the screen vertically with two hands.

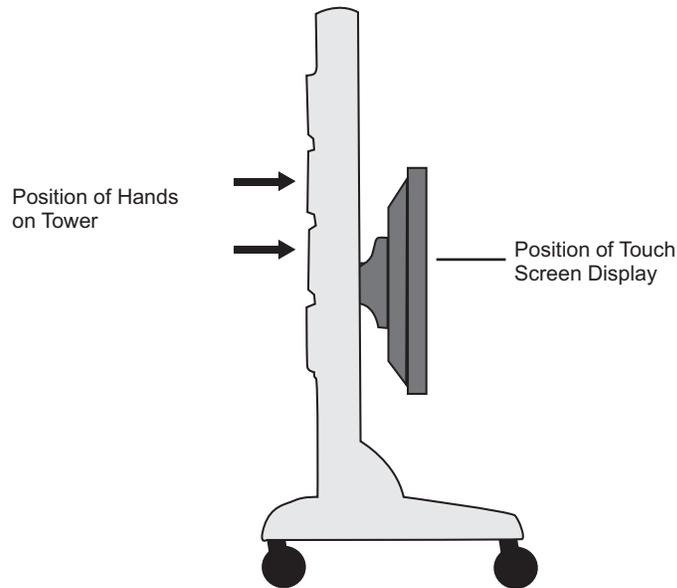


Figure 17: Correct Position for Moving Portable Display Stand

6. Plug the power cord on the Power Strip into a 3 pronged grounded wall outlet.

### Samsung Display Monitor

The Display Monitor requires the use of a Remote Control. See Table 1 below for descriptions of the commonly used buttons on the Remote Control.

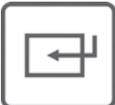
Icon	Description
	Power On: Press the Power On button to turn on the Display.
	Source: Press the source button to select the correct HDMI input.
	Menu: Press the Menu button to open the Display settings.
	Navigation: Use the Up, Down, Left and Right arrow buttons to navigate through the available options.
	Enter: Press the Enter button to make selections and confirm setting changes.
	Exit: Press the Exit button to close the Display settings.

Table 1: Remote Control Buttons

## Input Source

After plugging the Power Cord into the wall outlet, press the Power On button to turn on the Display Monitor.

1. Press the Source button on the Remote Control.
2. Use the Left and Right arrow buttons to navigate to HDMI 1 or HDMI 2.
3. Press the Enter button to confirm the setting.

## Moving the Balance Platform

 **Warning:** Make sure the Balance Platform is placed in a secured location when not in use to avoid tripping hazards.

### To move the Platform:

1. Ensure Platform feet are retracted all the way up and are not in an extended position. See Figure 18.



Figure 18: Platform feet position

2. Lift the Platform using the handles provided. See Figure 19.



Figure 19: Handles for moving the Platform

3. Place the Platform to desired location.

## Charging the Sensors

 **Warning:** Sensor should not be in use while charging.

### To charge the Sensor:

1. Plug charging block and cable provided by Bioness into a wall outlet.
2. Connect charging cable with Sensor. See Figure 20.



Figure 20: Charging the Sensor

## Turning the System On

1. Press the On/Off button on the center of the bottom edge of the Display Monitor.
2. Press the On/Off button on the computer.

**Note: The touchscreen display will enter a sleep mode and shut down when the computer is inactive. While in this sleep mode, turning on the computer will also activate the touchscreen display.**

3. Once the Display Monitor has turned on, touch the middle of the touchscreen and slide up to reveal the Windows Login Screen. See Figure 21.
4. Use the wireless keyboard or the on-screen keyboard to enter in "BITS" as the username and "bits" as the password. Press the Enter Arrow Button. See Figure 21.



Figure 21: Windows Login Screen

## Picture Settings

Users may need to adjust the Backlight, Brightness, Contrast or Sharpness of the display to accommodate patients with sensitive vision. Follow the instructions below to adjust the picture settings using the remote control. See **Table 1** for descriptions of the buttons on the remote control.

