

BIODEX VIBROTACTILE SYSTEM

For use with the Balance System SD and BioSway (Win CE versions)

INSTALLATION AND OPERATING MANUAL

950-430



BIODEX

Biodex Medical Systems, Inc.

20 Ramsey Road, Shirley, New York, 11967-4704, Tel: 800-224-6339 (Int'l 631-924-9000), Fax: 631-924-9338, Email: info@biodex.com, www.biodex.com

This manual contains operating procedures for the following Biodex products:



- 950-430 VibroTactile System, 115 VAC
- 940-440 Balance System SD, 12.1" Display, 115 VAC
- 950-460 BioSway 12.1" LCD with Tabletop Stand and Case, 115V/230V 50/60V
- 950-461 BioSway 12.1" LCD with Tabletop Stand, 115V/230V 50/60V



Contact Information

Biodex Medical Systems, Inc.
20 Ramsey Road, Shirley, New York, 11967-4704
Tel: 800-224-6339 (Int'l 631-924-9000)
Fax: 631-924-8355
email: supportservices@biodex.com
www.biodex.com

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1. Overview

Vibrotactile Feedback

Biodex has incorporated vibrotactile feedback into our balance products. Vibrotactile feedback—or “cueing”, as it may be thought of in this application—adds a new element to postural sway biofeedback. Vibrotactile cueing incorporates a position triggered, localized vibrating sensation that provides patients with additional sensory enrichment to therapy tasks.

Therapists commonly emphasize their verbal cues to patients by gently tapping them as well. Tapping contact can be arbitrary and not reproducible. With vibrotactile cueing, vibrations are activated on various parts of a belt worn by the patient; these vibrations can be either positively reinforcing or negatively reinforcing, based on the positional feedback.

Real-time biofeedback about one’s performance is an important aid for rehabilitation. Feedback can be based on visual, audio and/or tactile inputs. Tactile feedback is unique in that it directly engages the motor learning system. In balance training, to really focus on the vestibular system, one’s visual system input needs to be temporarily eliminated. When patients close their eyes during a balance training session, the Biodex VibroTactile System provides biofeedback in the form of a “buzz” or vibration-cued signal.

The origin for this technology is in the military, where it was used to enhance spatial awareness for jet pilots. (Sensors embedded into flight suits activate when disoriented pilots steer their aircraft towards the ground.) Since then, the technology has been adapted to balance rehabilitation training practices with excellent results. There are several published papers supporting the technology, application and benefits. Please see the last section of this document for more information on these studies.

2. Installation

Software Download and Installation

If you purchased your Biodex balance device in late 2015, the VibroTactile System functionality will be part of the device's software—you just have to activate it (see below). If you have an earlier model, you can download the updated software with the VibroTactile System functionality from the Biodex website.

On the Updates page, find the link for the most recent release of either the Balance System SD or BioSway software, which will have a version number of 3.04 or higher:

<http://biodex.com/physical-medicine/products/software-updates>

Save the software .exe file on the root directory of a USB flash drive, and then place the USB flash drive into one of the USB ports on your Balance System SD or BioSway display.



Figure 2.1 Save the TactileBelt software file within the root directory of a USB flash drive.

Once the USB flash drive has been inserted into the USB port, your device should automatically recognize the software file and ask you if you want to install it. Follow the on-screen prompts to install the software on the device.

Once the VibroTactile System software is installed, you need to enable the vibrotactile functionality on your device. From the Main Screen of the interface, choose the <Utilities> button, followed by the <Configuration> button. Then touch the <VT> button, which acts as an on/off toggle.

NOTE: The “VT” button (Fig 2.2) will be a light blue when it is toggled ON and a dark blue when toggled OFF.

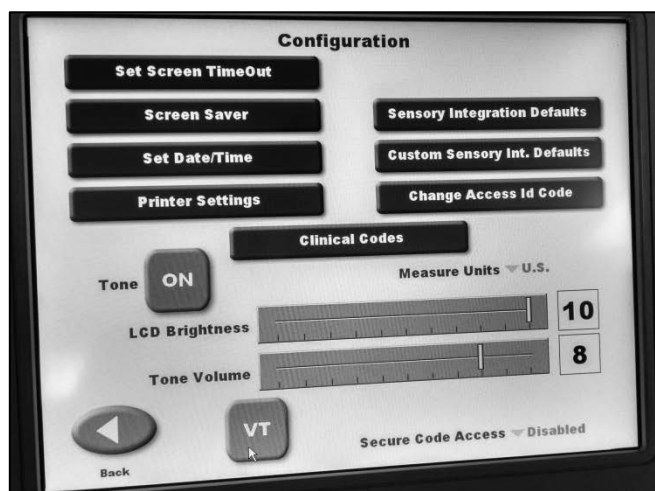


Figure 2.2 The “VT” button acts as a toggle switch for the device’s vibrotactile functionality. When the button is light blue—as shown here—the vibrotactile functionality is activated.

