GAIT TRAINER™ 3 (v3.X software)

REACTIVE STEP TRAINER

INSTRUCTIONS FOR USE

950-400
950-401
950-402
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950-407
950-408
950-413
950-414
950-600
950-601
950-604

BIODEXREHAB™
A Salona Global Company

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FN: 19-225-CLR Rev D

Gait Trainer™ 3 (v3.X software)

Reactive Step Trainer (RST)

This Instructions For Use document covers safe operation of the Gait Trainer 3 with Reactive Step Trainer (RST)

Additional information and resources are available upon request or directly from the Biodex website: https://biodexrehab.com/our-products/gait-trainer/.

The Biodex website also includes information for compliance and clinical support. If the desired information is not found, Biodex can be contacted directly at support@biodexrehab.com .

Thank you,

Biodex Medical Systems, Inc.

Contact information.

Manufactured by:

Biodex Medical Systems, Inc.

49 Natcon Drive, Shirley, New York, USA 11967-4704, United States
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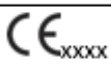
Table of Contents

Definition of Symbols

The following symbols and their associated definitions are used and implied throughout this manual.

Symbol	Definition
	Carefully read these instructions prior to use
	Operating Instructions
	Caution
	General Mandatory Action
	Dangerous Voltage
	"On" Power
	"Off" Power
	Pinch Point
	Earth (ground)
	Alternating Current
	Fuse
	USB Connector/Cable
	Non-Ionizing Electromagnetic Radiation
	Waste in Electrical Equipment
	Disposal Classification and Identification of Equipment
	Date of Manufacture
	Manufactured By
	Medical Device
	Type B Applied Part
	CE Mark with Notified body reference

Product Certifications and Classifications

This product has received the following certifications and falls within the following classifications:

· IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)

· ANSI/AAMI ES60601-1:2005+A1:2012+C1:2009+A2:2010.

· CAN/CSA C22.2 No. 60601-1:14

· FDA Class I Equipment

· Type B Applied Part

· Electromagnetic Compatibility: This equipment complies with the Medical Equipment IEC 60601-1-2:2014 EMC Standard.

NOTE: *Component part lists, descriptions, calibration instructions, or other information used to assist service personnel to repair those parts of the equipment that are designated as repairable for this product are provided on the Biodex Rehab website, https://biodexrehab.com/or can be obtained by contacting Biodex Customer Service (see Contact information).*

Gait Trainer Models (950-401, 950-403, 950-407) European Compliance

Authorized European Community Representative:

Emergo Europe
Westervoorsedijk 60
3827 AT Arnhem, Netherlands

BERNINA International AG
Seestrasse 161
8266 Steckborn, Switzerland

Before Proceeding

NOTE: *The cautions and instructions provided in this manual must be read, followed and kept available for consultation at all times. Observing the information, instructions, and procedures presented throughout this manual is essential for using this product both properly and safely.*

SPECIFIC CAUTIONS

- Allow only qualified, trained personnel to operate or service this product.
- If the equipment is used in a manner other than specified in this operation manual, the protection provided by the equipment may be impaired and results could be compromised.
- Never leave patient unattended.

CAUTION: Unauthorized modifications to this product are not permitted and will void the manufacturer's warranty. Unauthorized modification of the product may result in a hazard to the user and/or patient. Do not modify this equipment without authorization from the manufacturer.

Training

This operation manual includes assembly and operating instructions. Operating/assembly questions can be directed to the service department during business hours.

Important Safety Information

CAUTION: Federal Law restricts this device to sale by or on the order of a physician, or other licensed professional.

NOTE: Follow the unpacking and assembly instructions document.

NOTE: Before using this equipment, read the entire operation manual carefully. Failure to read the manual may result in user error or injury. Be sure to save all provided documents for future reference.

NOTE: Make certain to understand all caution labels as explained in the Before Proceeding section of this manual.

NOTE: This product should be used only as specified in the operation manual.

NOTE: For product specifications, refer to the Table of Contents.

NOTE: This medical electrical equipment requires special precautions regarding EMC and must be assembled and placed into service according to EMC information provided in this manual. For electromagnetic compliance definition, refer to the Table of Contents.

NOTE: Reference Cleaning and Maintenance instructions in Table of Contents.

CAUTION: Operation for 950-400: 115 VAC; 950-401: 230 VAC; 950-404: 100 VAC.

CAUTION: Only use approved power supplies.

CAUTION: To avoid risk of electric shock, this equipment must only be connected to supply mains with protective earth.

CAUTION: The plug is considered the method of disconnecting the product from main power. Do not place the product in a position where the plug is not easily accessible.

CAUTION: This product is intended to remain in one location during operation. It is provided with wheels for relocation that should be used when moving.

CAUTION: Safety lanyard should always be worn while using the treadmill. If the safety lanyard is detaches, this will stop the treadmill movement.

NOTE: There should not be any object (e.g., chair, shoes, etc.) placed on the treadmill deck. Wheelchair and treadmill belt should not touch each other.

CAUTION: User should avoid wearing a long dress or skirt that could get stuck in the belt.

CAUTION: Avoid multi-tasking while using the treadmill, especially at higher speeds. Avoid side walking on the treadmill at higher speeds.

CAUTION: Do not put the treadmill on high speed and then jump on the deck. Do not stand on the side rail while the treadmill is at high speed.

CAUTION: Secure the patient with appropriate safety harness before using the Reactive Step Training operation.

NOTE: Use the treadmill standing in the middle of the deck. Avoid using it at the lower portion of the deck.

NOTE: Any serious incidents occurring with the use of this device should be reported to the manufacturer and appropriate local regulatory agency by end user, operator, or patient. Examples of local regulatory agency are EU competent authority, country specific Health Agency, or FDA.

CAUTION: No liquids allowed during use of the equipment as this unit is not IPX rated. Liquid spillage can damage the electronics part of the equipment.

CAUTION: Do not unplug the power by pulling the power cable. Avoid touching the power cable for any possible exposed wire in case of any accidental damage.

NOTE: Avoid grabbing the display on the top left/right side especially during a session in progress. This will avoid the accidental increase/decrease of the speed and/or elevation of the deck.

CAUTION: Keep fingers away from the belt while it is in motion. Possible injury can happen.

CAUTION: Application software does not do automatic backup of the database. User is responsible to perform periodic backups in case of any hardware corruption happens to the system.

1. Introduction

Intended Use

Gait Trainer 3

The Biodex Gait Trainer 3 is an assessment tool for measurement of functional gait. It is a versatile product, providing capabilities for objective measurements of specific gait parameters as well as physiological measures of kinesthetic, proprioceptive abilities and neuromuscular control. It is intended to be used as a training tool to assist patients with Gait Velocity, Average Step Cycle Time, Average Step Length, Co-efficient of Variation, and Time on Each Foot.

Reactive Step Trainer

The Biodex Reactive Step Trainer is a powered treadmill and harness system that provides a dynamic postural perturbation to improve step recovery and dynamic balance which may reduce the incidence of falling. The RST provides capabilities for objective measurements of specific gait parameters as well as physiological measures of kinesthetic, proprioceptive abilities and neuromuscular control.

Indications for Use

Gait Trainer 3

The Biodex Gait Trainer 3 is a gait training tool that can be used for various populations such as neurological disorders, orthopedic, deconditioned, concussion management and other general conditions.

Reactive Step Trainer

- For individuals who have been identified as having an elevated risk of falling or are suspected of having an elevated risk of falling
- Lower limb amputees
- Balance / coordination / postural training
- Indications for use of the Reactive Step Trainer are similar to the indications for use of a treadmill or balance exercise program. The following guidelines are recommended:
    - The patient should be cleared by his or her physician for treatment on the Reactive Step Trainer.
    - The patient should be able to stand and support his or her own weight.
    - The patient should have no physical conditions that would limit his or her participation in a light exercise program.
    - The patient has the required cognitive abilities to follow the instructions for the protocols.

Patient Group

- Gait trainer Weight: 60lbs (27 kg) to 400lbs (182 kg)
- RST Weight: up to 225 lbs (102 kg)
- Height: 48 inches (122 cm) - 74 inches (187 cm)
- Age: 10 years – 83 years

Contraindications for Use

The Gait Trainer 3 and Reactive Step Trainer should not be used for patients with severe osteoporosis, non-union fractures, debilitating dizziness, or poor safety awareness/cognition. Do not use for patients weighing greater than 400 lbs (bariatric) or less than 60 lbs. Do not use for patients with acute conditions such as pulmonary embolus, thrombus, acute MI, acute fractures, or BP over 180/110 Hg.

Additional Contraindications for Reactive Step Trainer

- When loading of the hip, pelvic, abdominal, and chest regions is prohibited.
- Fractured ribs
- Large disc bulge / rupture
- Skin graft in harness area
- Inability to stand unaided.

Precautions

Clinicians should be aware of the appropriate clinical treatment prior to testing and training the following:

- patients with poor safety awareness/cognition,
- patients with global weakness,
- patients with a history of hazardous falls,
- patients with severe fatigue,
- patients with lower extremity joint pain
- patients training with assistive devices,
- patients with impaired cognitive abilities

NOTE: *Patients less than 60 lbs may receive skewed data results.*

Assembly and Installation

The display monitor receives power from the larger Gait Trainer device. Therefore, the Gait Trainer must be plugged into a wall outlet or surge suppressor and powered on by the ON/OFF switch at the front base of the unit.

The Gait Trainer deck is instrumented with a strain gage at each of the four corners. It is important that the Gait Trainer be level for optimal footfall detection. When not level, the user may see messages concerning Leveling or Offset Calibration. Depending on the situation, instructional screens will be displayed leading the user through any required process.

When first installed, or if the Gait Trainer is moved, the leveling foot may require an adjustment. This will require a ¾" wrench. Adjust the rear leveling foot by turning it with the wrench until the on-screen gage turns green. Please note that there is a jam nut that should be loosened first, and re-tightened after leveling the foot. Press <OK>.

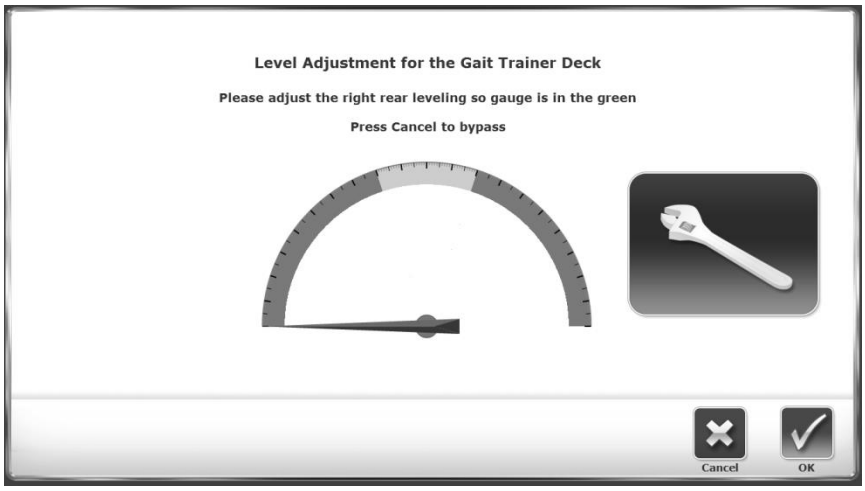


Figure 1.1. Leveling Foot Requires an Adjustment.

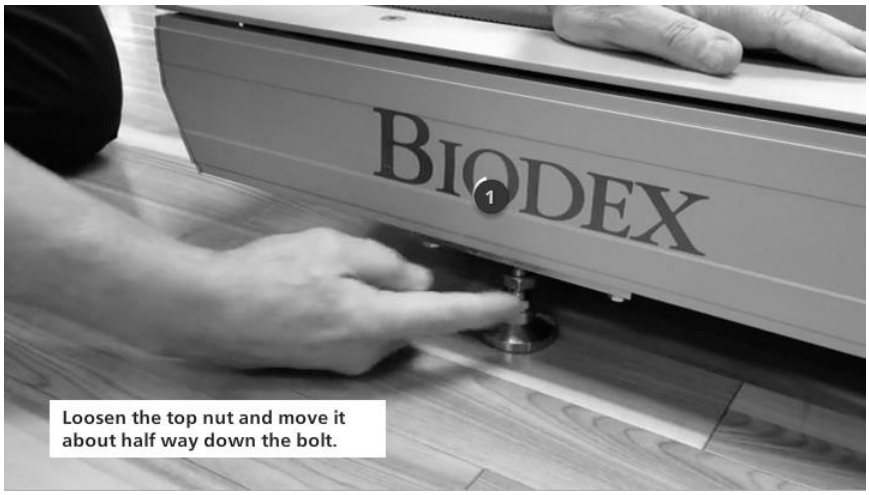


Figure 1.2. Loosen the Top Nut

Figure 1.3. Adjust the Bottom Nut

Figure 1.4. Adjusting Gait Trainer Height

Power-down

In order to prevent the device's database from becoming corrupted, it is essential that the correct power-down sequence is performed. Always turn off the display, by touching the "X" in the upper right corner of the home screen, followed by "Shut Down".

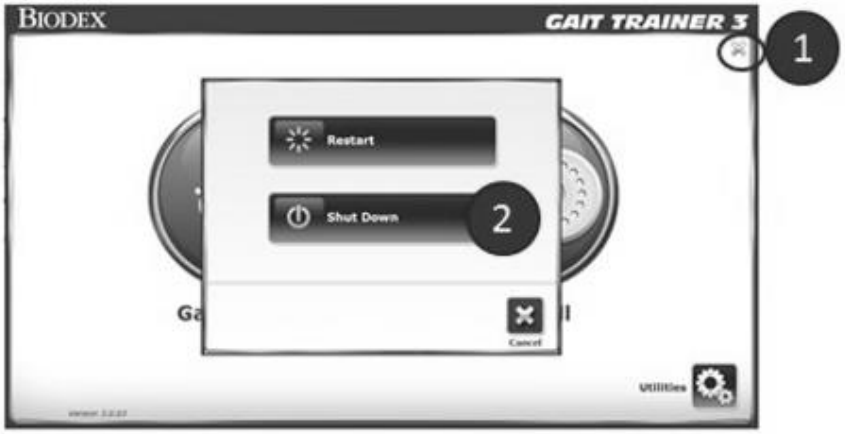


Figure 1.5. Power-Down Sequence.

Once the display has finished its shut down sequence, power may be removed from the treadmill using the main ON/OFF switch located on the front of the base where the power line cord enters the treadmill.

CAUTION: Do not unplug the device or turn off the ON/OFF front base switch before powering down the display!

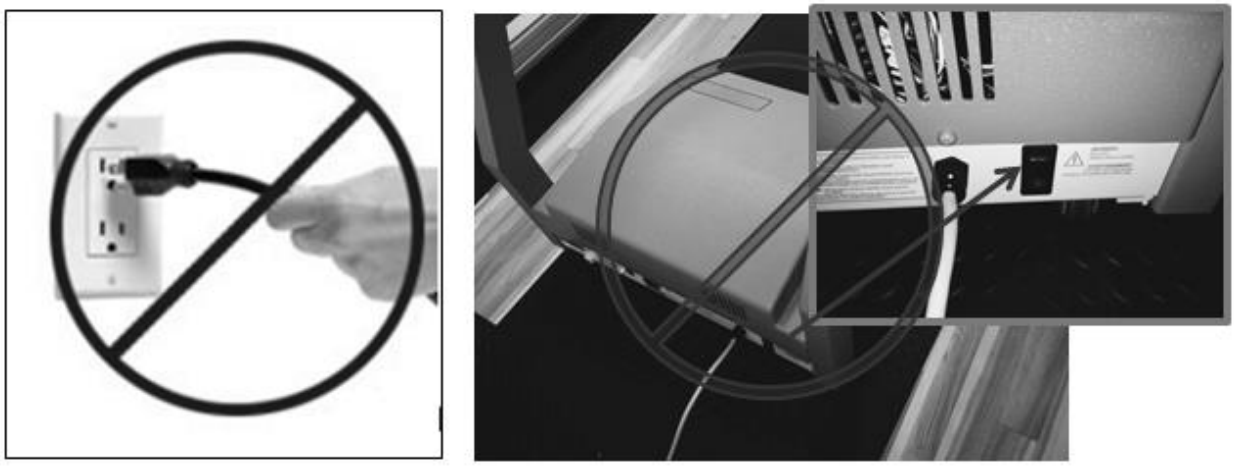


Figure 1.6. Do not unplug the device or turn off the controller tray circuit breaker front base switch before powering down the display.

Initial Setup and Activation

When the system is first powered on, the following screen is displayed if someone is standing on the treadmill deck:

Figure 1.7. Footfall Initialization Screen

NOTE: *It is important to not be standing on the treadmill deck when OK is selected to perform the footfall initialization. The footfall initialization calibrates the treadmill sensors to patient footfalls. Standing on the treadmill deck while the initialization is in process, will result in inaccurate footfall readings.*

Printer Installation

1. Refer to the supplied printer manual to unpack the printer and ensure that it has not been damaged by shipping.
2. Position the printer on the Biodex-provided printer stand.
3. Locate the printer power cable. Plug the small end into the power receptacle on the back of the printer.
4. Insert the AC plug end of the printer power cable first into the Biodex-provided power adapter, and then insert the adapter plug into the power cable receptacle on the back, lower base of the Gait Trainer 3. Do not connect any other equipment to this receptacle.
5. Locate the 15ft USB cable that will be pre-installed in one of the USB ports on the Gait Trainer 3 display. Connect the other end of the cable to the port at the back of the printer.
6. Ensure both cables are positioned such that they will not interfere with the patient or get caught in the Gait Trainer 3 platform or handles.
7. Refer to the printer manual for directions on installing ink cartridges and paper.
8. With power ON to the Gait Trainer 3, press the <Power ON> switch on the printer. Refer to the printer manual for additional printer information.

USB connection – The Gait Trainer 3 display will be shipped with a USB cable plugged into one of the display's USB ports. Plug the other end into the data port on the back of the printer.

Power connection – Plug the smaller end of the printer power cable in here. Plug the AC end of the cable into the power cable adapter. Lastly, plug the adapter into the receptacle on the base of the Gait Trainer 3.

Figure 1.8. Connect Power Cable and USB Cable to Rear of Printer.

Connecting Components

In addition to the printer that is shipped with the Gait Trainer, other printers may be used with the device. Most printers are compatible with the Gait Trainer display, but the drivers for many of those printers may need to be installed (example: some Windows compatible printers). Similarly, any keyboard or mouse will automatically connect using one of the USB connections. It is possible to connect the device to a printer wirelessly.

NOTE: *For help, please call Biodex Customer Support at 631-924-9000, Option 2.*

An external monitor can also be connected via the VGA port on the bottom of the display. Once the external monitor's cable is connected, the <Mirror to External Monitor> button in System Utilities must be selected. (This button is accessed by the following navigation steps from the Home screen: Utilities > Configuration > System Configuration > Screen Configuration.)

Accessing Additional Ports and Connections

The Gait Trainer provides the user with the ability to access additional ports and connections from the back, bottom side of the monitor. These connections can be used to attach an additional printer, external monitor, or other component. In the example below, the monitor has been removed from the device column for demonstration purposes.

To access these ports and connections, the back of the monitor can be temporarily removed as detailed in Figure 1.9.

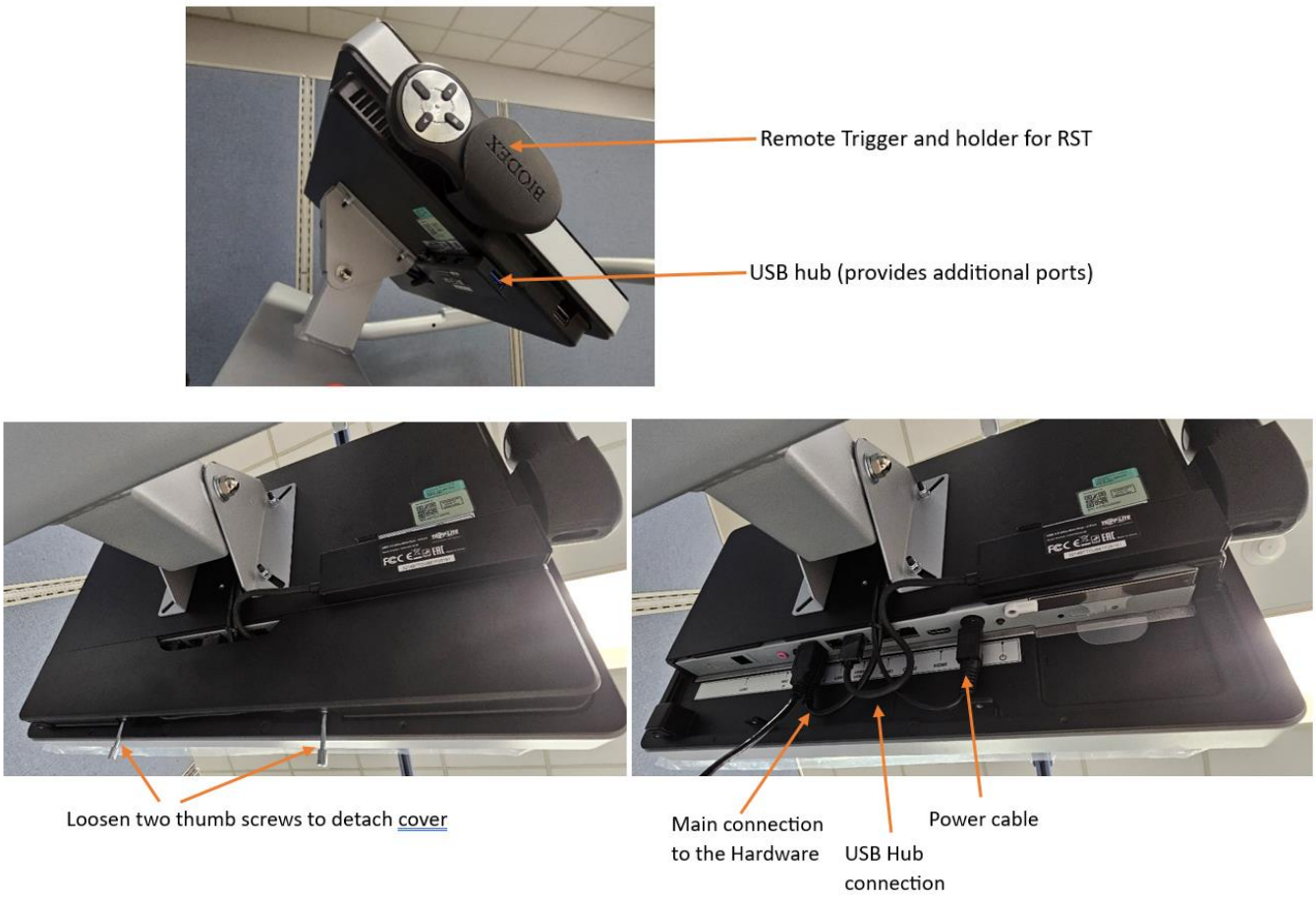


Figure 1.9. Accessing Additional Ports and Connections

Wireless Connection to the Internet

To wirelessly connect to the Internet from the Gait Trainer, use the following directions, or watch this video: https://youtu.be/Uc8f5fxiZ70