1. Press the Menu button.
2. Press the Enter button to select Picture settings.
3. Use the Up and Down buttons to navigate to the Backlight, Brightness, Contrast or Sharpness setting, and press the Enter button to select it.
4. Use the Left and Right buttons to increase or decrease the selected setting.
5. Press Enter to confirm the setting changes.
6. Press Exit to close the display Menu.

## Calibrating the Touch Screen Display

1. Access the Windows 10 Start Screen by pressing the Start button in the lower-left corner of the screen.
2. Click on the tile for the folder called, "PulseIRUtility\_1.0.1.8\_"
3. A File Explorer window will open. Open the file called, "Pulse IRController.exe"
4. The User Account Control pop up window will display. Press the "Yes" Button to proceed.
5. The PulseIRController window will appear. Touch the Reset Button.
6. Confirm that the Parameter Settings shown on the PulseIRController window are the following:
  - Touch ON/OFF: On
  - Touch Mode: Stylus
  - Mouse R-Click: Long Down
  - Touch Action: Drawing
  - Rotation: 0
7. Once the settings have been confirmed, touch the Apply Button. See Figure 22.

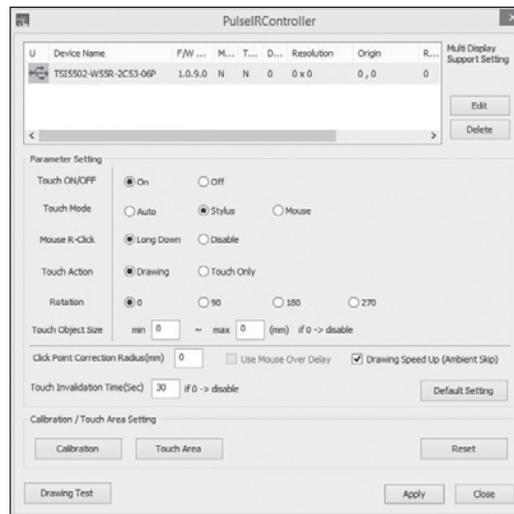


Figure 22: PulseIRController Window

8. A pop up window will appear stating, "Complete!" Touch the OK Button.
9. To calibrate the touch area, press the Calibration Button on the PulseIRController Window. See Figure 19. The calibration screen will display. See Figure 22.
10. Position your body in the center of the Display Monitor and press the center of each consecutive target. Targets will appear in the top left, top right, and bottom left corners of the touchscreen. Once all targets have been accurately touched, the user will need to press the OK Button.
11. The display screen will go back to the PulseIRController Window. Touch the Apply Button.
12. A pop up window will appear stating, "Complete!" Touch the OK Button.
13. To verify that the calibration was completed accurately, drag the tip of a finger across the desktop and confirm that the cursor tracks with finger movement.

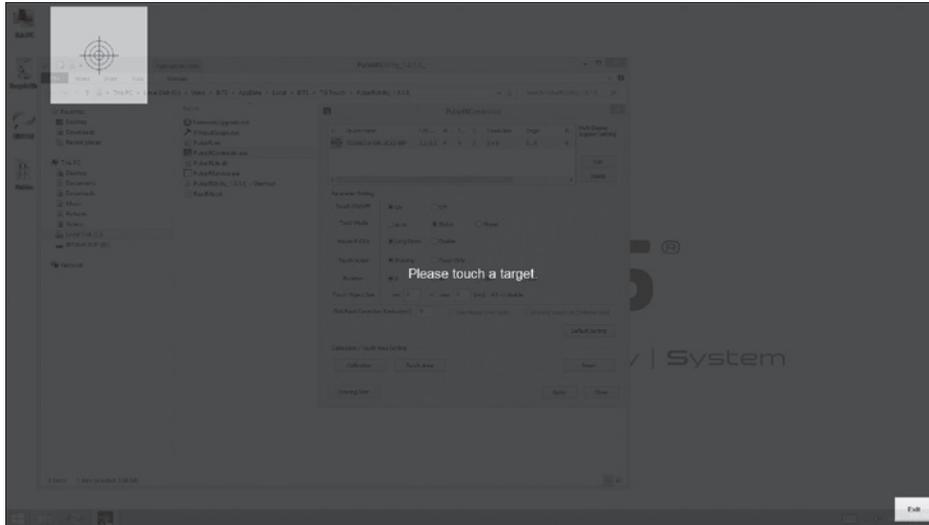


Figure 23: Calibration Screen

## Date and Time Settings

The computer date, time, and time zone settings will need to be verified.