Installing the LinkBox

The LinkBox mechanism is attached to the back of your device’s display with a fastener strip. The LinkBox provides for a wireless link between the TactileBelt on the patient’s waist and the biofeedback seen on the display.

To install the LinkBox, peel off the protective coverings on both parts of the fastener strip, and position it on back of the display as shown in Figure 2.3. There are two cables: a serial communication cable and a short USB cable (for power). Once connected, a blue light will come on indicating the LinkBox is powered.

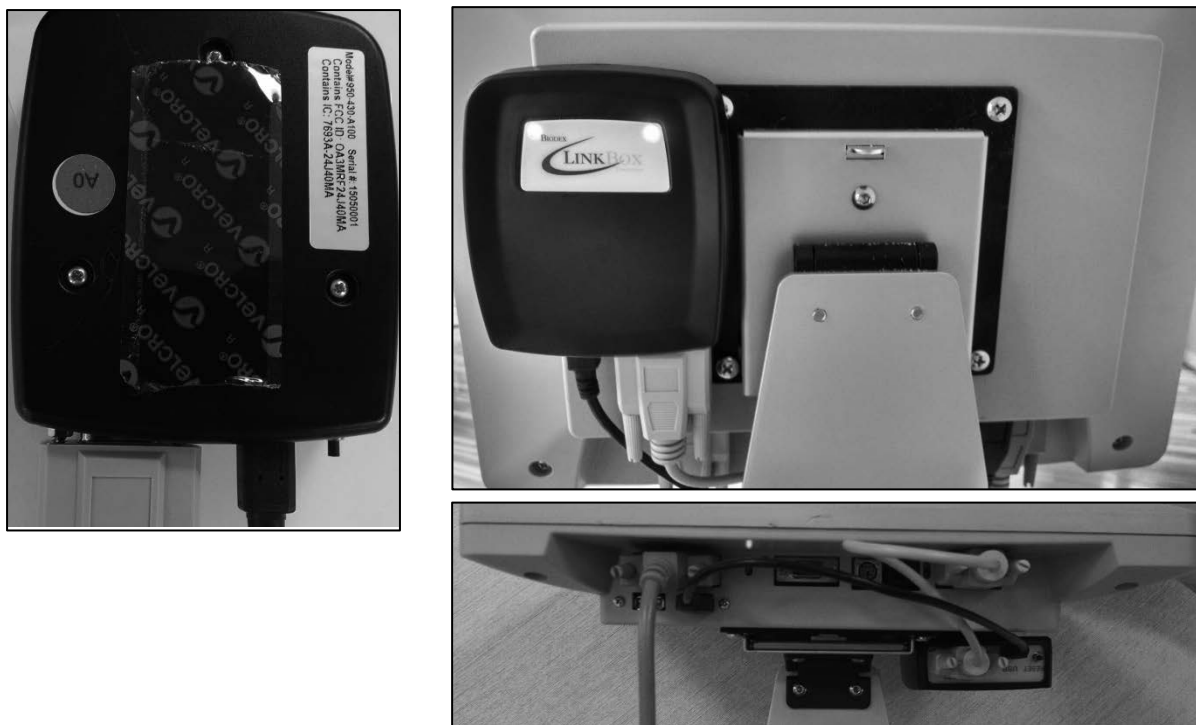


Figure 2.3 Installing the LinkBox to the back of the display.

Connecting and Applying the TactileBelt

Two belts are provided, sized 28"-36" (71-91 cm) and 36"-48" (91-122 cm). Select for best fit. The TactileBelt Receiver boxes are the same for both and can be interchanged if needed.

Use the short cable to connect the TactileBelt Receiver box to the connector on the TactileBelt.

NOTE: Be sure to charge the batteries in the TactileBelt Receiver boxes for a minimum of 8 hours before use.



Figure 2.4 Attaching the TactileBelt Receiver box to the belt.

Clip the TactileBelt Receiver box to the belt fabric. Place the belt around the patient's waist, arranging it so the red arrow points up and aligns with the patient's navel.

Press the LINK button to wirelessly connect with the LinkBox. RESET can be used to re-establish communication with LinkBox should the connection be lost.



Figure 2.5 Align the red arrow on the TactileBelt with the patient's navel.

3. Battery and Wireless Connection Status

LED Indicator Lights

The LinkBox is powered by the USB connection to the balance device's display. The TactileBelt Receiver boxes have rechargeable batteries. The batteries should provide more than enough service for a full day of clinical usage.

There are two LED indicator lights on the TactileBelt Receiver boxes. The light on the left is for the battery status. The light on the right is for USB power.

