BTE™

ECCENTRON™

OPERATOR'S MANUAL

MD CE 0413

Original Instructions

Printed in the U.S.A.
This manual supports the BTE Eccentron System
Instructions for use and technical description are included.

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Manufacturer Information:

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Warranty

We guarantee that the BTE Technologies rehabilitation products are free of manufacturer defects in both workmanship and material. We will replace or repair defective parts or equipment for a period of time and in accordance with the conditions set forth below:

This warranty covers the structure and framework for 1 year of normal institutional use. All mechanical components including bearings, bushings, pulleys, and glides are warranted from manufacturer defects in both workmanship and material for a 1-year period. Paint, straps, cords, padding, and other rubber and plastic products are covered for a 90-day period.

This limited warranty is in lieu of all warranties, expressed or implied, and all other obligations or liabilities on the part of BTE Technologies. We neither assume nor authorize any person to assume any other obligation or liability in connection with the sale of this product.

Under no circumstances shall BTE Technologies be liable by virtue of this warranty or otherwise, for damage to any person or property what so ever for any special, indirect, secondary, or consequential damage of any nature however arising out of the use or inability to use this product.

This limited warranty applies only while the BTE Technologies product re- mains in the possession of the original purchaser and has not been subject to accident, misuse, abuse, unauthorized modification, failure to follow instructional use, failure to do proper maintenance, incorrect adjustments, or failure due to cause beyond the manufacturer’s control.

Disclaimer

The information presented in this manual is given in good faith and is to the best of our knowledge accurate. However, anyone who uses this information in any way does so entirely at his or her own risk. Neither BTE Technologies, its officers nor their representatives can accept any responsibility for any damage or injury incurred as a result of information presented here except under the terms of the product warranty.

ECCENTRON Operator's Manual

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Safety

Before Operating the Eccentron

1. Remove the transport casters
2. Attach the front cover
3. Attach the rear side covers
4. Adhere to all usage and positioning instructions
5. View the Clinician Usage Video prior to setting up clients for exercise

Warnings

Grounding

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

Equipment Placement

Do not position the equipment to make it difficult to disconnect the power cord.

Touch Screen Display

- **The openings on the display enclosure are for air convection that protects the equipment from overheating. Do not cover the openings.**
- **Never pour any liquid into the openings; this could damage the system or cause electrical shock.**

Equipment Frame

- **Do not lean against, push, pull, or hang onto the touch screen monitor.**
- **Do not lean against, push, pull, or hang onto the monitor post.**
- **Do not sit anywhere on the device except the designated seat bottom.**
- **Do not stand or step anywhere on the device except the designated step-over platform.**
- **Do not place hands or feet anywhere other than recommended.**
- **Keep fingers, clothing, shoelaces, and any loose items away from pedals and other moving parts.**
- **Keep pendant in its proper storage place; do not allow it to drop or fall onto the seat or floor.**
- **Do not push or pull on the seat or seat arms in an attempt to move the equipment.**

Transport Casters

Do not operate the system with the transport casters attached.

To remove the casters, see the *Assembly and Maintenance* section.

Covers

Be sure the front cover and both rear side covers are securely attached prior to operating the system.

For instructions on removing or replacing covers, see the *Assembly and Maintenance* section.

Network Connection

The Eccentron is not intended to be connected to a network, do not do so unless instructed by BTE.

Equipment Modification

- **Do not modify this equipment without authorization of the manufacturer**
- **Do not modify the parts of the equipment while in use with a client**

Client Safety

Instruct clients on proper positioning and exercise motion for safety and efficacy. It is very important that all Clients and Clinicians are aware of correct and incorrect positioning before and during exercise.

- **The Eccentron is not recommended for use by people under the age of 16.**
- **Follow instructions for use**
- **Never exercise without the Knee Bar properly positioned for the client**
- **Use the Emergency Stop buttons to immediately end the exercise**
- **Verify that the client is exercising under his/her own Login**
- **Verify that seat settings are correct for each client**
- **Do not modify the device in any way including pedals, seat, and arm rests** (a rolled towel for lumbar support is acceptable)
- **Clients should remain seated with full contact against seat back and seat bottom while exercising**
- **Use the Pause button before repositioning clients in the seat**
- **Clients should not rise up out of the seat, nor twist or lean over the seat while pedals are moving**
- **Heels should stay inside and against the heel rims while pedals are moving. Do not allow feet to move upward on the pedals, as this will straighten the knee**
- **Feet should stay fully flat on the foot pedals at all times during stride**
- **Never place both feet on one pedal**
- **Clients who have conditions that make them unable to have force applied to the surface of the leg should not use the Eccentron**

Permissible Environmental Conditions for Transport and Storage:

Ambient temperature:	-20°C to +40°C
Relative humidity:	30% to 90%
Atmospheric pressure:	550 hPa to 1060 hPa

Permissible Environmental Operating Conditions

Ambient temperature:	+10°C to +40°C
Relative humidity:	30% to 75%
Atmospheric pressure:	700 hPa to 1060 hPa

Important Notes

This page highlights important considerations regarding the Eccentron. Please follow these important notes.

- **ANY CHANGES OR MODIFICATIONS TO THE DEVICE OR SOFTWARE NOT EXPRESSLY APPROVED BY BTE COULD VOID THE WARRANTY**
- A dedicated circuit is necessary to operate the Eccentron. The circuit should have:
    - Voltage Supply 100/115/200/230 VAC
    - Supply Frequency 50–60 Hz
    - Power Input 2300 VA (volt-ampere)
- The Eccentron should not be plugged into an ungrounded circuit. Voltages ± 10 percent of the rated voltages for your country can result in error messages. Even if you have a dedicated outlet for your Eccentron, have a technician check the outlet with a voltmeter to ensure that the wall voltage does not exceed the specified voltage ± 10 percent**. If your wall voltage exceeds these voltage specifications, call BTE immediately.**
- Position the Eccentron in the desired location, near a dedicated outlet for the appropriate voltage for your country. **Do not plug device into an outlet until installation is complete.**
- The Eccentron houses the control module. The terms touch screen display and monitor will be used interchangeably throughout the manual.
- The initial settings of Login are as follows:
    - Username: BTEAdmin
    - Password: 7455
- To create a new username and password, select Administration→Clinician Access→Add Clinician.
- The Eccentron sound pressure level does not exceed 70dbA at the workstation.
- The Eccentron should not cause electromagnetic interference with any other equipment. The equipment needs to be placed into service according to electromagnetic compliance information provided in Appendix 1 of this manual.
- The Eccentron is categorized as Class 1 ME Equipment and as such an earth ground is required
- The Eccentron has a maximum 30 mins of continuous operation.

Definitions of Symbols and Certification Marking

	Manufacturer		General Warning Sign
REF	Catalogue Number (Product and Model Number)	MD	Medical Device
SN	Serial Number		Type B Applied Part
EC REP	Authorized Representative In The European Community	CE 0413	Where applicable: CE Marking with the Notified Body number
	Follow Instructions for Use		SGS Product Certification Mark
	Alternating Current		Temperature Limit
	“ON” (Power)		Humidity Limitation
	“OFF” (Power)		Atmospheric Pressure Limitation
	Protective Earth (Ground)		Do Not Forklift
	Danger, High Voltage inside		Do Not Stack
	Do Not Lean against Monitor		Warning, Leg Angle

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Maintenance

The Eccentron requires the following checks to be performed daily before use:

- Verify that the seat locking pin engages and prevents the seat from moving.
- Verify that the emergency stop switches for both the pendant and the monitor arm stop the motion of the pedals.

The following checks should be carried out every 2 weeks:

- Verify that the pedals are reading between 0 and 10 pounds with no one pressing on them. If they exceed this limit please calibrate the pedals using the procedure outlined in this manual.

Short Description

A recumbent, closed-chain exercise device that provides eccentric (negative) resistance to lower extremity motion. It also measures strength and dynamic workload through its control mudle interface.

General Description

The Eccentron is a closed-chain exercise device that provides eccentric (negative) resistance to patient motion. The equipment includes bilateral, adjustable motorized pedals, an interactive display, a control system and a control module for user interface, user data storage and reporting.

The system measures force and (stride length or pedal movement) distance, and calculates dynamic work (force x distance) and dynamic power (work/time) of patients training with the device.

The information gathered by the data collection system on the device is used:

- In the documentation of patient progress trends among treatment sessions
- As visual performance feedback
- To compare the symmetry in strength of lower extremities

Intended Use (Intended Purpose)

Summary
The system is intended to be used to increase muscle strength of the lower extremities.

Detailed
The Eccentron is intended for use in physical rehabilitation of patients with injuries and conditions that affect lower extremity strength. It is used in functional and sport rehabilitation where the patient performs compound motions to strengthen muscles used in real life tasks, for example transitioning between standing and sitting, descending stairs, jumping, and stopping forward motion (braking motion). The intent of exercising in this manner is to improve the patient's general strength for performing such movements.

Application Specification

Intended Patient Population
Patients using this device include those with deficiency of lower extremity muscle strength. The intended patient population is:

- 16 years of age or older
- Weighs up to 400 lbs.

Indications
Generalized muscle weakness associated with musculoskeletal and neurological conditions or diseases.

Contraindications
Contraindications to use include conditions where tensile strength of tissues and/or structures is compromised, i.e. healing bone fractures and tendon, ligament, and muscle repairs or where the surface of the leg is unable to have force applied to it. Clinical judgment is required to determine whether subject should perform assessments and/or treatment.

Intended Anatomical Applicability
Lower extremities

Intended User Profile
Medical healthcare professionals

Intended Conditions of Use
Office or clinic setting

Frequency of Use
There is no frequency of use restrictions for this device.

Use of Energy Source
An electric power source is required to provide pedal motion, for system communication, and computing purposes.

Transfer of Energy to Patient
Kinetic energy is the only energy transferred to the patient.

Applied Parts
Applied parts include the seat, pedals, and pendant

Operating Principles

The Eccentron is a device that supplies a constant force to a user's lower extremities at varying speeds. The user is meant to resist the force using their legs and feet in order to create an eccentric exercise for the lower extremities. The amount of force applied to the user is dependent on how much force the user applies to the device. Force is delivered through pedals that are attached to a motor through a gear box. The speed of the motor is controlled through a motor driver that is set to specific speeds through the use of a user controlled program residing in a control module on the Eccentron. The program suggests speeds to use for exercise and what force the user should apply to the Eccentron. The Eccentron measures the force applied to the pedals from the user, the speed at which the device moves and time. The data collected allows the program to track a user's capabilities through multiple calculated variables. Reports are generated form the control module program that can be used to evaluate a user's capabilities over single or multiple uses of the Eccentron.

Essential Performance

The device does not have any essential performance characteristics.

Essential Functions

- The Eccentron measures accurately within determined tolerances.
- Application supports muscle strengthening.
- Creates reports that provide representation of user performance.
- Creates real-time feedback that reflects user performance.
- System must be able to shutdown automatically when patient applies excessive forces.

Frequently Used Functions

All device functions are used on regular basis. The Eccentron features a streamlined interface as the device supports only one type of exercise. Multiple parameters can be selected to accommodate the client's physical features and the exercise objectives.

Specific to physical features parameters include fixed stride length and seat position. Addressing exercise objectives, the system provides variable speed of pedal movement, adjustable force target zone, ability to choose from pre-programmed sessions or manually set exercise parameters. Reports provide feedback to clients related to their training session performance (work, power, percent on target), as well as change in performance measures over time.

Performance Characteristics

- Force range 0 – 750 lbs., accuracy $\pm$ 0.1% of range
- Speed 12 - 48 repetitions/min, $\pm$ 1 rep/min

Components Designated as Repairable by Service Personnel

There are no components on which preventative inspection and maintenance shall be performed by service personnel. Components will be replaced if needed in accordance with BTE service policy. In addition, documentation and instructions for any in-field repairs to be conducted by service personnel will be provided.

Environmental Protection

At the end of the equipment service life, dispose the device components in accordance with all local, state and federal laws for electronics recycling.

Notice – Serious Incident Reporting

If a serious incident occurs while using this device, the user needs to report the incident to BTE Technologies.

For users in the European Union, the user needs to report the incident to BTE Technologies and to the competent authority of the Member State in which the user and/or patient is established (per *EU Medical Device Regulation (EU 2017/745), Annex 1.23.4(z)*).

The contact information for BTE Technologies is:

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EU Declaration of Conformity

A copy of the EU Declaration of Conformity (for the Medical Device Regulation *(EU 2017/745, as amended)*, the Machinery Directive *(EU 2006/42/EC, EU 2019/1243, as amended)*, along with other requirements) is provided with the Instructions for Use, and can also be obtained by sending a request to BTE at the listed above address or via email, or through the BTE Technologies' website.

Assembly & Maintenance

This chapter will guide you through the steps necessary to get your Eccentron ready to use, and includes recommended maintenance. The Eccentron is shipped with transport casters. These are designed to provide maximum protection in transit and ease of installation.

System Components

Please inspect all parts for any visible damage from shipping. Notify BTE upon discovery of any damage.

The system consists of the main Eccentron frame, display, front console, 2 rear side covers, and the pendant attachment. Four removable transport casters are attached to the device for delivery.

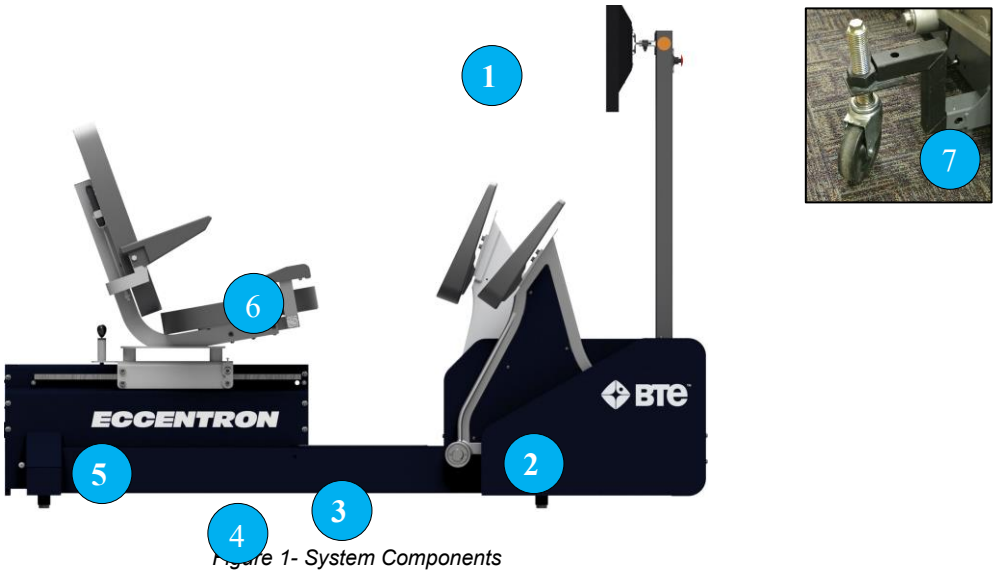


Figure 1- System Components

1. Touch Screen Display
2. Front Console
3. Eccentron Frame
4. Rear Side Covers
5. Pendant Attachment
6. Transport Casters

Installation and Assembly Tools Required

The following tools are needed for installation and assembly of the equipment:

- Phillips Screwdriver (#2)
- ¾" Wrench

Unpack the Eccentron

Unwrap all packaging around the Eccentron frame and discard. Keep the front console and rear side covers packaged until ready to be attached to the frame.

Installation

CAUTION: DO NOT PLUG DEVICE INTO AN OUTLET UNTIL INSTALLATION IS COMPLETE.

- Use the transport casters to position the Eccentron in the desired location, close to its dedicated outlet. Do not plug into an extension cord.
- You may position the Eccentron with the front or side, or back against the wall. There must be a minimum of 36” (91 cm) distance between the wall and the equipment front or back. This space is required for on-site assembly and servicing. If the unit is placed parallel to the wall, leave enough clearance to the wall in order to remove the transport casters and attach the front console, side housings, and side covers.
- Carefully unpack and separate the rear side covers. During the installation process, ensure all parts are properly protected, as mishandling may cause damage to the parts.

NOTE:

- The casters must be in place in order to move the device.
- The casters must be removed prior to using the device.
- The casters cannot be attached while side covers and front console are in place.
-

Remove the Casters

1. After the system has been moved to its desired location, use a ¾"wrench to lower the Eccentron to the floor via the four casters.

Figure 2 - Lower Casters

2. Use a ¾” wrench to remove the screw from frame tube on the side of the frame. Then, pull the caster out of the frame tube.

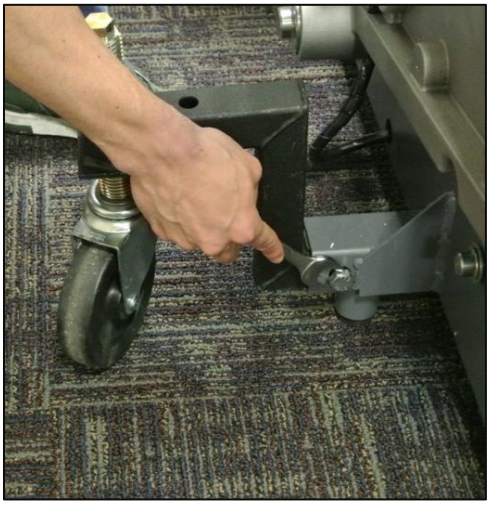


Figure 3 – Unscrew Tube Screw

Figure 4 - Remove Caster

3. Repeat this for the remaining 3 casters.
4. Store the casters and related hardware together.

Attach the Touch Screen Display

1. Carefully unpack the Touch Screen Display from the enclosed box.
2. Remove the four screws and bracket from the back of the monitor.

Figure 5 - Bracket Screws

Figure 6 - Display with Screws Removed

3. Line up the holes on the back of the display with the holes on the mounting plate. Use the four M4 X10 screws sent with the system to attach the monitor to the mounting bracket.

Figure 7 - M4 x 10 screws

4. Plug the Power cable, DVI cable, and USB cable into the back of the monitor.

Figure 8 - Monitor Cables

Attach the Rear Side Covers

1. Using a Phillips screwdriver, remove the washer and screw in the frame. Repeat on the opposite side.

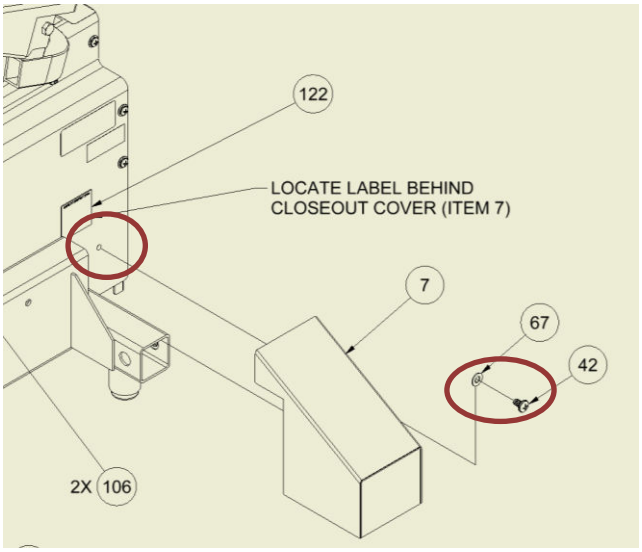


Figure 9 - Frame Screws

2. The side housing assemblies are not interchangeable; the truncated apex faces forward on both the right and left sides.