1. From the Windows Settings menu, select the Time & Language settings icon. See Figure 24.

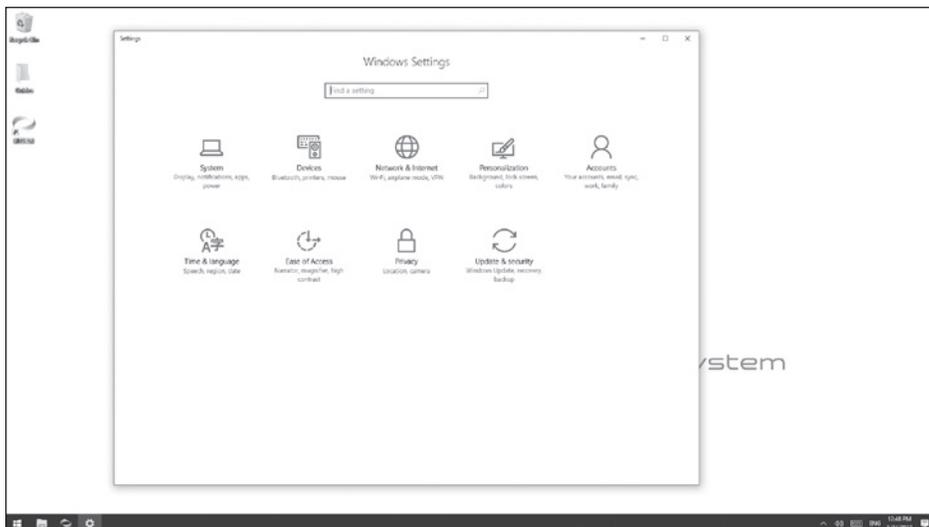


Figure 24: Windows Settings Menu

2. Select the appropriate time zone from the drop down menu. See Figure 25.
3. Verify that the time and date is correct, and press the Change Date and Time Button to adjust the date and time manually if needed.

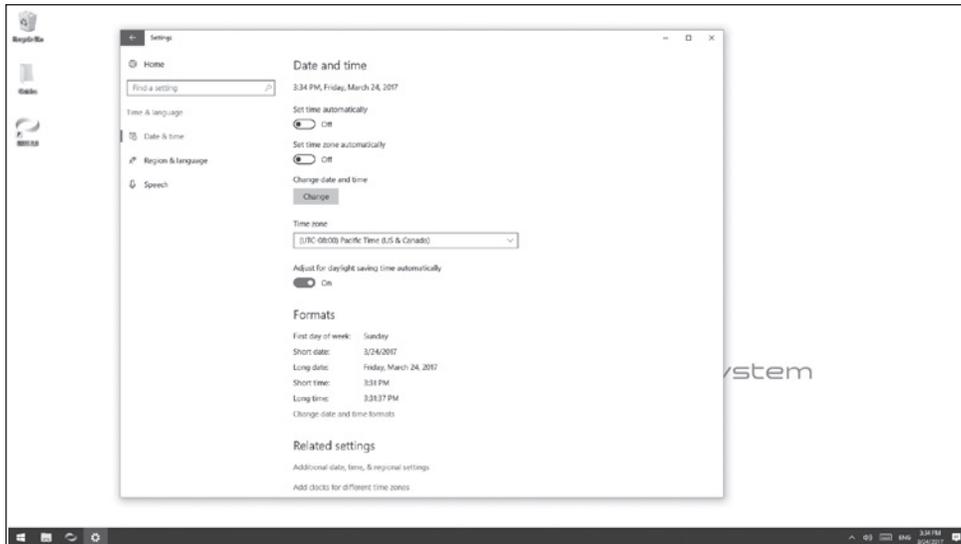


Figure 25: Date and Time Settings Menu

## Printer Setup

Only USB connected printers should be connected to the BITS PC.