The battery indicator shows various states:

- Solid Green: Battery charged half capacity or greater, trickle or not charging
- Solid Orange: Battery charge less than half but not critical, not charging
- Solid Red: Battery charge is critically low, not charging
- Slow Blink Green: Battery charged half capacity or greater, actively charging
- Slow Blink Orange: Battery charge less than half but not critical, actively charging
- Slow Blink Red: Battery charge is critically low, actively charging
- Fast Blink Red: Temperature out of range (0-40C, 32-104F)
- Fast Blink Orange: Initializing (one second only)

USB power status:

- Solid Blue: USB port powered
- Dark: USB port not powered

LinkBox Indicators (see Fig. 2.3):

LED on Left:

Solid Blue: Receiver Board is/was connected

Slow Blink Blue: Building wireless network (searching)

LED on Right

Solid Blue: Active communications to application software

Dark: No communications to application software

NOTE: When connecting a TactileBelt Receiver box you may see the connection status light alternating from green to red, but the screen does not display a channel selection. If the belt has been idle for some time, it is "sleeping" and will not immediately connect. By clicking the RESET button the belt receiver "wakes up" and should connect correctly.



Figure 3.1 TactileBelt Receiver box LED indicators.

Charging / Power Options for TactileBelt Receiver Boxes

There are two ways to charge the TactileBelt Receiver boxes:

- 1.) Wall outlet charger (for quickest charge)
- 2.) USB connection to display



Figure 3.2 TactileBelt Receiver boxes can be charged with a connection to a wall outlet or to the display on the device.

On-Screen Indicators

The wireless reception and battery symbols on the upper left corner of the display indicate TactileBelt/LinkBox communication and TactileBelt battery status.



Figure 3.3 On-screen indicator showing wireless connection and approximately 75% battery life.

NOTE: Be sure to charge the batteries in the TactileBelt Receiver boxes for a minimum of 8 hours before use.

4. Coordinating LinkBoxes and TactileBelt Boxes

Configuring Equipment in Facilities with One VibroTactile System

Your Biodex VibroTactile System comes with one LinkBox and two TactileBelt belts and Receiver boxes. The LinkBox will be labeled with a sticker denoting “A0”, and the two TactileBelt Receiver boxes will be labeled “A1” and “A2”.

The TactileBelt Receiver boxes will “time out” and power down after 2 minutes of non-usage. If both are active, however, you will have to select which one the LinkBox should communicate with.

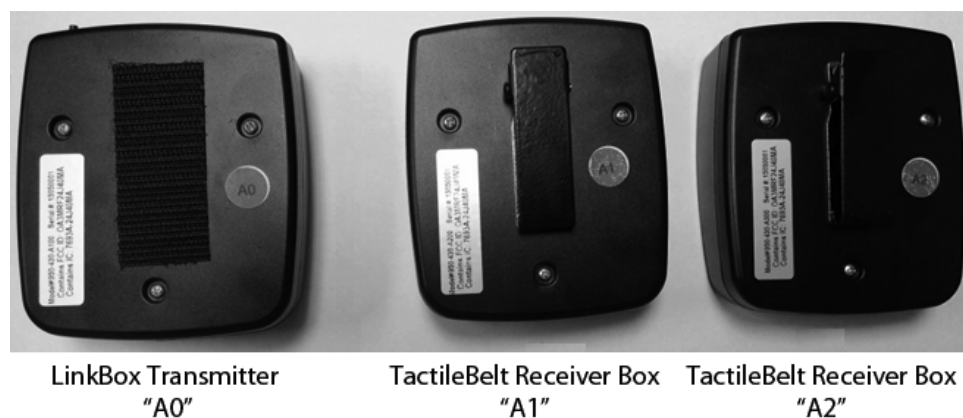


Figure 4.1 The VibroTactile System will come shipped with labels denoting “A0” for the LinkBox and “A1” and “A2” for the TactileBelt Receiver boxes.

On the screen shown below, the wireless/battery symbol denotes that no TactileBelt is communicating with the LinkBox. Touch the wireless/battery symbol once to configure TactileBelt A1 or A2. In this example, we will proceed with configuring A1.



Figure 4.2 The wireless/battery symbol is in the upper left corner.

Select TactileBelt Receiver (Box) A1.