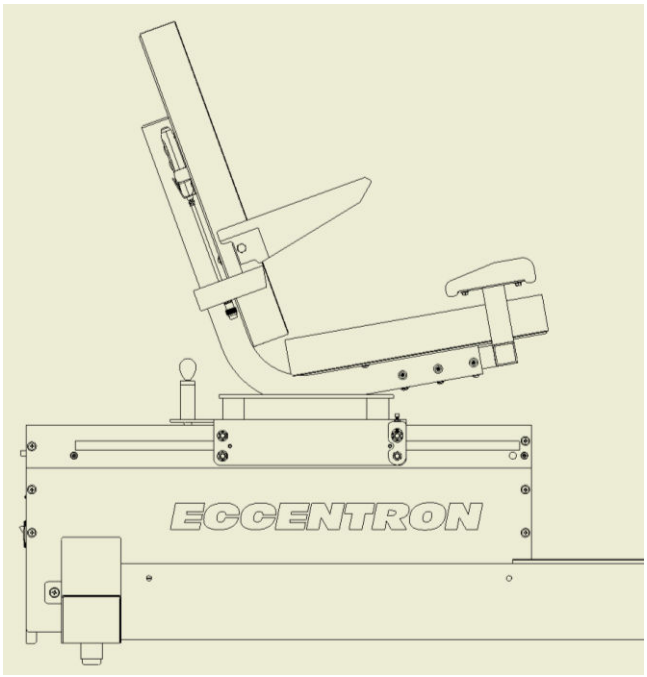


Figure 10 - Side Housing Orientation

3. Align the right side housing and secure it using the screw and washer previously removed from the frame. Repeat for the left side housing.

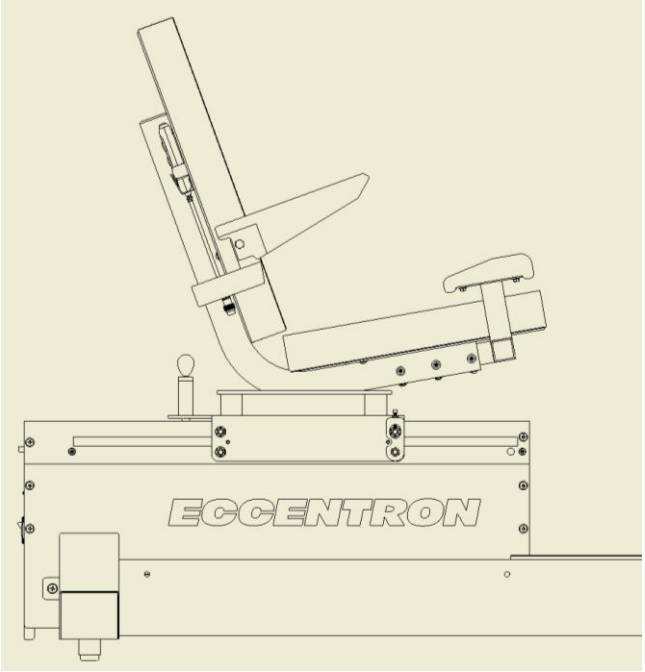


Figure 11 - Side Housing Attachment

Attach the Front Console

1. Remove the 2 screws and washers on each side of the frame.

Figure 12 - Console Frame Screws

2. Attach the Front Console Brackets (L-Brackets) to the frame using the washers and bolts.

Figure 13 -

Figure 14 -

Figure 15 - Front Console Hooks

Figure 16 - Lower Console onto Frame

3. Remove the bolts and washers from the horizontal plate of the Monitor Arm.
4. Install the Front Closeout Cover and secure it with the washers and bolts.

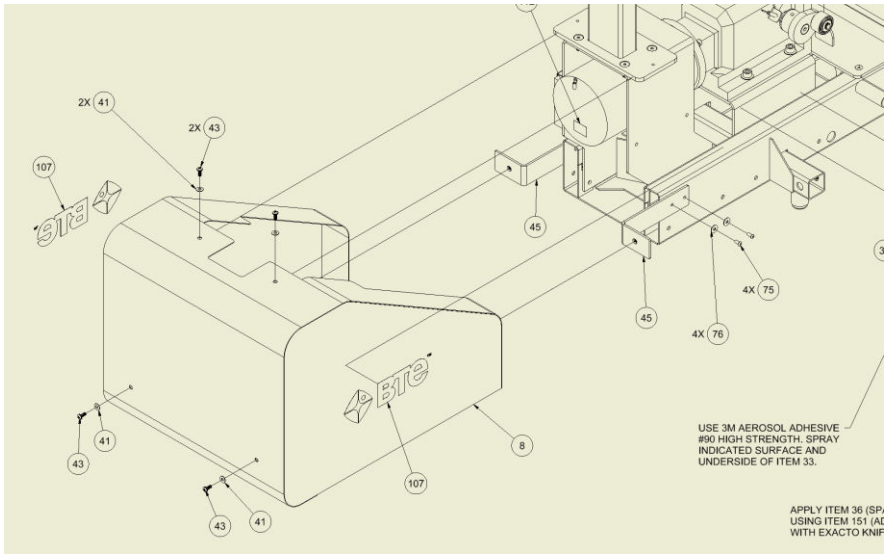


Figure 17 - Console Screw Attachments

Figure 18 - Console Screw Attachments

Connect the Pendant Cable and Power Cable

1. Insert the pendant cable into the back panel and tighten it.
2. Place the pendant into its holder as shown.

Figure 19 - Pendant Cable

Figure 20- Pendant Holder

3. Plug the power cord into the rear cover, and plug into the dedicated outlet.
4. Turn on the power switch on the back panel.

Figure 21 - Power Cord

Figure 22 - Power Switch

Your Eccentron is now ready to use!

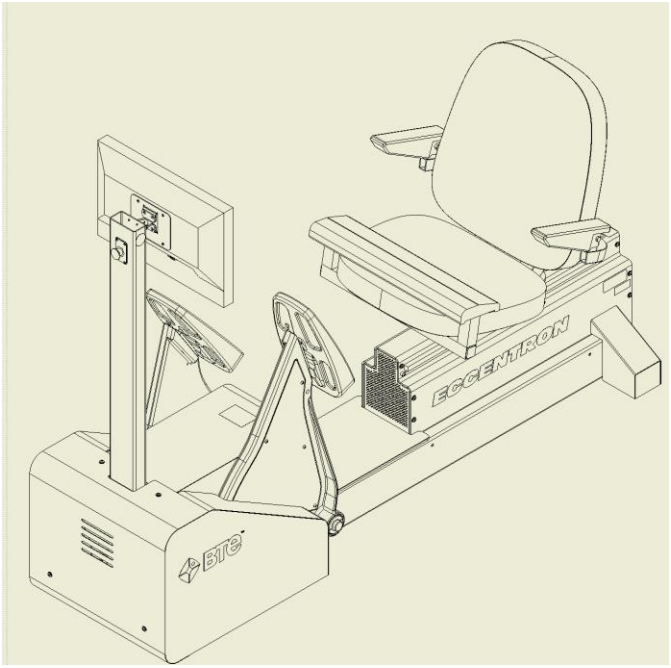


Figure 24 – Fully Assembled Eccentron

Relocation

This section describes how to move the Eccentron to another location in the facility.

1. Shut down the software, turn of the power switch, and unplug the power cable from the wall outlet.
2. Have the transport casters and hardware ready.

Remove the Rear Side Covers

1. Unscrew the screw and washer holding the rear side cover. Carefully remove the covers and safely store until the relocation is complete.

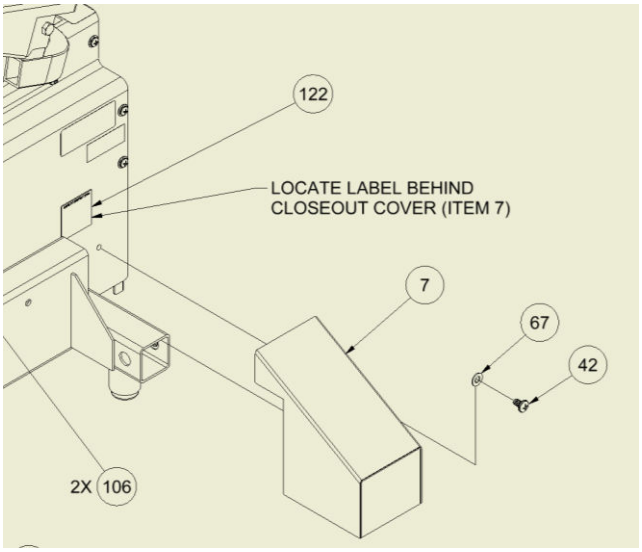


Figure 25 - Side Panel Screws

2. Repeat on the other side.

Remove the Front Console

1. Remove the 2 screws and washers on the front console cover and the 2 screws and washers from the top of the front console.

Figure 27 - Console Screw Attachments

2. Carefully lift and remove the front console.

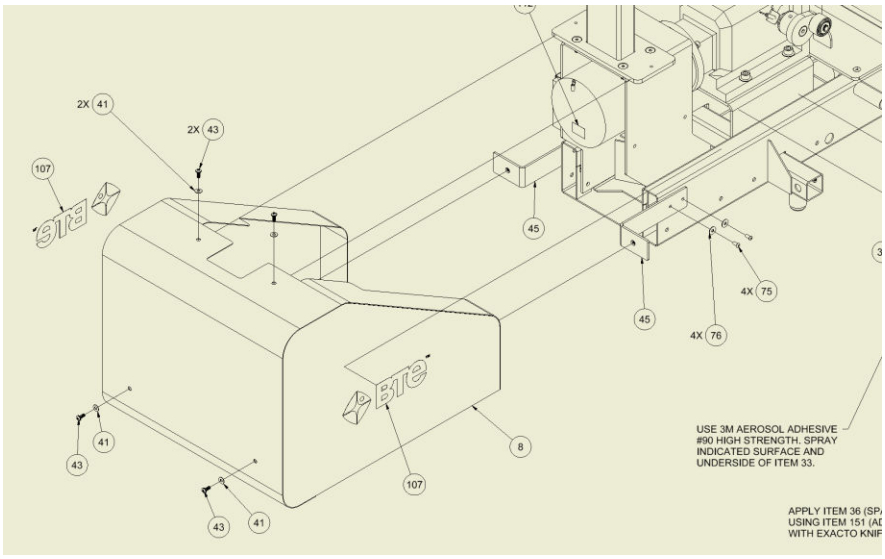


Figure 28 - Lift Console off Frame

Attach the Transport Casters

1. The casters must be in place in order to move the device.
2. Slide the four casters into the square tubes located at the base of the frame.
3. Using a ¾” wrench, attach and tighten the screw securing the transport caster to the frame. Repeat for the other 3 casters.

Figure 29 - Attach Caster to Frame

4. Use a ¾” wrench to raise the casters and lift the Eccentron off the floor.

Figure 30 - Raise Casters to Lift Frame

5. Carefully move the device to the desired location, and remove the casters. Follow the “Installation” instructions to attach the side housing, side panels, and front console.

Recommended Enhancements

In addition to the equipment shipped to you from BTE, the purchase of the following items from a local supplier is recommended for additional protection of your clients, equipment, and data:

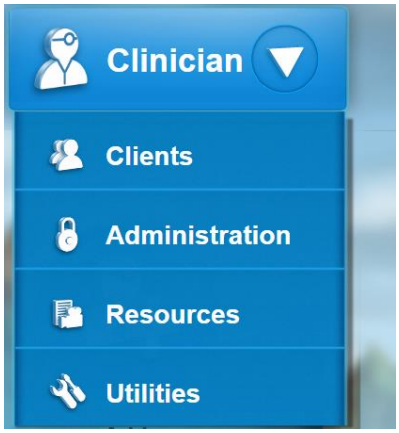
- Disinfectant wipes to clean the commonly used surfaces
- Display cleaner recommended by manufacturer of touch screen display.
- USB flash drive for backing up and archiving copies of client data

Recommended Maintenance

Calibration

- Calibration of Eccentron is not normally needed other than when prompted to do so when first using the Eccentron. Further calibration should only be performed at the direction of a service representative. To perform a calibration of the pedals follow the procedure below.

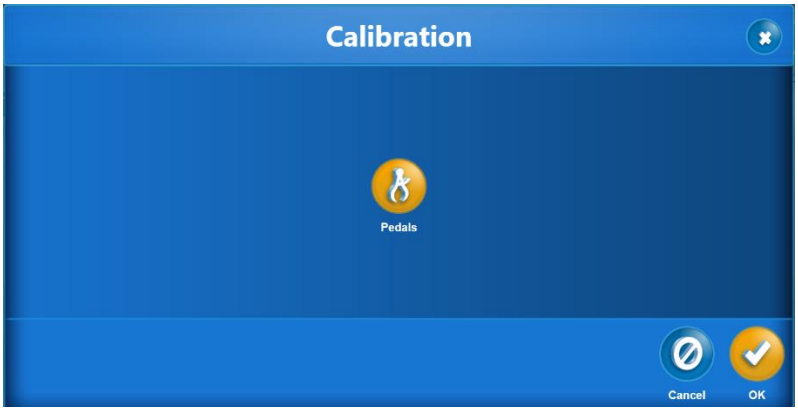
1. Log into the system as a clinician and select Administration from the Clinician drop down menu



2. Press the system configuration button from the administration Menu.

3. From the System configuration menu press the calibrate button.

4. From the calibration screen choose pedals. The Eccentron should go through the motions and moving the pedals.



5. Once complete the Calibration should indicate it has finished successfully. Press OK to exit the pedal calibration and continue pressing ok to exit to the main screen.

Control Module Care

- For optimal performance, shut down the software and turn of the power switch the every night.
- Do not install any additional software onto the control module. The BTE Eccentron system is in constant communication with the control module, so a “clean,” dedicated control module is crucial to the integrity of the system. Also, if unapproved software is installed, the control module will not be covered under the warranty.

Software Maintenance

Creating a log file

- You may be instructed by a representative of BTE to supply a log file from the system during a service event. To retrieve the log file from the system follow the procedure below.

1. Plug a USB flash drive into the USB port on the back of the monitor.
2. Log into the Eccentron as a clinician
3. From the clinician drop down menu select Utilities.
4. From the utilities screen select Software

5. From the software screen select Export Log Files

6. After less than 60 seconds a message will be shown that the log files have been exported. Press OK to exit the screen.

Updating software

- To update the software you will require a USB flash drive with the software update installed on the USB flash drive.

1. Plug a USB flash drive into the USB port on the back of the monitor with the software update.
2. Log into the Eccentron as a clinician
3. From the clinician drop down menu select Utilities.
4. From the utilities screen select Software

5. From the Software screen select Update

6. The system will update the software and restart the application upon completion.

Exporting the database

- To export the database you will require a USB flash drive

1. Plug a USB flash drive into the USB port on the back of the monitor
2. Log into the Eccentron as a clinician
3. From the clinician drop down menu select Utilities.
4. From the utilities screen select Database

5. From the database screen select Export

6. The system will export the database

Restoring the database

- To restore the database you will require a USB flash drive with the database to restore on the flash drive

1. Plug a USB flash drive into the USB port on the back of the monitor with the database
2. Log into the Eccentron as a clinician
3. From the clinician drop down menu select Utilities.
4. From the utilities screen select Database

5. From the database screen select Restore

6. The system will restore the database

Cleaning

Touch Screen Display

- Moisten a soft towel with a manufacturer recommended cleaner and wipe off the screen.
- Do not spray any liquid onto the back of the touch screen display.

Eccentron Frame

- Wipe down the system with an alcohol-based or approved disinfectant solution.

Housing

- Moisten a soft towel with water and wipe down the plastic housing.

Seat and Arm Rests

- Wipe down seat and arm rests with an alcohol-based or approved disinfectant solution.

Foot Pads and Step Over

- Wipe down foot pedals with an alcohol-based solution.
- The step-over mat can be wiped with cleaning solution or vacuumed to remove any dirt and dust.

Preventive Inspections

- Prior to each use, be sure the pendant is stored correctly and the cable attachment is free of cracks or other damage.
- Periodically inspect the seat adjustment mechanism for any unusual wear or damage.
- Periodically inspect the cables for unusual wear or damage.

Environmental Protection

At the end of the system's useful life, please remove the hard drive and have it professionally cleaned to remove all data; then, recycle the control module and electronics board as standard electronics. The remainder of the system should be recycled as scrap material.

General Operation

This chapter highlights features of the Eccentron and how they work. It is important that clinicians familiarize themselves with the instructions in each section for best results.

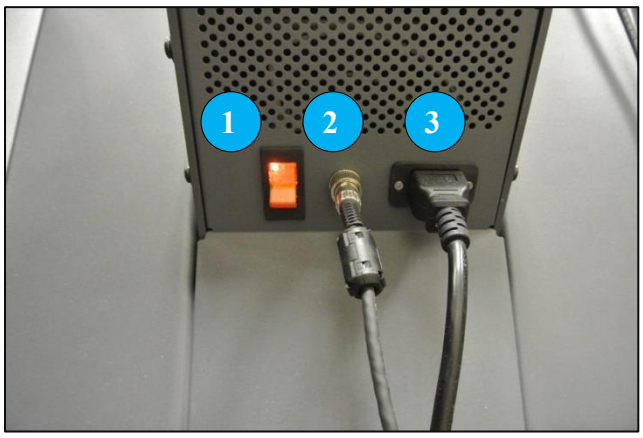


Figure 1 - Back Panel

1. Power Switch
2. Pendant Cable
3. Power Cord

System Startup

1. Connect the Pendant cable (2) on the rear base of the Eccentron, and place the pendant in its holder.
2. Verify that the power cord (3) is plugged into the rear base of the Eccentron frame and then plug into a dedicated wall outlet.
3. Turn the power switch (1) located in the back to the “ON” position (the switch will illuminate when on).
4. The Log In screen will load, providing access to the system.

Plug the Eccentron into the outlet only AFTER all cables are attached.

General Hardware Operation

Seat

The seat has features designed to facilitate access and client positioning. These include pivoting armrests and a sliding seat; both are described below.

Armrest Adjustment

For ease of client access to the seat, the armrests are moveable. Manually raise the armrests as needed for clients to get in and out of the seat. Keep the arms down (parallel to the floor) while the Eccentron is in use.

Note: If the lowered arms create discomfort for the client, move them into the “up” position.

Figure 2 - Chair Armrest Up

Figure 3 - Chair Armrest Down

Seat Position

CAUTION: Do not allow knee extension beyond 30°

Proper client positioning in relation to the pedals is critical for safe and effective use of the Eccentron. Follow the on-screen instructions carefully for seat set up.