1. From the Home screen, select the Utilities icon.

2. *Figure 1.10. Gait Trainer or Reactive Step Trainer Home Screen*

3. *Select the Wifi Settings icon.*

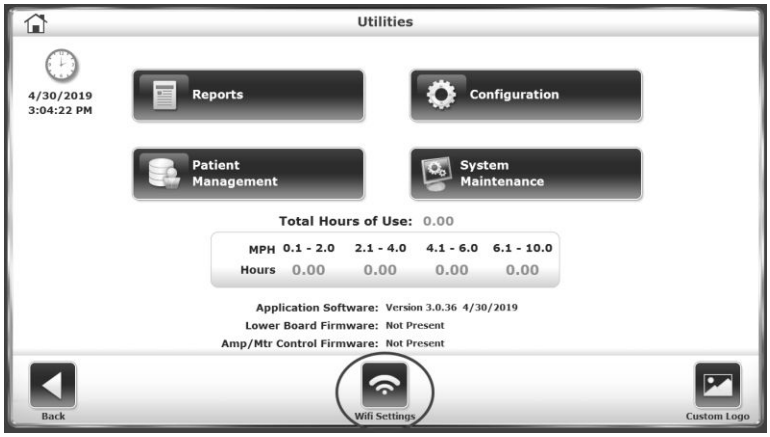


Figure 1.11. Wifi Settings Icon

4. Touch the drop-down menu and select a Wifi network.

Figure 1.12. Available Wifi Networks

5. Select the keyboard icon. An on-screen keyboard displays.

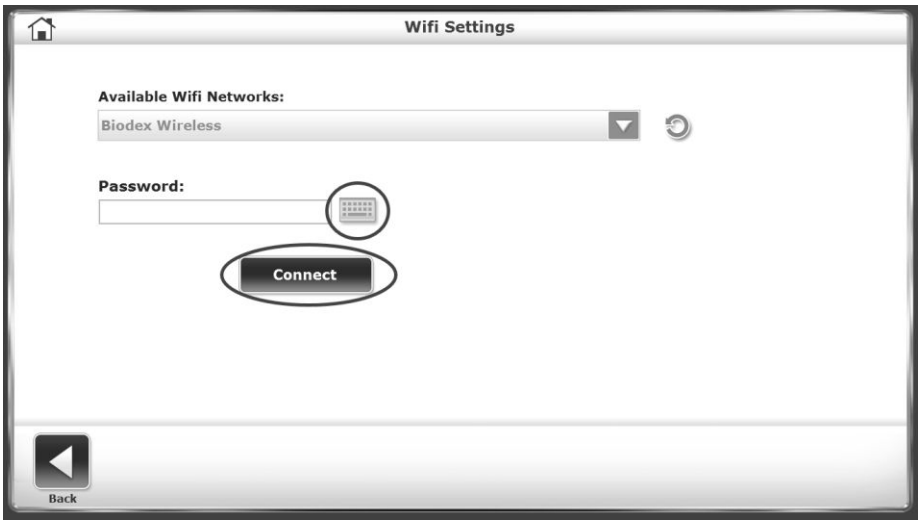


Figure 1.13. Keyboard Icon and Connect Button

6. Enter your password and select the Connect button. A message will display with the wireless network you are connected to.

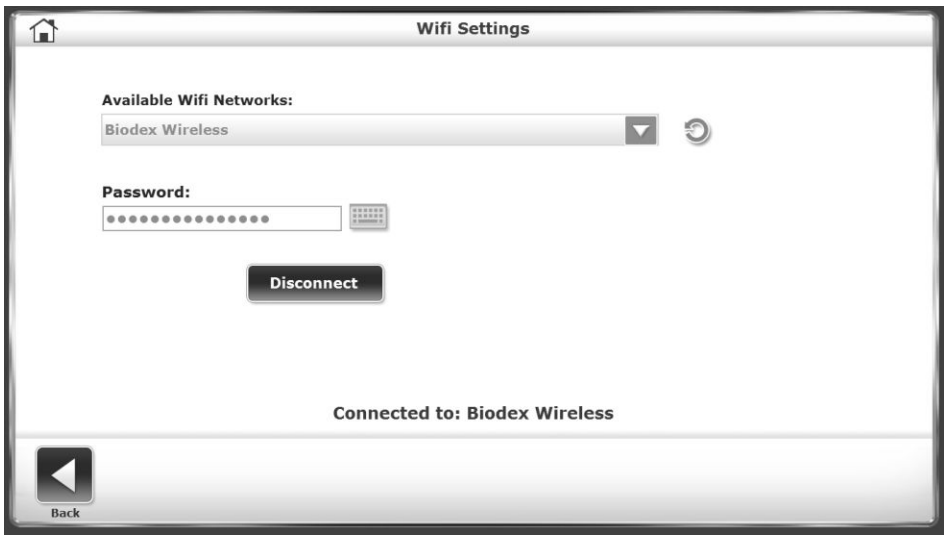


Figure 1.14. Connected Screen

Wired Connection to the Internet

1. Plug the cable modem into the device. Ensure the device is near a wall cable socket.
2. Plug in the cable modem's power cord. Most modems do not have an on/off switch. They are turned on or off by either plugging or unplugging the cord into the wall cable socket.

2. Getting Started

This manual addresses operation in **Gait Training mode, Treadmill mode, and Reactive Step Training mode.** If the **Music Therapy option** is included, please refer to the Music Therapy instructions for use.

The Gait Training operation The Biodex Gait Trainer can be used for gait training applications or as a rehabilitation treadmill. The following section describes use in the Gait Trainer Mode. The rehabilitation treadmill operation is described later in this manual.

Gait Trainer Mode

The Gait Training Mode is useful for the rehabilitation and retraining of gait for patients with neurological and orthopedic gait dysfunctions. It provides both audio and visual feedback for the patient. The rhythmic movement of the treadbelt, along with the audio and visual biofeedback, provides the necessary stimulus for retraining neural pathways thus improving gait pattern.

NOTE: *It is recommended that an overhead support harness system be used in conjunction with the Gait Trainer and Reactive Step Trainer to provide a safe environment for the patient and clinician, and also when gait training to allow for proper patient positioning for weight distribution and coordination of balance.*

The Opening Menu displays three icons: Gait Trainer, Treadmill, and Utilities. Touch <Gait Trainer> to advance to the Patient Setup screen. This screen allows entry of patient information and parameters used for gait training.

Figure 2.1. The Home screens for Gait Trainer with Reactive Step Training

NOTE: *Please be aware that entering patient information into the system for the first time will require some effort. This information is very important if reports are to be run for statistical purposes. After the initial set up, information for existing patients is very quickly retrieved making the session set up faster and easier.*

The Reactive Step Training does not currently store patient data. There is no need to enter patient information when using Reactive Step Trainer. At the completion of a Reactive Step Training session, results are presented to be printed or saved as a PDF to a USB device. (See section ***8.17*** *for more information about Reactive Step training results.)*

The Gait Trainer Patient Setup Screen

At the Patient Setup screen, touch the appropriate icon to begin entering information. A pop-up keypad is used to enter some parameters such as Name and Age. Once the desired information is entered/selected, touch <Next> to advance to the Footfalls/Histogram screen. Other adjustments can be made using the icons along the bottom of the screen. The presence of some of these icons is set in the system Utilities section.

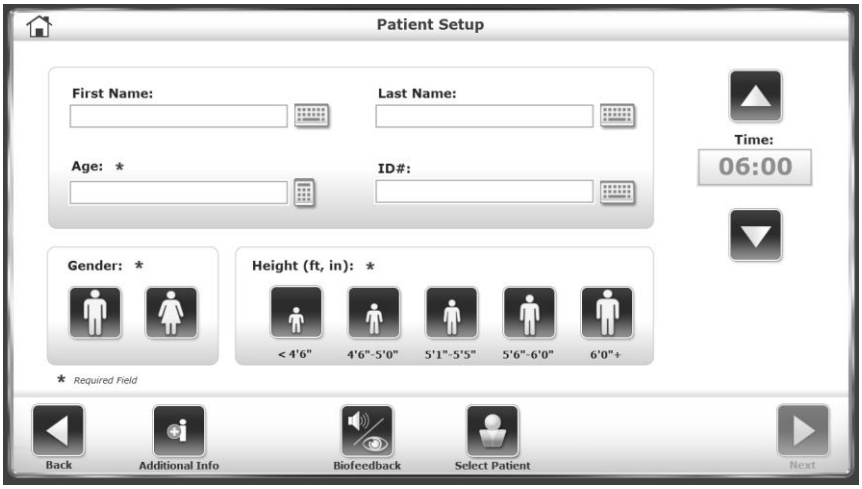


Figure 2.2. The Gait Trainer Patient Setup Screen.

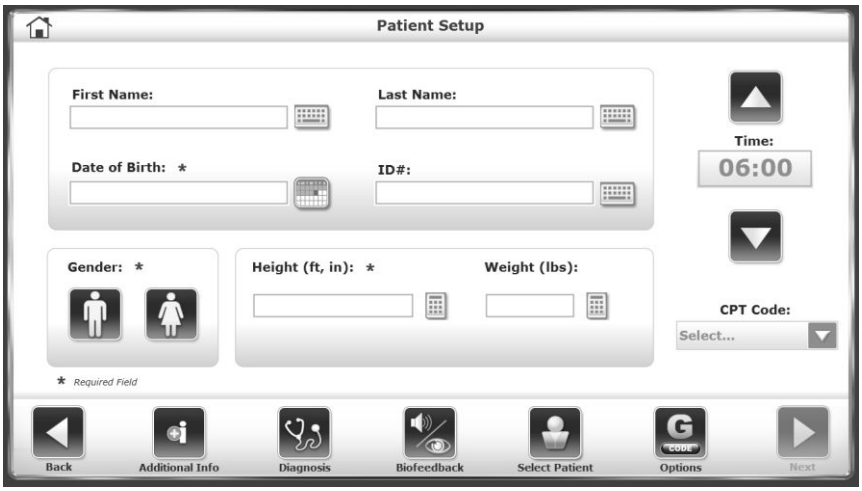


Figure 2.3 The presence of certain icons and ways to input height, weight, and age information can be set in Utilities.

A brief explanation of each parameter and function on the Gait Training Patient Setup screen follows.

***NOTE:** For all screens, <Next> advances to the next screen and <Back> returns the user to the previous screen. The <Home> icon at the top, left corner returns the user to the Gait Trainer Opening Menu screen.*

Gait Training Patient Setup Screen Parameters

NOTE: *The three parameters for Gender, Height, and Age are mandatory fields and must be completed before gait training can begin.*

- *First and Last Name*: Optional, touch the pop-up <Keypads> to enter the first and last name. Touch <OK> to continue.
- *ID#*: Optional or required depending on Configuration settings. Touch the pop-up <Keypads> to enter an identification number. Touch <OK> to continue.
- *Gender*: Touch the appropriate icon to choose <Male> or <Female>.
- *Height*: This setting is used to determine step length. Touch the appropriate <Height> icon to select the desired range. This value can also be a manual number entry (see Figure 2.3). The manual height entry option can be set within the Configuration option in system Utilities.
- *Weight*: For new patients, a weight can be entered here in pounds. Entering weight data is optional.

NOTE: *If a patient has been selected using the Select a Patient function, the application will display the existing height and weight as was previously recorded. If height or weight has changed, the numbers can be adjusted and new test results will feature the updated information. Once a test is performed, there is no way to edit the height or weight recorded for that test result. Patient height and weight can also be changed at any time from the Patient Management screen in system Utilities. The new numbers will be used for any subsequent tests.*

- *Age / Date of Birth*: Range is from 10 to 120 years old. Touch the <Age> keypad and use the pop-up keypad to change the value. This value can also be derived from a Date of Birth entry (see Figure 2.3). The Age/DOB option can be set within the Configuration option in system Utilities. Touch <OK> to continue.
- *Gait Training Time*: Default value is 6:00 minutes. Use the<▲> and <▼> icons to change the value.
- *Additional Info (*Figure 2.4*)*: Touch <Additional Info> to enter information regarding the patient's health status and the facility where treatment is taking place. In addition to the predefined categories, the bottom four drop-down menus can be customized to define new categories and associated selection lists. Entering Additional Information data is optional.
- *Biofeedback Options (*Figure 2.6*)*: Touch <Biofeedback> to adjust biofeedback options on the audio/visual Biofeedback Options screen.
- *Select Patient (*Figure 2.7*)*: Touch <Select Patient> to designate an existing patient within the device's records for a new training session.

Additional Gait Training Patient Setup Screen Parameters

NOTE: *The following parameters are only visible when they are activated within the Gait Trainer Configuration settings (i.e., in system Utilities.)*

- *Diagnosis (*Figure 2.5*)*: Touch <Diagnosis> to enter diagnostic information for the patient, including an ICD code.
- *CPT Code* (Figure 2.3): Touch the <CPT Code> drop-down menu to assign a particular CPT (Current Procedural Terminology) code to the patient.

The Additional Information Screen

Figure 2.4 The Additional Information Screen

The Additional Information screen contains a series of drop-down menus and editable fields in which users can enter various types of information about the patient. In each menu, users can enter a new value or item into the drop-down list.

The Diagnostic Information Screen

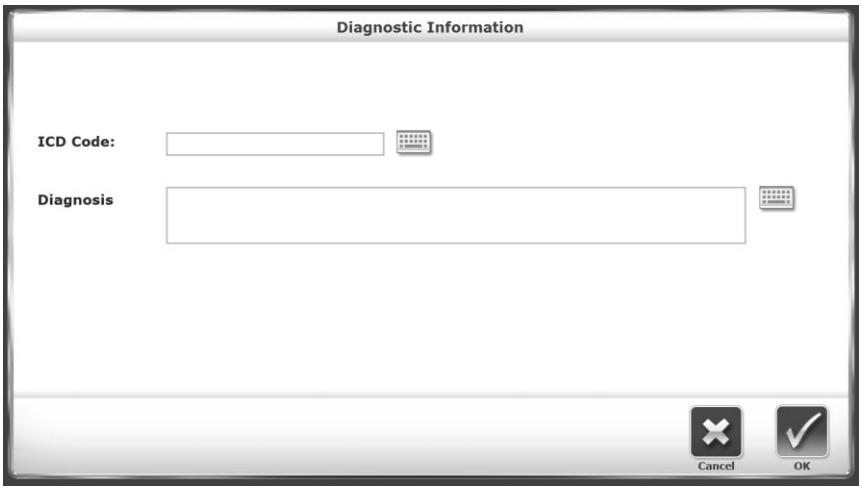


Figure 2.5. The Diagnostic Information Screen

On the Diagnostic Information screen, users can manually enter an ICD code in one field and more specific text in the other larger field. Note that this screen does not necessarily have to feature an ICD Code field; this can be activated or deactivated in system Utilities.

The Biofeedback Options Screen

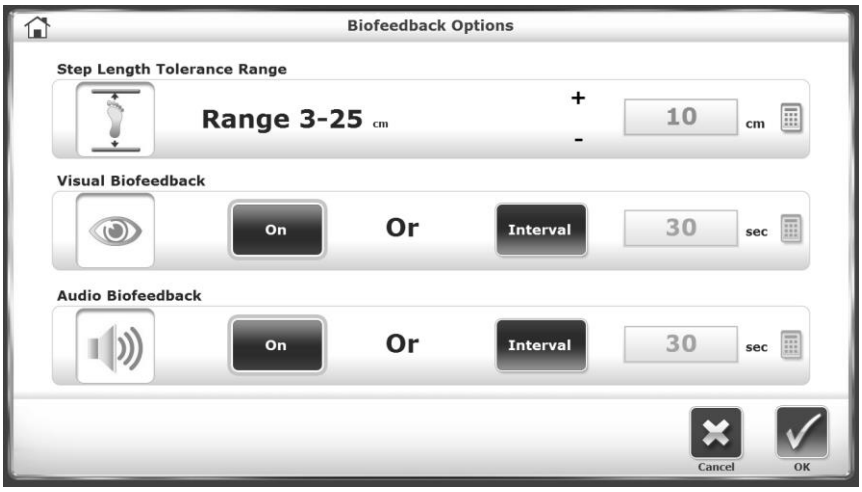


Figure 2.6. The audio/visual Biofeedback Options Screen

The Biofeedback screen is accessed from the Gait Training User Information screen by touching the <Biofeedback> icon. At this screen, biofeedback parameters can be entered or set. A brief explanation of each parameter and function follows.

Audio/visual biofeedback screen parameters and functions:

- *Set Step Length Tolerance Range*: Touch <Set Range> and use the pop-up keypad to increase or decrease the distance between the target lines the patient must achieve in the steps they take.
- *Set Visual Biofeedback ON/OFF Interval Time*: Touch <ON>, <OFF>, or <Interval> and enter the desired feedback time intervals via the pop-up keyboard.
- *Set Audio Biofeedback ON/OFF Interval Time*: Touch <ON>, <OFF>, or <Interval> and enter the desired feedback time via the pop-up keyboard. The audio tone is not a metronome tempo. The audio tone is timed to be in sync with the appearance of the target box. Tone is also based on the last footfall. A tone can be heard without a footfall. After a while, due to the rhythmic nature of walking, the tone falls into a seemingly real-time tempo.

Once the desired parameters have been set/entered on the A/V screen, touch <OK> to return to the Patient Setup screen.

The Select Patient Screen

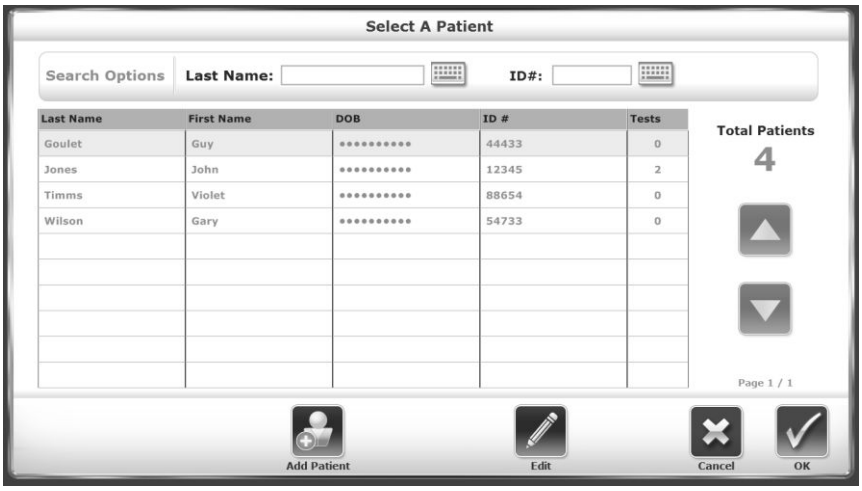


Figure 2.7. The Select/Edit Patient Screen

In previous versions of the Gait Trainer software, a patient with existing data on the device could only be re-tested by either: a) typing in the patient's name exactly as it is spelled on an existing record, or b) finding the patient within the set of records in the Patient Management section of system Utilities. Now, with the Select Patient option, users can quickly find an existing patient and started on a new gait training session.

There are two ways to identify specific existing patients from this screen. At the top there are search options for a patient's last name or an identification number that has been assigned to the patient. Select one of these fields and enter either a patient last name or the ID number. Select <OK> to display a listing of search results. To return to the list of all patients, select the circular refresh arrow icon at the top right of the screen:

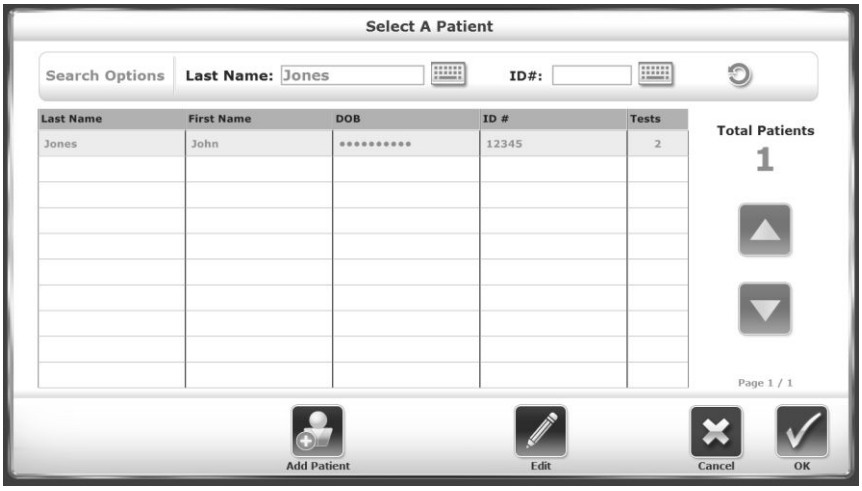


Figure 2.8. The Select/Edit Patient screen, showing search results. To reset listing of all patients, select the circular refresh arrow in the upper right corner.

If the number of patient records on the device is relatively small, it may be easier to scroll through the records with the<▲> and <▼> arrows.

Patient records can be edited on this screen, or a new patient can be added. Many of the same information fields that are in the Patient Setup screen will need to be entered.