1. Follow the setup instructions specific to the printer being attached to the BITS PC.
2. Upload the necessary printer drivers onto a USB memory device
3. Connect the USB printer cable to the empty USB port on the USB hub.
4. Insert the USB memory device into the USB Extension Cable, and install the necessary printer drivers onto the BITS Computer.

**Note: Connecting the BITS PC to the Internet will void the warranty.**

## Testing the BITS Software

You will need to log into BITS software application to confirm that it is running.

1. Press the BITS Icon located on the desktop. See Figure 26.



Figure 26: BITS Icon on Desktop

- The BITS Login Screen will open. To open the on-screen keyboard, press the Keyboard Icon located at the bottom right of the screen. See Figure 27.

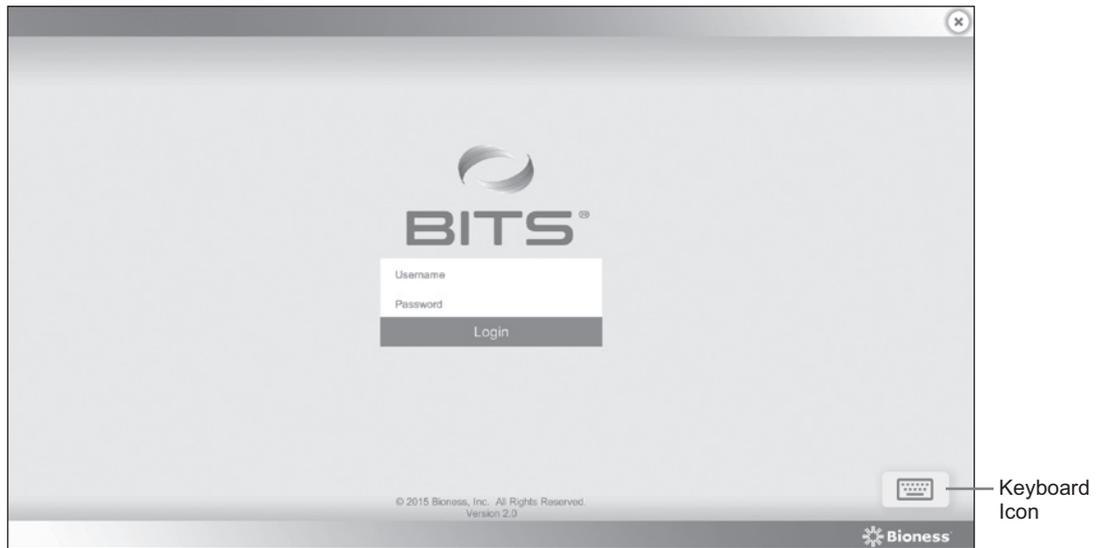


Figure 27: BITS Login Screen

- Use the keyboard to enter "admin" as the username and "BITS" as the password.
- Press the Login Button to complete the login process.
- The Home Screen will open. See Figure 28.