1. While the Client is seated with feet on pedals and heels touching the bottom pedal rim, position the seat so that the knee of the most extended leg has at least 30° of knee flexion.
2. To move the seat, lift the seat lock pin and keep it raised while sliding the seat to the desired positioning hole. Release the pin and be sure it has locked into place before proceeding. If necessary, slightly move the seat back and forth until the seat pin snaps into position.
3. Enter the value on the seat position label in the Seat Position box on the Seat Adjustment screen.

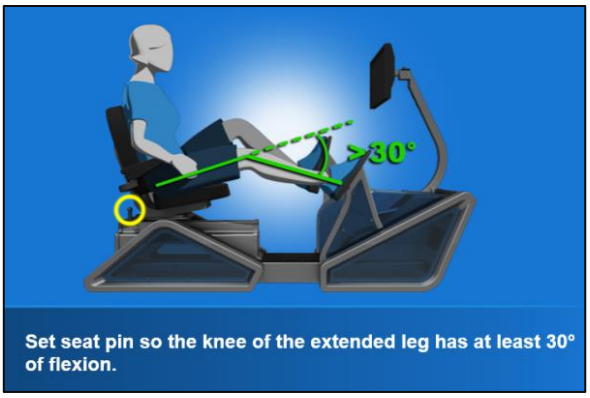


Figure 4 - Correct 30° Flexion Position

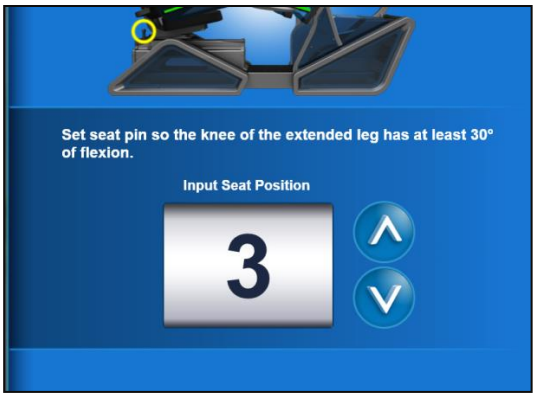


Figure 5 – Confirm Seat Setting

Machine Settings Match

Once a client is set up into the system, the software will require the same seat settings to be used each time for that client. As a reminder for seat positioning, the seat setting saved will show on screen.

Pendant

Pendant Actions

The pendant offers four simple functions for client convenience: Start and Pause exercise; Emergency Stop; Pedal Speed adjustment; and End exercise session. All other functionality must be performed on the touch screen display by the clinician. Always return the pendant to its holder when the device is not in use.

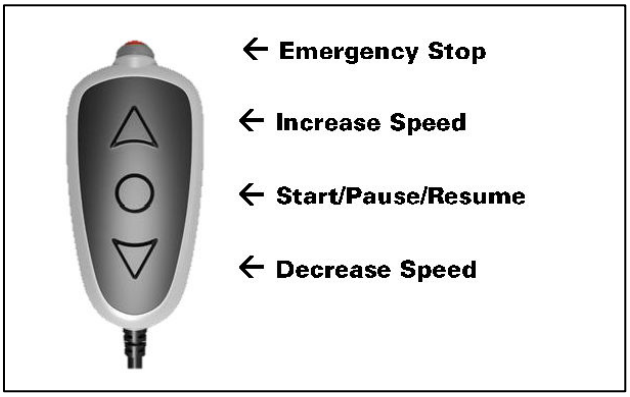


Figure 6 - Pendant

Emergency Stop (“e-stop”)

Press the emergency stop button at any time to immediately stop the pedal motion and exit the exercise program. When the e-stop is activated, data collected up to that point will be saved.

After the e-stop has been activated, the system will take less than a minute to reset. Press “OK” when prompted, and then wait for the “Please Wait” message to finish displaying before proceeding.

Adjust Pedal Speed

To increase pedal speed, press the up arrow button. Pushing the up arrow button will increase the pedal speed by 1 rep per minute, and pressing the down arrow button will decrease speed by 1 rpm.

Pause and Resume Exercise

To temporarily pause the pedal motion and screen activity, press the center button once. Press it again to resume the exercise session. Use the Pause feature if any user repositioning is needed.

Session Stop

The Session stop is a 2-button sequence. To stop a session under non-emergency circumstances, first push the center Pause/Resume button to pause the session, then press the Decrease (down arrow) button to stop the session. This will bring up the Session Report screen with the current (incomplete) session data loaded.

General Software Operation

Software Navigation

To navigate through the software, you will select various buttons and icons.

Frequently used icons can be found in the Quick Start Guide for convenient reference.

Login Requirements

Each Eccentron user (clinician and client) should have a unique login in order to use the system. Logins must contain a unique username plus a 4-digit PIN. A Clinician login allows access to all functionality within the software. A Client login provides access only to his or her exercise related screens. If Clinicians wish to exercise on the Eccentron, they must create a client log in for themselves to do so.

First Time User Login

The first screen that appears in the software is the Welcome, or Log In, screen. A Username and PIN are required to access the software, so BTE has provided a default log in for first time access to the system. The default log in is:

Username: **BTEAdmin**

PIN: **7455**

From here, each clinician should create his or her unique Username and PIN in alphanumeric and numeric format, respectively. Once this is done, **discontinue use of BTEAdmin and its associated PIN**.

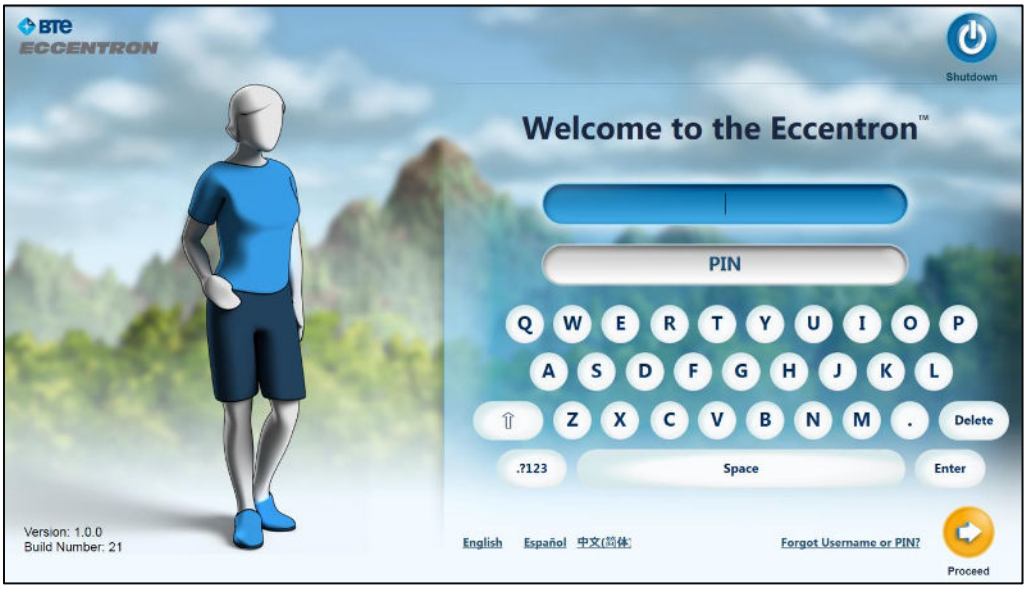


Figure 7 – Log In Screen

Enter the Username and PIN. The first clinician who uses the BTEAdmin log in can perform the following functions.

- View the Usage Video
- Set up the Clinic information
- Add New Client Users
- Add New Clinician Users

Clinician Functions

Within the Eccentron software program Clinicians can:

- Create, view, modify, and delete Client and Clinician records
- Train new Clinicians to use the software
- Train new Clients to perform the exercise
- Select pre-programmed sessions or manually set exercise parameters
- Perform testing and training
- Record RPE per session for Client dosing and comfort
- Review and compare performance and progress over the duration of treatment
- Export reports for printing and insurance submittal
- Provide Demo exercise sessions

Details on these features and more are found in the **Clinician Management** section.

Client Functions

Within the Eccentron software program Client users can:

- Learn correct positioning and motion for exercise
- Practice resistance prior to first recorded exercise session
- Practice pendant use prior to first active exercise session
- Exercise with visual cues and rewards for appropriate effort
- Exercise at individual, submaximal effort with each leg
- View real-time feedback on effort
- Review Session performance
- Review Exercise Progress by parameter (force, work, power, etc.)

Details of these options and more are discussed in detail in the **Client Management** section.

Shut Down the System

The control module is sensitive to improper shutdown. Shutting down the Eccentron system improperly can cause damage to the control module and/or the database utilized by the Eccentron software that can render the Eccentron system inoperable.

When you are done using the equipment for the day, it is recommended that you shut down the system. To shut down the Eccentron, perform the following steps:

1. Log off by clicking the Log-out icon at the top right of the screen. The following screen appears:

Figure 8 - Shutdown Screen

2. Click the Shutdown button.
    a. Clicking on the X will close the shutdown screen and revert back to the previous screen.
    b. Clicking Restart will prompt a system restart.
    c. Clicking Shutdown will shut down the control module.
    d. Clicking Cancel will cancel the shutdown or restart, and revert to the previous screen.

3. After the control module has finished shutting down, the monitor on the Eccentron system will turn black. You can then safely turn the Eccentron off using the power switch on the back.

> **ATTENTION:**
>
> **Damage to the Eccentron control module from improper shutdown may not be covered under Warranty, Service, or Rental Agreements.**

Dosing & Exercise

This chapter presents a general testing and treatment paradigm and a step-by-step process for a first time Client user.

As with any exercise program, it is necessary to determine a client's baseline performance in order to administer proper exercise and progression parameters. For best results, clients should be regularly evaluated against their baseline to be sure treatment is sufficient and effective. The Eccentron Testing and Training Paradigm were developed to provide objective measurement and gradual acclimation to exercise while accommodating exercise progression—and regression—needs.

Eccentron Testing and Training Paradigm

The Eccentron Testing and Training Paradigm involve performing an initial dosing test followed by bouts of 3 exercise sessions, and then re-dosing. This keeps the patient progressing at an appropriate level without the Clinician having to guess at progression of time or force range.

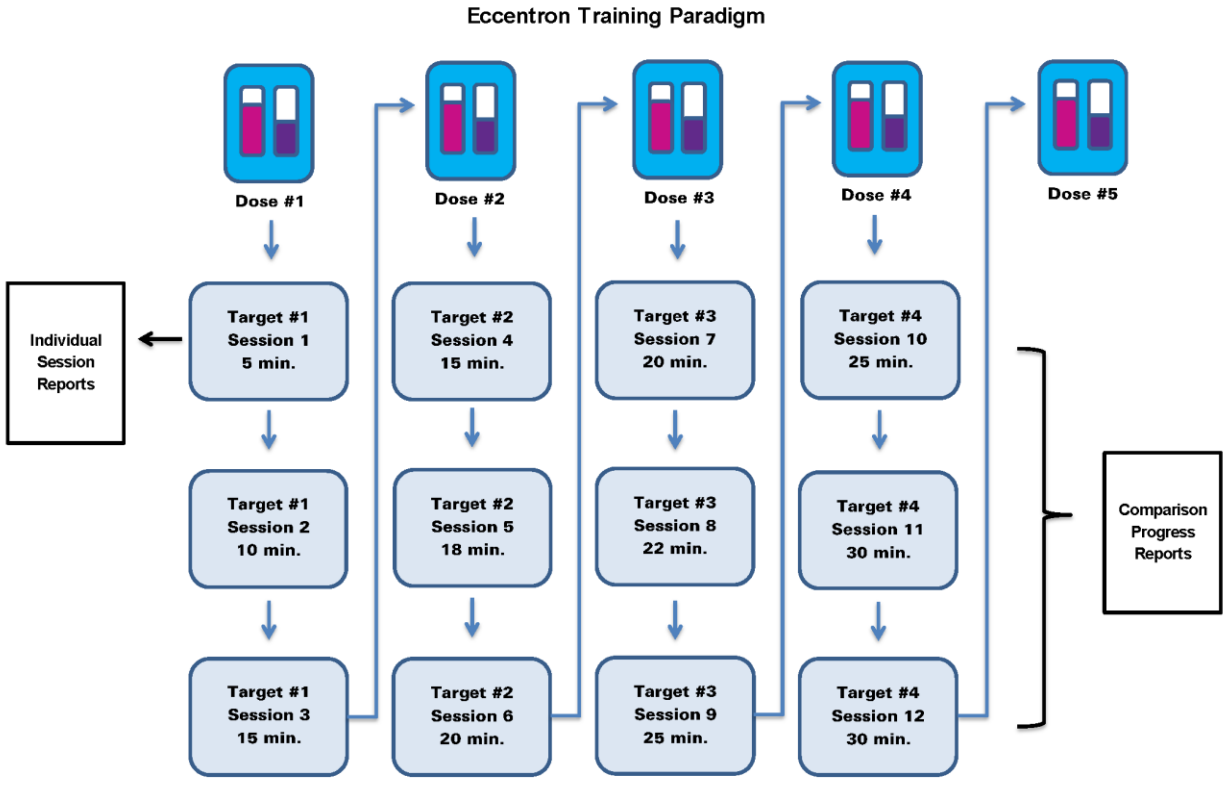


Figure 1 – Training Paradigm

Dosing Test

The Dosing Test begins with a warm-up, consisting of 6 repetitions (12 strides total) performed at a submaximal effort. The purpose of the warm-up is to ease the client into their dosing test so that maximum effort is not applied from a cold start.

The Dosing Test itself consists of 6 repetitions (12 strides total), performed at the Client's safe maximum effort. The target force is based on the performance of the weaker leg, so as not to over-exert an injured or underperforming limb.

After dosing, the greatest force values for each leg are discarded. Then, the next greatest force values are compared for each leg. The leg with the lower force value in this comparison is used to calculate the target force. This force value is divided in half to provide the suggested level for resistance.

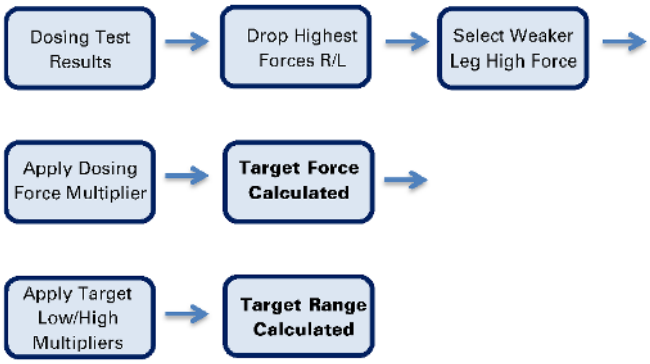


Figure 2 – Dosing Calculation

Because the dosing test involves only 6 reps and exercise sessions can involve hundreds, we apply a percentage to the target force as a level to be maintained over the duration of the session. The default reduction is 50%. If a Client resists 100 pounds as their second highest force, their target range will be 50 lbs. for 3 sessions of increasing duration.

The extra range allotted around the target is 20% by default. In this case the target range would be 40–60 lbs. An example of this process and subsequent calculations can be seen in figure below.

Target Force and Range Calculations

Dosing Test Rep	**1**	**2**	**3**	**4**	**5**	**6**
Left Leg Force	96	98	97	~~102~~	100	99
Right Leg Force	103	105	~~112~~	108	105	107

1. Disregard highest value for each leg.
2. Compare next highest value for each leg.
3. Use the lower value. **100 lbs.**
4. Divide 100 in half to determine the Target Force **50 lbs.**
5. Multiply 50 by 80% to determine the Target Range Minimum **40 lbs.**
6. Multiply 50 by 120% to determine the Target Range Maximum **60 lbs.**

Progression

During the first week, the pre-set progression adds 5 minutes per session until the Client reaches 15 minutes. This helps mitigate DOMS as the client acclimates to the novel exercise. Two, three, and five minute intervals of duration are added throughout the progression until the client reaches a maximum duration of 30 minutes.

Dosing Re-Test

BTE suggests re-testing Clients after they complete 3 successful exercise sessions, due to the rapid strength gains many people experience with eccentric muscle work on the Eccentron. Re-testing every 4th session provides an appropriate and accurate target range that is individually tailored to each Client's current capability. The default exercise progression automatically initiates these dosing tests at appropriate times.

Client Training

First time Clients go through a short series of training and practice screens prior to their first Dosing Test and Exercise Session. Because the software collects and reports data, it is important that the Client uses the equipment correctly to ensure accurate treatment and optimal results. Following are a series of screens and information that new Clients will experience in their first Eccentron Session.

Clinicians should supervise Client training. Clients are first informed of important safety and use guidelines, and then are required to agree to the Eccentron usage terms. The Client will not have access on the Pendant to progress through the training screens, so the Clinician must provide navigation and acceptance of terms at the touch screen display.

Client Training Screen Sequence

Introduction

The training introduction screens provide basic instruction and safety guidelines to follow.

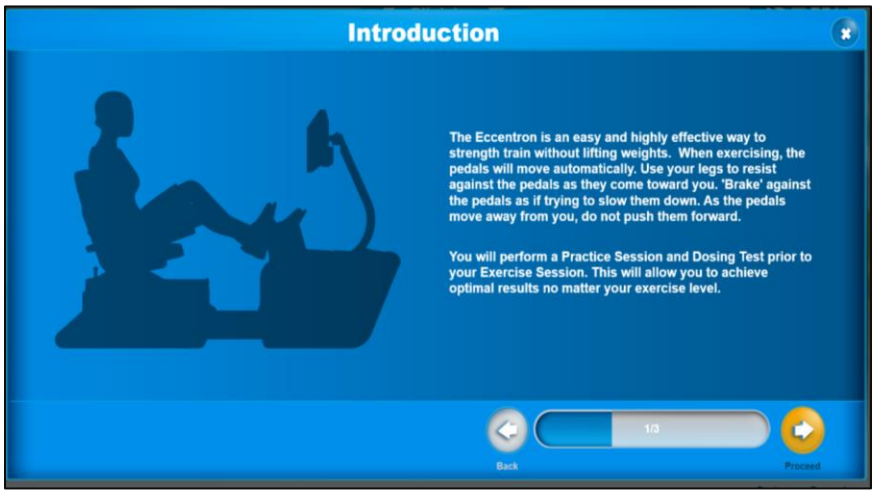


Figure 3 - Training Introduction Screen

> “The Eccentron is an easy and highly effective way to strength train without lifting weights. When exercising, the pedals will move automatically. Use your legs to resist against the pedals as they come toward you. “Brake” against the pedals as if trying to slow them down. As the pedals move away from you, do not push them forward.
>
> You will perform a Practice Session and Dosing Test prior to your Exercise Session. This will allow you to achieve optimal results no matter your exercise level.”

Safety Guidelines

Important safety info regarding positioning during exercise is explained.