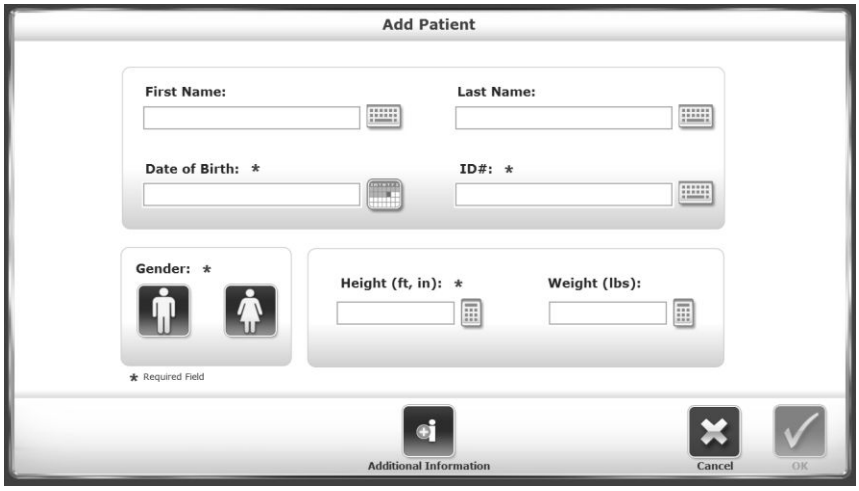


Figure 2.9. The Add Patient Screen

Footfalls/Histogram Screen

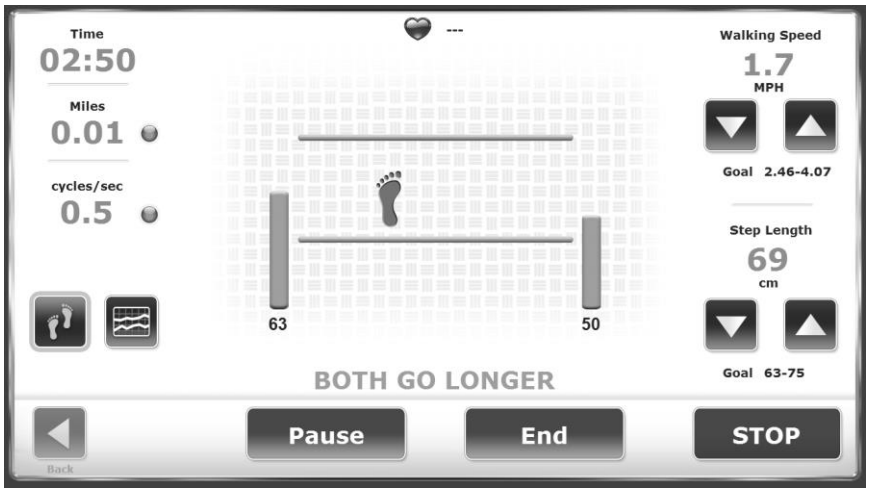


Figure 2.10. If the Patient's Steps are outside of the Target Step-Length Range, one or two orange bars are displayed.

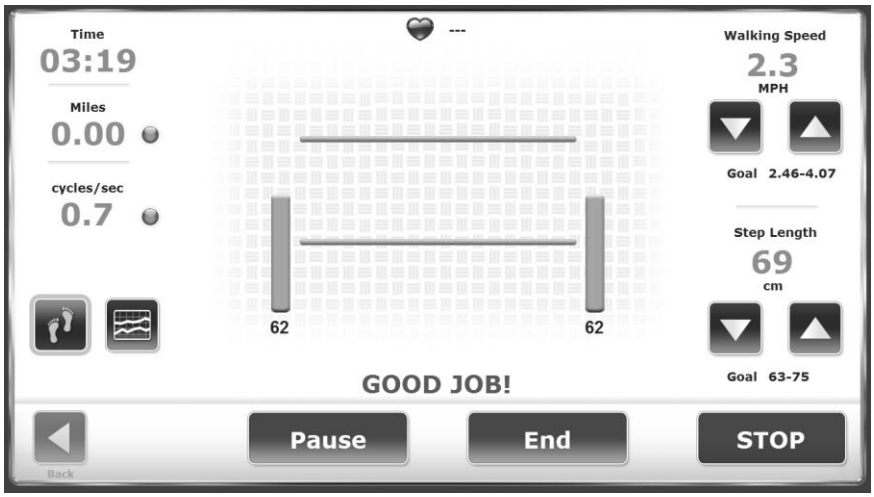


Figure 2.11. If the patient is achieving the Desired Step-Length Target, two green bars and a "Good Job!" message is displayed.

Figure 2.12. Patients Receive Feedback on Step-Length Targets in Histogram View.

In the Footfalls screen, the blue foot marks the user's last foot placement while the space between the two green lines is a target for the next foot placement. The user can toggle by pressing the blue dots to display speed as cycles/sec, MPH, or meters/sec. The numbers in the left and right corners of the Footfalls display illustrate the real time average of the patient's last five steps. (In Figure 2.11, it is 62 for both the left and the right legs.) There is also a reading for step length.

In the Histogram view, the Y axis represents Step Length and can be displayed in scales of 0-60 cm, 0-80 cm, 0-100 cm, or 0-120 cm. The X axis can be TIME, DISTANCE, or STEPS.

To change the axis label, touch the axis label (in Figure 2.12 the words *Number of Steps*) to toggle between selections.

Footfalls/Histogram Screen Parameters

Touch <Next> at the Patient Setup screen to advance to the Footfalls/Histogram screen. At this screen, users can view patient progress via either a footfall or histogram display. Touch the appropriate icon at the bottom of the left to toggle between display formats. With either display, the following parameters can be adjusted at any time as follows:

- *Walking Speed (mph):* Located at the top right of the screen. Use the associated <▲> and <▼> icons to set this goal to match the desired cycles per second.

  NOTE: *The walking (gait) speed can be increased in two ways: Increase the step frequency (step cycle) or increase the step length.*

  Walking speed is displayed in MPH or KMH. The default value depends upon how the Gait Trainer is set up (English or Metric). Most people can relate better to MPH or KMH than cycles per second. To determine what the cycles/second are, toggle the speed on the left. When step length is increased or decreased, the green lines will move up or down. The patient's goal is to place their foot between the lines. The numeric bars show the real time average of the last five step lengths for the respective side. Two vertical green bars are displayed if the patient is stepping within the lines (Figure 2.11) and change to orange when the footfall is too short (Figure 2.10).

  Clinical tip: *Increase the step length to challenge the patient to take longer steps.*

  NOTE: *For visual and audio biofeedback, the treadbelt speed must be greater than 0.3 mph (0.48 kmh).*

  A step cycle is a successive heel strike for the same foot (i.e., right step, left step, right step). Set the treadbelt speed based on how many complete successive heel strikes occur within a second. 0.1 cycles per second is very slow; 3 cycles is fast. A normal walking step cycle approximates 1 cycle per second.

  The cycle/sec speed and step length settings regulate the treadbelt speed. If the treadbelt speed is below 0.3 mph (.48 kmh), a message will display noting that the treadbelt is moving too slowly for biofeedback.

- *Time*: Located at the top left of the screen, counts down from the timing set at the Patient Setup screen.

- *Step Length:* A range equaling [Leg length (cm) x .69] to [Leg length (cm) x .86]. Step Target is placed within this range plus or minus the entered standard deviation. Located at the bottom right of the screen. Use the associated <▲> and <▼> icons on the right side of the screen to increase or decrease goal value.

  NOTE: *A Step Target is a theoretical footfall area based on calculated step length. When the step target distance is increased, the treadbelt moves faster because steps need to become longer. If target distance is decreased, treadbelt speed decreases because steps need to become shorter.*

- *Distance*: Located at the left of the screen, touch the blue dot <o> to toggle units of measure between miles, meters, and kilometers.

- *Speed (Treadbelt Speed)*: Located at the left of the screen, touch the blue dot, to toggle units of measure between KMH, MPH, and meters/second.

- *Heart Rate*: Heart rate monitoring is accomplished by having the patient hold onto both heart rate handgrips on the front handrail. The heart rate value will be displayed at the top of the screen when the handgrips are held.
- *Histogram or Footfall*: Located at the bottom left of the screen, touch the desired icon to toggle between these two choices.

Footfalls

When the patient's actual footfalls are detected, they are displayed with respect to the step length lines. When the patient falls within the set step length tolerance as set in biofeedback option, the footfalls are synchronized with the target and the message GOOD JOB will show in the display. Should they fall outside of the step length tolerance, the display will tell the patient what footfall is outside of the range by displaying a prompt to go longer or shorter on the respected foot or feet (Figure 2.10).

NOTE: *Because footfalls are projected based on the patient's last step the screen is always one step behind. This should not be apparent once the patient falls into a rhythmic walking pattern. If a step does not go in front of the opposite step, the target box will not appear.*

Histogram

The Histogram displays footfalls as a two-pixel wide dot. The X-axis shows distance traveled and the Y-axis shows the deviation, where 1 pixel is equal to 1cm of deviation. If the patient goes beyond the Standard Deviation (SD), the histogram will deviate from straight path.

NOTE: *On the histogram graph, the upper and lower horizontal green lines are the target step length area, plus or minus the step length tolerance. The Step Length Tolerance Range can be adjusted in the Biofeedback Options screen (from the Patient Setup screen).*

3. Normative Data

The normative data charts provided in this manual can be used to develop rehabilitation programs and discharge criteria for patients. The normative values are based on age and gender; therefore, comparisons can be easily made.

NOTE: *Clarification of Normative Data for the Gait Trainer: The normative data and goals presented in the Biodex Gait Trainer are derived from the reference tables in Gait Analysis, An Introduction, 2nd. Edition, Michael W. Whittle, 1997, pgs. 218 - 219.*

The cycle time in Whittle's research is measured in seconds, whereas the Gait Trainer uses cycles/second. Therefore, data are presented as the inverse function of the cycle time:

Cycles per second = $Cycles^{-1}$

Whittle also presents normative data for stride length. The Gait Trainer uses step length. A stride equals two steps; therefore, these tables represent stride length divided by two.

Table 3.1. Stride Length Tables

Table A.1 *Approximate range (95% limits) for general gait parameters in free-speed walking by normal FEMALE subjects of different ages*

Age (years)	*Cadence (steps/min)*	*Cycle time (s)*	*Stride length (m)*	*Speed (m/s)*
13–14	103–150	0.80–1.17	0.99–1.55	0.90–1.62
15–17	100–144	0.83–1.20	1.03–1.57	0.92–1.64
18–49	98–138	0.87–1.22	1.06–1.58	0.94–1.66
50–64	97–137	0.88–1.24	1.04–1.56	0.91–1.63
65–80	96–136	0.88–1.25	0.94–1.46	0.80–1.52

Table A.2 *Approximate range (95% limits) for general gait parameters in free-speed walking by normal MALE subjects of different ages*

Age (years)	*Cadence (steps/min)*	*Cycle time (s)*	*Stride length (m)*	*Speed (m/s)*
13–14	100–149	0.81–1.20	1.06–1.64	0.95–1.67
15–17	96–142	0.85–1.25	1.15–1.75	1.03–1.75
18–49	91–135	0.89–1.32	1.25–1.85	1.10–1.82
50–64	82–126	0.95–1.46	1.22–1.82	0.96–1.68
65–80	81–125	0.96–1.48	1.11–1.71	0.81–1.61

4. Test Results

Exercise results can be reviewed on the Test Results screen. This screen appears after touching <Results> on the Gait Training screen.

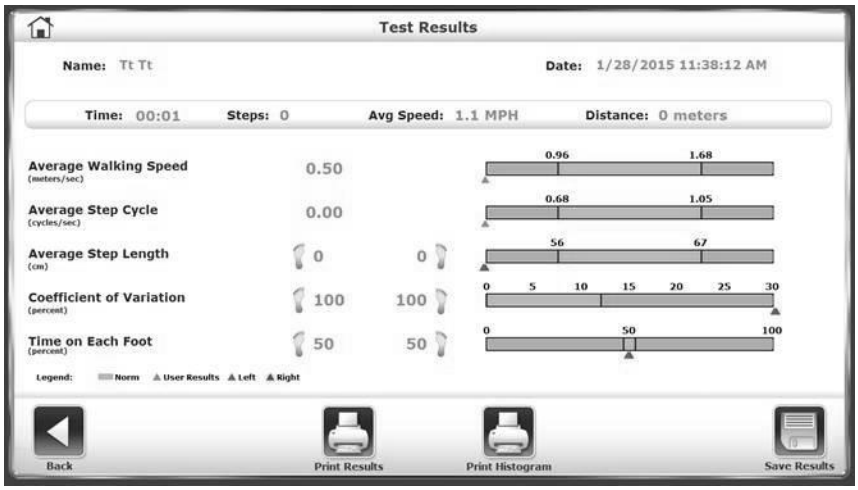


Figure 4.1. The Test Results Screen

Test Results Parameters

Time: This displays the total elapsed time from the start of the exercise session until either the end of the session or when the <STOP> icon is pushed.

Steps: Total Steps during the exercise session.

Average Speed: Average speed of the treadbelt during exercise session.

Distance: This is the total distance traveled by the treadbelt, which is in essence the distance traveled by the patient.

Average Walking Speed: Normative values have been established and are dependent on age and sex. The norms are expressed next to the real time value.

Average Step Cycle: This is calculated by taking an average for the step cycles during the exercise.

Average Step Length: This number is calculated by taking an average for all of the step lengths.

Coefficient of Variation: This is calculated as the amount of variation occurring between footfalls.

Time on Each Foot: This is the actual time spent on the mentioned limb. The time spent on each limb should be equally distributed between right and left. Should they be different, the patient is spending more time on one leg than the other.

Test Results Screen Functions

From the Test Results screen the user can perform the following functions:

Back: Return to the Footfalls/Histogram screen by touching <Back>. All current exercise data will be lost if <OK> to proceed is touched. To cancel and return to the Test Results screen, touch <Cancel>.

Print Results: Touch <Print Results> to print out a Gait Training Exercise Summary.

Progress Report: Touch <Progress Report> to compare results over time. For more details, refer to the section on progress report. This icon will only be visible if there is more than one exercise session (test) to compare.

Print Histogram: Touch <Histogram> to print a histogram for this exercise session.

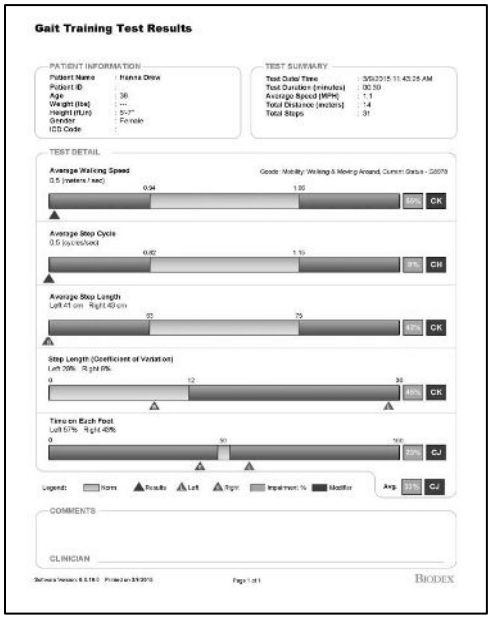
Save Results: This option allows the user to save exercise results for later reporting or export as follows:

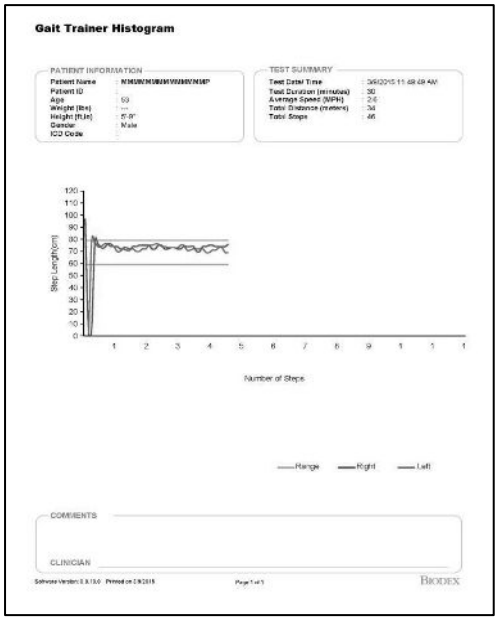
1. At the Test Results screen, touch the <Save Results> icon to save the results of the latest gait training session.

   NOTE: *If no patient name has been entered, the system will prompt that the "The Patient Name is Undefined". Enter the Patient Name to Save the Data. Touching <OK> will display the Add a New Patient screen where the patient's name and other data are entered. Touch <OK> again to save the results.*

   If the user tries to continue without entering a patient name, a prompt will appear stating that all exercise results data will be lost. Press <OK> to return to the Patient Setup screen, or <Cancel> to return to the Patient Name is Undefined screen.

2. If the patient name has already been entered, touch <OK> on the Test Results screen to save the results for later reporting or export.





Figures 4.2 and Figure 4.3. Gait Trainer printouts include a Gait Training Test Results and Gait Trainer Histogram.

Gait Trainer Progress Report

A progress report is perfect for showing need, progress, and outcome. Progress reports for specific parameters are available when a patient has multiple exercise reports.

Figure 4.4. Select any of the patient records by touching a row.

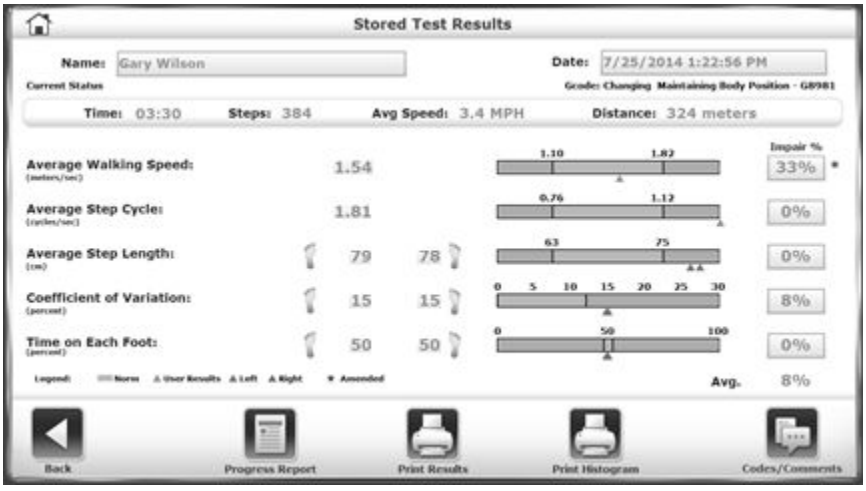


Figure 4.5. The Stored Test Results Screen

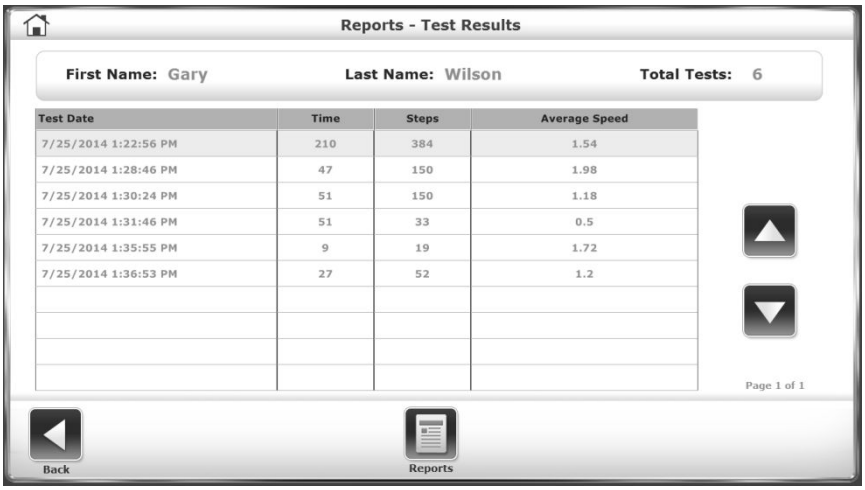


Figure 4.6. Select Progress Report, and Reports on the following screen.

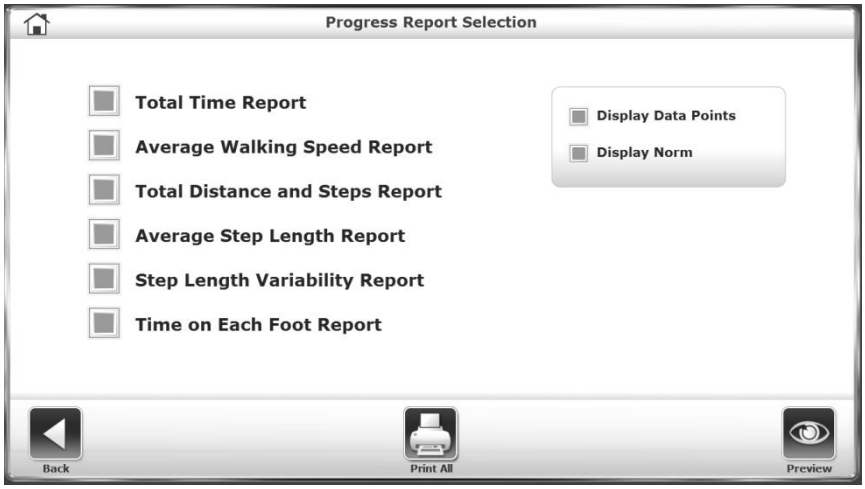


Figure 4.7. Touch the progress parameters that you are interested in viewing and/or printing. Green boxes indicate selected parameters. Also, choose to have data points on the report and/or Normative data ranges.

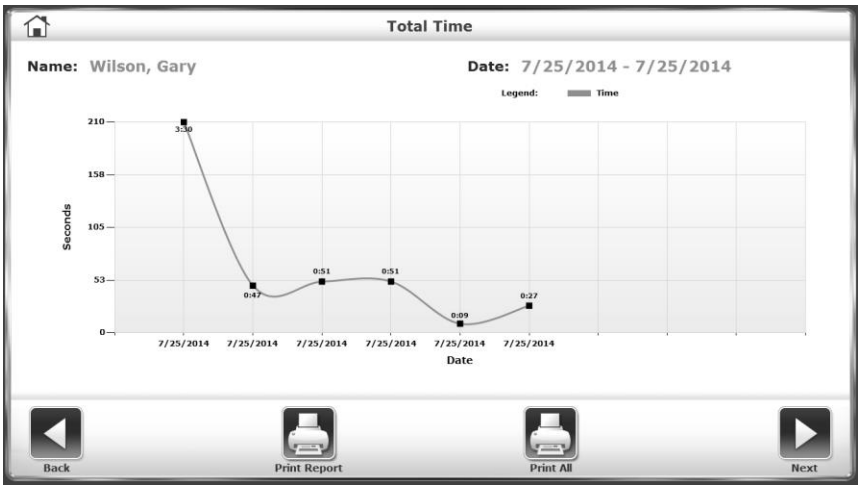


Figure 4.8. Progress report showing total time in seconds for each exercise session

Figure 4.9. Progress report showing increase or decrease in average walking speed over the six sessions

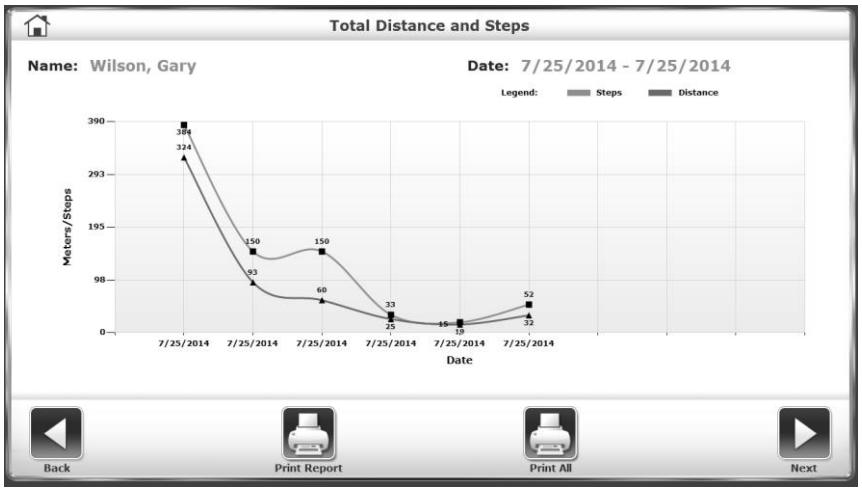


Figure 4.10 Progress report showing increase or decrease in total distance covered and steps taken

Figure 4.11. Progress report showing increase or decrease in average step length

Figure 4.12. In this case, the progress report shows an increased step length variability over the sessions

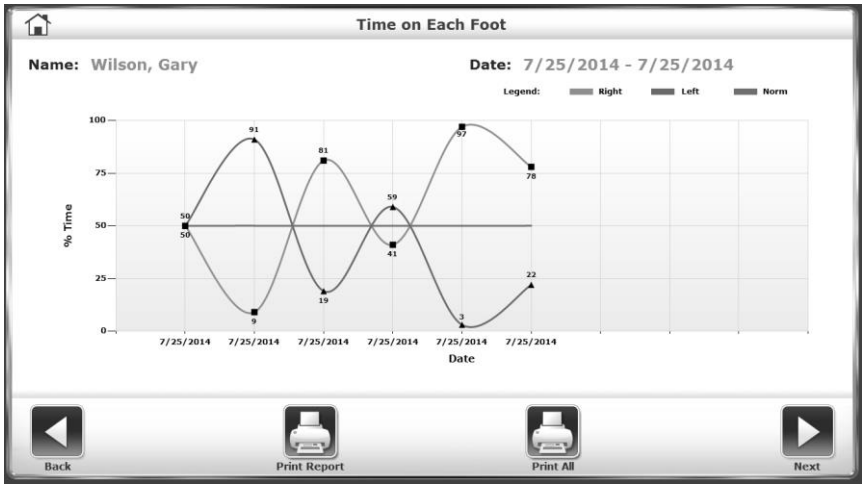


Figure 4.13. Progress report showing the percentage of time spent on each foot

5. Treadmill Operation

Figure 5.1. The Quick Start feature allows the user to begin the exercise session with minimal input.