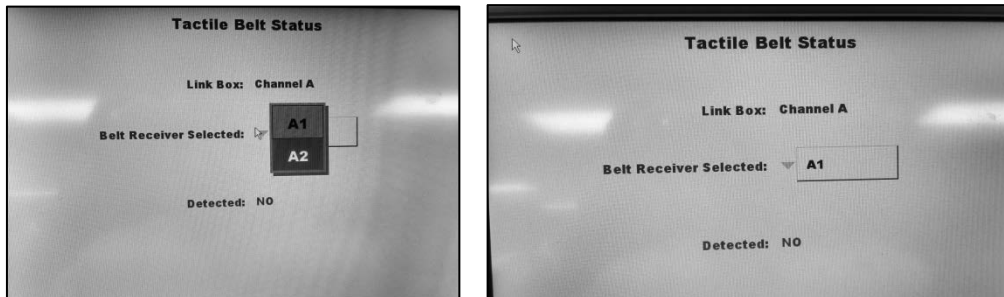


Figure 4.3 Use the dropdown menu to select a TactileBelt Receiver box.

Check the label to ensure that you are holding TactileBelt Receiver box A1, and then press the LINK button on that box. The A0 LinkBox should detect and connect with the A1 TactileBelt Receiver box.

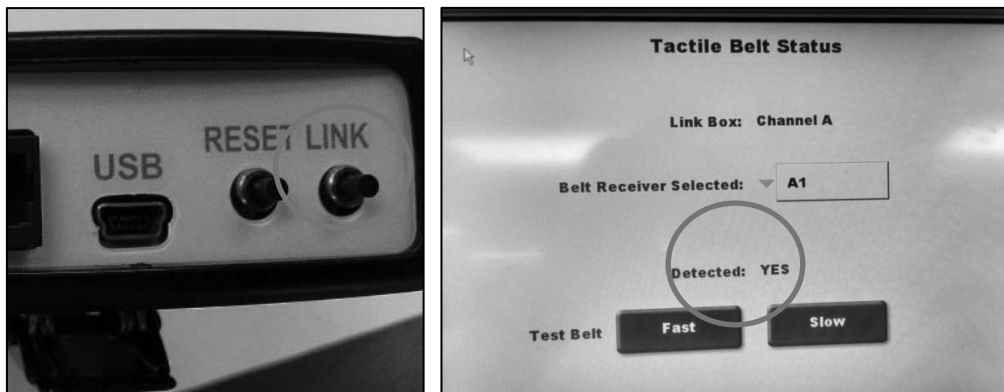


Figure 4.4 Press the LINK button to wireless connect the TactileBelt Receiver box.

Once the TactileBelt box has been detected, you should perform a quick test. In a test, each tactor along the belt will vibrate. In addition to testing the tactors, this allows for the user to experience what the vibrotactile sensation feels like.

NOTE: Even if you do not need to configure your LinkBox and TactileBelt Receiver boxes, you can still perform a tactor test by touching the wireless/battery symbol on the main testing/training screen (Fig 4.2).

For a tactor test, select <Fast> or <Slow>. In the “Fast” test, each tactor will vibrate for a ½ second. In the “Slow” test, tactors will vibrate for 1 second.