Figure 4 - Safety Guidelines Screen

Always

- Follow the usage instructions and warnings.
- Exercise only under your own Log In.
- Stop the exercise and see a Clinician if you feel pain or discomfort.
- Maintain access to the Emergency Stop button while exercising.
- Keep out of the way of moving parts.

Never

- Exercise with straight, locked, or hyperextended knees.
- Resist the pedals when you are out of the correct exercise position.
- Allow feet to lift, drift, slide up or drop off the moving pedals.
- Twist, move, or rise up out of seat while exercising.

Acceptance of Terms

The Client must agree to the proper usage instructions. Because the pendant is not yet operational, the Clinician must enter the selection at the display. If the Client does not agree to the terms, select Cancel and the software will revert back to the Client record. Select **Proceed** to proceed under the usage terms.

Figure 5 - Acceptance of Terms Screen

> “I understand and agree to follow all safety, positioning, and usage guidelines for the Eccentron.
>
> If further information is desired, please contact a facility Clinician, or BTE.”

Client Positioning

The key to safe and successful outcomes on the Eccentron is proper Client positioning. It is very important to follow the positioning recommendations provided here and in the Clinician and Client Training materials.

Ingress and Egress

The Eccentron is designed to facilitate Client seating regardless of level of assistance they may need. Raise the armrests as needed for Clients to get in and out of the seat. Upon entering the Seat Position screen, the software will move one pedal to its furthest position after a dialog appears.

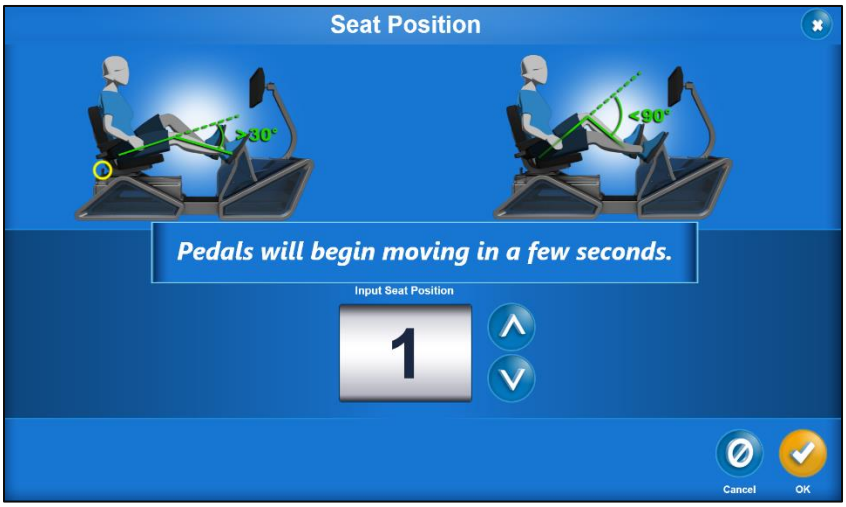


Figure 6 - Machine Settings

Seat Setting

Figure 7 - Seat Position

1. To set the correct seat position, have your client place one foot on the farthest pedal.
2. Lift and hold the seat lock pin, and slide the seat until the client's knee has no less than 30° of flexion. If you are unsure between 2 seat settings, use the one closer to the screen.

3. Once the proper setting is found, input the number on the screen.

CAUTION: Do not allow knee extension beyond 30°

Knee Bar

Eccentron includes a knee bar, installed to aid in ensuring correct patient leg positioning. The ideal position for the knee bar is for the top of the cushion to be directly under the knee however it can be adjusted for comfort. Do not use Eccentron without the knee bar in place.

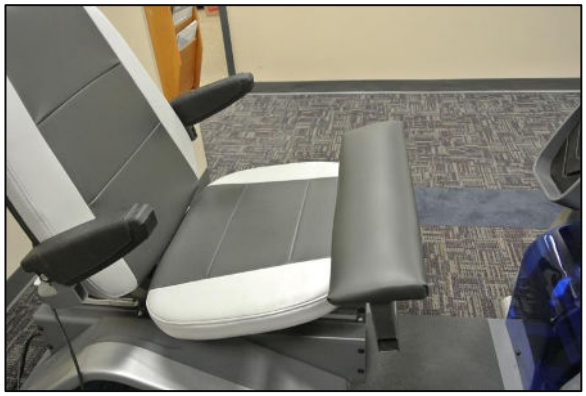


Figure 8 – Knee Bar in place

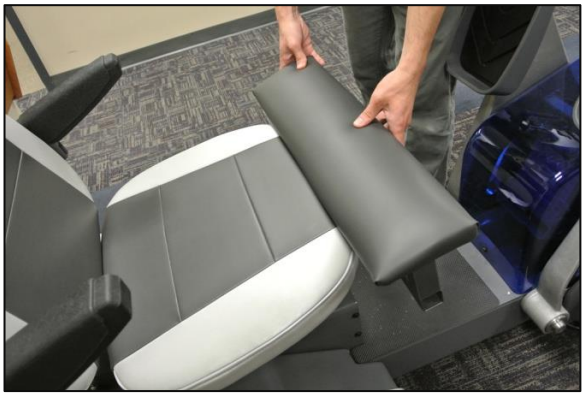
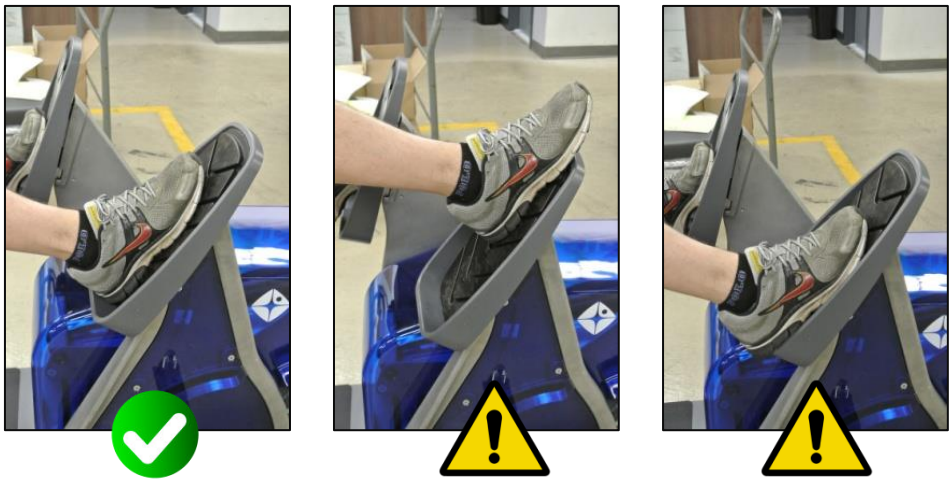


Figure 9 – Knee Bar adjustment

Foot Position



Instruct clients to keep their feet flat on the foot pedal beds with heels against the heel cup at all times during exercise, and to never remove feet from the moving pedals. If foot movement is needed for any reason like repositioning, Pause the exercise first. Feet should be parallel and aligned directly with knees and hips.

Keep hair, clothing, fingers, shoe laces, and any other loose items clear from the path of the moving pedals.

CAUTION: Do not allow feet to slide up the pedal during use.

Once the screen controls and resistance exercise are understood, the client will perform the dosing test (see **Dosing Test** Section).

Practice Session

The software allows first-time users an opportunity to practice the exercise prior to performing the Dosing Test. During the Practice Session, encourage the Client to resist against the pedals as they come toward the Client. Effective cues, depending on the advised effort, include, “Try to slow down the pedal motion,” and, “Try to stop the pedal from coming toward you.” The Client should not actually try to stop the pedals, but this action produces the correct muscle activity for the exercise. The leg that is not resisting should relax and passively move with the pedal. The Client should not push the pedal forward in a concentric fashion.

Follow the instructions on screen to learn to use the pendant and control the pedals.

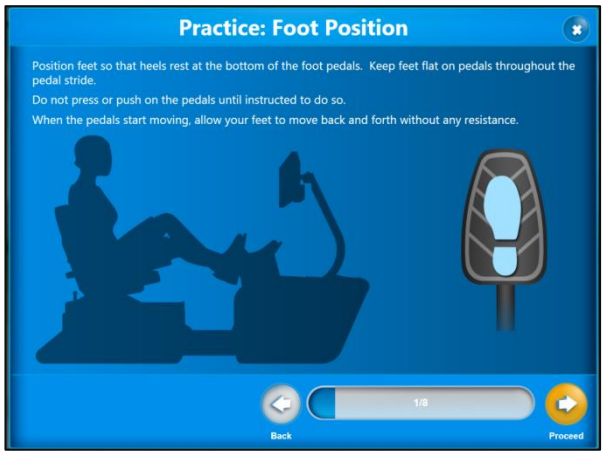


Figure 10 - Foot Position Screen

“Position feet so that heels rest at the bottom of the foot pedals. Keep feet flat on pedals throughout the pedal stride.

Do not press or push on the pedals until instructed to do so.

When the pedals start moving, allow your feet to move back and forth without any pressure.”

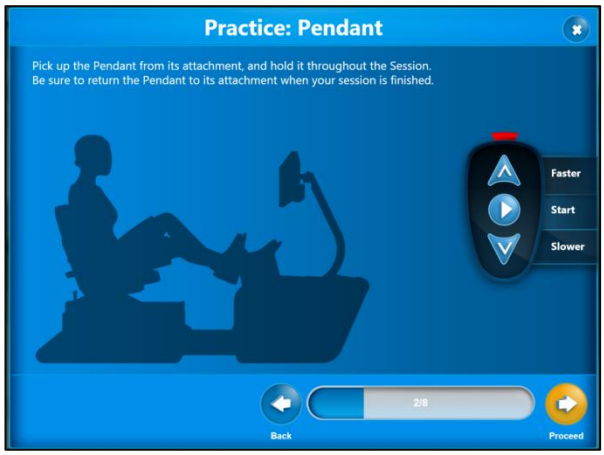


Figure 11 - Pendant Screen

“Pick up the Pendant from its holder, and hold it throughout the Session. Be sure to return the Pendant to its holder when your session is finished.”

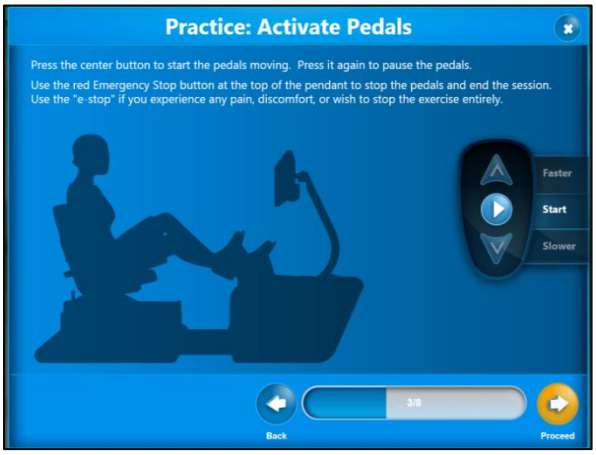


Figure 12 - Activate Pedals Screen

"Press the center button to start the pedals moving. Press it again to pause the pedals.

Use the red Emergency Stop at the top of the pendant to stop pedals and end the session. Use this "e-stop" if you experience any pain, discomfort, or wish to stop the exercise entirely."

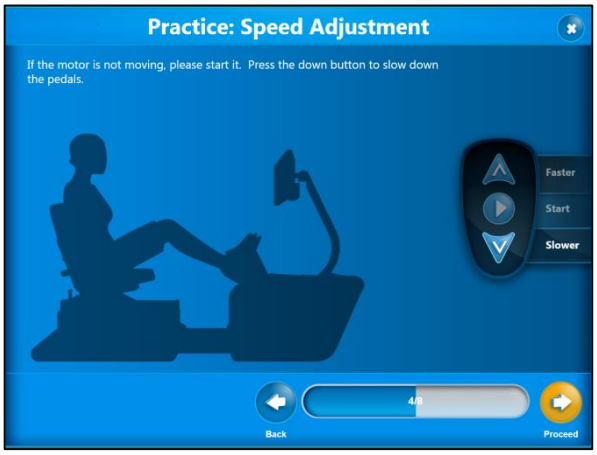


Figure 13 - Speed Adjustment Screen

"If the motor is not moving, please start it. Press the down arrow button to slow down the pedals."

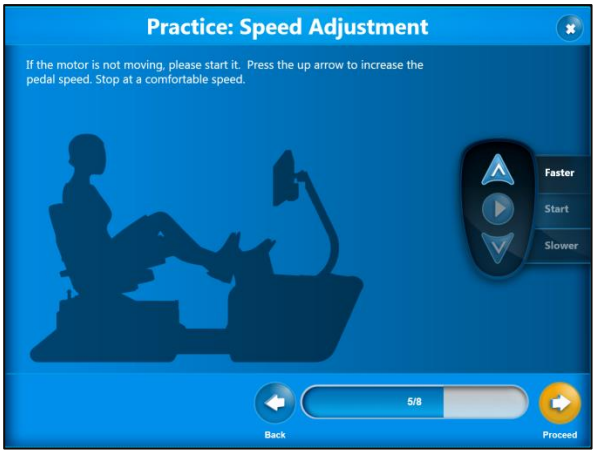


Figure 14 - Speed Adjustment Screen

"If the motor is not moving, please start it. Press the up arrow to increase the pedal speed. Stop at a comfortable speed."

Figure 15 - Resistance Motion Screen

"Now it's time to resist.

Using just your right leg, resist—or brake—against the pedal as it comes toward you, as shown.

You will see the purple bar move from the bottom to the top of the screen during the stride if done correctly."

Figure 16 - Resistance Motion Screen

Figure 17 - Resistance Motion Screen

"Now we'll try the other leg.

Using just your left leg, resist—or brake—against the pedal as it comes toward you as shown.

You will see the pink bar move from the bottom to the top of the screen during the stride if done correctly."

"Now let's try both legs.

Practice resisting on both legs until you see the pink and purple bars on each stride for several reps.

Press the center button when you are ready to proceed to the Dosing Test."

The Practice Resistance Motion lasts up to 1 minute. The exercise can be stopped at any time using the Start/Pause/Resume button on the pendant. The Client should have several even stride bars in a row for both legs (though they may not be equal in force) prior to moving on to the Dosing Test. Because the Dosing Test is recorded and sets the Target for the subsequent 3 exercise sessions, it is important that the Client correctly and comfortably resists the pedals to their best ability, and thus utilizes the resistance practice time as needed.

Default Speed Settings

Pedal speed pre-sets are in place, but are adjustable via the pendant and screen buttons during all use except the Dosing Test.

- The Practice Session begins at a speed of 18 RPM. Speed changes occur in intervals of 1 RPM.
- The default speed set for the Dosing Test is 18 RPM. The Dosing Test speed is fixed in order to standardize all the tests.
- The default speed for Exercise is 23 RPM. If desired, the Client can adjust the speed during the Practice and Exercise Sessions to find a comfortable RPM for exercise.

Dosing Test Screens

The Dosing Test consists of a warm-up of 6 reps (full strides on each leg), and then a recorded test of 6 reps. During the warm-up, instruct the Client to resist at a comfortable submaximal level.

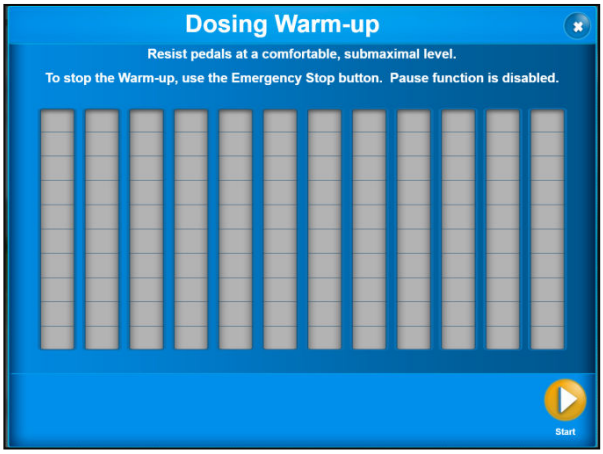


Figure 18 - Dosing Warm-up

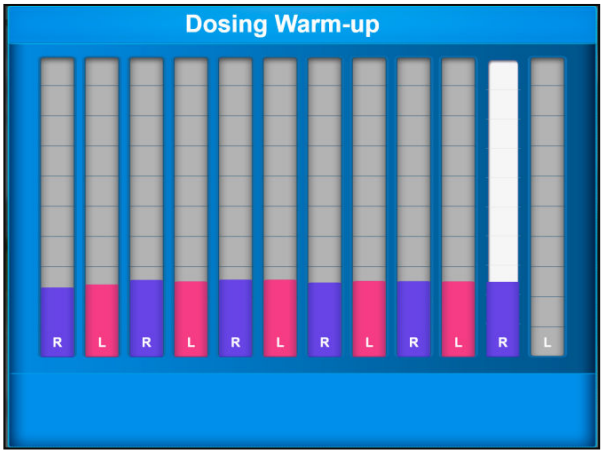


Figure 19 - Dosing Warm-up

During the Dosing Test, instruct the Client to resist at their safe maximum level for each stride.

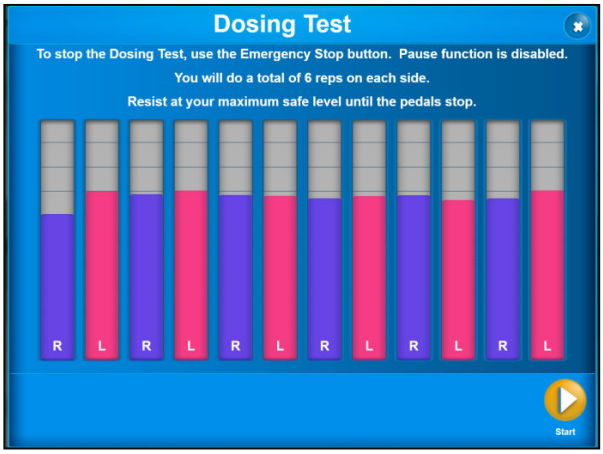


Figure 20 - Dosing Test Progress Screen

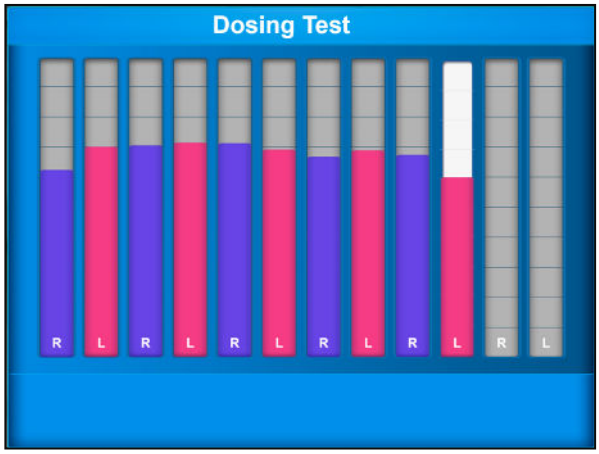


Figure 21 - Dosing Test Results Screen

CAUTION: To stop the Dosing Test in progress, use the Emergency Stop button

Once the Dosing Test is finished, there are 3 options for proceeding.