Quick Start Operation

Although the Gait Trainer offers advanced programming capability, it also features a "Quick Start" function that allows the user to immediately begin exercise on the system with 1/4-mile scaled track views.

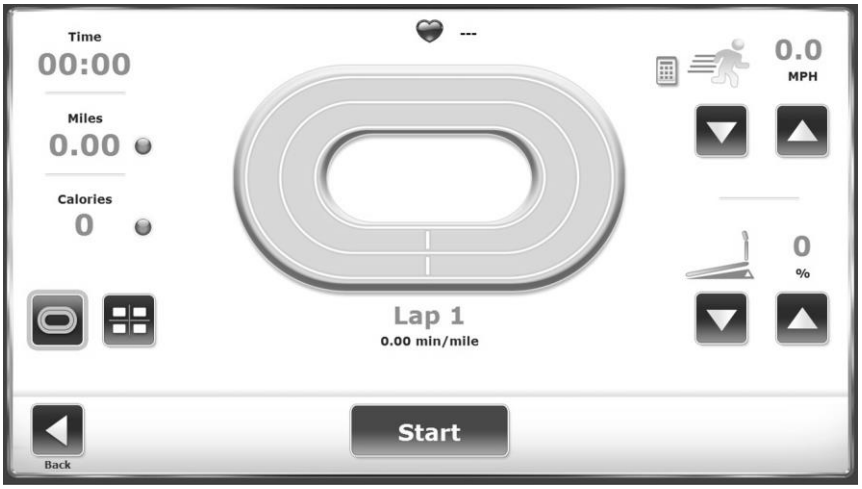


Figure 5.2. Quick Start Track View

Quick Start operation is simple. With the system turned ON, position the user on the treadbelt and proceed as follows:

1. Touch <Treadmill> on the Opening Menu. The Treadmill Opening Menu is displayed. Touch <Quick Start>.
2. Press <Start> on the display to activate the treadbelt. The treadbelt will ramp up to 0.1 mph (0.16 km/h)
3. Touch the <▲> and <▼> arrows on the screen to adjust the Speed and the Elevation as desired.
4. Touch the display icons at the bottom left of the screen to toggle between the Quick Start Exercise Track display and a Numeric display.
5. Touch <Pause> to pause the exercise session at any time. Touch <Resume> to resume the exercise session.
6. Touch <End> to end the exercise session at any time.

Quick Start Track / Numeric Display Parameters

Users can choose from a Quick Start Exercise Track or Numeric display during Quick Start exercise sessions. The following parameters are displayed for both choices.

NOTE: *To toggle between displayed parameters (i.e., to change measurement units for calories, pace, or distance), touch the blue dot next to each parameter heading.*

Time: Cumulative time in minutes/seconds from the point at which the treadbelt begins to move in either direction.

Distance: The distance covered in miles or KM from the beginning to the end of the current exercise session.

Calories: Toggle between:

- Calories: Total calories burned by the user during the current exercise session. This value is displayed in real-time.
- Calories/Hr: Total calories burned in one hour if exercise continues at the current rate. This parameter is dependent upon a default weight of 150 pounds.
- METs: This value reflects the resting rate of oxygen consumption with one MET equal to the oxygen consumption of a seated individual at rest. Thus, a seated individual in a resting state is consuming one MET. A seated individual exercising at a rate of two METs is consuming twice the oxygen of a seated resting individual. A person exercising at 10 METs is consuming ten times the oxygen of a seated resting individual. To compute the METs of a person actively exercising on the Gait Trainer, the system uses standard calculations based on American College of Sports Medicine Guidelines for Testing and Exercise. The METs value is always displayed in real/time for current speed.

Lap Count/Pace: The amount of time it will take the user to move one mile or KM at the current treadbelt speed. Toggle between miles or kilometers by clicking on the number below the Lap text.

Heart Rate: Displayed at the top of the screen, this is the real-time heart rate of the user during the exercise session measured using the contact handgrips.

Quick Setting Option for Speed Value: Clinicians and users have the option of bringing the treadbelt to a designated speed without having to press the <▲> button multiple times. To use this option, select the keypad located to the left of the Speed setting in the upper right corner (see Figure 5.2). The keypad will appear on the screen for ten seconds. If a Speed Limit has been enabled, the speed limit — in MPH or KMH — will appear at the top of the screen. Users will not be able to select a number value that is higher than the speed limit. (For more information on the Speed Limit setting, refer to the System Configuration section of this document.) To set a speed, touch a number button. The window will close and the treadbelt will start "ramping up" to that speed.

Figure 5.3. The Manual Start Setup Options screen allows entry of patient-specific information and parameters.

Manual Treadmill Operation

Manual treadmill operation is easy. Like the Quick Start function, Manual Start allows the user to begin exercising quickly. Rather than using default settings, however, this mode of operation prompts the clinician to enter the patient's body weight, select the treadbelt direction, and enter values for Time, Distance, and Calories. During the exercise, the user can choose between Exercise Track or Numeric displays.

Manual Operation Procedure

NOTE: *For all screens, <Next> advances to the next screen, <Back> returns the user to the previous screen.*

1. At the treadmill Opening Menu select <Manual Start>. The Setup Options screen is displayed.

2. At the Setup Options screen, touch the appropriate icons to enter information and select treadbelt direction. In addition to the <▲> and <▼> arrows, a pop-up keypad can be used to enter values for Distance, Calories, and Body Weight. Once the desired information is entered/selected, touch <Next> to advance to the Exercise Track display.
3. Touch the Display icons at the lower left of the screen to toggle between the Exercise Track display and a Numeric display.
4. With the Exercise Track or Numeric Display on the screen, touch the yellow dot next to any heading or icon to change the value. To toggle between value settings (i.e., miles / KM), touch the displayed parameter.
5. When all parameters are entered/selected, press <Start> on the display to activate the tread-treadbelt and begin the exercise session. The treadbelt will ramp up to 0.1 mph (0.16 km/h).
6. Use the <▲> and <▼> arrows on the Exercise Track or Numeric Display to adjust the speed setting to the desired value. Both speed and elevation can be adjusted at any time during the exercise session.
7. Touch <Pause> to pause the exercise session at any time. Press <Resume> to resume the exercise session.
8. Touch <End> to end the exercise session at any time.

Manual Mode Exercise Track and Numeric Display Parameters

The same parameters are displayed on both the Exercise Track and Numeric displays. A brief explanation of these parameters can be found in the previous (Quick Start) section.

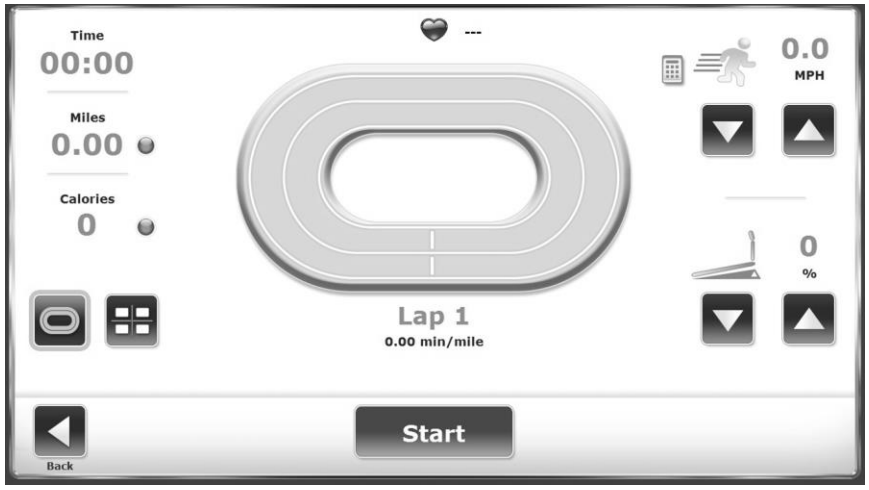


Figure 5.4. The Exercise Track Display

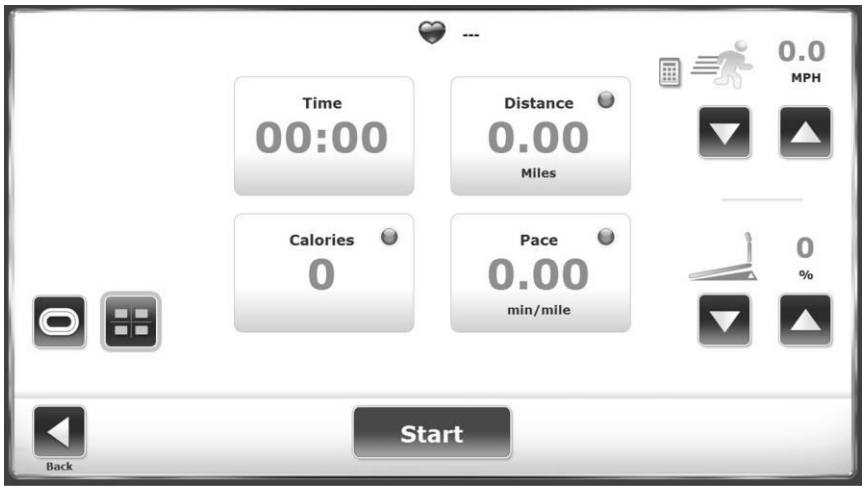


Figure 5.5. The Numeric Display

6. Treadmill Profiles

The Biodex Gait Trainer treadmill mode features five pre-loaded exercise profiles and the ability to create and select up to 12 custom exercise profiles. These programs allow the clinician to select pre-determined exercise format routines. Exercise profiles are divided into as many as ten segments each. Users can select any of the pre-defined exercise profiles, review or edit any exercise profile, or delete an existing exercise profile.

The pre-defined exercise profiles include:

- Anaerobic
- Aerobic
- Pyramiding
- Surge
- Random

Selecting a Pre-Defined Exercise Profile

To select a pre-defined exercise profile:

1. At the treadmill Opening Menu, touch <Profile>. The Select Profile screen is displayed.
2. Touch to select the desired pre-defined exercise profile. The Profile Setup Options screen is displayed.
3. At the Profile Setup Options screen, enter the Time duration, user's Body Weight, and the Maximum Elevation for the exercise profile. Touch <Next> to advance to the Profile Exercise screen.
4. At the Profile Exercise screen, push <Start> on the display to activate the treadbelt and begin the exercise session. The treadbelt will automatically ramp up to the speed required by the first segment of the desired protocol. The treadmill will also automatically rise or lower to the required elevation.
5. The treadmill will automatically beep to signal the end of each profile segment and proceed to match the required speed and elevation for the next segment. If necessary, the <▲> and <▼> arrows on the Exercise Track or Numeric Display can be used to adjust the speed and elevation setting at any time.
6. Touch <Pause> to pause the exercise session at any time. Press <Resume> to resume the exercise session.
7. Touch <End> to end the exercise session at any time.

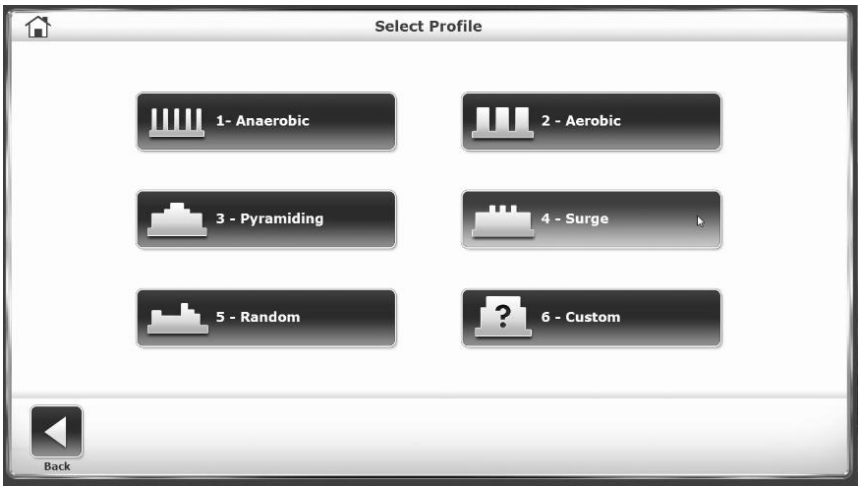


Figure 6.1. The Select Profile screen allows the user to choose from five pre-defined profiles.

Figure 6.2. At the Profile Setup Options screen, users can enter values for time, body weight and maximum elevation.

Profile Mode Exercise Track and Numeric Display Parameters

The same parameters are displayed on both the Exercise Track and Numeric displays. A brief explanation of these parameters can be found in the Quick Start section.

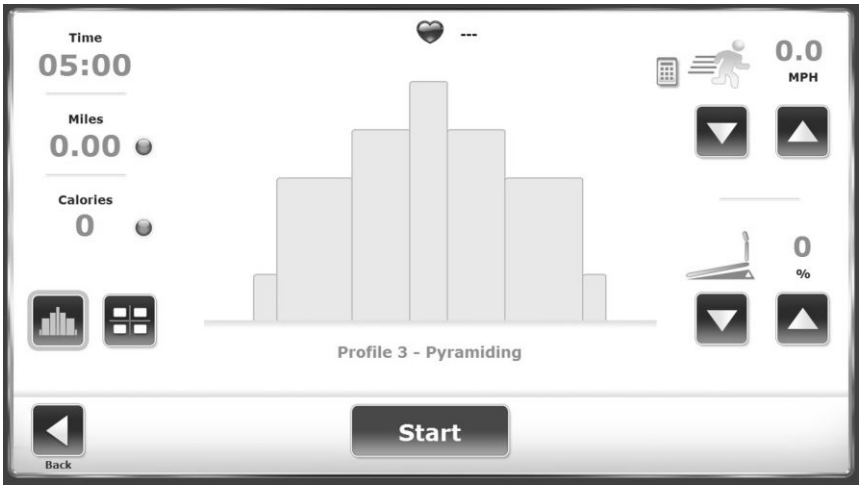


Figure 6.3. Ready to begin an exercise session with Profile 3, Pyramiding, selected.

Designing a Custom Exercise Profile

To design a custom exercise profile:

1. At the treadmill Opening Menu, touch <Profile>. The Select Profile Menu is displayed.
2. Touch option six, <Custom>. The Custom Profiles screen is displayed.
3. Touch the <Empty> (1-12) icon of the profile to be designed. Touch <Edit Profile> at the bottom of the screen. The Editing Profile screen is displayed.
4. Each exercise profile can be divided into as many as ten separate stages. Enter the speed, elevation, and time duration for each stage. To add stages, touch the “add row below” icon to the right of the Time field. If it is necessary to clear a stage, touch the recycling can on that row. If it is necessary to clear all of the stages, touch <Delete All>. Touch <OK> to return to the Custom Profile menu.
5. At this point, the user can select any of the custom profiles designed. The Custom Profile Setup Options screen is displayed. Proceed as if using a pre-defined profile.

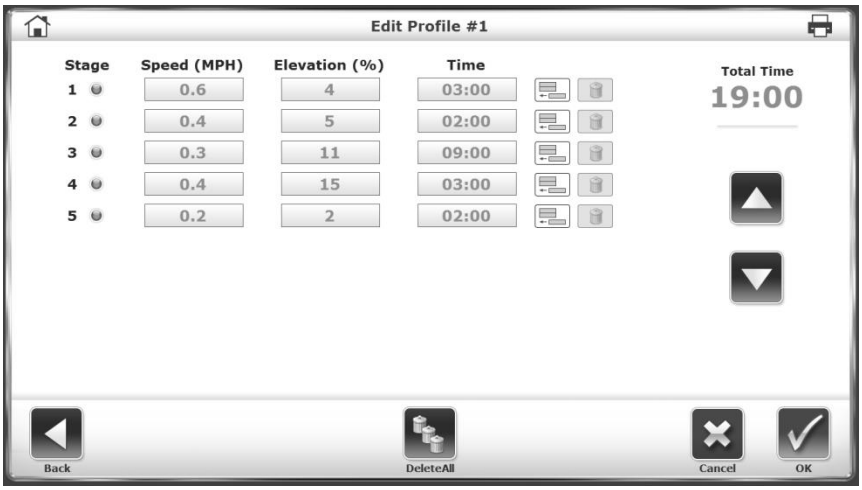


Figure 6.4. *At the Editing Profile screen, clinicians enter values for speed, elevation and time for each of up to ten stages for any profile.*

7. Gait Trainer Utilities

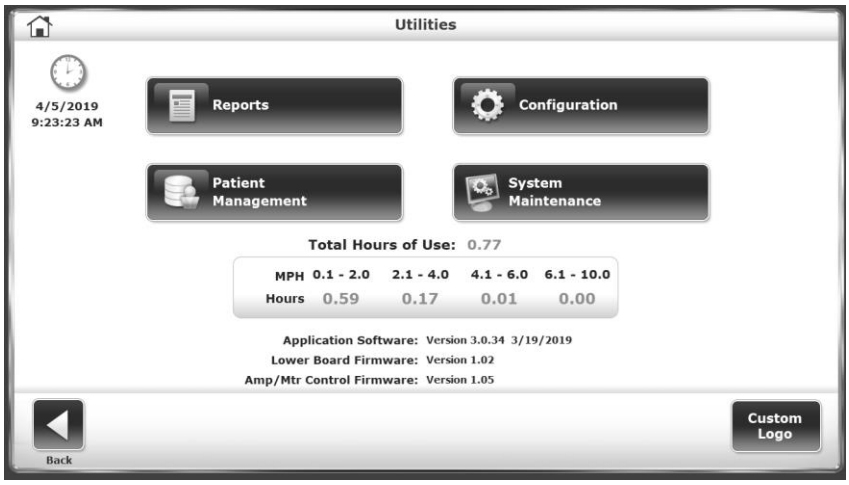


Figure 7.1. The Utilities Menu

To access the Utilities menu, touch <Utilities> on the Main screen. The Utilities Menu allows access to the Configuration, Patient Management, Reports, System Maintenance, and Advanced System Maintenance (not displayed) screens. The Utilities menu also displays technical information about the Gait Trainer firmware version.

NOTE: *The Advanced System Maintenance is an icon that is normally hidden; instructions on accessing it will be discussed later in this section.*

Reports

Touch <Reports>. On the Reports – Test Results screen, test results can be viewed or printed. Four Report Types are available: Test Results, Histogram, Progress Report – All, and Progress Report by Selection.

NOTE: *Codes/Comments data cannot be edited in Reports section screens.*

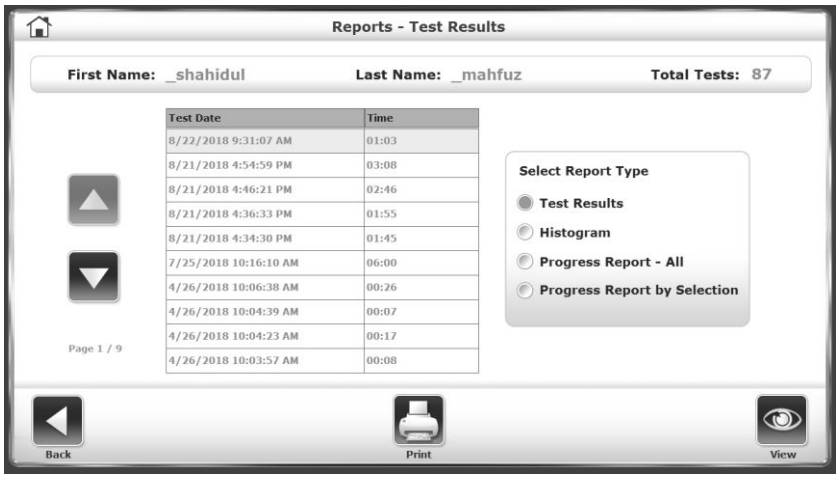


Figure 7.2. Reports – Test Results Screen

Configuration

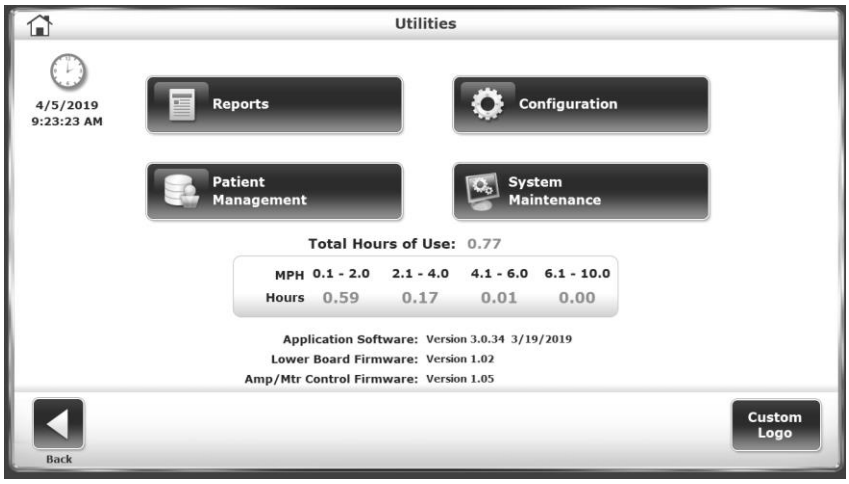


Figure 7.3. Configuration – Utilities Screen

To advance to the Configuration screen from the Utilities Menu, touch <Configuration>. There will be a submenu featuring two icons; one for System Configuration and one for Gait Trainer Configuration. For either option, the user must enter 159 at the "Access ID Code" prompt and touch <OK>.