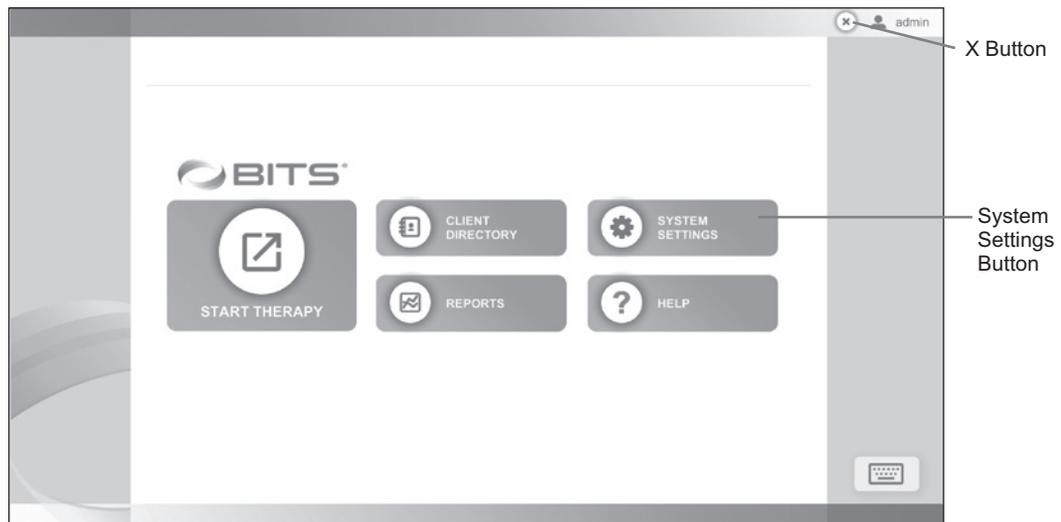


Figure 28: Home Screen

## Changing the Administrator Profile Password

For security purposes, it is recommended that the default Administrator Profile Password be changed before adding Client Profiles or entering patient data into the BITS System.

1. From the Home Screen, press the System Settings Button. See Figure 28.
2. From the System Settings Screen, select the admin account from the User List by pressing the row.
3. The User Detail Screen will open. See Figure 29.
4. Enter a new User Name, First Name, Last Name, and Clinical Credentials into the text fields.
5. Press the Change Password Button. See Figure 29.



Figure 29: User Detail Screen (Left), Change Password Pop Up Window (Right)

6. The Change Password pop up window will open. Enter a new password, confirm the password, and Press the Done Button. Figure 29.
7. Give the revised password to the administrator.

## Activating BITS Balance

Refer to BITS Balance Activation Guide included with the BITS Balance Accessory Kit.

## Changing the Language Preference Settings

The default language setting for BITS is English (US). Please note that if BITS Balance is activated, language settings will no longer be available.

1. Navigate to the System Settings Screen.
2. Click on the Global Language Preference field. See Figure 30.

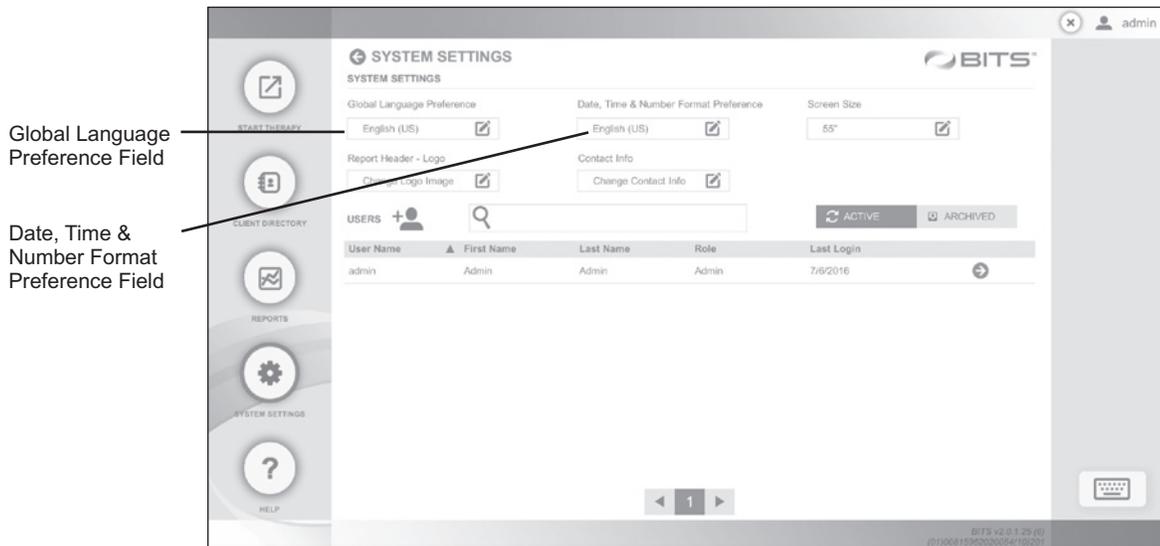


Figure 30: Change the Language Settings from the System Settings Screen

3. Select the desired language, and press the Done Button. See Figure 31.



Figure 31: Select the Desired Language

4. Click on the Date, Time & Number Format Preference field. See Figure 30.
5. Select the desired language and press the Done Button. See Figure 32.