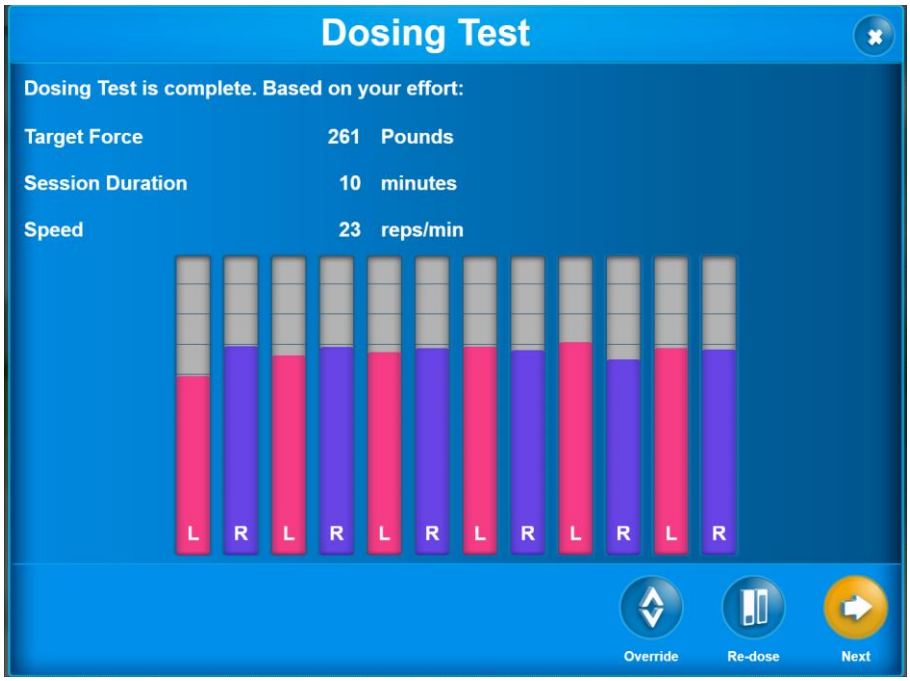


Figure 22 - Dosing Test Completion Screen

1. Manually override the set exercise parameters for the Client by modifying the Session Settings. To do this, select the **Override** icon, which takes you to the Session Settings screen. Manually enter the desired values and proceed to exercise. Doing this will set the client into manual mode for the remainder of their sessions.

2. Re-test the Client and repeat the Dose Test. To do this, select the **Re-dose** icon and the Dosing Test start screen will appear. Select **Start** to re-do the Dosing Test.

3. Accept the Target value given and proceed to the Exercise session by selecting the **Proceed** icon.

After the initial Dosing Test, we recommend repeating the Dosing Test prior to every 4th successful Exercise Session. This allows the Client 3 sessions to acclimate to the level of exercise, as well as the opportunity to reduce or increase the target range as needed on a frequent basis. This way the Client is always working at an appropriate force level, based on their recent output. The default progression initiates dosing tests at appropriate times.

Exercise Screen Controls

There are various screen controls that the Clinician and Client should be aware of during exercise. See **General Hardware Operation/Pendant.**

Pendant Buttons

The pendant allows the client to start, pause, resume, and stop the exercise program. The clinician can use the corresponding buttons on screen for the same functions.

During exercise, be sure the client maintains a hold on the pendant where all buttons are within easy reach.

The pendant should be placed back in its holder when the exercise is complete.

Emergency Stop Buttons

In addition to the Emergency Stop button on the Pendant, there is another one behind the monitor for Clinician access. Utilize the E-stop behind the monitor at any time to immediately stop the pedals and exit the exercise program.

Be sure client is able to quickly activate the “e-stop” button on the pendant if needed. If not, Clinician should closely supervise the Client during exercise.

Figure 23 - Monitor Arm E-Stop

Adjust Speed

Pedal speed (RPM) can be adjusted by using the up/down arrows on the pendant. Clinicians can adjust speed by touching the up/down arrows on the touch screen. Speed adjustments occur in intervals of 1 RPM.

Dosing Tests are pre-programmed to run at 18 RPM, and the Exercise Session default speed is 23 RPM. In the presence of complaints of patellar pain, a modification in speed may be an effective means of minimizing or eliminating the pain.

Pause/Resume Exercise

The Client can pause the exercise (pedal and screen activity) by pressing the center button once. To resume exercise, press it again.

To exit the exercise session from the Pause screen, hit the down arrow button. Session data will be saved.

Clinicians can perform the same software functions by pressing the corresponding buttons on screen.

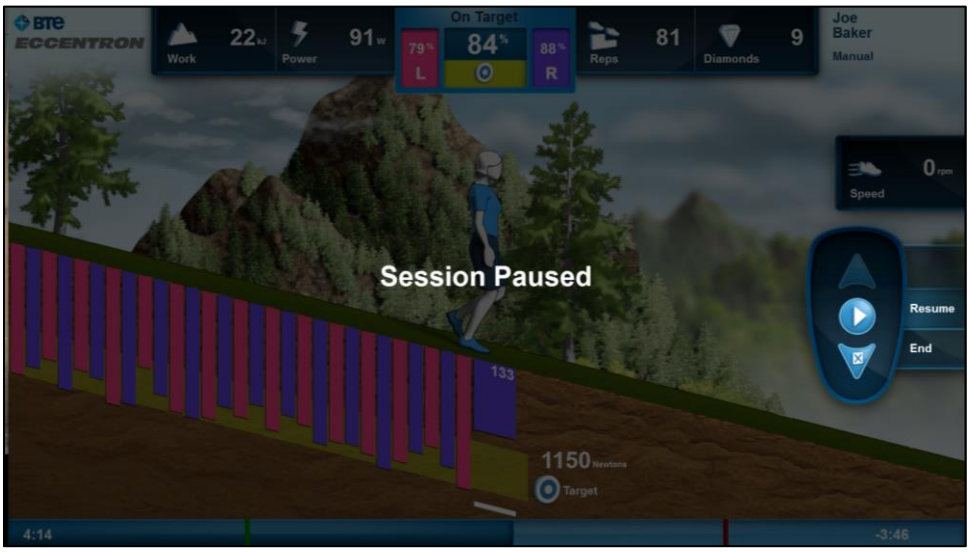


Figure 24 - Exercise Pause Screen

CAUTION: Pause the exercise prior to making any Client adjustments for comfort or positioning.

Exercise Program

The Eccentron exercise program provides a “ramp-up” of gradually increasing duration, with intermittent Dosing Tests to properly set the Target Range. Additionally, the exercise session itself includes a short warm-up, active exercise, and brief cool-down stages.

Exercise Preparation

Clients should perform a general warm up for 5–10 minutes, or as Clinician recommends, prior to using the Eccentron.

Eccentric Resistance

Encourage the Client to resist smoothly and evenly throughout the entire stride, with uniform pressure through the foot. Start resistance as soon as the pedal has finished returning to its farthest position.

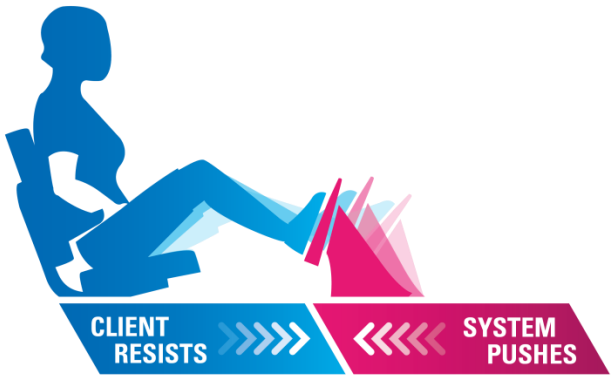
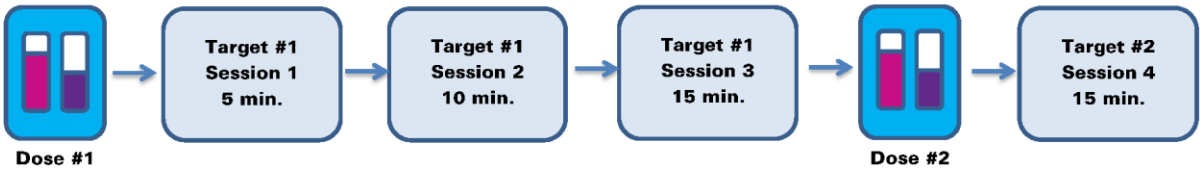


Figure 25 - Exercise Motion

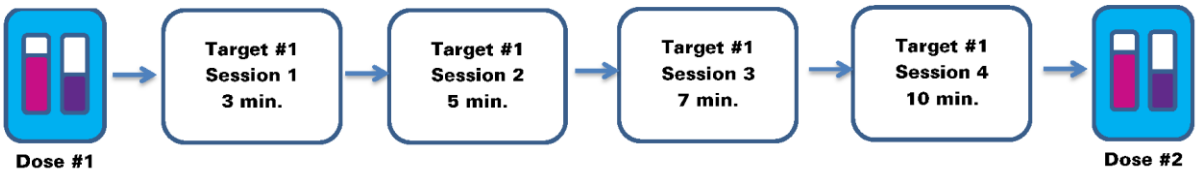
Conditioning Series

The pre-set Exercise Session starts out at a low duration and which gradually increases throughout the progression. This allows the Client to become acclimated to the novel mode of exercise. It also helps mitigate the DOMS that often accompanies eccentric muscle work. While there may be muscle soreness with some Clients, it should subside within 1-3 weeks. If a Clinician has concerns about DOMS for certain Clients, the number and duration of conditioning sessions can be modified by using the Manual Option (edit **Session Settings**) rather than the pre-set sessions. Once the Manual Option has been entered, there is no way to return into the pre-set series. In addition, there are no automatically-scheduled dosing tests in Manual Mode.

Pre-set Exercise



Manually-set Exercise Sample



Exercise Session Stages

Warm Up

In addition to the general therapy warm up, the pre-set exercise session provides a short period of time at the beginning of the session for the Client to become adjusted to the exercise resistance. This lasts for 1 minute, or 10% of the duration, whichever is greater. During the “warm up” stage, the target is set at 50% of the Exercise Stage target. This adjustment period allows the Client to ease into the force resistance. Force and power data from this stage are not recorded for the Session Report totals. Work performed during this stage is recorded.

Exercise

The Active Exercise Stage consists of the submaximal force resistance with the goal of exerting force into the target range with each stride. This is the data that is recorded and reported in regards to Client performance and progress.

Cool Down

The final stage is for cooling down. The cool down lasts for 1 minute, or 10% of the duration, whichever is greater. The target during Cool Down is 50% of the Exercise Stage target, and the force and power from this stage data is excluded from the Client reporting totals. Work performed during this stage is recorded. It is important the Client slow down and reduce effort after the Exercise stage.

NOTE: Do not abruptly stop at a high speed and/or high force effort

Interactive Game

The Eccentron software displays a fun, animated game screen to teach, entertain, and motivate the client while exercising.

The game screen portrays the Client as a hiker going downhill. Select **Start** to begin the pedal and screen activity. Force bars below the hiker show real-time force effort exerted on the pedals.

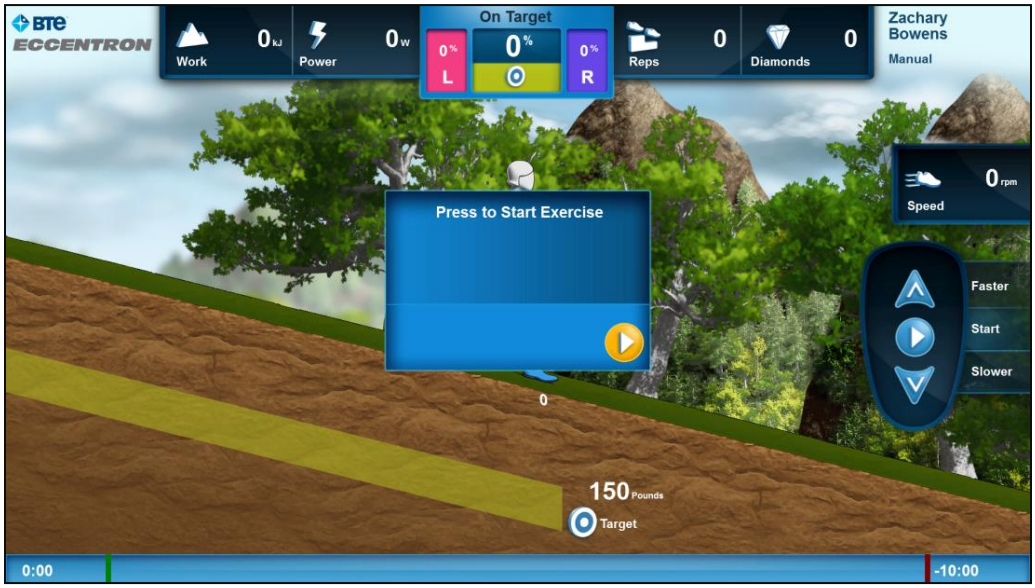
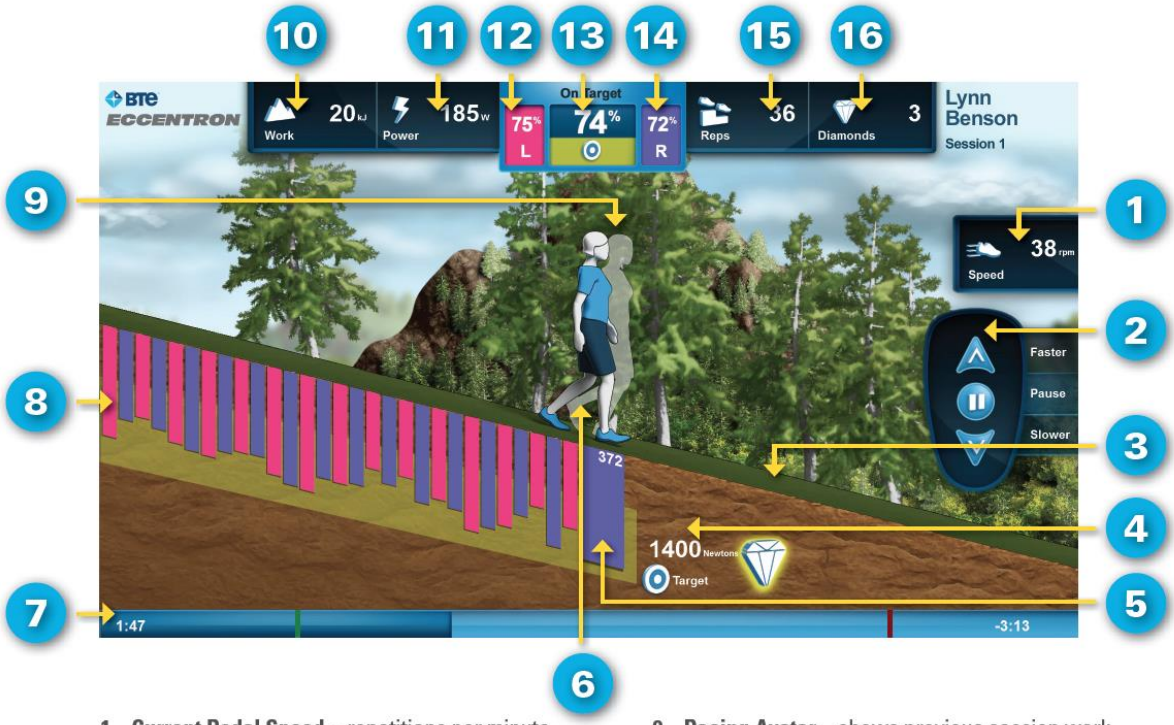


Figure 26 - Start of Game Screen

Live Data Display

The screen displays live collection data for the exercise to help the Client and Clinician monitor performance. For details see figure below.



1. **Current Pedal Speed** – repetitions per minute
2. **Control Pendant Replica** – active buttons are highlighted
3. **Diamond Reward**
4. **Target Force** – from Dosing Test
5. **Real Time Force Resisted** – shown for each leg, each stride
6. **Hiking Avatar**
7. **Duration Progress Bar** – elapsed and remaining minutes shown
8. **Target Range** – Target Force +/- 10% (default)
9. **Pacing Avatar** – shows previous session work
10. **Total Work** – in kilojoules
11. **Average Power** – in Watts
12. **Percent on Target (L)** – how often left leg hits target range
13. **Percent on Target** – accuracy of both legs, averaged
14. **Percent on Target (R)** – how often right leg hits target range
15. **Total Reps**
16. **Diamonds Accrued**

Performance Motivation

The interactive game trains clients to stay in a particular force range, for neuromuscular performance gains. The goal for the “hiker” is to have all the force bars land inside the Target Range band. The “% on Target” area displays the accuracy of each leg individually in hitting the target, as well as an average for both legs.

The diamond collection activity provides further entertainment as well as motivation and reward for exercising at the proper level. The game consists of diamonds segments appearing by the target bar. Diamonds are created by performing 6 on-target strides.

- 6 on-target strides build 1 diamond; they do not have to be consecutive.
- A diamond is earned if the stride immediately following the completed diamond is also on target.

- If a diamond is earned, the diamond accrual at the top of the screen increases.
- If a diamond is missed, there is no “penalty”. A new diamond will start forming with the next on-target stride.

Excessive Effort Control

Force exceeding the Target Range is discouraged and will not earn diamonds. For safety and efficacy of treatment, warnings and shutoffs are built in to the system to help Clients adhere to the proper exercise level.

- If a Client exceeds the device maximum force of 750 lbs. the software will engage an Emergency Stop event.
- If a Client exceeds their Target Range maximum by 20% or more, a warning message appears indicating that continued force above the target shall pause the machine. This warning appears on every applicable stride, and persists until target range is achieved.
- If a Client exceeds the Target Range maximum by 40% or more for four strides in a row, the software and pedals will pause. Hit the Resume button to continue exercise.
- Conversely, if Client effort falls below 60% of their target range minimum, a message will display indicating they should increase their effort. There is no mechanical response to falling below the target range, however, the message will persist until the target range is reached.

Client Effort Evaluation (RPE)

When an exercise session ends, the option to record Rate of Perceived Exertion (RPE) appears. Clinicians may enter the Client’s RPE on a 0-10 scale, not enter RPE for this session, or opt to skip recording the RPE for the Client’s duration of treatment. RPE entered will appear on Session Reports.