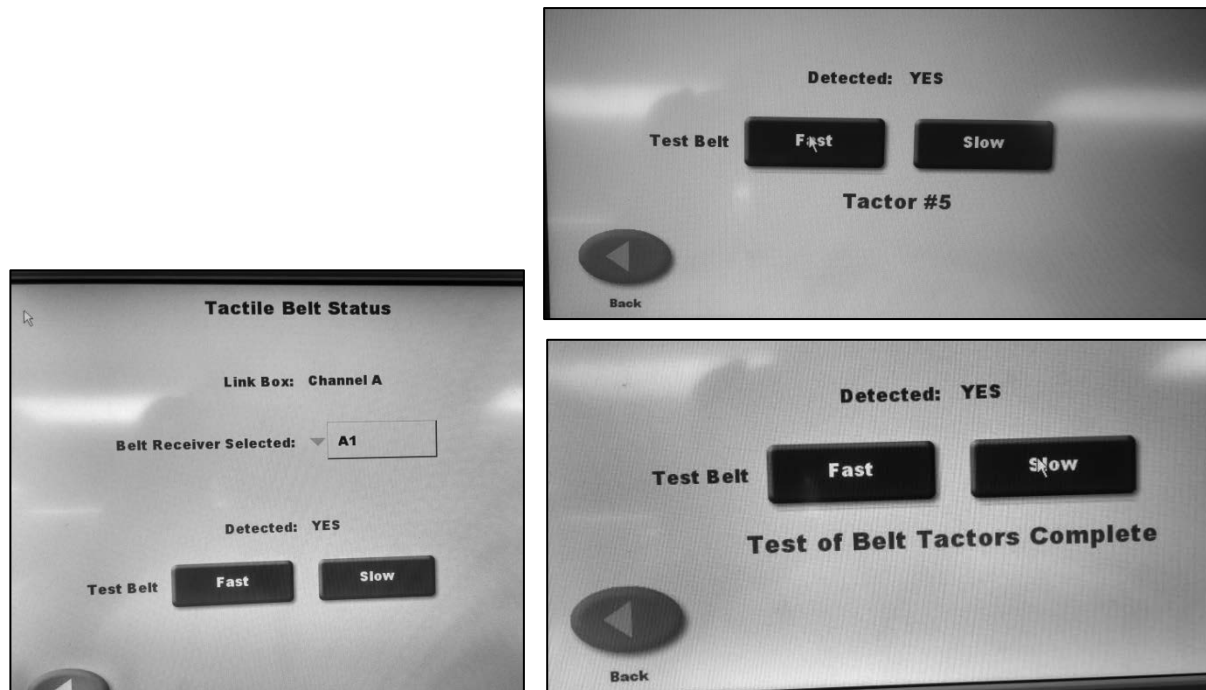


Figure 4.5 Testing the tactors in the TactileBelt.

When finished, a screen will appear noting that test is complete. There is no error message if a tactor did not vibrate. If a tactor is not vibrating during this test, something is not working correctly. Try performing the configuration steps again. If there is still a problem, contact Biodex customer service.

Press the <Back> button to return to the main testing/training screen. You will now note that the wireless/battery symbol shows wireless connectivity, battery life, and the specific TactileBelt box that the LinkBox is communicating with. (In this case, TactileBelt Receiver box A1.)



Figure 4.6 A Postural Stability Training screen, showing wireless connectivity and battery life of TactileBelt A1.

Configuring Equipment in Facilities with Multiple VibroTactile Systems

If your facility has purchased more than one VibroTactile System, you will need to take some steps to ensure that the various LinkBoxes and TactileBelt boxes do not interfere with each other.

The process for configuring two VibroTactile Systems to work in the same facility consists broadly of two major steps: 1) Configuring a VibroTactile System set (one LinkBox and two TactileBelt boxes), and then, 2) Configuring those boxes on the balance device itself.

Step 1: Configuring VibroTactile System Components on Your Windows 7 or 8 Computer

Begin by downloading the Vibrotactile Configuration Utility from the Biodex Software update web page:

<http://www.biodex.com/physical-medicine/products/software-updates>

Follow the prompts to install the software on your Windows 7 or 8 computer.

After you have launched the software, connect the LinkBox you wish to reconfigure to your computer with a USB cable. Once connected, the connection status indicator in the lower right of the Vibrotactile Configuration Utility screen will turn green.

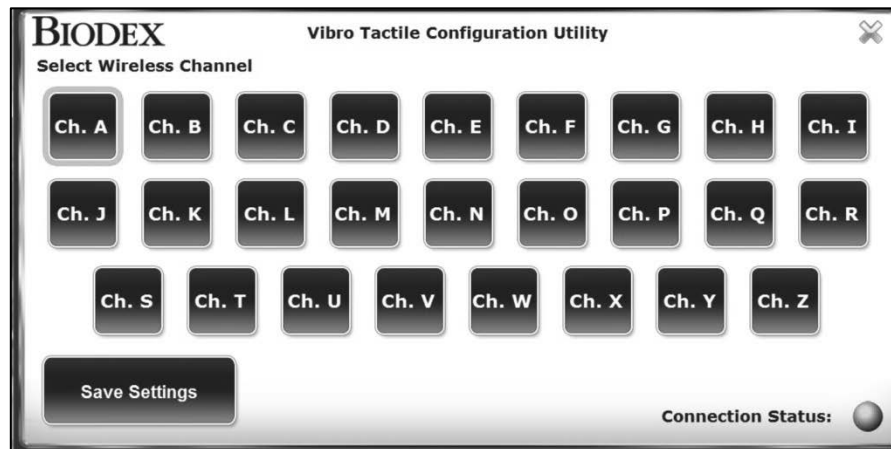


Figure 4.7 Vibrotactile Configuration Utility main screen.

Select a Wireless Channel other than “A”—for this example, assume <Ch. B> is selected. Press <Save Settings>. A message will appear indicating that the LinkBox is being updated.



The LinkBox has now been designated “B0”. Disconnect the LinkBox, and connect one of the TactileBelt boxes. Press either the RESET or LINK button to activate the box. (This will allow your computer to “recognize” the device.) Repeat the previous steps, ensuring that you also select <Ch. B> for both of the TactileBelt boxes, making them “B1” and “B2”.

After all three components have been configured with the Channel B setting, it may be helpful to replace the “A” sticker labels on each of the boxes with the “B” stickers. The sticker sheet shown below should be included in the box that your VibroTactile System was shipped in.