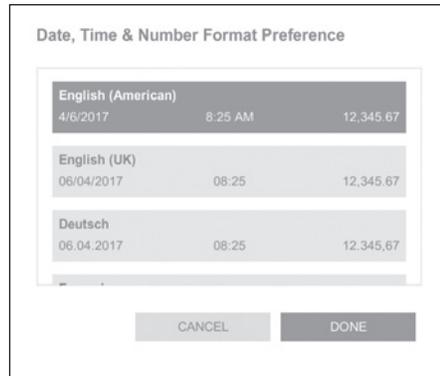


Figure 32: Select the Desired Language for Date & Time Format

6. From the Windows Settings menu, select the Time & Language settings icon. See Figure 33.

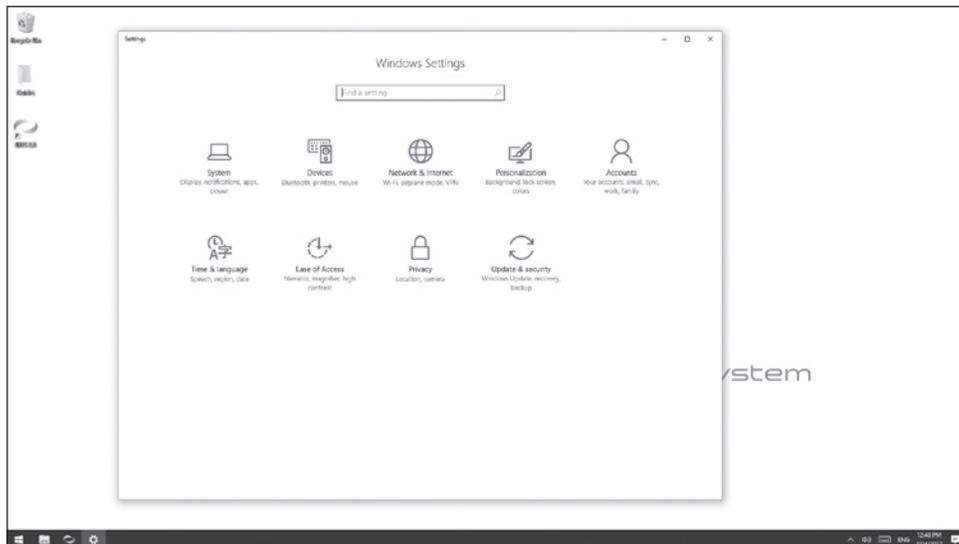


Figure 33: Windows Settings Menu

7. From the Region & Language menu, select the appropriate language and press Set as default. See Figure 34.

8. Restart Windows for the change to the Windows Display Language to take effect.

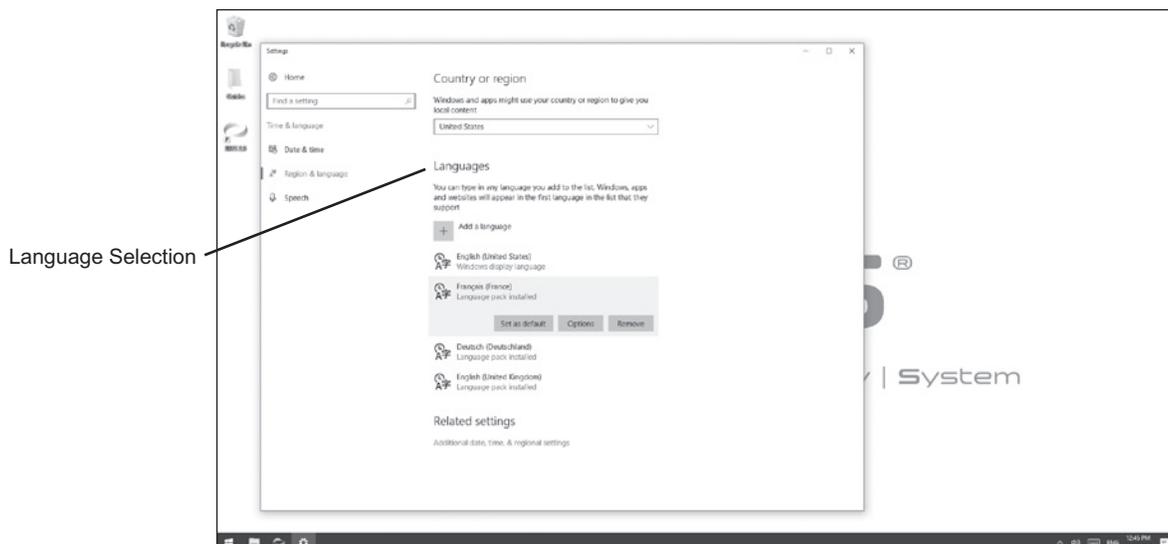


Figure 34: Region & Language Settings Menu

## Log Out and Exit

To log out of the BITS software application, press the "X" Button. The "X" Button is located in the upper right corner of the display screen in the BITS software, see Figure 26. Pressing the Logout Button will bring the user back to the Login Screen.

To exit the BITS software application, press the "X" Button located in the upper right corner of the Login Screen. The display screen will return to the operating system's desktop.

The installation process for the Bioness Integrated Therapy System is now complete.

## Technical Specifications

### 55" Display Technical Specifications

Stand Specifications	
Lift Range	20" (50.8cm)
Tilt Range	20 degrees
Display Rotation	90 degrees
Mobility	Four (4) low friction casters, Two (2) lockable
Keyboard Shelf	Supplied
Cord Management	Supplied
Shipping Dimension	66" (167.6cm) (l) x 20" (50.8cm) (h) x 14" (35.6 cm) (d)
Shipping Weight	122 lbs. (55kg)
Assembly	Pre-Assembled

Computer Specifications	
Operating System	Windows 10
Type	Intel NUC®
USB Ports	Four (4) with expansion hub
Keyboard	Wireless Bluetooth with integrated mouse

Display Specifications	
Touchscreen	Integrated 5-point touchscreen
Size	55" (139.7cm)
Calibration	Recommended upon initial set-up
Material	Glass with aluminum border
Cleaning	Use the provided Touchscreen Cleaning Kit, or, non-abrasive disinfectant (alcohol & ammonia free) followed by glass cleaner on a soft cloth