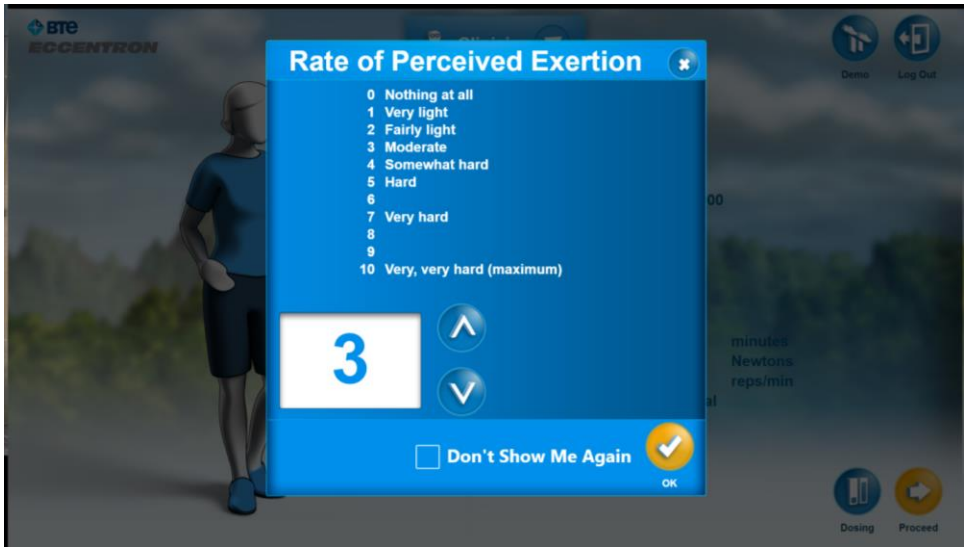


Figure 27 - RPE Screen

Demo Exercise

There is a “demo” session pre-programmed on the Eccentron. This is available to test out the device and get a feel for the eccentric resistance motion as well as the software and game features. Demo data results are not saved.

The Demo parameters are:

- Duration 3 minutes
- Target Force 50 lbs.
- Speed 23 reps/min

Before the 3 minutes are up a message will appear offering an option to extend the demo for another minute. The additional minute feature continues to appear until the user decides to end the Demo exercise.

To run a Demo:

1. Position the test subject with proper seat setting.
2. Select “Proceed” then “Start” the Demo Exercise. There will not be a Practice or Dosing Test.

Figure 28 - Seat Position Screen

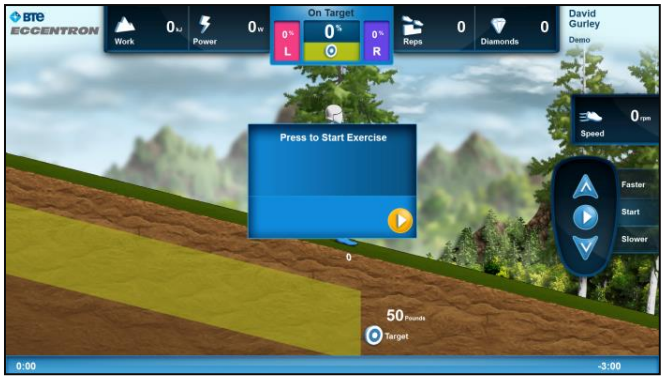


Figure 29 - Demo Screen

Clinician Management

The Eccentron software provides helpful administrative and treatment features in order to get the most out of your equipment. In addition to the ability to add and search for client records, more options and features are available via the Clinician Menu. Clinicians should execute the **Administration** and **Resource** sections prior to treating Clients on the Eccentron.

Navigating the Clinician Menu

The Clinician Menu provides easy navigation throughout the software via the drop-down selections.

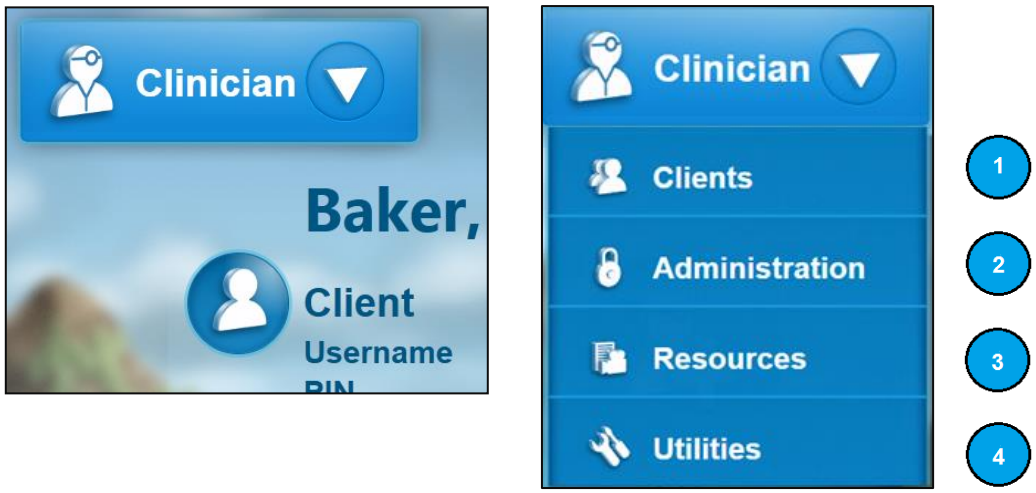


Figure 1 - Clinician Menu

The following action menus available under the Clinician drop-down menu enable setup and use of the Eccentron.

1. **Clients**

The Clients section will be the most frequently used area for most Clinicians. For details on the following functions, see the **Client Management** section.

- Client Record Management
    - Add
    - Modify
    - Delete

- Machine Settings for the client
    - Seat Setting
- Session Settings for exercise
    - Target Force
    - Duration
    - Pedal Speed
- Reports
    - Session Reports
    - Progress Reports

2. Administration

The Administration section contains the Eccentron setup information. This section allows the modification of software, exercise, and data collection defaults. For details on these features, see the **System Configuration** section below.

For details see the **Administration** section below.

- Clinic Setup
    - Contact information
- Clinician Setup
    - Name
    - Log in
    - Credentials
- System Configuration
    - Units of Measure — Default = Metric
    - System Language — Default = English
    - Dosing Force Multiplier — Default = 50%
    - Exercise Pass Threshold — Default = 70%
    - Target Range Minimum — Default = -20%
    - Target Range Maximum — Default = +20%
    - Power Calculation — Default = average of 5 reps
    - RPE Recording — On/Off
    - Logging Level — Default = 4
    - Calibrate — Enter values as instructed

3. **Resources**

The Resources section contains usage and training materials.

- Operator's Manual
- Clinician Usage Video

4. **Utilities**

- Software
    - Update
    - Export Log Files
- Database
    - Export
    - Restore

Administration

Use the Administration section to set up the clinic, clinical users, and system preferences. Action buttons at the top right of the screen allow for Demo exercise, and Log Out of the system.

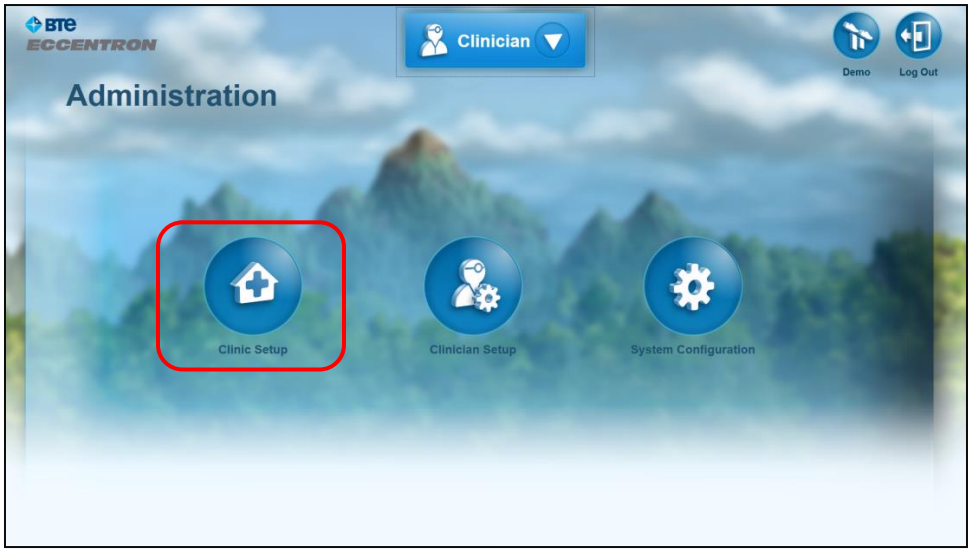


Figure 2 - Administration Screen: Clinic Setup

Clinic Setup

From the Administration screen, select **Clinic Setup** to enter your clinic information. This step is optional, however, if it is filled out your clinic information will print on the client reports.

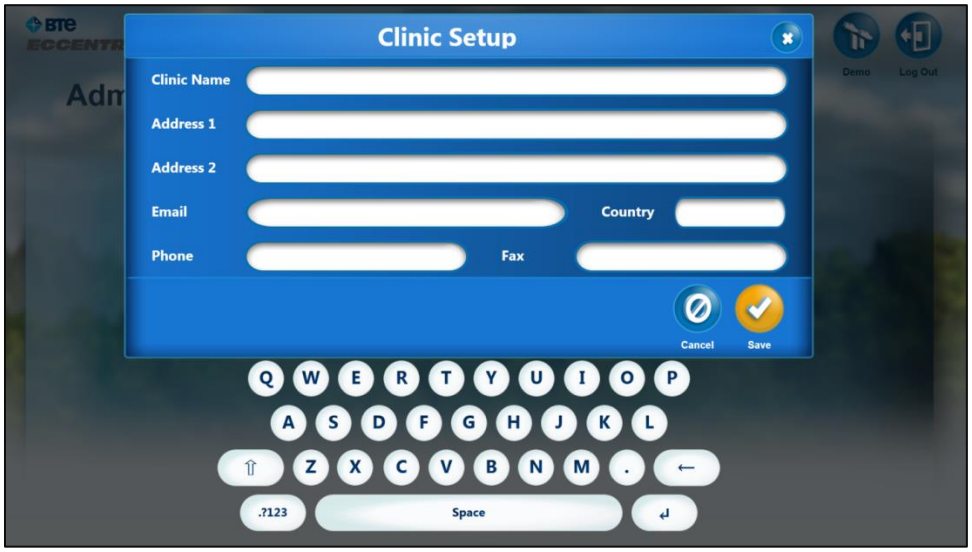


Figure 3 - Clinic Setup Screen

1. Enter the following Clinic information from the keypad:
    a. Clinic name in ≤ 40 alphanumeric characters
    b. Clinic address in ≤ 100 alphanumeric characters (an extra line with 100 characters is provided if necessary)
    c. Clinic email in ≤ 40 characters and symbols
    d. Clinic phone number in ≤ 20 or less numbers (dashes/slashes/periods are optional)
    e. Clinic fax number in ≤ 20 numbers (dashes/slashes/periods are optional)
2. Click **OK** to Save the record
3. **Cancel** to go to the previous screen and forego clinic setup information
4. To edit any clinic information, select the Clinic Setup icon and modify the desired text fields

Clinician Setup

The Clinician Setup screen is used to Add, Search, and Display Clinician records.

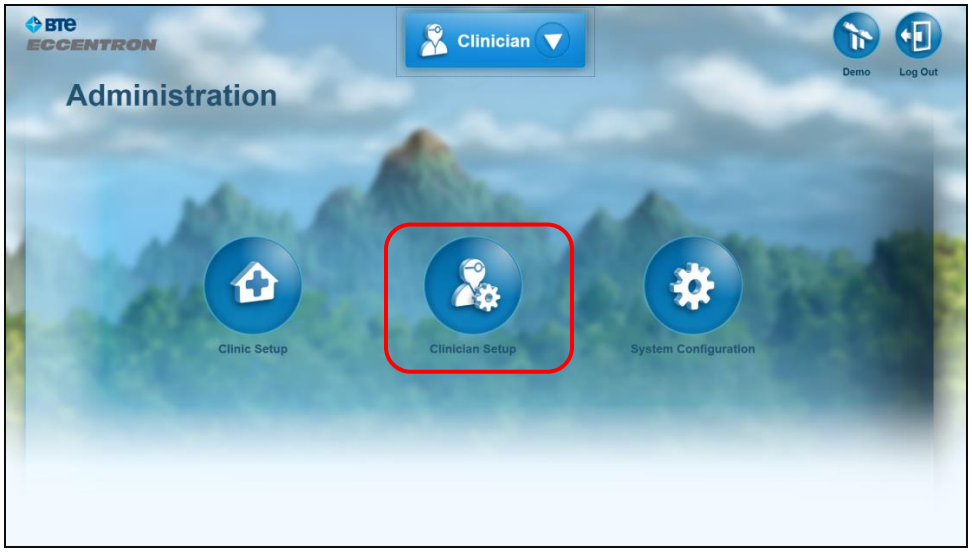


Figure 4 - Administration Screen: Clinician Setup

Add Clinician

Each Clinician should have an individual Login, and each user must have a unique Username. Clinician name and credentials (if entered) will print on Reports. When the **Add Clinician** icon is clicked, the following screen appears.

Figure 5 - Add Clinician Screen

1. Select the Add Clinician icon
2. Enter the new Clinician name in < 25 characters

3. Create a Username of ≤ 25 alphanumeric characters (required)
4. Create a 4-digit PIN using the numeric keypad (required)
5. Enter Clinician credentials of ≤ 50 characters (optional)
6. Save the entry when finished by choosing **OK**

Search/Select Clinician

Use the Search feature to locate an existing Clinician record.

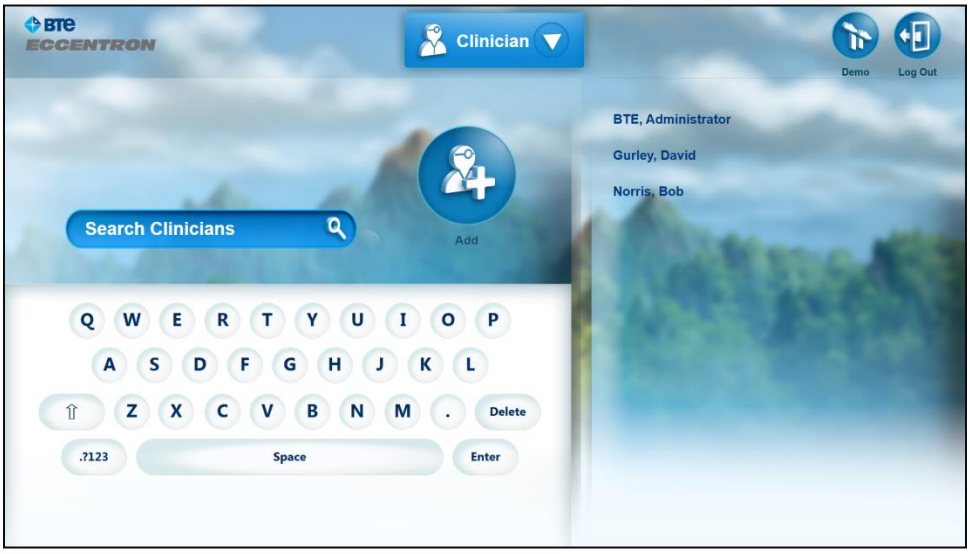


Figure 6 - Clinician Add/Search Screen

1. Type last name into the search field. As you add letters, the list of names will narrow down your selection based on the starting letter of the last name.
2. Select the desired record name from the list to open the selected record.

Edit Clinician

Clinician information can be edited as needed, or permanently deleted from the Clinician Record screen. Select a Clinician name from the list to get to the Clinician Profile screen. From there, select the Clinician icon to edit the clinician information.

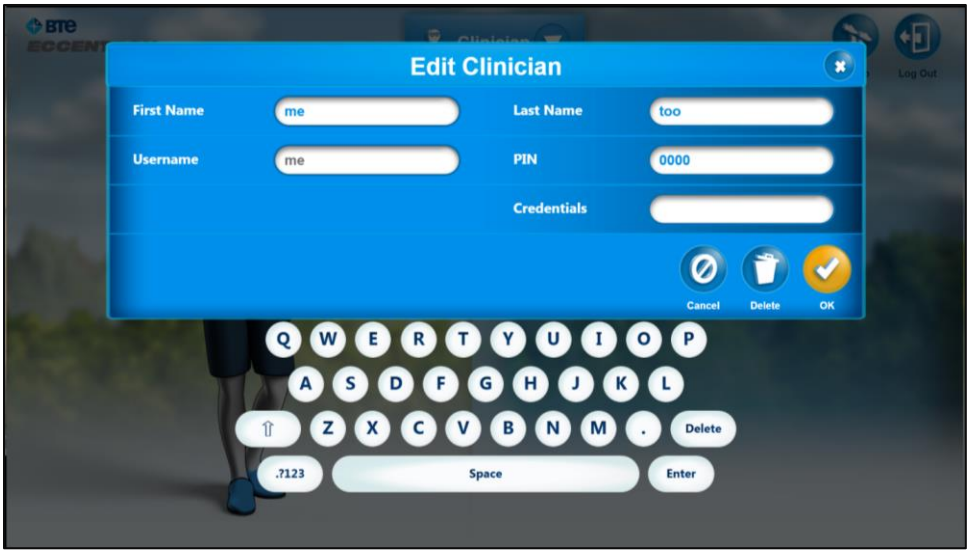


Figure 7 - Edit Clinician Screen

1. To edit Client info, touch inside the field you wish to edit. All information can be edited except Username.
2. Save the entry to keep your changes, or select Cancel to keep the current information.

Delete Clinician

Press the **Delete** (trash can) icon to permanently delete a clinician record.

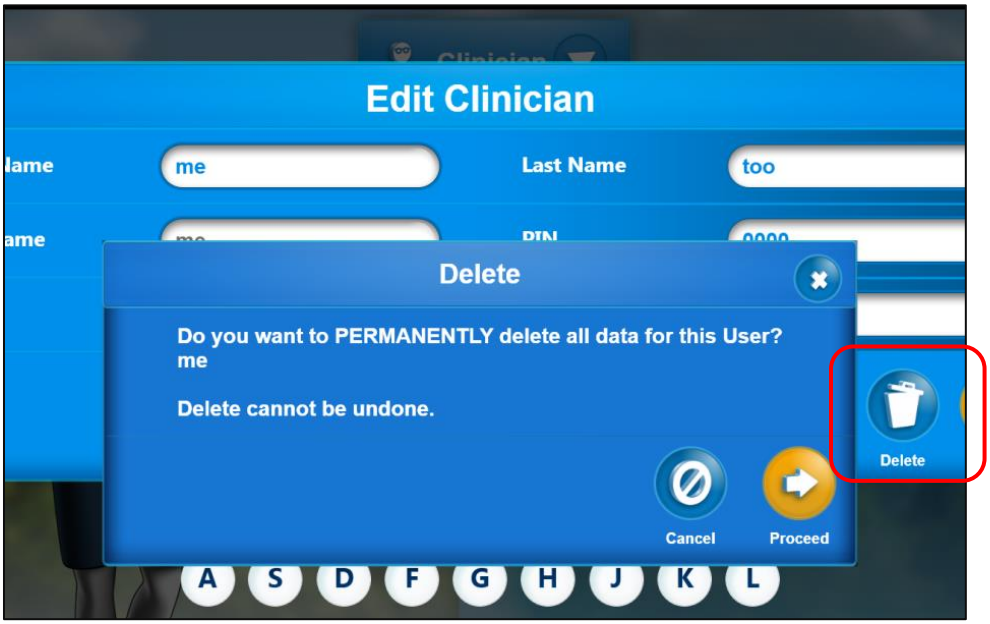


Figure 8 - Delete Clinician Screen

1. Select the Delete icon, which prompts a warning asking for confirmation.
2. If you chose Delete in error, select Cancel.
3. If you wish to continue with the deletion, select OK.