System Configuration

The System Configuration screen allows the user to choose between various display options and to set specific parameters for a variety of treadmill functions.

Following is a description of Configuration screen options. Once all parameters and values are set, touch <Back> to exit and return to the Utilities Menu. Touch <Back> a second time to return to the Main Menu.

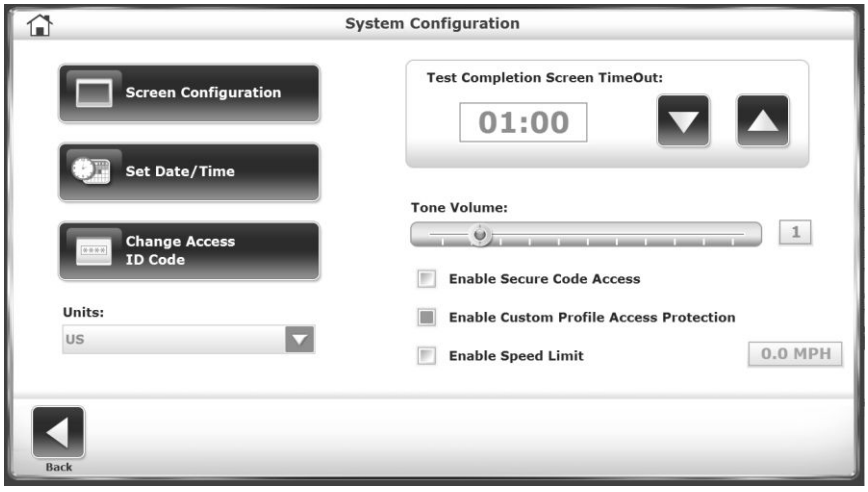


Figure 7.4. System Configuration Screen

System Configuration Screen Parameters

Test Completion Screen TimeOut: This setting determines how long the Test Results screen will be displayed before the screen saver activates following completion of the exercise session. The default is “OFF” but the range can be adjusted from 0:15 seconds to 60:00 minutes. Touch the <▲> and <▼> icons to increase or decrease the value.

Screen Configuration: The Screen Saver setting determines how long the display screen remains ON when the system is no longer in use. Once the selected time expires, the screen fades to black even if the Gait Trainer remains ON. To enable the Screen Saver function, touch the radio box next to <Enable Screen Saver> causing it to turn green. Use the <▲> and <▼> icons to increase or decrease the value displayed in 1-minute increments. The “time out” range is from 00:00 to 50:00. To enable a mirror image of the display on an external monitor, touch <Mirror to External Monitor> (An external monitor must already be connected to the VGA port on the bottom of the display.) Touch <OK> to confirm the changes and return to the Configuration screen. Touch <Cancel> to return to the Configuration screen without making any changes.

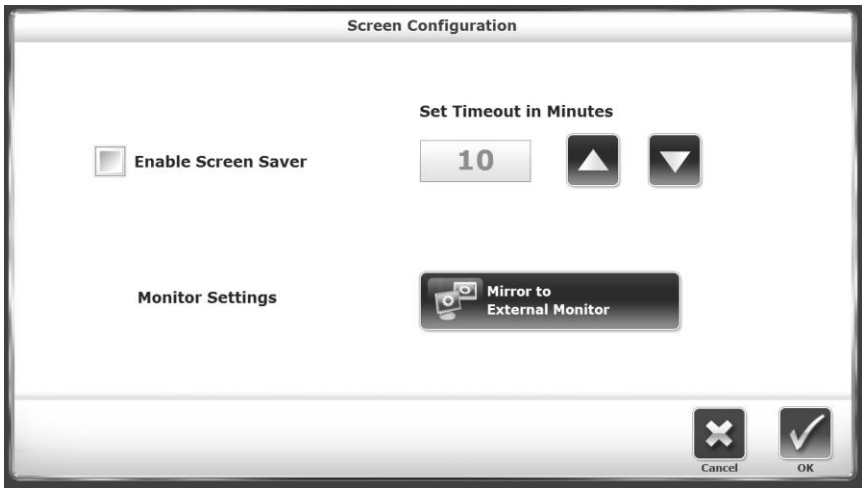


Figure 7.5. Screen Configuration Screen

Set Date/Time: Touch <Set Date/Time> to change the system time, date, or time zone. Touch the button to highlight the value to change and use the <▲> and <▼> icons to increase or decrease the value as desired. To change the Time Zone, touch the drop-down menu once and scroll through the list to make a selection. Touch <OK> to save the changes and return to the Configuration screen.

Figure 7.6. Set the System Date/Time Screen.

Tone Volume: Touch any section of the horizontal bar to select a new tone volume setting. Selecting low numbers along the bar will result in lower volume while selecting high numbers makes the louder. Tone volume settings range from 0 to 10.

Change Access ID Code: Users can change the default Access Code (159) used to access secure settings in the device software. To change the access ID code, select a new Access ID Code by pressing this button and entering the value using the <▲> and <▼> arrows or the numeric buttons on the key pad. Press <OK> to save the New Access ID Code and return to the System Configuration screen.

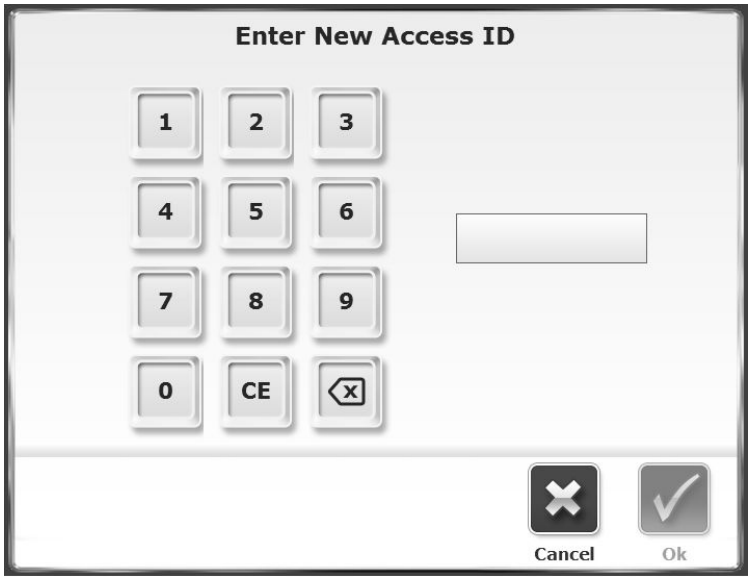


Figure 7.7. Enter New Access ID Screen.

Units: (see Figure 8.4.) Treadbelt speed can be measured in either US (MPH) or metric (KMH) units. Touch this menu to toggle between the two.

Enable Secure Code Access: Having this function enabled will require users to input an Access ID Code before changing certain settings on the device. The default Access ID Code is 159.

Enable Custom Profile Access Protection: Having this function enabled will require users to input an Access ID Code when they attempt to alter a customized profile that has been created in the Custom Profiles section of the Treadmill mode.

Enable Speed Limit: The software for the Gait Trainer 3 includes an additional safety setting to limit treadbelt movement to a predetermined speed during Treadmill Training activities. Clinicians can determine what speed limit would be most appropriate for the type of patients in their facilities. To enable the Speed Limit functionality, touch the box once to turn it green. To change the default Speed Limit from 5 MPH, touch the enabled "5 MPH" window once; a keypad is displayed for altering the speed limit. Speed limits can be set in either MPH or KMH by toggling the "Units" function in the bottom left portion of the screen. The device will be shipped with the Speed Limit functionality disabled.

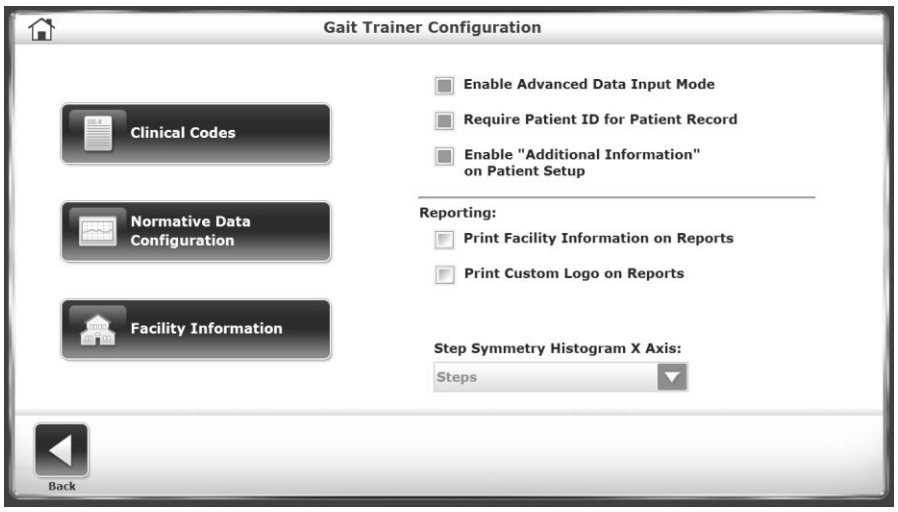


Figure 7.8. Gait Trainer Configuration Screen

Gait Trainer Configuration

The Gait Trainer Configuration screen allows the user to further configure the Gait Trainer user settings (e.g., Normative Data).

Descriptions of the Gait Trainer Configuration screen options are detailed below. Once all parameters and values are set, touch <Back> to exit and return to the Configuration submenu. Touch <Back> a second time to return to the main Utilities menu.

Gait Trainer Configuration Screen Parameters

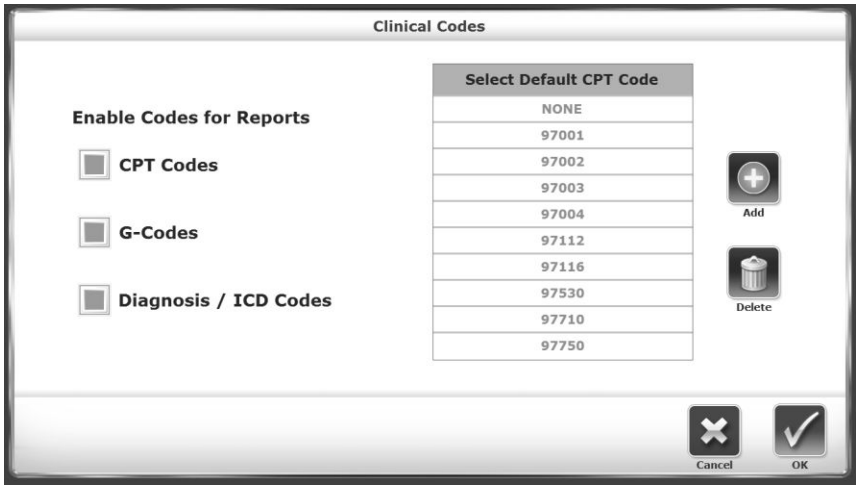


Figure 7.9. Clinical Codes Screen

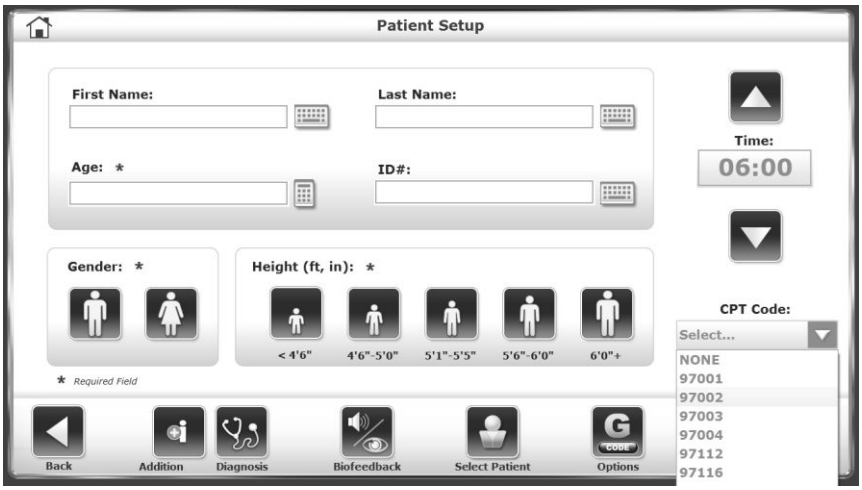


Figure 7.10. Patient Setup screen with Clinical Codes (CPT) option activated

Normative Data Configuration: Normative data can be specified to each facility's needs. Select a particular row of demographic information and touch the pencil icon beside the row to edit the norms for performance in the settings at the bottom of the screen. Selecting the <Restore Defaults> icon returns the normative data back to the factory setting.

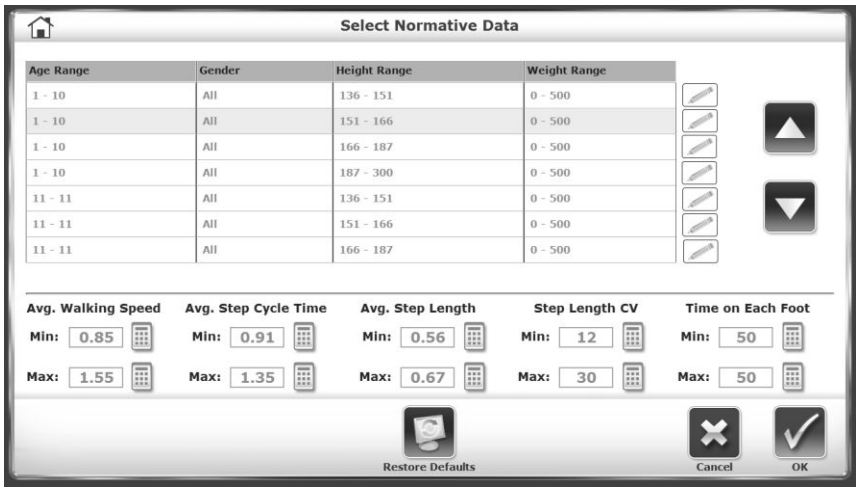


Figure 7.11. Select Normative Data Screen.

Facility Information: Use this screen to enter the facility's name, which can be featured on printed reports.

Enable Advanced Data Input Mode: Touch this checkbox to input a patient's exact date of birth and height numbers in the Gait Training Patient Setup Screen (as opposed to simply designating an age number and height range).

Require Patient ID# for Patient Record: Touch this checkbox to require that users input a specific Patient ID# for each new patient that performs gait training sessions.

Enable "Additional Information" on Patient Setup: Touch this checkbox to enable the Additional Info icon at the bottom of the Gait Training Patient Setup screen.

Print Facility Information on Reports: Touching this checkbox allows the user to input information about the facility that will be displayed on printed reports.

Print Custom Logo on Reports: Touching this checkbox will display the logo on printed reports.

Step Symmetry Histogram X Axis: This setting allows the X axis for the Reports/Test Results histograms to be units of time, steps, or distance.

Patient Management

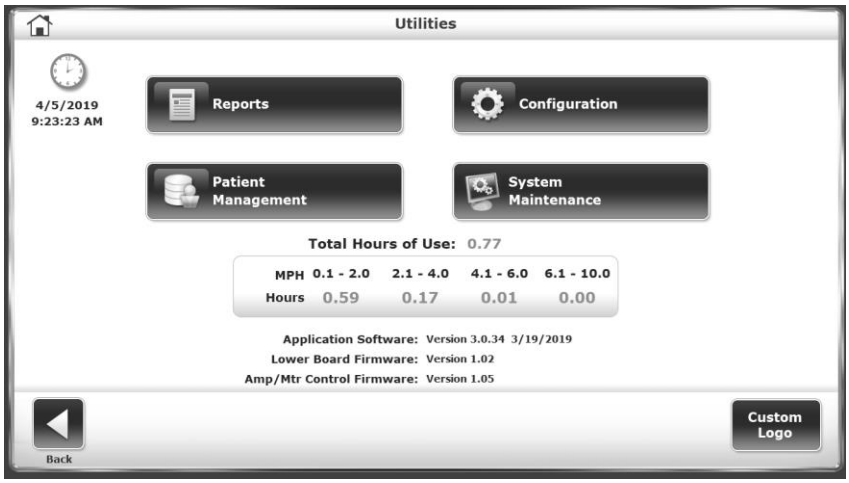


Figure 7.12. The Utilities Menu

Figure 7.13. The Patient Management – Select a Patient Screen

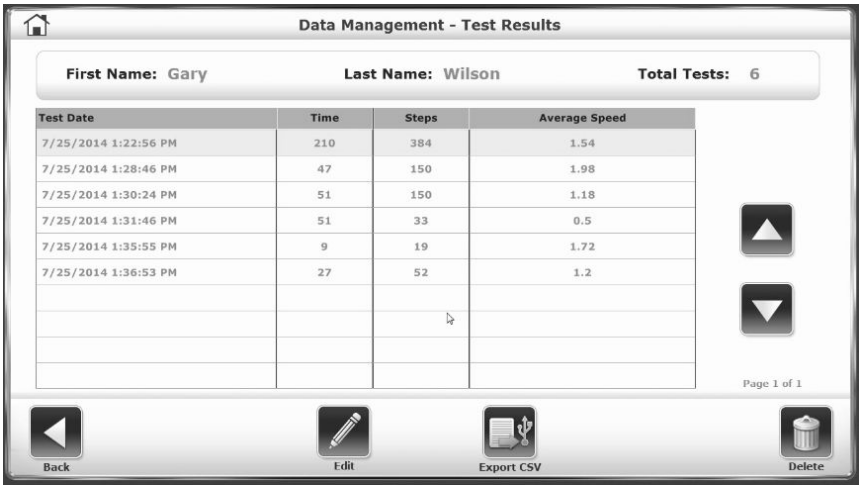


Figure 7.14. The Patient Management – Test Results Screen

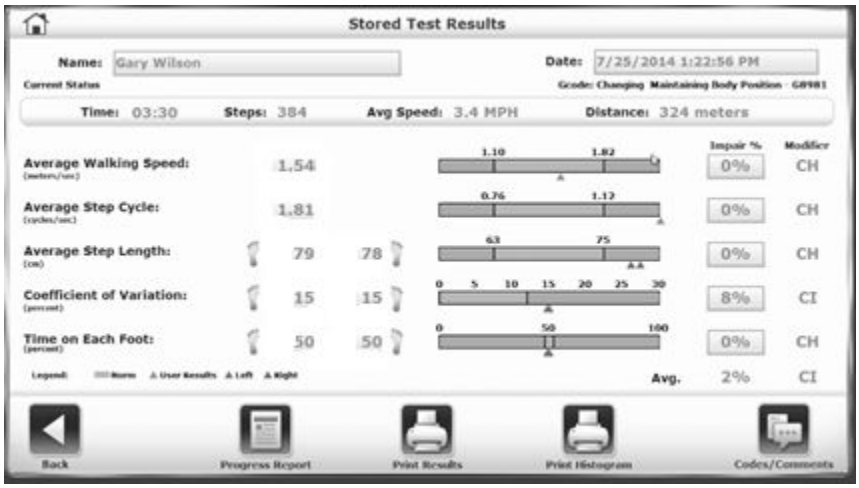


Figure 7.15. The Stored Test Results Screen

To advance to the Patient Management screen from the Utilities Menu, touch <Patient Management>. Enter 159 at the "Access ID Code" prompt and touch <OK>. The Patient Management screen is displayed.

To view an individual's records or an individual's test results, select the row listing the patient to be viewed from the main Patient Management screen (Figure 7.13), and select <Next>. From the Data Management – Test Results screen (Figure 7.14), select <Edit>. This displays the Stored Test Results screen (Figure 7.15).

Patient Management functions include the ability to add or edit an individual patient file, delete a file, delete single or multiple patient files, and import or export patient data. A description of each feature follows.

Adding Patient Files

To Add a Patient File:

1. From the Patient Management – Select a Patient screen, touch <Add Patient>.
2. On the resulting screen, there will be several fields to populate. Depending on how the system is configured, either the First and Last Name fields will be required or the Patient ID number field will be mandatory.
3. The user may also select to enter data on the Additional Information screen. On this screen, just to mention two options, the user can add details about the facility where the patient is being treated or create customized drop-down menus.
4. After inputting the new patient information, touch <OK>. The new file will be saved and the system will return to the Patient Management – Select a Patient screen.

To make the Patient ID# a required field when adding new patients:

1. From the Main system Utilities screen, touch <Configuration>.
2. On the next screen, touch <Gait Trainer Configuration>.
3. Check the box for "Require Patient ID# for Patient Record".

4. When the system returns to the Add Patient screen (from the Patient Management – Select a Patient screen) the First and Last Name fields are no longer required, but the Patient ID# field is required.

Editing Patient Files

To Edit a Patient File:

1. From the Patient Management – Select a Patient screen, touch a patient row, and touch <Edit>.
2. On the resulting screen, the fields that were present when the patient file was created are displayed. Depending on how the system is configured, either the First and Last Name fields will be required, or the Patient ID number field will be mandatory. If the Patient file was created when one of these fields was not required, a value must be entered in the now-required field in order to save any other changes (Refer to the previous section for instructions on changing this setting).
3. The user may also edit the data in the Additional Information screen. On this screen, the user can add details regarding the facility where the patient is being treated or create customized drop-down menus to name two options.
4. After editing the patient information, touch <OK>. The file is saved with the changes and the system returns to the Patient Management – Select a Patient screen.

Deleting Patient Files

To Delete a Single Patient File:

1. Touch to highlight the patient file to delete.
2. Touch <Delete> to delete the selected patient file. The system will display a prompt to ensure the selected file is to be deleted.
3. Touch <OK> to delete all test results associated with the patient. The system returns to the Patient Management screen.

To Delete An Entire Range of Patient Files:

1. Touch the <Delete Range> icon. On the next screen, the user can select a range of patient records to delete: All records, records from a certain date to present time, records Prior To a certain date, or all records between certain dates (From/To). The system will display a prompt to ensure all the selected files are to be deleted. Touch <OK> to delete the selected files and return to the Patient Management screen.

Importing Patient Data

The Import Patient Data function allows patient data from a stored test to be imported in a binary (.biodata) file format.