## Motion Sensor Technical Specifications

Motion Sensor Specifications	
Dimensions	Length 57.404 mm (2.26 in.), Width 37.084 mm (1.46 in.), Height 11.5 mm (0.45 in)
Weight	28 grams (0.704 oz.)
Service Life	2 years
Charging	USB-C charging port
Classification	Type BF applied part
Operating Voltage	Rechargeable Lithium Polymer 3.7 volt battery, 310 mAh capacity
Connection	Wireless, Bluetooth Low Energy 5.0 (BLE)
Cleaning	Ensure Sensor is powered off. Using a low-level disinfecting wipe, wipe the outside of the Sensor. Do not allow liquid to enter the charging port.
BLE Communication	2.4 GHz
Wireless Link Specification	Bluetooth Low Energy (BLE) Transmission Power: Complies with FCC 15.249 (for U.S.)
Environmental Conditions	Transport & Storage Temperature: -20°C (-4°F) to 55°C (+131°F) Operating Temperature: 5°C (41°F) to 55°C (+131°F) Relative Humidity: 25% to 85% Atmospheric Pressure: 50 kPa to 106 kPa Protection Against Ingress of Water: IP68 per IEC 60529
Conformity Certification	The BITS Sensor complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: 1. This device may not cause harmful interference, and 2. This device must accept any interference received, including interference that may cause undesired operation

## Radio Communication Information

Several components of the Bioness Integrated Therapy System use radio communication. They have been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 (Radio Frequency Devices) of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in an environment. This equipment generates, uses, and can radiate radio frequency energy. If not used as instructed, this equipment may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular environment. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the clinician is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna
- Move the equipment farther from the receiver.
- Consult the manufacture, dealer, or an experience radio/television technician for assistance.