NOTE: Deleted records cannot be recovered.

System Configuration

The Eccentron software is pre-programmed with default settings allowing a clinician to safely use the system while becoming familiar with all its functionality. Once the clinician is knowledgeable with all the parameters, the default settings can be modified. Be aware that these are global settings that apply to every client. They are not configurable for individual clients or sessions.

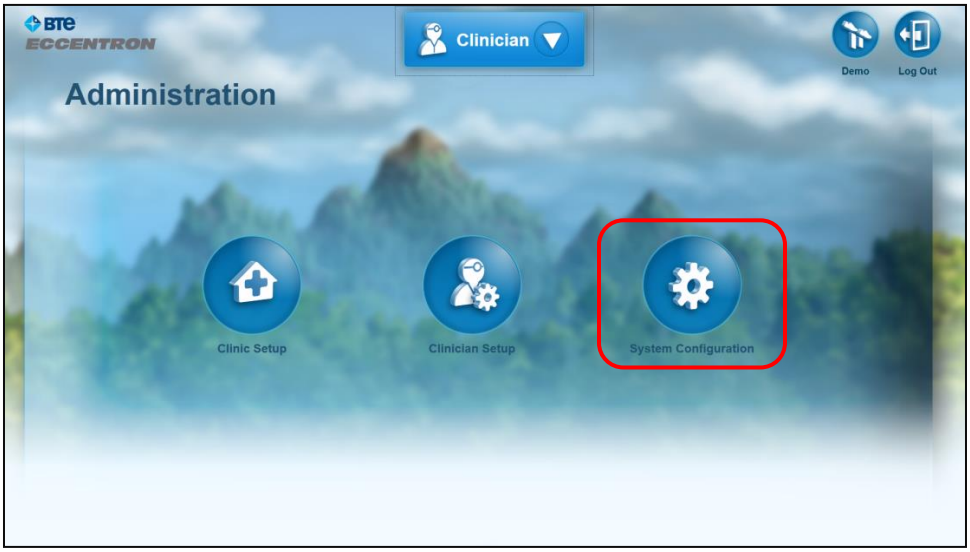


Figure 9 - Administration Screen: System Configuration

At the Administration screen, select System Configuration to access the default settings for the system. These include language, units of measure, exercise target range, dosing test calculation, minimum requirement for exercise progression, power calculation, logging level, and RPE collection option. In addition, hardware calibration is accessed here. To modify a setting, click in the text field and enter the new value.

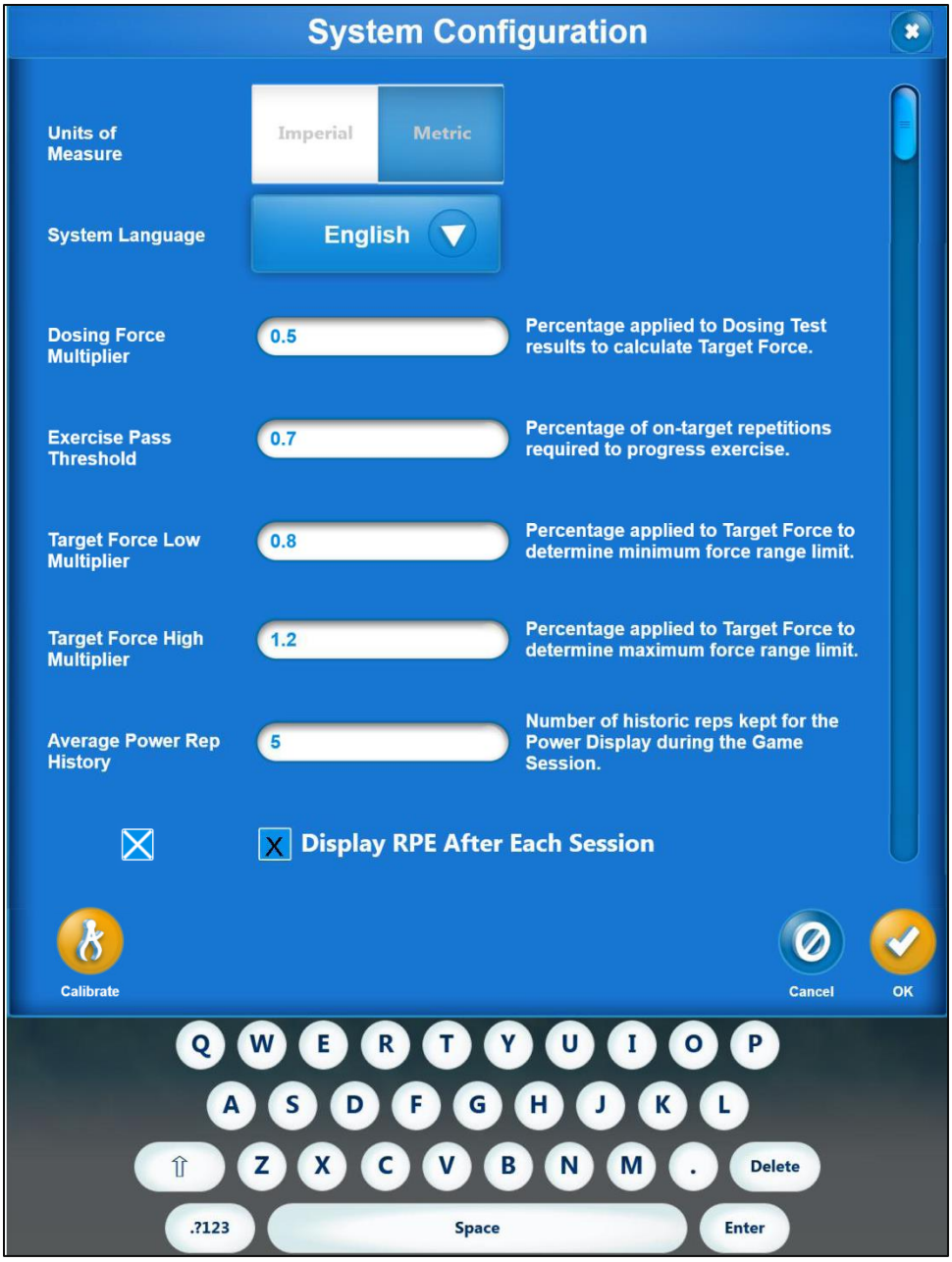


Figure 10 - Compilation of System Configuration Options

NOTE: It is recommended that no changes be made to the formula default settings until the Clinician has a thorough understanding of the Eccentron usage guidelines and pre-set treatment plan.

Before making changes to these parameters, it is critical that you have an understanding of functions and calculations. Therefore, a brief explanation of functionality and definitions is provided below.

Units of Measure

The system permits the user to set force readings in either Imperial (pounds) or Metric units (Newtons) for force measurement. Press the toggle button to change from one to the other. The default measurement displayed is Metric.

System Language

The default language displayed on the Eccentron is English. The system language can be changed by selecting from the drop down menu in System Configuration, or by selecting the appropriate language icon on the Log In screen. A software restart will occur after language has been changed.

Language options are:

- English
- Chinese
- German
- Japanese
- Russian
- Spanish

Dosing Force Multiplier

A Dosing Test consists of six repetitions (12 strides total) of safe maximum effort. Based on the resulting force values, the software will determine a target force for the exercise session using the Dosing Force Multiplier (see Dosing Text and Target Calculation Example). The Dosing Force Multiplier default value is 0.5 or 50%. For further information see **Dosing and Exercise.**

To change the Dosing Force Multiplier:

1. Touch inside the entry field
2. Using the numeric keypad, enter the desired value. A lower value will result in a lower Target Force, and vice versa.
3. Save the value change by selecting **OK**, or **Cancel** to keep the default

Target Force

The Target Force is the force goal for the exercise session based on the Dosing Test results. The limb with the lower average force readings is evaluated, and the highest force reading on that side is discarded. The next highest value is multiplied by the Dosing Force Multiplier to create a custom Target Force for each client.

Target Range

The Target Range is the Target Force plus some “cushion” around the target force value. Achieving the target force precisely on a repetitive basis is very difficult, especially with a novel type of exercise. In order to increase positive reinforcement and successful outcomes, the software counts any force that falls into

the Target Range as 100% on Target. The specified percent of “cushion” is determined by the Target Force Multiplier (defined below).

Target Force Multiplier

The Target Range can be modified by adjusting the Target Force Multiplier. The default setting is 20% above and below the Target Force. The ranges above and below the target force can be set independently. A greater range will be easier for clients to achieve, and a smaller range will provide more challenge and require more neuromuscular control.

To modify the Target Force Multiplier:

1. Touch inside the entry field
2. Using the numeric keypad, enter the desired value.
3. Save the value change by selecting **OK**, or **Cancel** to keep the default setting.

Exercise Pass Threshold

The Eccentron pre-set exercise program provides sequential bouts that include a Dosing Test followed by 3 Sessions of increasing duration. (See **Dosing and Exercise/Training Paradigm.**) A new dosing test is recommended prior to every 4th session in order to keep the Client working in an appropriate Target Range. Duration is not increased for the Sessions immediately following Dosing Tests since the Target Force is likely to increase. This way, only one variable is changed or increased at a time.

To further guide Clients along an individualized exercise program, the Eccentron requires the Client to “pass” each Exercise Session before proceeding to the next Session in the sequence. To advance to the next Session, the Client must finish the duration of the exercise in addition to meeting the Target Range at least 70% of the time (at least 70% on Target). Warm-up and cool-down periods are excluded from this calculation.

If the Session is stopped before the clock runs out, and/or the Target Range is not met a minimum of 70% of the time, the Session data will be saved. The Client’s subsequent Session shall have the same parameters (Target Force and Duration) as the previous “incomplete” Session.

To modify the 70% default threshold:

1. Tap inside the entry field
2. Using the numeric keypad, enter the desired value. A lower value will result in an easier threshold, and vice versa.
3. Save the value change by selecting **OK**, or **Cancel** to keep the default value.

Logging Level

The Eccentron software logs a baseline level of information during its use to aid diagnostic purposes in case any troubleshooting by technical support is necessary. Increasing this setting may result in a degradation of software performance, as additional information is stored in the log file. Decreasing this setting will decrease the usefulness of the diagnostic logging utility. Unless specified by BTE, it is strongly encouraged to leave the logging level at 4.

Rate of Perceived Exertion Display

At the conclusion of an exercise session, the Rate of Perceived Exertion (RPE) scale appears, providing the clinician an opportunity to track client effort during treatment. RPE tracking is an optional feature on an individual client basis if utilized.

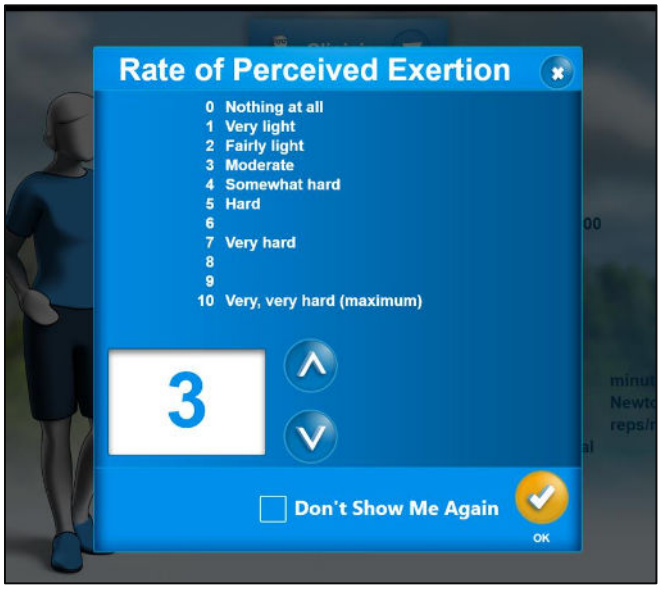


Figure 11 - RPE Selection Screen

The ability to track RPE also can be globally turned on or off for individual clinicians if desired. To change the default setting (On), follow the steps below in the System Configuration screen.

1. Click the box to remove the ‘X’. The RPE box will no longer appear at the end of an exercise session.
2. Click the box again to restore the default setting of “On”.

Resources

The Resources section contains all usage information related to operation and performance of the Eccentron.

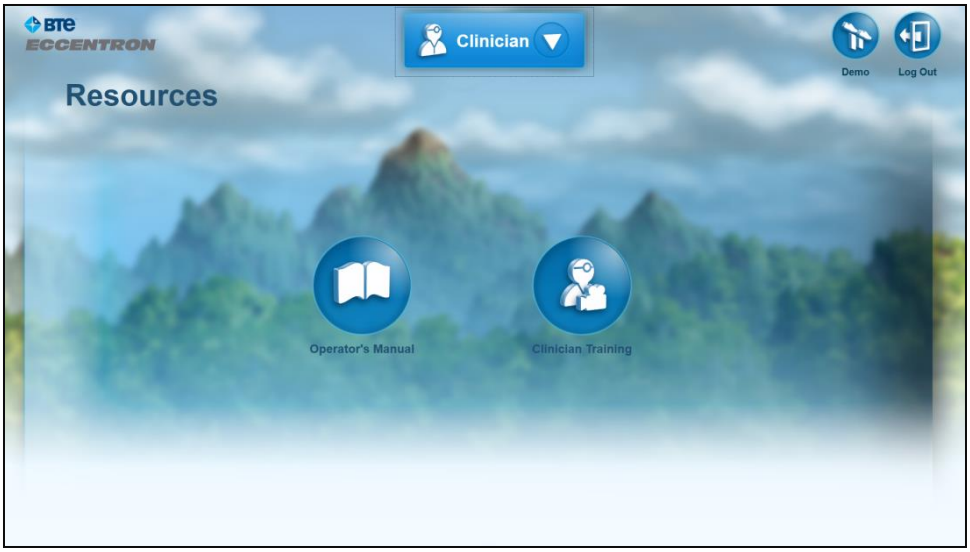


Figure 12 - Resources Screen

Operator's Manual

Instructions for use included in this Operator's Manual must be followed. For your convenience, clicking on the Operator's Manual icon will open on screen a digital version of the printed Operator's Manual provided with your Eccentron device.

Clinician Usage Video

The training materials provided include a brief Usage Video on the use and performance of the Eccentron. This video demonstrates proper Client positioning and use of the hardware features. It is strongly recommended that all Clinicians view the video prior to putting Clients on the Eccentron.

Immediately after a new Clinician is entered into the system, the Clinician is instructed to view the Usage Video. If the Clinician opts to view the video at a later time by selecting Cancel, the message will continue to appear each time that login is entered. Once the training video has been viewed, the request message will no longer appear.

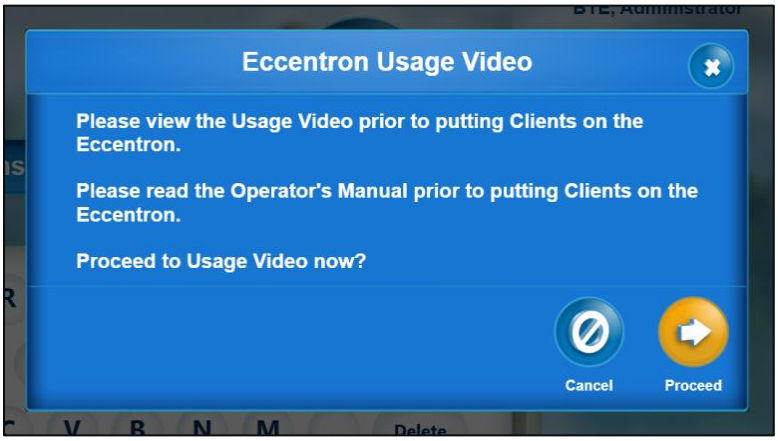


Figure 13 - Video Alert Message

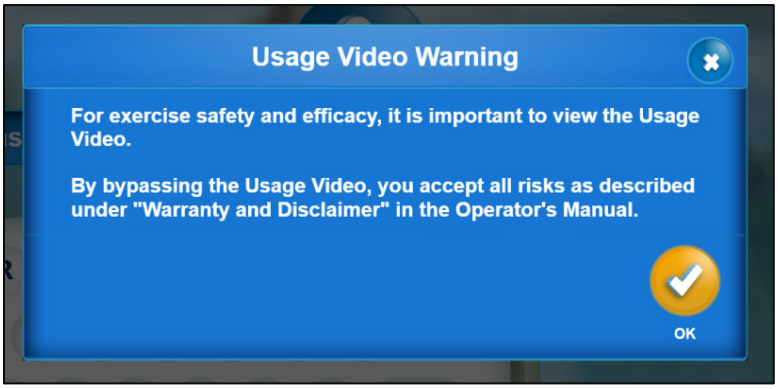


Figure 14 - Video Warning Message

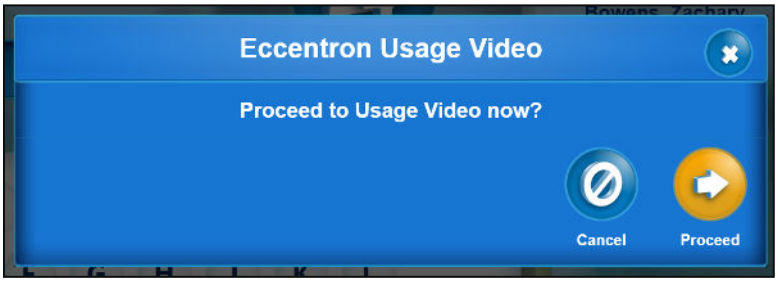


Figure 15 - Video Reminder Message

The Usage Video can be accessed 2 ways: Immediately after a new Clinician is added to the database, and via the Resources tab under Administration. Clinicians will be able to conveniently review any of the training materials as needed.

The following video player screen is launched when the training icon is selected.