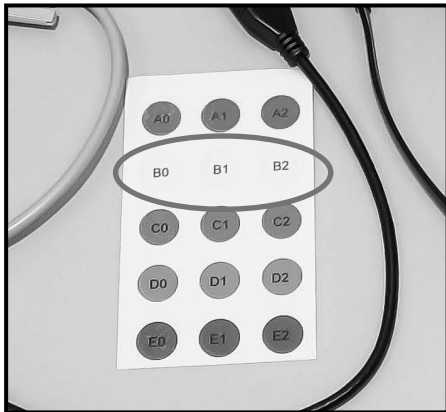


Figure 4.8 LinkBox / TactileBelt box sticker labels.

Step 2: Coordinating the reconfigured LinkBox and TactileBelt boxes on your Biodex balance device

Once the three VibroTactile System components (LinkBox and two TactileBelt boxes) have been reconfigured to the new wireless channel—in this case, Channel B—follow the steps outlined in the previous section (“Configuring Equipment in Facilities with One VibroTactile System”) for coordinating the boxes.

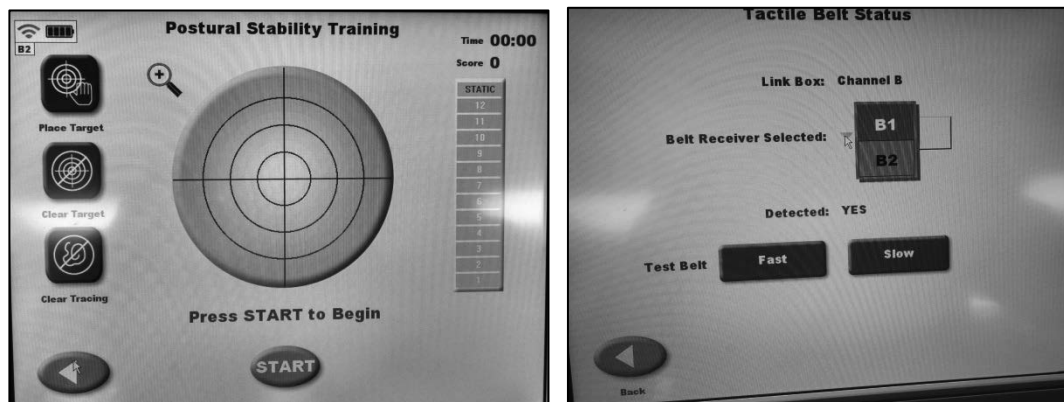


Figure 4.9 Coordinating the reconfigured LinkBox and TactileBelt boxes.

5. Clinical Applications

The Biodex VibroTactile System provides augmented feedback and cueing during balance training when the patient is performing either eyes-open or eyes-closed exercises.

Vibrotactile feedback can be used as an indicator of positive reinforcement to affirm positional control. It can also indicate negative outcomes in instances where positional control is not achieved.

Therapists should not limit themselves to the set of clinical applications and training exercises listed below.

Postural Stability Training

If targets are set, the TactileBelt factors will vibrate when the target is hit. Location of target will determine which factor vibrates. (A target at “3:00” on the screen will activate a factor on the patient’s right hip, for example.)

When the therapist touches one of the concentric circles, it will become a “boundary” for the patient to stay within. As the patient moves the cursor over the screen, the factor corresponding with boundary crossing will vibrate.

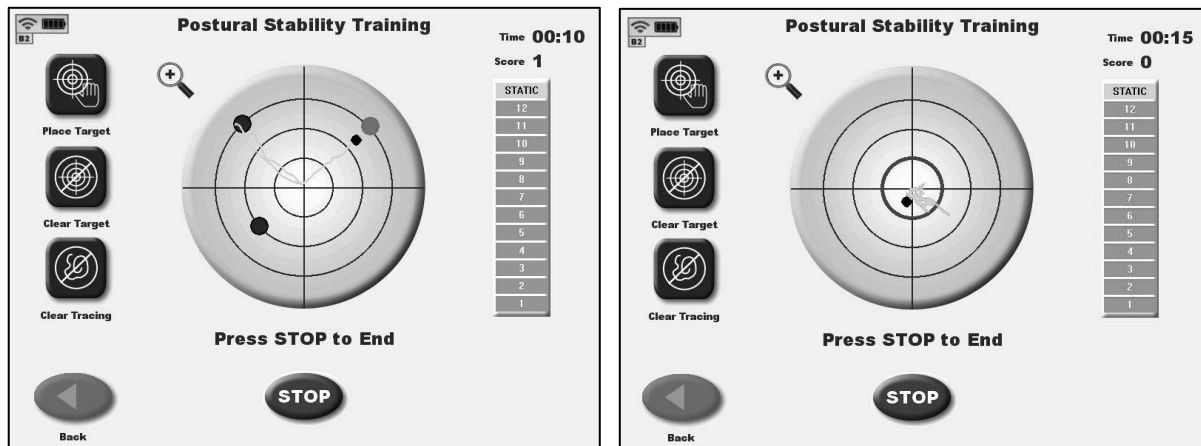


Figure 5.1 Postural Stability Training mode, with targets set (left) and the most inner concentric circle set as a boundary (right).