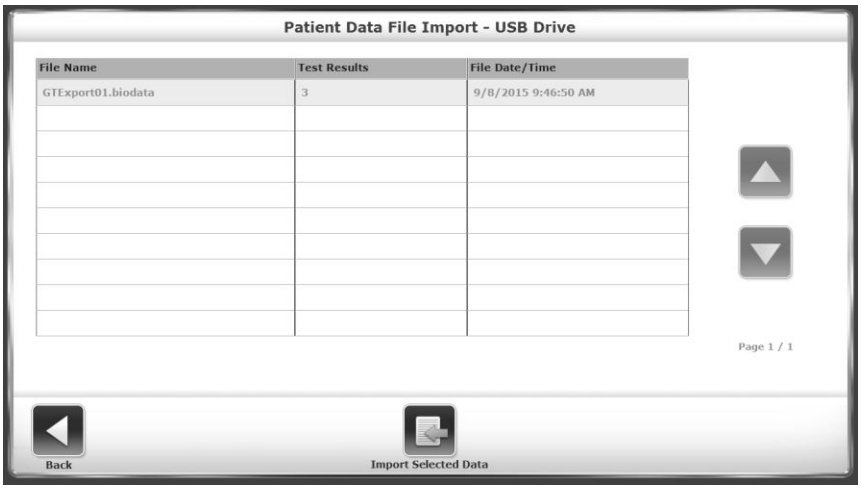


Figure 7.16. Select a File Name from the Patient Data File Import Screen.

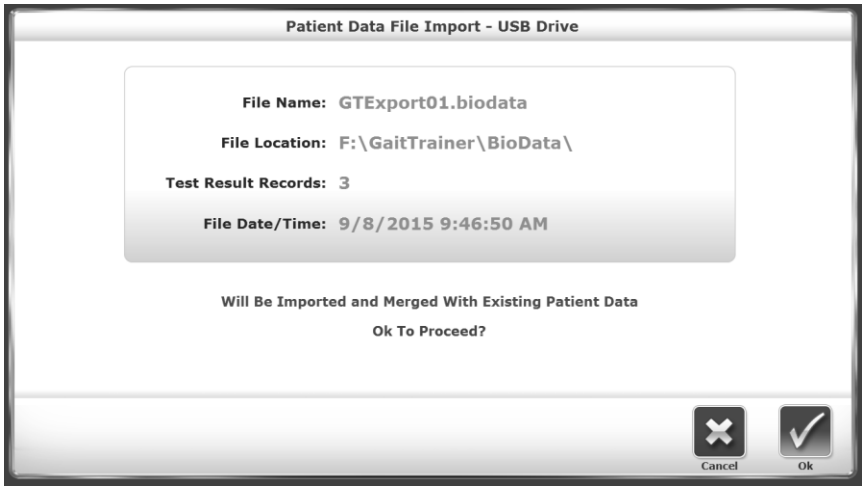


Figure 7.17. The Patient Data File Import Screen

To Import a Patient Data Set:

1. From the Patient Management – Select a Patient screen, touch <Import>.
2. The system displays the contents of a biodata folder from an attached flash drive. Select a data set to import by touching a particular row.
3. Touch <Import Selected Data>.
4. A confirmation screen is displayed prompting the user whether or not to proceed. Touch <OK> to update the system's data set with the patients and their associated test results in the imported data.

Exporting Multiple Patient Data Sets

The Export Multiple function allows patient data from stored tests to be exported in either a binary (.biodata) file format or a CSV format.

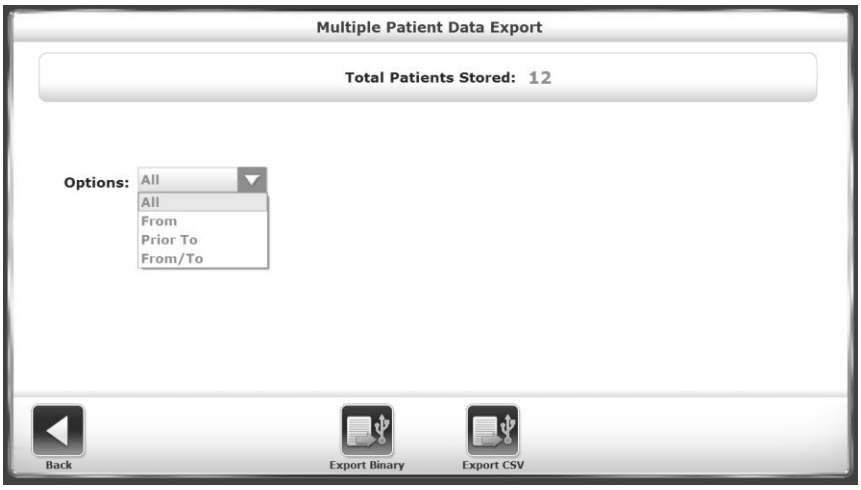


Figure 7.18. The Multiple Patient Data Export Screen

Figure 7.19. The Multiple Patient Data Export Screen

1. From the Patient Management – Select a Patient screen, touch <Export Multiple>.
2. On the next screen, the user has the option to select what range of patient records to export: All records, records from a certain date to present time, records prior to a certain date, or all records between certain dates (From/To).
3. Touch either the <Export Binary> button or the <Export CSV> icon. A confirmation screen is displayed prompting the user whether or not to proceed.
4. Touch the <Export Binary> or the <Export CSV> button again to complete the export process. The selected files are exported to the attached flash drive in the designated format.
5. Touch <Back> to return to the Patient Management – Select a Patient screen.

Working With Individual Patient Records

To export an individual patient data file:

1. From the Patient Management – Select a Patient screen.
2. Select a patient row, and touch <Next>.
3. On the following Data Management – Test Results screen, touch <Export CSV>. The CSV file will be saved to an automatically generated folder titled "BioCSV" (refer to Appendix A for details regarding how to perform a CSV file export).

   NOTE: *The user has the option to export patient data either to a Binary file or a CSV file, which can be stored locally on a hard drive.*

Printing Stored Results

To Print a Stored Test Result or Histogram:

- Touch <Next> at the Patient Management – Select a Patient screen.
- At the Data Management – Test Results screen, touch <Edit>.
- Touch <Print Results> to print out the patient file, or touch <Print Histogram> to print out a patient histogram.
- At the Print screen, the user has the option to send the record to a connected printer or to export the document to a PDF on a USB flash drive without printing it.

  Note: *When <Export PDF> is selected, the PDF will be exported to an automatically generated folder titled "BioReports" on an inserted USB flash drive.*

- After printing, the system returns to the Stored Test Result screen.

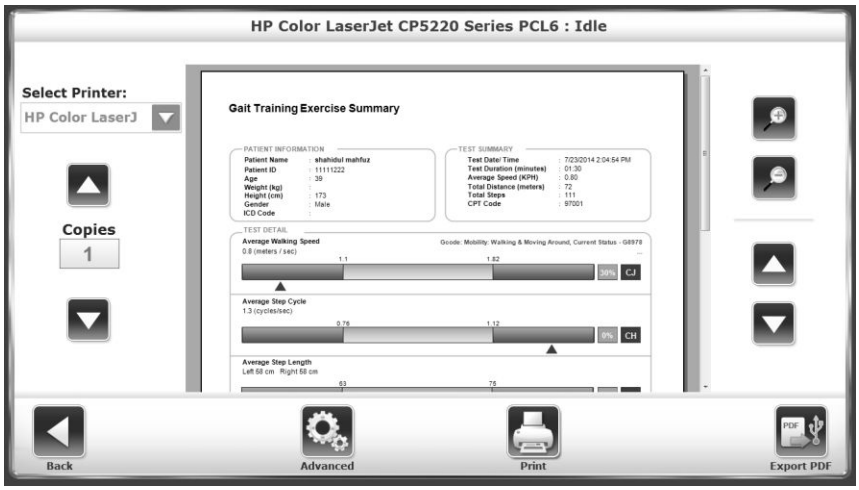


Figure 7.20. Print Results Screen

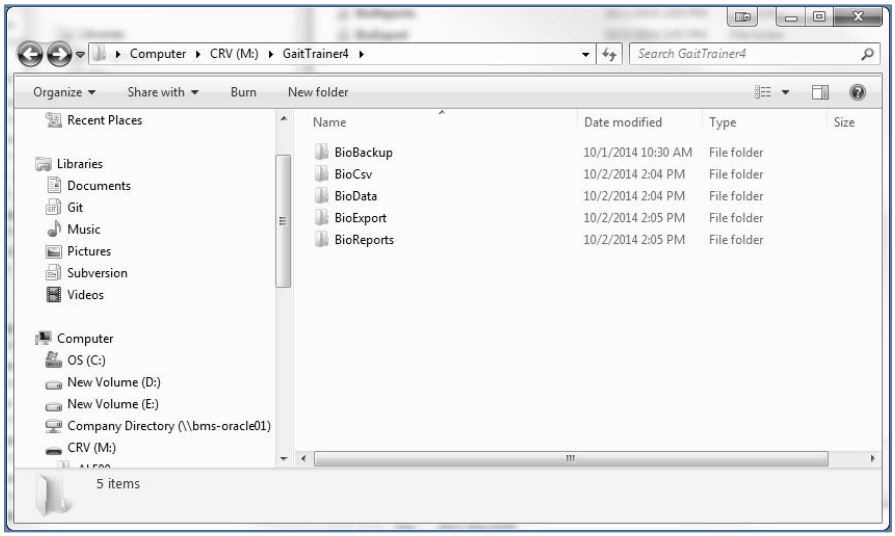


Figure 7.21. The hard drive saving location for the <Export PDF> function

Figure 7.21 illustrates that the BioReports folder is just one of several subfolders that are automatically generated in the main GaitTrainer4 directory, which is automatically generated by the system. Here is a list of the subfolders, along with the types of files they contain:

- *BioBackup*: The backup of system settings with database.
- *BioCsv*: Both individual CSV file and multi data CSV file.
- *BioData*: The patient test results as Binary file.
- *BioExport*: The event log file.
- *BioReports*: The reports in PDF format.

System Maintenance

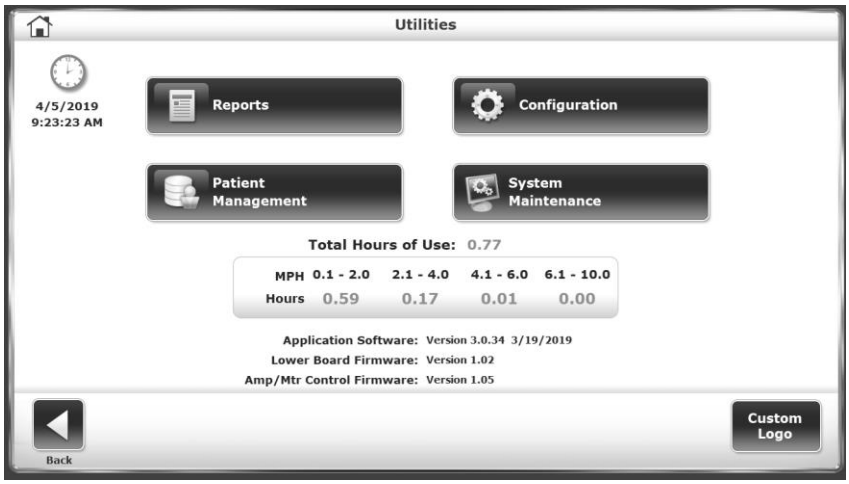


Figure 7.22. Utilities Screen

The System Maintenance main menu contains icons for the three configurations related to database maintenance:

1. Backup to USB.
2. Restore from USB.
3. Database Cleanup.

Figure 7.23. System Maintenance Screen

Backup to USB

The Backup to USB function creates a backup database of current patient records on a removable USB flash drive. After a flash drive is inserted into one of the device's USB ports, selecting the <Backup to USB> icon will generate the following screen:

Figure 7.24. Backup to USB Screen

Restore from USB

The Restore from USB function allows users to restore a previously backed up database to be the Gait Trainer's current data set. The restoration will be from a removable flash drive that was used in the Backup to USB function.

Selecting the <Restore from USB> icon displays the following screen:

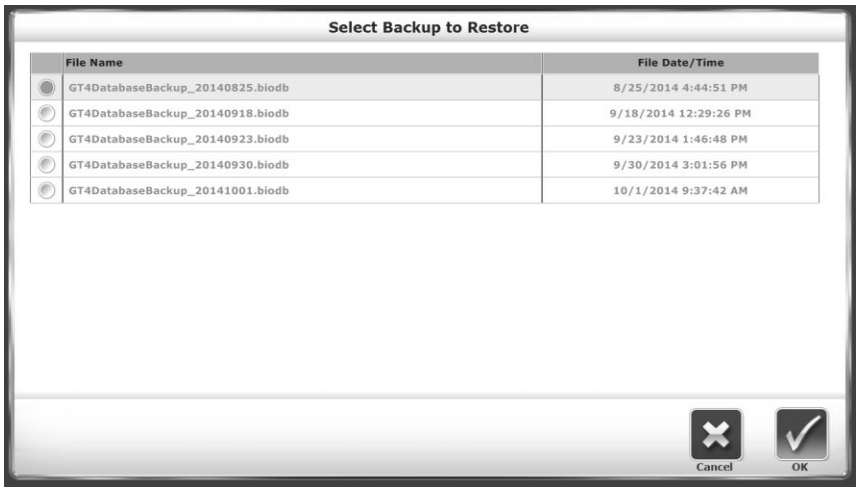


Figure 7.25. Restore from USB Screen

The Select Backup to Restore screen displays a list of backed up databases that have been created. The most recently backed up database will be the top row of the list. Select the database to restore as the Gait Trainer's current data set and select the <OK> icon. The Database Restore Complete screen is displayed as illustrated below:

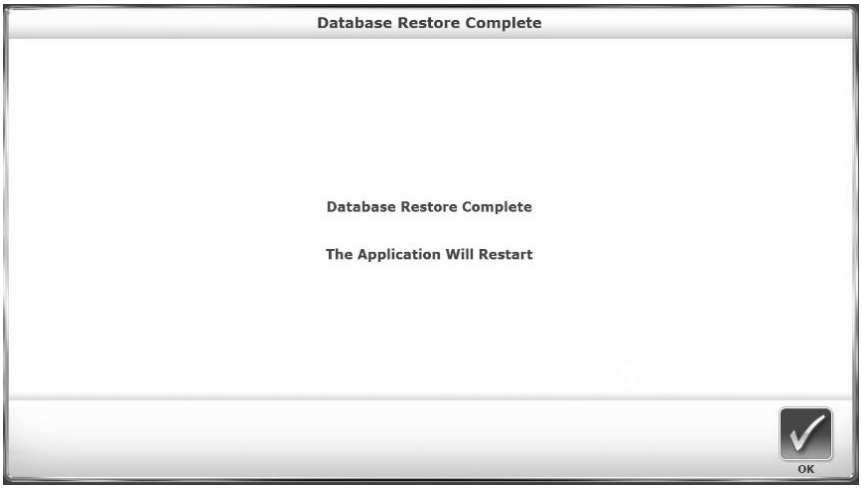


Figure 7.26. Restore from USB Confirmation Screen.

Depending on the size of the database, it can take some time to reach the Database Restore Complete screen. The Gait Trainer application will restart once <OK> is touched.

The Backup operation makes a backup of the entire system — not just the database. All system selections and settings will be backed up and the Restore operation will restore all of these settings in addition to the patient data. This includes the backup and restoration of the facility name. Also, for added safety/security, all backup data are encrypted.

Database Cleanup

Database Cleanup is an administrative maintenance function that reduces the system's overall file size.

Selecting the <Database Cleanup> button displays a confirmation screen prompting the user whether or not to proceed with the clean up or cancel the action.

Custom Logo

Use the following steps to select a custom logo:

1. Insert a USB flash drive containing the desired logo.
2. Touch <Custom Logo> on the Utilities screen.
3. Select the logo to be displayed on the screen and on printed reports.

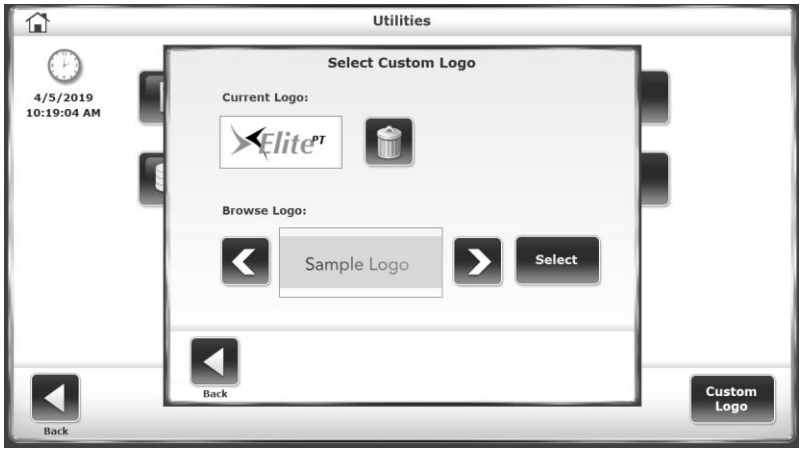


Figure 7.27. Utilities: Select Custom Logo Screen

Advanced System Maintenance

The Advanced System Maintenance screen is hidden from normal view. This screen, when active, allows the user to make adjustments such as selecting a language preference, performing speed and elevation calibration, and performing strain gauge calibration.

To access the System Maintenance screen:

1. Touch <Utilities>.

   NOTE: *The next step requires pressing the hidden keypads in the right and left corners of the displays touch screen.*

2. To access the <System Maintenance> prompt on the display:

a. Touch the right side of the Utilities screen.

b. Touch the left side.

c. Touch the right side again (see screenshot below). The <Advanced System Maintenance> button will display.

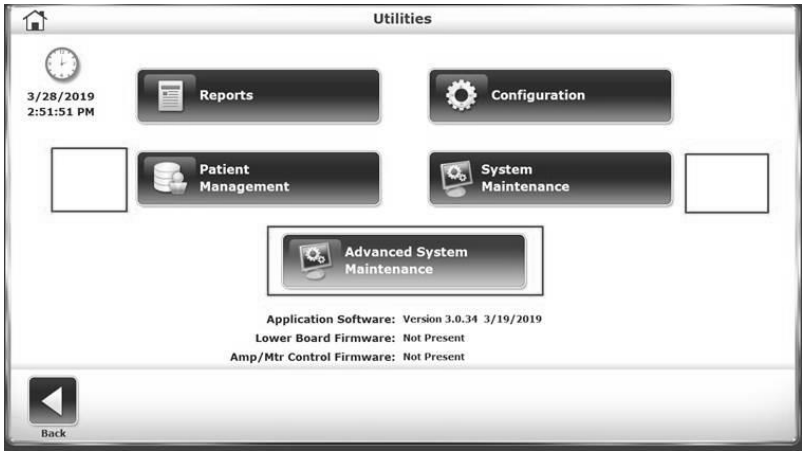


Figure 7.28. Unmarked touch areas for Access to the Advanced System Maintenance Screen

3. Touch <Advanced System Maintenance>. The Advanced System Maintenance screen is displayed.

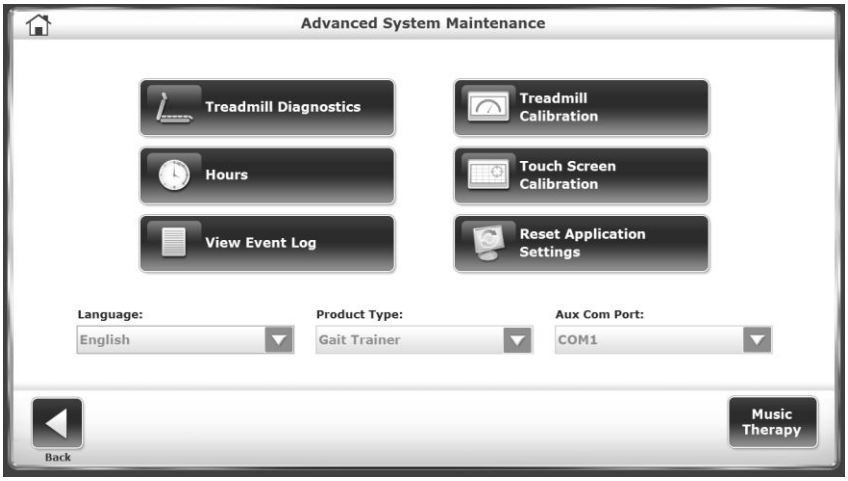


Figure 7.29. Advanced System Maintenance Screen

Advanced System Maintenance Screen Settings

Treadmill Diagnostics: The Treadmill Diagnostics screen allows the user to conduct some diagnostic tests with regards to treadmill performance. The strain gauges can be reset to the factory calibration and the strain gauge board can be re-initialized.

- Touch <▼ > for the elevation until the elevation motor stops. The reported elevation counts must be between 12 and 15. If they not, loosen the nut on the elevation pot and adjust the

pot for a count between 12 and 15.

- Touch <▲ > until the treadmill is fully elevated. The counts must be between 121 and 125.

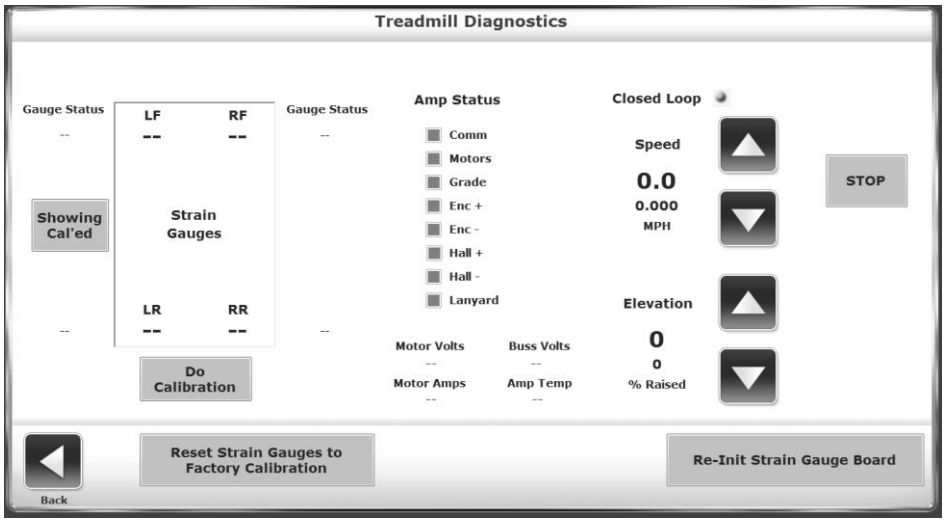


Figure 7.30. Treadmill Diagnostics Screen

Treadmill Calibration: Use this gauge when manually adjusting leveling.

Figure 7.31. Treadmill Calibration Screen

Hours: The Hours of Use screen provides a breakdown of device usage along with the option to reset the hour count.