## Radio Equipment Directive (RED) Declaration of Conformity Statement

Hereby, Bioness, Inc. declares that the radio equipment is in compliance with Directive 2014/53/EU. This product operates at 2402-2480 MHz with the maximum RF output power not to exceed 4dBm.

## Electromagnetic Emissions

The Bioness Integrated Therapy System is medical electrical equipment and applicable components were tested for electromagnetic compatibility (EMC) in accordance with International Electrotechnical Committee (IEC) 60601-1-2. The Bioness Integrated Therapy System should be configured and used in accordance with the instructions provided in this guide.

## Chest Strap Technical Specifications

Chest Strap Specifications	
Sizes	XSmall – Small   20 to 33 in. (50.0 - 83.8cm) Medium – XLarge   28 to 52 in. (71.1 - 132.1cm) XXLarge – XXXLarge   42 to 77 in. (106.7 - 195.6cm)
Material	65% Polyamide, 35% Spandex
Environmental Conditions	Transport & Storage Temperature: -20°C (-4°F) to 55°C (+131°F) Operating Temperature: 5°C (41°F) to 55°C (+131°F) Relative Humidity: 25% to 85% Atmospheric Pressure: 50 kPa to 106 kPa Protection Against Ingress of Water: IP68 per IEC 60529
Cleaning	Spray the straps with Clorox® Hydrogen Peroxide Disinfecting Cleaner. Wipe the straps thoroughly with a cloth to clean and remove any remaining residue of the solution.

## Balance Platform Technical Specifications

Balance Platform Specifications	
Dimensions	24" (61cm) x 24" (61cm) x 6.125" (15.6cm)
Tilt Range	5°-20° range (Range limiting feet can extend and have three settings: 2.5" (6.3cm) (not extended), 3.25" (8.3cm) (medium extension) and 4" (10.2cm) (fully extended))
Weight	30 lbs. (13.6kg)
Material	Aluminum plate, rubber bladder filled with foam
Environmental Conditions	Transport and Storage Temperature: -20°C (-4°F) to +60°C (+140°F) Operational Temperature: +5°C (+41°F) to +60°C (+140°F) Relative humidity: 25% to 85% Atmospheric Pressure: 50 kPa to 106 kPa
Cleaning	Wipe down the top plate with water on a cloth or towel.

## Patch Technical Specifications

Patch Specifications	
Size	1.6 in <sup>2</sup> (10.3 cm <sup>2</sup> ) per patch
Material	Hydrogel, polyethylene foam
Environmental Conditions	Transport and Storage Temperature: +5°C (+41°F) to +27°C (+81°F) Operational Temperature: +15°C (+59°F) to +40°C (+104°F) Relative humidity: 25% to 85% Atmospheric Pressure: 50 kPa to 106 kPa
Cleaning	Single Use Only

## Software Specifications

Software Specifications	
Indications for Use	The Bioness Integrated Therapy System (BITS) is intended to challenge and assess the visual, auditory, cognitive, motor, and balance abilities of individuals, including those with deficits resulting from traumatic injuries and movement disorders as well as competitive athletes. Examples of these abilities include: <ul style="list-style-type: none"> <li>• Visuomotor Coordination</li> <li>• Reaction Time</li> <li>• Visuospatial Perception</li> <li>• Visual &amp; Auditory Processing</li> <li>• Working Memory</li> <li>• Physical &amp; Cognitive Endurance</li> <li>• Balance Control</li> <li>• Postural Stability</li> </ul>
Encrypted	The database file uses AES-256 Encryption
Privileges	Admin and user log-in privileges

The system consists of mechanical and electronic components. Inadequate handling of those components may cause health hazards. Disposal of the system must comply with local regulations.

## Product Code Testing Summary

- Expected or observed adverse events and/or complications: None Known
- Performance measurements do not apply to BITS Balance
- Repeatability of measurements are not applicable to BITS Balance
- Construct validity does not apply to BITS Balance