Weight Shift Training

In this exercise, factors will vibrate when either of the two vertical blue target lines is hit.

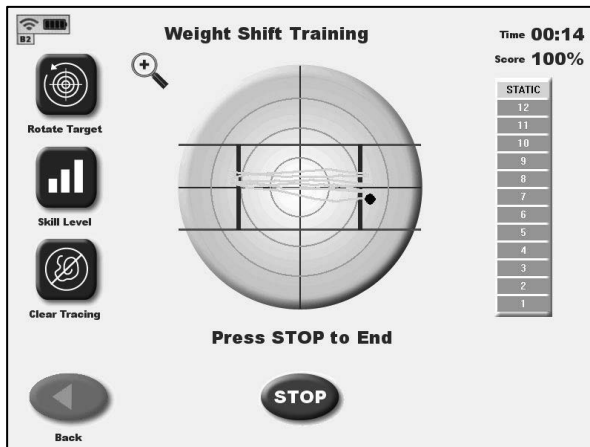


Figure 5.2 Weight Shift Training mode.

Limits of Stability Training

In Limits of Stability training, the factors corresponding with the on-screen targets will vibrate when the patient moves the cursor accordingly.

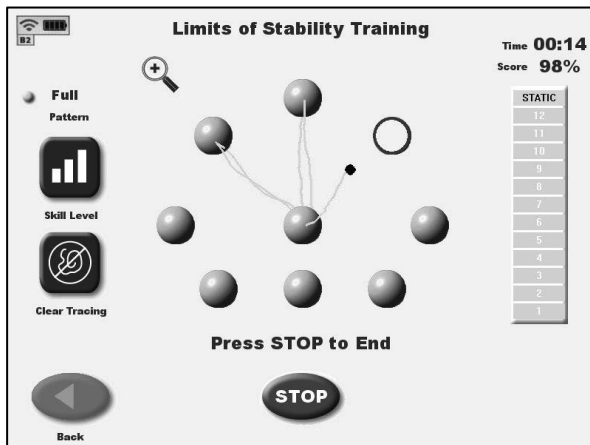


Figure 5.3 Limits of Stability Training mode.

Percent Weight Bearing Training

In Percent Weight Bearing training, factors corresponding with patient movement on direction planes will vibrate when the boundary is exceeded (on-screen graphic will display a blue color) and turn off when the patient stays within the boundary (graphic will be green.)

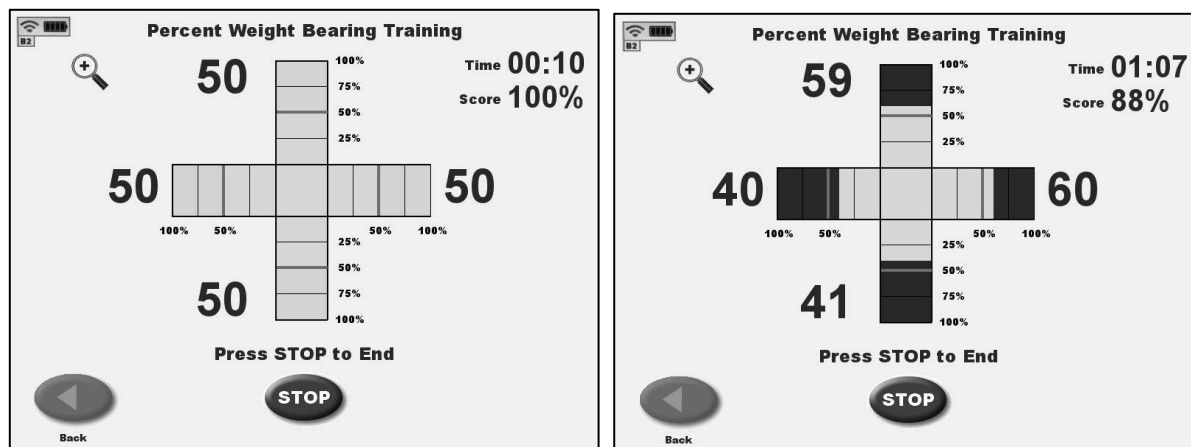


Figure 5.4 Percent Weight Bearing Training mode.

Random Control Training

As the patient moves to maintain the cursor within the randomly roaming circle, factors will vibrate if the cursor falls outside of circle. The vibration will stop when the patient is able to move the cursor back inside the circle.



Figure 5.5 Random Control Training mode.

Maze Control Training

The objective of this training is for a patient to move the cursor through the maze, hitting targets. If they hit the maze walls (boundaries), tactors will vibrate until the patient brings the cursor back onto the maze path.