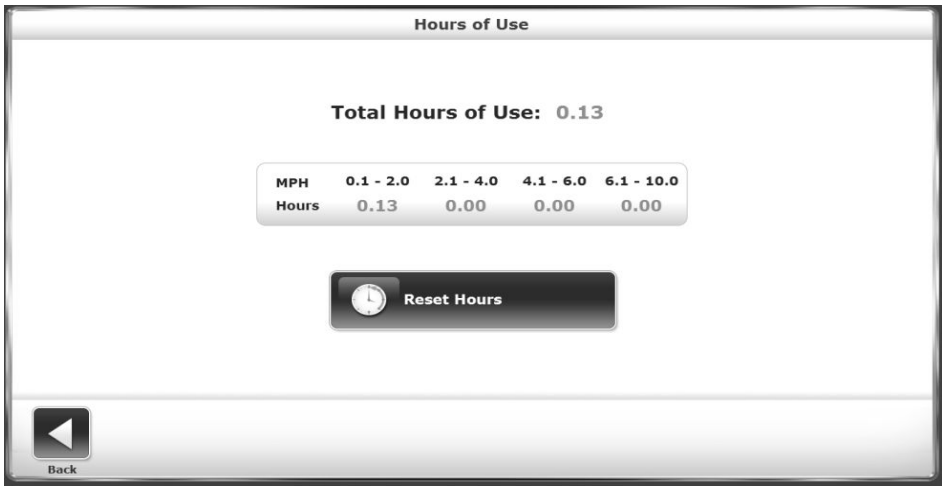


Figure 7.32. Hours Screen

View Event Log: The Event Log screen contains information on device events with options to filter by date ranges. The screen can be used to delete the log content or export it to a USB flash drive.

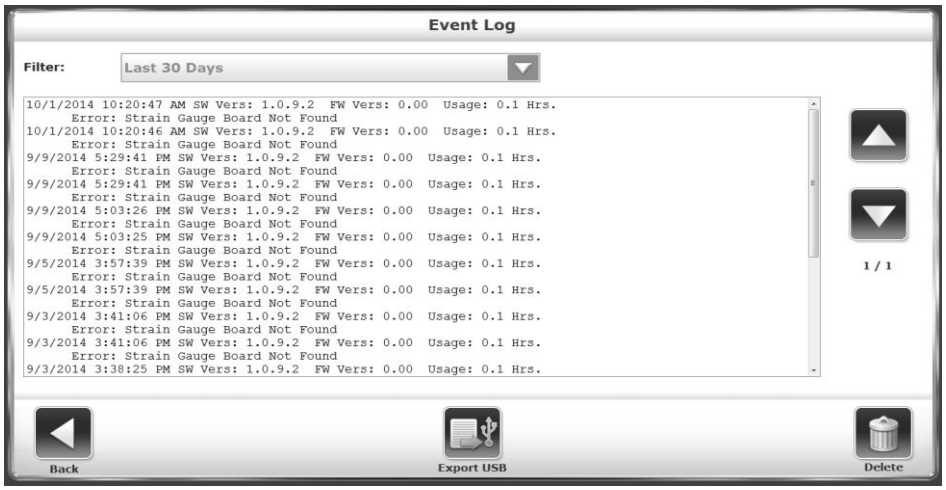


Figure 7.33. Event Log Screen

Reset Application Settings: Use this function to return all application settings to factory defaults. Patient data will not be deleted if a reset is performed.

Figure 7.34. Reset Application Settings Screen

Language: Use this function to set a language preference for the system.

Product Type: The product type can be designated as either Gait Trainer or RTM 600. Keep the Product Type selection set to "Gait Trainer."

Aux Com Port: The auxiliary port, which allows the device to transmit or receive data, can be set as COM1 or COM3.

Music Therapy: Please see the Music Therapy chapter and Appendix on the Biodex website.

Software Updates

From time to time, it may be necessary to update the device's software. The steps for updating the software are as follows:

1. Download the updated software from https://biodexrehab.com/our-products/software-updates/ to a portable thumb drive. Be sure to save the file in the root directory of the drive.
2. While the device monitor is displaying the main screen (with the <Gait Trainer> and <Treadmill> icons), plug the thumb drive into one of the USB ports. The Software Update screen (Figure 7.35) is displayed.
3. Follow the directions on the screen to complete the update.

Figure 7.35. Software Update Screen

8. Reactive Step Training

Reactive Step Training (RST) can be incorporated into any balance exercise program. Through Reactive Step Training, patients are conditioned to control their center of mass and to respond with an appropriate balance strategy to avoid losing their balance and falling.

Reactive Step Training is performed on a Biodex Gait Trainer that includes additional components and software to create perturbations. Reactive Step Training exposes patients to environmental challenges that mimic real-world situations in a safe environment which teaches the patient how to respond to each scenario.

CAUTION: An overhead safety support system must be used during reactive step training to ensure the training is safe. You may use any commercially available safety support system – affixed to the ceiling or free-standing – but a safety support system MUST be used for all fall-assessment and fall-prevention demos and trials. The safety support system can be used with an appropriate body harness of your choice. If a commercially available safety support system is used, you are responsible for ensuring that the entire safety support system remains compliant with the IEC 60601-1 standard. Please contact Biodex Rehab for guidance on the requirements for such a system.

Clinical application tip: One of the goals of RST training is to prevent the patient from anticipating Perturbation events. On screen, it will not show any information regarding when and what event will occur during an active session. The therapist may choose any of the following method to achieve that goal:

- Distracting the patient by engaging in conversation.
- Holding the Remote Trigger behind their back so that the patient does not see the clicks.
- Randomizing the sequence of events in the software.

Event Type Details

There are five types of events addressed by RST.

- **Trunk Stability Slip** - While standing, look for the patient to use a trunk stability movement strategy to avoid a fall. There will be no movement until the Perturbation happens. When Perturbation is initiated, the belt moves for a brief period and stops. The belt will move in reverse direction, the patient will move in the opposite direction. Duration and velocity (the magnitude of the Perturbation) will vary for each level of this event. Level difficulty is increased by increasing duration and/or belt velocity of the event.

	Level 1	Level 2	Level 3
Duration (msec)	100	120	100
Maximum Velocity (cm/s^2)	-24	-41	-72

*Negative velocity denotes belt movement in reverse direction.

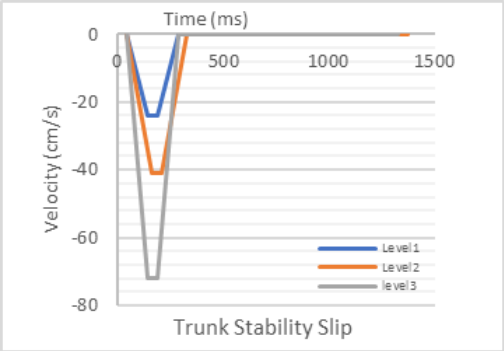


Figure 8.1. Trunk stability slip parameters and data output

- **Trunk Stability Trip** – While standing, look for the patient to use a trunk stability movement strategy to avoid a fall. There will be no movement until the Perturbation happens. When Perturbation is initiated, the belt moves for a brief period and stops. The belt will move in a forward direction, the patient will move in the opposite direction. Duration and velocity (the magnitude of the Perturbation) will vary for each level of this event. Level difficulty is increased by increasing duration and belt velocity of the event.

	Level 1	Level 2	Level 3
Duration (msec)	100	150	190
Maximum Velocity (cm/s^2)	37	55	70

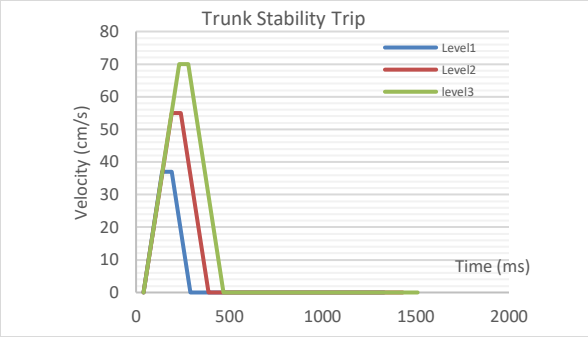


Figure 8.2. Trunk stability trip parameters and data output

- **Step Stability** - While standing, look for the patient to take (1) one step to avoid a fall. When Perturbation is initiated, the belt will start abruptly, maintain a constant speed for a short period of time, then stop abruptly. The belt will move in a forward direction, the patient will move in the opposite direction. Duration and velocity (the magnitude of the Perturbation) will vary for each level of this event. Level difficulty is increased by reducing duration and increasing belt velocity of the event.

		Level 1	Level 2	Level 3
	Duration (msec)	650	410	280
	Maximum Velocity (cm/s^2)	31	48	67

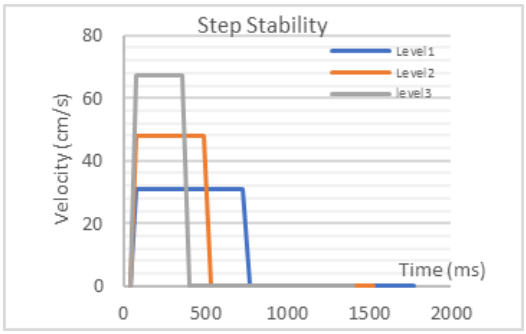


Figure 8.3. Step stability parameters and data output

- **Walk Stability** –While standing, look for the patient to take one (1) step and then continue walking to avoid a fall. When Perturbation is initiated, the belt will move a little longer period than the trip event after a Perturbation. The belt will move in a forward direction, the patient will move in the opposite direction. Duration and velocity (the magnitude of the Perturbation) will vary for each level of this event. Level difficulty is increased by increasing belt velocity, keeping the duration of the event the same.

		Level 1	Level 2	Level 3
	Duration (msec)	500	500	500
	Maximum Velocity (cm/s^2)	31	48	67

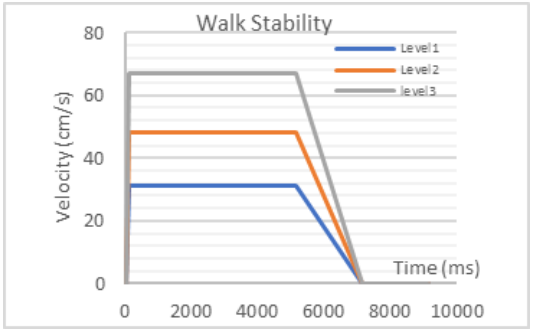
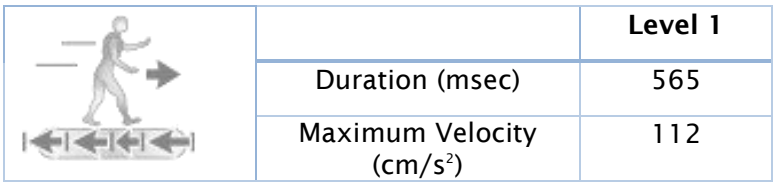


Figure 8.4. Walk stability parameters and data output

- **E-Trip** – While walking, look for the patient to return to their natural stride after perturbation. The belt will be moving at the comfortable walking speed that was

determined before the session started. While walking on the belt, a Perturbation will occur at a random time followed by a short walking period after the event.



	Level 1
Duration (msec)	565
Maximum Velocity (cm/s^2)	112

Figure 8.5. E-Trip parameters

** Numbers on these tables are approximate values and may vary with patient weight.

Pass/Fail Guidelines

The Reactive Step Training sessions are intended to condition a patient for an unexpected event that could cause them to lose balance and fall. Recording Pass or Fail denotes if the patient was able to apply the appropriate strategy to avoid falling. The objective is to demonstrate successful progression though each and all perturbation events and difficulty levels.

Trunk Stability Slip – The belt moves a small distance in reversed direction, after quickly accelerating up to a maximum of 24 cm/sec^2 then decelerating. The patient should attempt to maintain balance while not taking a step and relying only on trunk movement.

Trunk Stability Trip – The belt moves a small distance after quickly accelerating up to a maximum of 37 cm/sec^2 then decelerating. The patient should attempt to maintain balance while not taking a step and relying only on trunk movement.

Step Stability – The belt starts abruptly, maintains a constant speed for a short period of time, and then stops abruptly. The patient is asked to take one recovery step as the belt moves a longer distance than the Trunk Stability profiles. Acceleration is to a maximum of 67 cm/sec^2.

Walking Stability – The belt starts abruptly and maintains a constant speed before gradually slowing to a stop. The patient is asked to take a recovery step and transition into normal walking gait. Acceleration is to a maximum of 67 cm/sec^2.

eTrip™ – delivers perturbations while walking. The patient begins walking at a constant walking speed until presented with an abrupt acceleration up to a maximum of 112 cm/sec^2 followed immediately by deceleration back to constant speed. This rapid change in belt speed simulates a trip. The patient recovers from this event through step and balance recovery.

Reactive Step Training Session

A) Remote Trigger Description

A Remote Trigger is a wireless device that allows the therapist to send commands (mimicking a keystroke) during a perturbation session. It uses a 2.4GHz USB transceiver (not Bluetooth) that is connected to one of the USB ports on the back of the display.

Each RST configured unit will ship with a Remote Trigger. The Remote Trigger in this picture needs two AAA batteries and has an ON/OFF switch on one side. Make sure that it is turned ON before use.

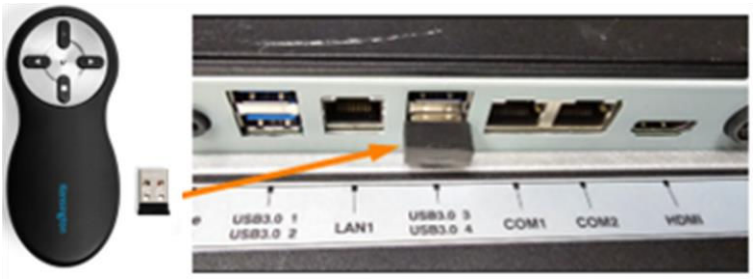


Figure 8.6. USB transceiver connected to the back of display on a USB port.

Button configuration -

The Remote Trigger comes with the buttons pre-configured as shown below. During an RST session the Top button is to start a session or perform a Perturbation, the Left side button is to record Fail and the Right side is to record Pass. If further configuration is needed, follow the steps mentioned in the "Button re-configuration" section of this document.

Figure 8.7. Remote Trigger button pre-configuration

NOTE: *In case of use of after market Remote Trigger (/other than the original), use the steps below to configure the trigger.*

i. *Make sure the device is charged or has fresh batteries.*
ii. *Make sure the device is ON.*
iii. *Make sure the USB transceiver is connected to the display, which will communicate with the Remote Trigger.*
iv. *The Remote Trigger must be configured using the button configuration menu item in the RST software.*

B) Setting Up the Events to Perform a Session

Use the following steps for a Reactive Step Training session:

1. Select the <Reactive Step> icon on the Home screen. A Warning message will appear explaining that the patient should be in a safety harness.

Figure 8.8. Home screen

2. Ensure the patient is safely and securely strapped into a safety harness.

Figure 8.9. Reactive Step Training safety harness warning

3. Click the "Safety Checked" box.
4. Click the <Next> button.
5. Set a comfortable speed for the patient using the up and down arrows. This will be the default speed used for E-trip event.

NOTE: *The maximum speed is 2 mph (3.2 km/h).*

Figure 8.10. Reactive Step Training speed parameters screen

6. Press the <Stop> button when you have found a comfortable speed.

CAUTION: The Stop button will stop the belt movement very quickly. At higher speeds (~2mph / 3.2 km/h), the stop will feel abrupt and there may be a strong shaking sensation.

7. Click the <Next> button.
8. The Warning will be displayed again. After ensuring the patient is securely strapped into their harness, click the "Safety Checked" box again.
9. Click the <Next> button to go to Reactive Step Training screen.

Figure 8.11. Reactive Step Training event selection screen

10. On the screen, it will display drop downs containing different event types with option to change difficulty level.

Each of the five rows allows you to select the same or different events. For example, a user/ therapist could select Walk Stability five times but choose various levels. Or, a combination of event types can be selected, depending on what the patient's needs are.

11. Select the difficulty level for each event type (1, 2, or 3) using the – and + buttons (3 being the most difficult). For E-Trip, you can adjust the comfortable walking speed instead of choosing a level.

12. Select "Sequential" if you want the events to happen in the order shown. Choose "Random" for the event types to be mixed up. When the "Repeat" option is ON, it will repeat the whole session. When "Repeat" is OFF, a single row/event will not repeat more than once.

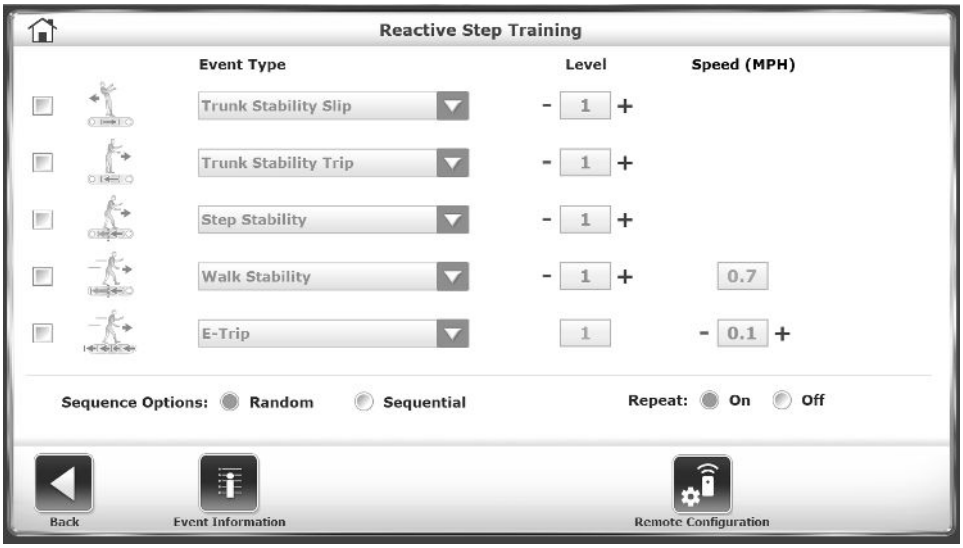


Figure 8.12. Reactive Step Training event selection screen allows for parameter adjustments.

At this point, if any of the RST operations do not have an assigned button on the remote, a message will be displayed on the screen.

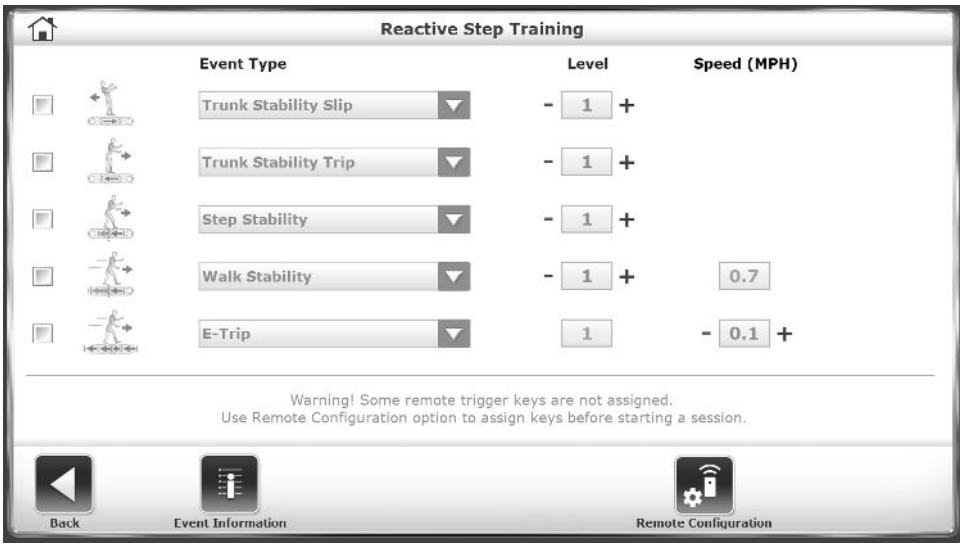


Figure 8.13. Reactive Step Training screen displays Remote Trigger warning.

Use the <Remote Configuration> button to assign a Remote Trigger button (see steps described in Button re-configuration section) and then the error message will be removed and <Start> button will be available.

13. Select the checkbox for the desired event type(s). If no events are selected, the <Start> button will not appear.

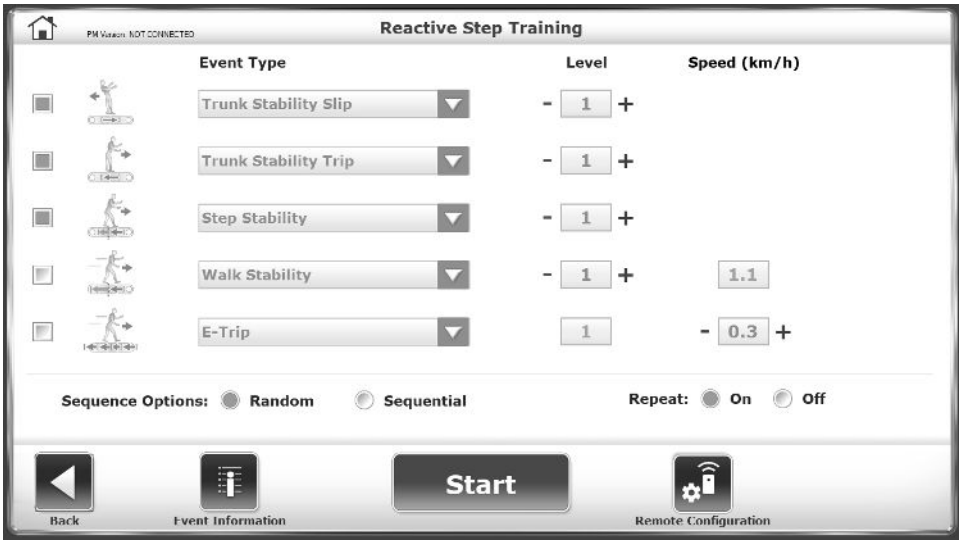


Figure 8.14. Reactive Step Training screen displaying Start button

C) Perform Operations Using the Remote Trigger

14. Click the Start button. A message will be displayed explaining that the session is active and be prepared to start.

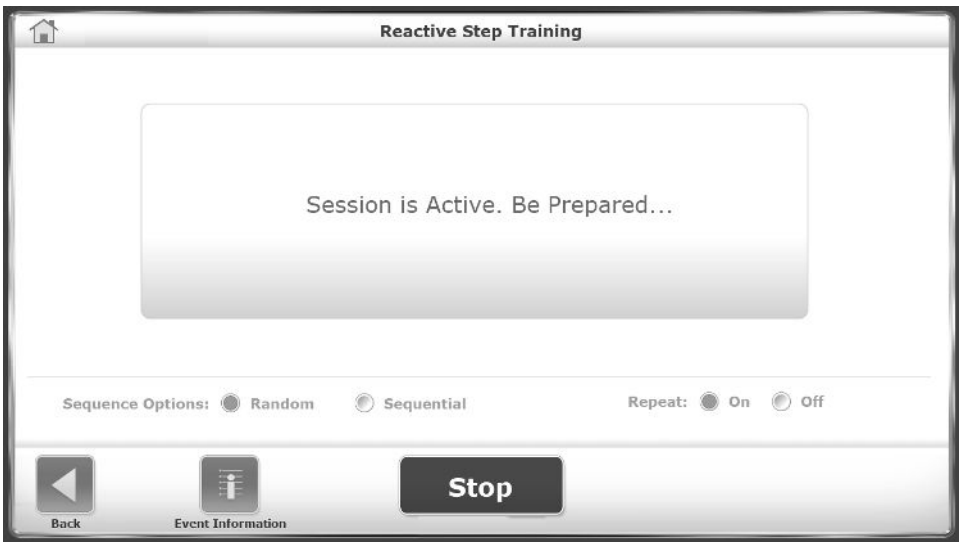


Figure 8.15. Reactive Step Training Start preparation screen

15. On the Remote Trigger, with the default configuration, click the top (perturbation) button. The screen will show the message that the session is in progress. This means the software is ready for the Perturbation session. The Stop button will terminate the session in progress.