Figure 5.6 Maze Control Training mode.

Vibrotactile Designation on Training Reports

When vibrotactile feedback is being employed during a training session, this will be denoted at the top of the training report page (“VT Belt”).

Postural Stability Training

<p>Date 06/01/2015 2:28 PM Name ED Height 60"-65" Age --- Diagnosis ---</p>	<p style="text-align: right;">PROTOCOL Protocol Setting Basic Device <input type="checkbox"/> VT Belt <input checked="" type="checkbox"/></p>
---	--

Time 7 secs
 Score 0

Comments _____

Clinician _____

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Figure 5.7 Sample of a Postural Stability Training mode report, with denotation that the VibroTactile System was activated during the training.

6. Supporting Research and Suggested Reading

Elliott, Linda R., Michael D. Coovert, Matthew Prewett, Ashley G. Walvord, Kristin Saboe, and Ryan Johnson. 2009. *A review and meta analysis of vibrotactile and visual information displays*. Aberdeen Proving Ground, MD: U.S. Army Research Laboratory.

Wall C 3rd. *Application of vibrotactile feedback of body motion to improve rehabilitation in individuals with imbalance*. J Neurol Phys Ther. 2010 Jun;34(2):98-104.

K.H. Sienko, M.D. Balkwill, L.I.E. Oddsson and C. Wall. *Effects of multi-directional vibrotactile feedback on vestibular-deficient postural performance during continuous multi-directional support surface perturbations*. Journal of Vestibular Research 18 (2008) 273–285. IOS Press.

Weber, B.; Schatzle, S.; Hulin, T.; Preusche, C.; Deml, B. *Evaluation of a vibrotactile feedback device for spatial guidance*. World Haptics Conference (WHC), 2011 IEEE, vol., no., pp.349,354, 21-24 June 2011.

Lee PY, Gadareh K, Naushahi MJ, Gresty M, Bronstein AM. *Protective stepping response in Parkinsonian patients and the effect of vibrotactile feedback*. Mov Disord. 2013 Apr;28(4):482-9. doi: 10.1002/mds.25227. Epub 2012 Oct 31.

Conrad Wall III, PhD, Diane M. Wrisley, PhD, PT, NCS, and Kennyn D. Statler, PhD. *Vibrotactile Tilt Feedback Improves Dynamic Gait Index: a Fall Risk Indicator in Older Adults*. Gait Posture. 2009 July ; 30(1): 16–21. doi:10.1016/j.gaitpost.2009.02.019.

Karen L. Atkins, PT, PhD. *Vibrotactile Rehabilitation of Adults with Vestibular Dysfunction*. BalanceSense LLC. Whitepaper. June 2014.

Febo Cincotti, Laura Kauhanen, Fabio Aloise, Tapio Palomaki, Nicholas Caporusso, Pasi Jylanki, Donatella Mattia, Fabio Babiloni, Gerolf Vanacker, Marnix Nuttin, Maria Grazia Marciani, and Jose del R.Millan. *Vibrotactile Feedback for Brain-Computer Interface Operation*. Laboratory of Neuroelectrical Imaging and Brain Computer Interface, Fondazione Santa Lucia IRCCS, Via Ardeatina 306, 00179 Roma, Italy. Computational Intelligence and Neuroscience 02/2007; 2007:48937. DOI: 10.1155/2007/48937. Source: PubMed.

APPENDIX A - SPECIFICATIONS

Belt Dimensions

Small/Medium: 28"-36" (71-91 cm)

Large/Extra Large: 36"-48" (91-122 cm)

LinkBox Transmitter

Voltage: 5v DC

Current: 50 mA

Auxiliary Ports: RS-232, USB

TactileBelt Receiver Box

Voltage: 5v DC

Current: 260 mA (when charging)

Auxiliary Ports: USB (wired); LR-WPAN (wireless)

Total Shipping Weight: 5 lb (2.3 kg)

Warranty: One year - parts and labor

For devices running on Windows CE operating systems only.

Field upgrades available.

APPENDIX B – CONFORMANCE TO STANDARDS

"Mi-Wi" communication software - Copyright JD Birck, LLC

United States:

Contains FCC ID: OA3MRF24J40MA

Canada:

Contains IC: 7693A-24J40MA

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Patients with pacemakers

At the time of writing for this user manual, we do not have information regarding use of the VibroTactile System with patients having pacemakers. Although the VibroTactile System uses considerably less power than the lowest power cellphone, it is best that pacemaker patients consult with their physician prior to using the device.

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Biodes Medical Systems, Inc.

20 Ramsey Road, Shirley, New York, 11967-4704, Tel: 800-224-6339 (Int'l 631-924-9000), Fax: 631-924-9338, Email: info@biodes.com, www.biodes.com