    NOTE: *An unlimited number of events can be performed in each session.*

Figure 8.16. Reactive Step Training Session in Progress screen

16. Click on the button on the Remote Trigger that was assigned for "Perturbation". The patient will react to the belt movement. To record Pass/Fail for each event type, click on the corresponding assigned buttons on the remote. If no button is pressed, it will not record any Pass/Fail.

Figure 8.17. Reactive Step Training Active Session screen confirming that the Walk button was pressed on the Remote Trigger

As a visual confirmation of the Remote Trigger button being pressed, a letter representing the event that was just performed will be displayed.

The Letter “R” indicates a for Slip, “T” for Trip, “S” for Step, “W” for Walk, “E” for E-trip event type.

It will also display a Green/Red square acknowledging the Pass/Fail button was clicked on the trigger.

The <Stop> button will terminate the session in progress.

17. Click the <Print Results> icon on the bottom right of the screen. The Reactive Step Training Results will be displayed. From this screen you can select the <Print> icon to print the result to a printer or select the <Export to PDF> icon to export the results to a PDF file.

Figure 8.18. Reactive Step Training Results screen

***NOTE:** The RST session does not save any results. Results will be lost unless they are printed out or exported as PDF to a flash drive.*

Reactive Step Training Results

Test Date / Time : 12/1/2023 10:41:22

TEST SUMMARY

100%	67 %	100%	---	75 %
Slip (3)	Trip (2)	Step (3)	Walk (0)	E-Trip (3)

Event Type - Success Rate

TEST RESULTS

	Event Type	Level	Speed (MPH)	Score
1.	Trunk Stability Trip	3	-	Pass
2.	Trunk Stability Slip	3	-	Pass
3.	Walk Stability	3	1.5	Fail
4.	E-Trip	1	0.2	Pass
5.	Step Stability	3	-	Pass
6.	Step Stability	3	-	Pass
7.	Trunk Stability Trip	3	-	Fail
8.	E-Trip	1	0.2	Fail
9.	Walk Stability	3	1.5	Fail
10.	Trunk Stability Slip	3	-	Pass
11.	Walk Stability	3	1.5	Fail
12.	Trunk Stability Trip	3	-	Pass
13.	E-Trip	1	0.2	Pass
14.	Trunk Stability Slip	3	-	Pass
15.	Step Stability	3	-	Pass
16.	E-Trip	1	0.2	Pass

COMMENTS

CLINICIAN

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Figure 8.19. Reactive Step Training Results output – PDF export

Remote Trigger Button Configuration

On the Reactive Step Training screen, using the <Remote Configuration> button, the therapist will be able to see currently assigned buttons for each RST session operation. It will also allow the therapist to change/ re-configure the button assignments.

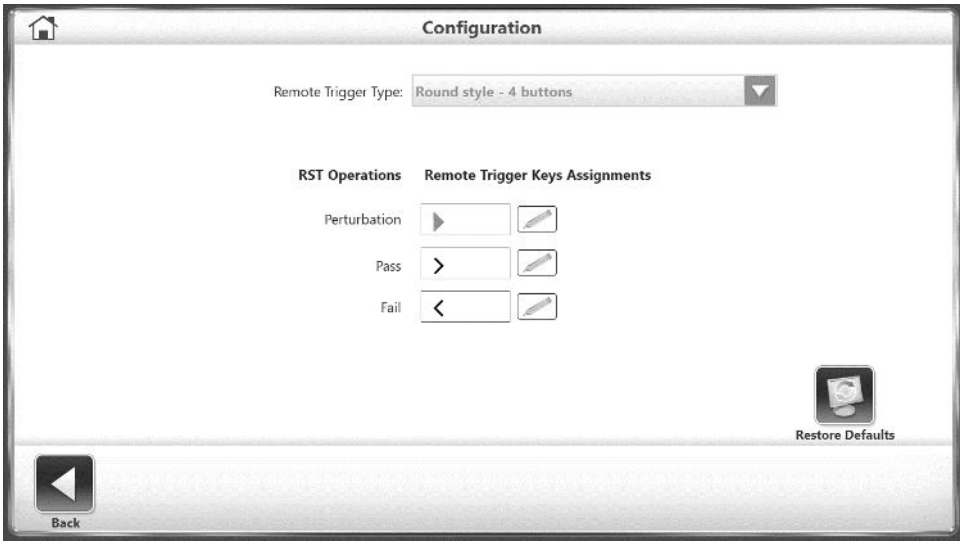
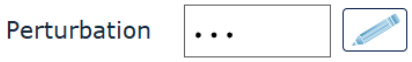


Figure 8.20. Remote Trigger button configuration screen

1. By default, the Remote Trigger Type will be selected as “Round Style- 4 buttons”, which will work with the Remote Trigger that will be shipped out with each unit.

2. To change the button assignment, click on the pencil icon for an operation.

3. Three dots indicate it is ready to accept a new button assignment.



4. Press the button on the remote to assign that button for that operation.
5. The newly assigned button icon will appear.

   Each operation will have to be assigned to a different button on the remote.

   Clicking on the <Restore Defaults> button will go back to factory settings, if needed.

6. Clicking on the <Back> button will automatically save any changes made.

***NOTE**: Application software supports one other Remote Trigger and an option to use a standard windows keyboard. For after market Remote Triggers, chose appropiate remote types first – 4 buttons or 3 buttons or Windows Keyboard. Then assign the buttons for each operation. Only one Remote Trigger type setting will be saved.*

9. Maintenance

The Biodex Gait Trainer 3 and Reactive Step Trainer should provide trouble-free operation as long as the following maintenance procedures are performed. To verify hours of operation, touch <Utilities> and touch the right-left-right sequence on the main system Utilities screen to activate the <Advanced System Maintenance> button (refer to Figure 9.2). From there, touch the <Hours of Use> button, where hours of use will be indicated, both in total and in MPH categories (see Figure 9.3). Be sure to adhere to the hours of usage guidelines in Table 9.1.

NOTE: *Without proper maintenance, excessive wear to drive components will occur. To assure trouble-free operation, scheduled maintenance must be performed. Failure to adhere to the scheduled maintenance instructions below will void the warranty.*

CAUTION: Only qualified persons should perform maintenance and repair on this device. This is a motorized device with many moving assemblies. Precaution is necessary.

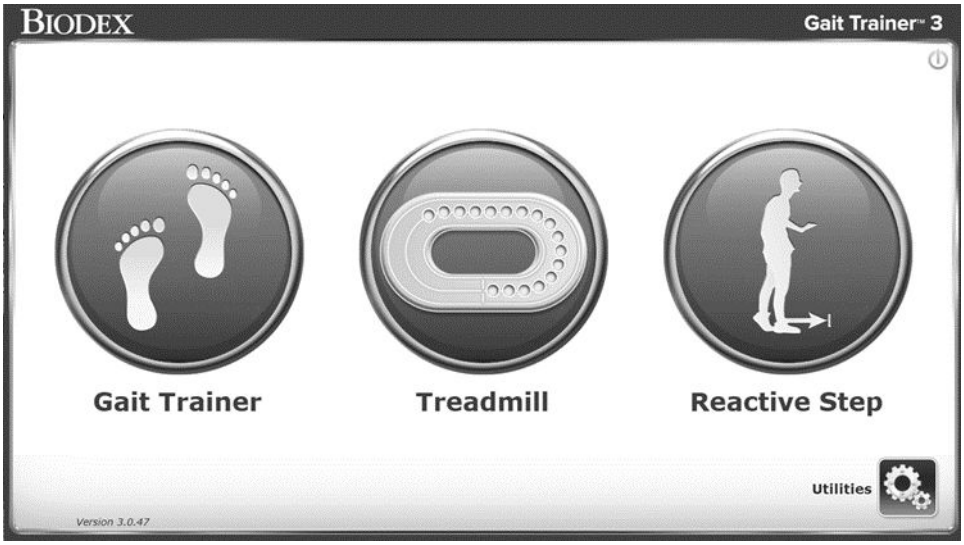


Figure 9.1. Main Screen for Gait Trainer or Reactive Step Trainer

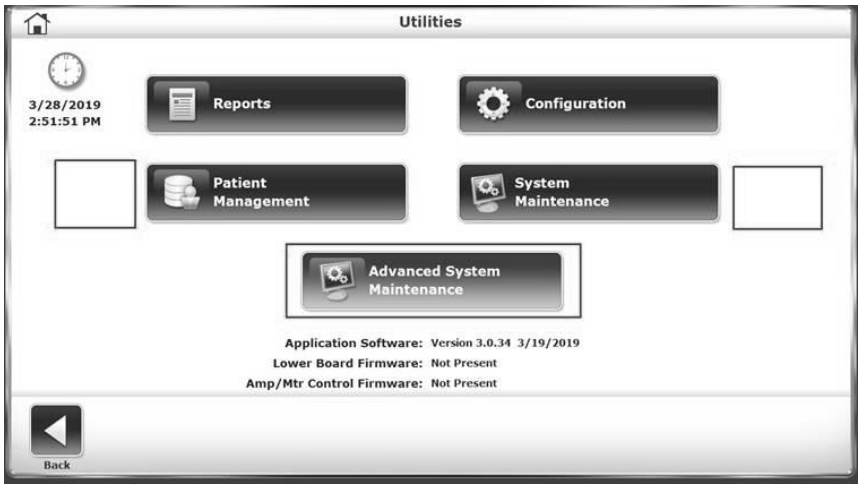


Figure 9.2. Main Menu, followed by right-left-right touches to activate Advanced System Maintenance button

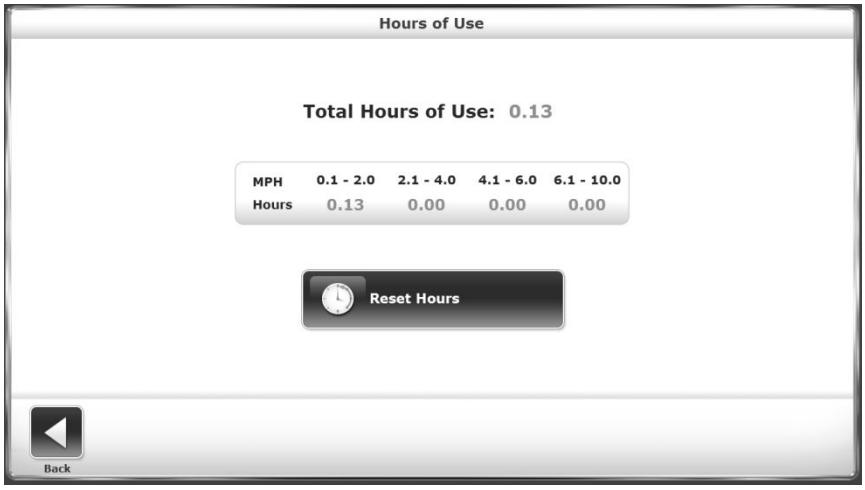


Figure 9.3. Hours of Use screen

Table 9.1. Hours of Usage Guidelines

Instruction	**Hours of Usage**
Lubricate Deck	75
Reverse Deck	1,000
Belt Replacement	1,000
Clean Motor and Amp	750
Front Roller Cleaning	375

Daily Maintenance

As required, clean all exterior surfaces, excluding the display with a light application of disinfectant and wipe dry with paper towels.

NOTE: *DO NOT use solutions containing ammonia.*

Hardware computer components should be wiped clean as needed using a soft rag dampened with alcohol.

Quarterly Maintenance

Lubricate the treadbelt and slider deck. The Biodex Lubricant Kit is designed to reduce friction between the treadbelt and the slider deck. It is required for all institutional treadmills. Proper and timely application of the lubricant will prevent premature failures due to excessive wear and load. Items affected by inadequate lubrication are the treadbelt, slider deck, motor, and motor controller.

Annually or Every 1,000 Hours Reverse Exact-Track Bed

Reverse the Exact-Track bed. The Gait Trainer 3 bed is double-sided, allowing it to be reversed and used over. Once both sides have been used, the bed must be replaced.

Replace Treadbelt

Inspect Treadbelt for cracks or tears. If none are found, continue to use. If any cracks or tears are apparent, replace the treadbelt.

Maintenance Procedures Belt/Deck Lubrication

1. Using the large syringe provided, squirt one-half tube of the lubricant underneath the center of the treadbelt (see Figure 10.4).
2. Walk ten steps on the Gait Trainer 3 at a speed of 1.0 mph (1.6 km/h). This will moisten an 8-inch track underneath the center of the entire treadbelt.
3. Allow the Gait Trainer 3 to dry for approximately ten minutes.

NOTE: *Use only the Biodex lubricant kit with the Gait Trainer 3. Most standard greases, waxes and silicon sprays will build up on the rollers causing belt slippage and affecting tracking.*

To re-order lubricant kit, use Biodex part # 945-276. Each container provides 12 applications.

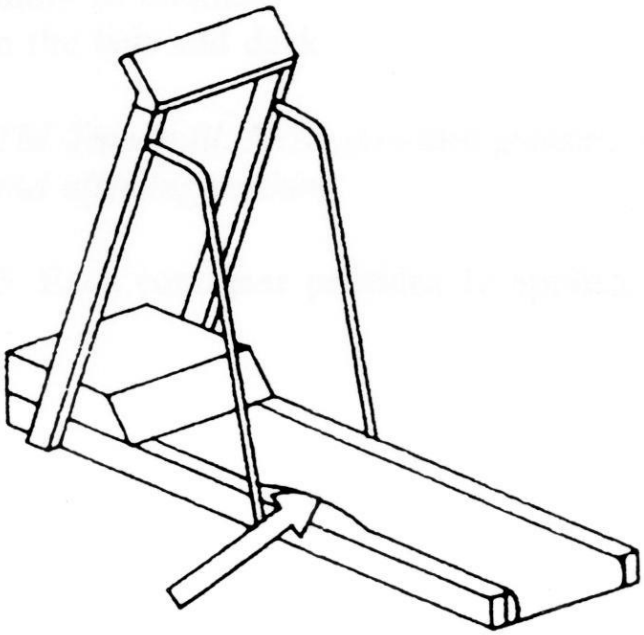


Figure 9.4. Squirt one-half tube of lubricant between the belt and deck.

Treadbelt Adjustment

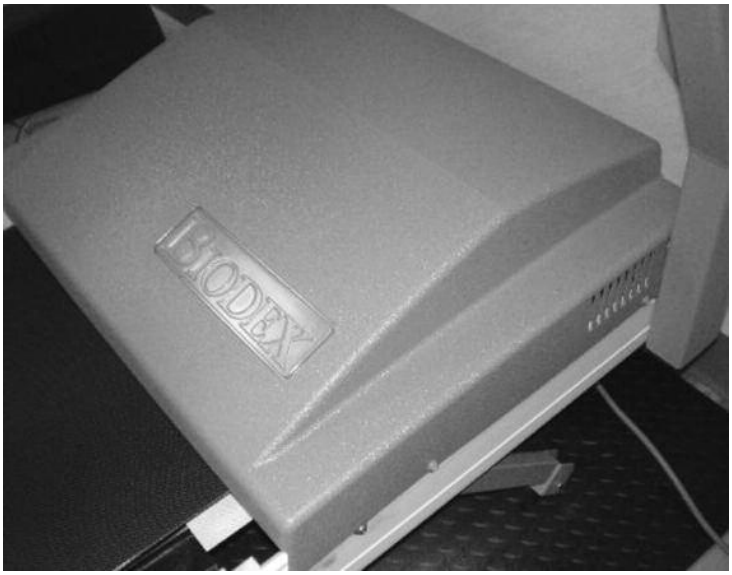


Figure 9.5. Treadmill Cover

1. Remove the 6 Phillips head screws from the cover. Lift the cover off the treadmill.

Figure 9.6. Quick Start Treadmill Screen

2. Access the Quick Start Treadmill function and adjust the speed to 1.0 MPH.

Figure 9.7. Treadmill shown without cover. Note the location of front roller.

3. Walk on the treadmill at 1.0 MPH and stop the treadbelt with a foot. Front roller should slip under the treadbelt .

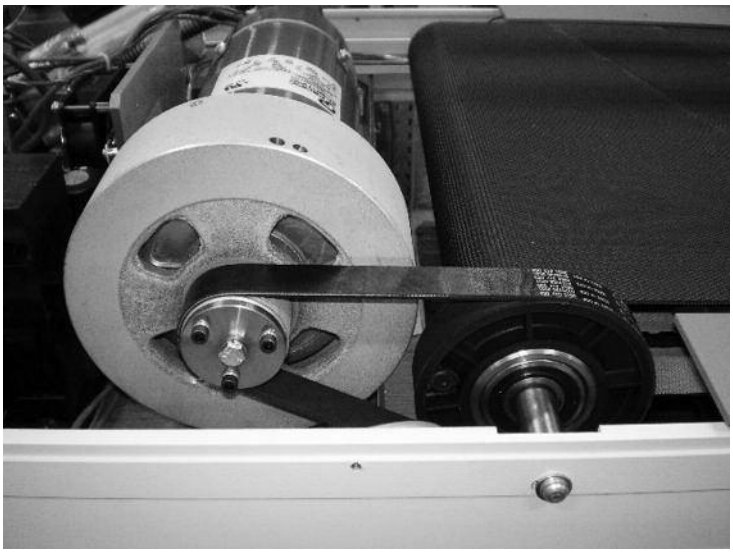


Figure 9.8. Close up of motor, showing front roller.

4. Front roller

Figure 9.9. Back of Treadmill shown for tensioning bolt location.

5. Adjust the two belt tensioning bolts evenly at the back of the treadmill so that the front roller slows down but continues to turn when you stop the treadbelt with your foot.

Treadbelt Alignment

Figure 9.10. Hex bolts shown to adjust belt left or right.

6. Adjust the two hex bolts so that the distance between the end of the roller and the edges of the belt are equal on both sides.
7. Turn the right hex bolt half turn clockwise to move the belt toward the left side of the roller.
8. Turn the left hex bolt half turn clockwise to move the belt toward the right side of the roller.

Disposal

An appropriate waste disposal company is to be contacted (i.e., the local collection point for waste separation). Properly dispose of the device at the end of its service life:
· The device packaging is disposed of through resource recycling.
· The metal parts of the machine go to scrap metal disposal.
· Plastic parts are disposed of as hazardous waste.

NOTE: *The disposal of equipment must be in accordance with the respective national regulations.*
Wear parts are considered hazardous waste! After being replaced, wear parts must be disposed of according to country-specific waste laws.

10. Accessories

Table 10.1. Accessories Table

Part Number	Description
950-485	Biodex NxStep Unweighing System
C14607	Remote Trigger (RST models only) - spare part
950-413	Music-Assisted Therapy Package Compatible with Gait Trainer 3 featuring Windows OS. Includes USB hub, music library and sound bar with input for headphones and microphone.

11. Troubleshooting

Symptom

Gait Trainer 3 is turned ON and speed control is inoperable (belt not moving).

Check for faults on display. The following diagnostic error codes apply:

Table 11.1. Diagnostic Error Codes Table

Code	Description
128	Communication between upper/lower board inop
64	Safety Lanyard Removed
32	Control fault (no amplifier)
16	Grade Error

8	Motor Tach Output Exceeds Selected Speed
4	Motor Tach Output is Below Selected Speed

NOTE: *The above faults indicate an issue with the treadmill. For fault 64-Safety Lanyard Removed, verify the safety lanyard is still attached in its proper location. For all other faults, please contact Biodex Support Services department at 1-800-224-6339 or* support@biodexrehab.com *and provide the fault code. Someone will provide instructions on how to proceed.*

12. Specifications

Dimensions: 86" l x 27" w (218x69cm)

Walking Area: 64" l x20" w (160x51cm)

Printer Stand: 24" l x 24" w (61x61cm)

All-In-One Flat Panel PC: 15.6" Color Touchscreen, Windows Operating System, Ethernet, USB, Video/Audio Out, Built-In Speakers, and Color Printer (HP Deskjet). Bolsters connectivity options to other devices enabling remote operation for data transfer and software upgrades.

Deck: 1" thick (2.5 cm) reversible Teflon™ impregnated high-density composite fiber

Motor: 2HP with 2Q-Pulse Width Modulation Control

Treadmill Speed Range:

Forward: 0-10 mph (0-16km/h)
Reverse: 0-3 mph (0-4.8km/h) in 0.1mph (.16km/h) increments

Gait Trainer Speed Range: .3 – 4.5 mph (.48 – 7.2 km/h)

Reactive Step Trainer Maximum Speed: 2 mph (3.2 km/h)

Elevation: 0-15% Grade

Heart Rate Monitoring: Polar® contact handgrips (telemetry compatible)

Power: 115VAC, 50/60Hz, 20AMP dedicated line, or 230 VAC, 50/60 Hz, 20 AMP dedicated line. Includes hospital grade plug with 12' (3.7m) power cord.

User Capacity: 60-400 lb (27-182 kg)*

Weight: 395 lb (179 kg)

Warranty: Two years on parts; one year on labor

Operating Conditions

- Temperature: 10˚ C to 37˚ C (50˚ F to 100˚ F).
- Humidity Range: 20% to 90% (non-condensing).
- Atmospheric Pressure: 70kpa (10psi) to 106kpa (15psi).

Transport and Storage Conditions

- Temperature: -20˚ C to 70˚ C (-4˚ F to 158˚ F).
- Humidity Range: 10% to 100%.
- Atmospheric Pressure: Sea Level 101kpa (14.7psi) to 10,000 feet, 69 kpa (10.1 psi)

Water Resistance Rating: IPX0

**Does not accommodate less than 60 lb in Gait Trainer mode.*

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