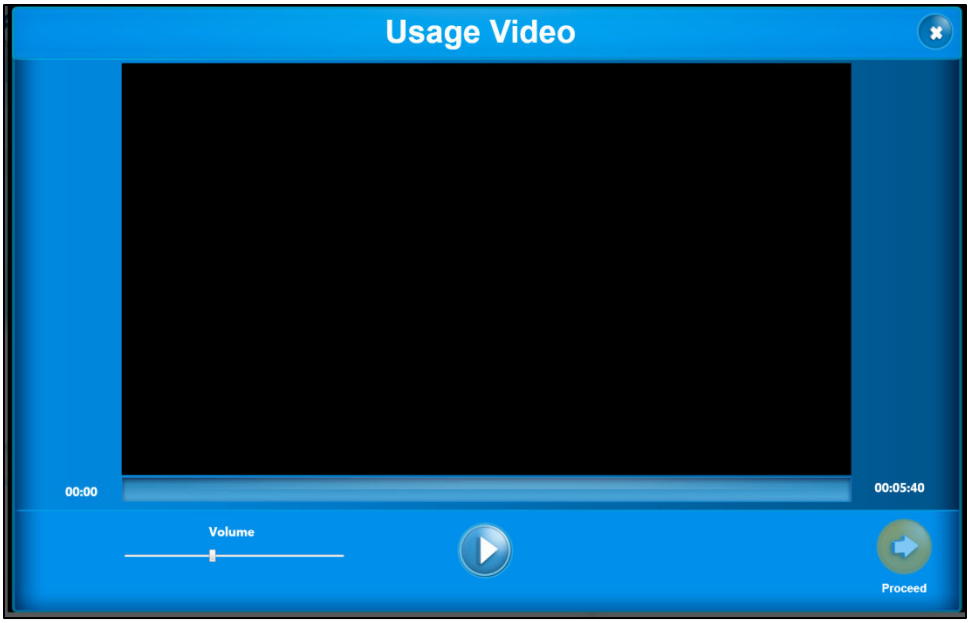


Figure 16 - Video Player Screen

The training video covers:

- Client access on and off the device
- Proper client positioning for exercise
- Pendant use
- Eccentric resistance motion
- Dosing Tests

Utilities (Database & Software)

Occasionally system maintenance may be necessary for database operations and software updates, which are accessed via the Utilities section.

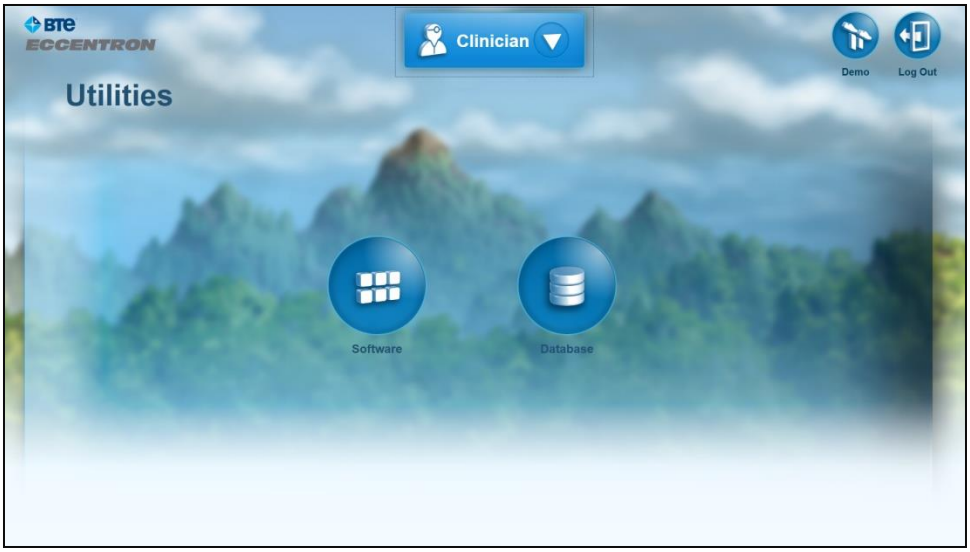


Figure 17 - Utilities Screen

Software Management

The Software screen provides two options: Update and Export Log Files.

Software Update

Software updates may periodically be provided via an external device. Press the Update button and follow the simple on-screen instructions. Once the update file is located, simply press “OK” to start the install. Any additional instructions for software updates will be provided as needed.

Export Log Files

Export Log Files is used for diagnostic purposes. All log files on the system will be compressed into a .zip archive and then exported to the first removable disk found, such as a flash drive. This will typically be used by customer service to aid in identifying software issues.

Database Management

All user records and performance data is automatically saved into the database. Database management should be performed as recommended in order to protect your data files.

Database Export

A backup or copy of the database should be made to prevent loss of data in case of a control module malfunction. To do so, use this Export feature. It is suggested that you export the database as a backup at least once a week to minimize any potential data loss.

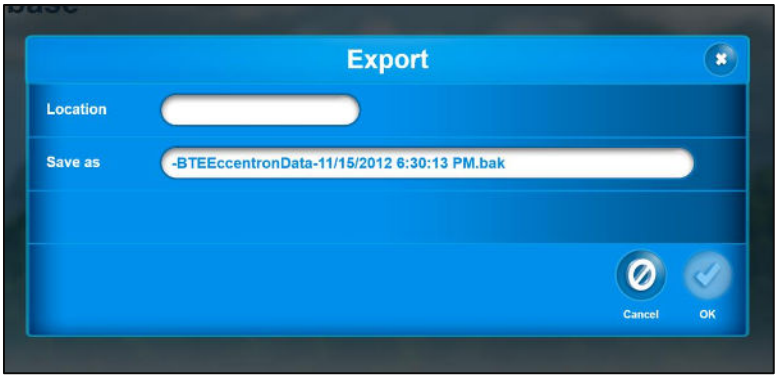


Figure 18 - Export Dialog

Purchase a USB drive and export the database from the control module on to the USB drive (the E: Drive) by clicking on the Export icon.

The unique export file name default shall be “Eccentron-C drive identifier-date-time”. The following screen appears when the database icon is clicked. Click OK to export the database or cancel to revert back to the previous screen. When you export, an SQL compatible file is created in the “*.zip” format.

NOTE: Be sure to keep the USB drive in its slot for at least 15 seconds after the export has begun.

Database Restore

The clinician shall be able to restore a database that has been saved as a backup.

- All information in the current database shall be wiped out.
- All information in the most recent backed up database shall be placed into the current database.
- Database Restore will automatically generate a system restart.

Back Ups

The data created by using the Eccentron (i.e. dosing, treatment, or exercise) is automatically backed up daily. When a backup file is created, the previous day’s file is overwritten. A new file is created with the most recent data.

Client Management

This Chapter addresses client record management, which includes adding, viewing, modifying, and deleting Client records. Additional options in this section allow for individual machine and session settings for each Client, including pre-set and manual exercise options.

Client Add/Search

To access the Client Add/Search screen, select Clients from the Clinician Menu. The Add and Search options appear on the left side of the screen and the Client List is to the right. Remember to click on the arrow to open this menu.

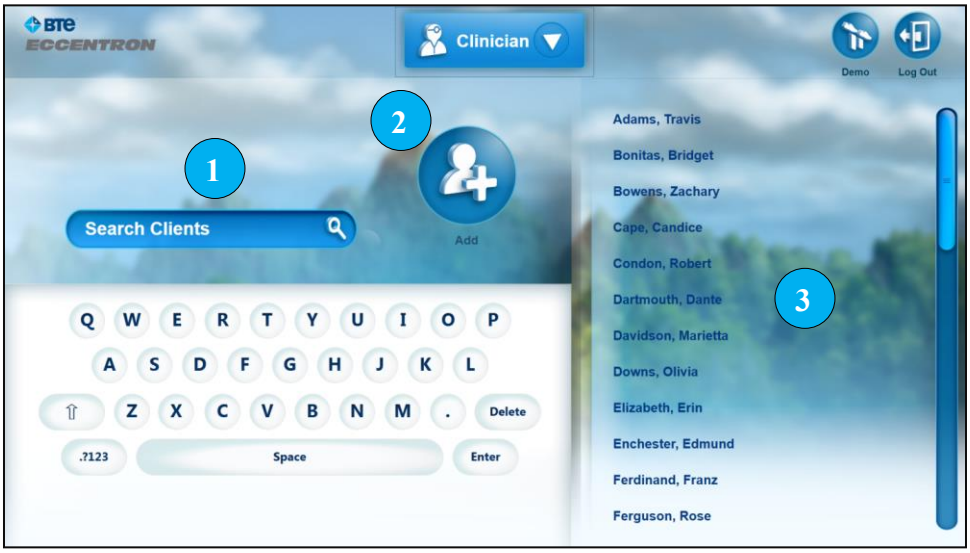


Figure 1 - Client Add/Search Screen

1. Search Client records
2. Add Client icon
3. Select Client record

Add Client

A Client record must be created in order to perform exercise, and a clinician login is required to access any client records. To add a new Client to the system, select the Add Client icon (2).

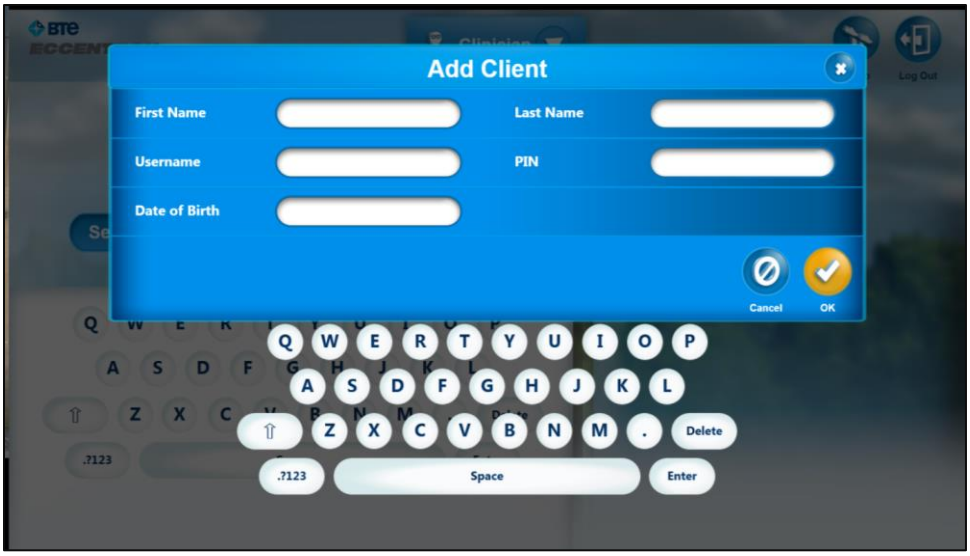


Figure 2 - Add Client Screen

1. Enter the new Client name of up to 40 alphanumeric characters into the First and Last Name text fields.
2. Create a Username of up to 24 alpha characters.
3. Create a 4-digit PIN using the numeric keypad.
4. (Optional) Enter a date of birth in a valid date format. Birthdates cannot occur before 01/01/1900.
5. Save the entry when finished by selecting **OK**. If **Cancel** is selected, any information entered will be lost.

Search Client

Similar to the search and select feature of the Clinician records list, Client records can be located alphabetically from the Add/Search Client screen.

1. To find a current Client record, type the client's last name into the search field. As you add letters, the list will narrow down your selection to the right of the screen.
2. Click on the desired name in the list (3) to open that Client Record.

Client Record

The Client Detail screen contains all data related to the Client's identification and performance.

Figure 3 - The Client Detail Screen

From the Client Record screen, a Clinician can:

1. Edit or Delete a Client
2. Modify seat settings
3. Set or modify exercise parameters
4. View Client Reports
5. Administer a Dosing Test
6. Proceed to the Exercise Session

Edit Client

Client information can be modified as needed or permanently deleted from the system. Also, if a client forgets their PIN, a new PIN may be entered here. To access the Edit screen, click the Client icon on the Client Record screen.

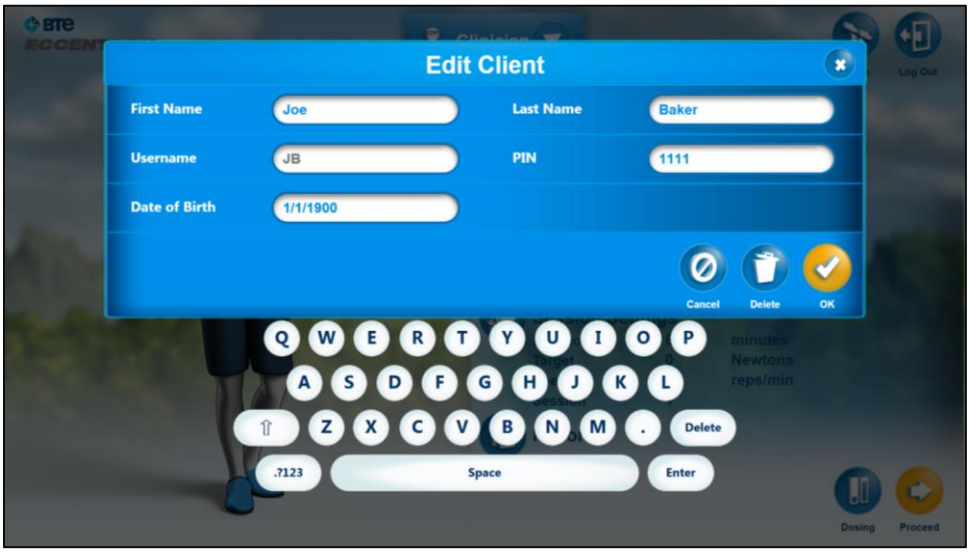


Figure 4 - Edit Client Screen

1. To modify the Client's name, PIN, or date of birth, touch inside the field to edit.
2. Select OK to Save your changes, or select Cancel to keep the original information.

Delete Client

The Delete option is available from the Edit screen. Press the **Delete** (trash can) icon to **permanently** delete a client record.

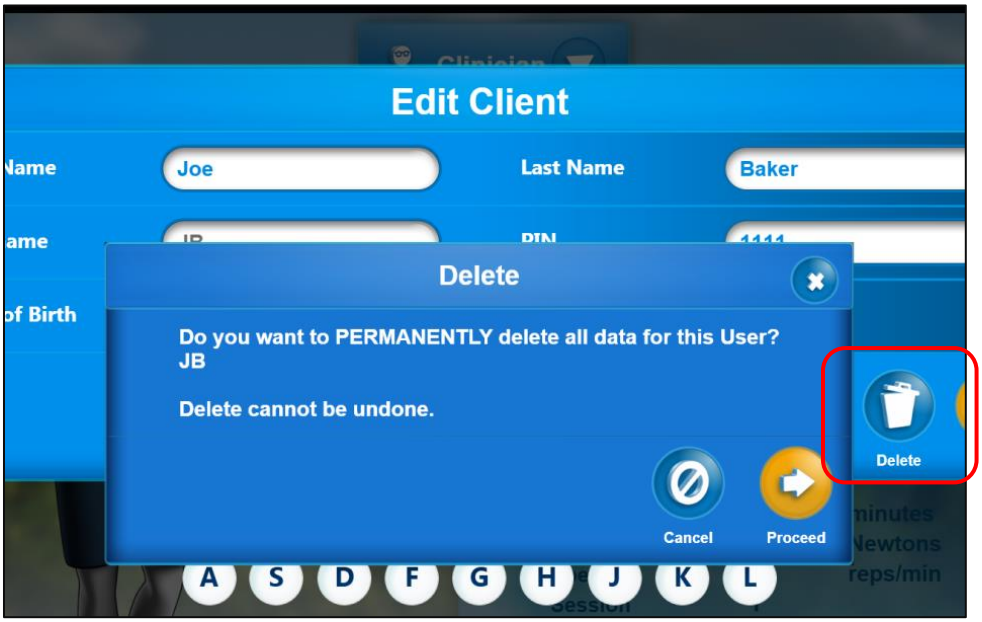


Figure 5 - Delete Client

1. Select the **Delete** icon, which prompts a warning asking for confirmation.
2. If you chose **Delete** in error, select **Cancel**.
3. If you wish to continue with the deletion, select **OK**.

NOTE: Deleted records cannot be recovered.

Machine Settings

Machine Settings are physical adjustments to be made on the Eccentron so that the Client is comfortably and safely positioned for exercise. The seat position setting is determined during the Client's first session. There may be instances when range of motion increases as the Client's rehab progresses, so seat settings may be adjusted if necessary.

Figure 6 - Seat Position Screen

To use this screen, click the up/down arrows to increase/decrease the number corresponding to the appropriate seat position. For detailed instructions on determining appropriate seat position, see **General Hardware Operation.**

CAUTION: Never allow a Client to exercise with a fully extended knee.

Session Settings

Session Settings refer to the parameters set for the current Exercise Session. Target Force, Session Duration, and Pedal Speed are pre-set in the software, or they can be manually set by the Clinician. Overriding the pre-set Session Settings is considered to be a Manual Session. Once the Client has performed a Manual session, the Session Settings will stay as entered until the Clinician changes them again. If a Client goes from the pre-set treatment plan to a Manual session, they will remain in “Manual mode” for the duration of treatment. The range for settings is as follows:

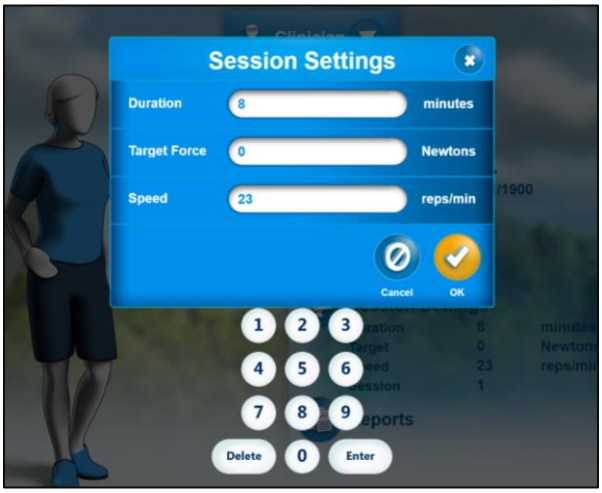


Figure 7 - Session Settings Screen

Setting	Minimum	Maximum
Duration	3 minutes	30 minutes
Target Force	1 lb./5 N	750 lbs./3337 N
Speed	12 reps/min	48 reps/min

To enter values into the text fields shown above:

1. Tap on the text field into which you want to enter a different value
2. Use delete button to clear current value
3. Enter new value using the number pad
4. Repeat steps 1 through 3 to make changes to other settings
5. Tap **OK** button to save changes. Selecting **Cancel** will result in previous values being restored.

Dosing

Refer to **Dosing and Exercise** Section

Reports

Refer to **Reports** Section

Reports

This chapter highlights the reporting functions of the Eccentron software. For each Client, reports can be generated, saved, exported, and printed. There are two types of reports available: session reports and progress reports.

Session Report Screen

After the completion of an exercise session, the performance data collected is displayed as a Session Report. Performance measures for the left leg are shown in pink, while those for the right are in purple. Force and Work graph views can be toggled using the tabs located at the lower left corner of the graph.

Figure 1 - Session Report Sample

The Session Report displays the following data for each exercise session:

- Average force, each leg (in pounds or Newtons)
- Peak force, each leg (in pounds or Newtons)
- Rate of Perceived Exertion (optional)
- Percent on Target accuracy, each leg
- Percent on Target average, both legs
- Total repetitions
- Average speed (reps per minute)
- Total work, both legs (in kilojoules)
- Average power, each leg (in Watts)

The Session Report can be exported here, or you can select the Progress icon to view the Progress Report (see **Progress Report Screen**).

If a client is logged in, selecting “Done” will log them out and return to the Login screen. The same happens if Exit is pressed.

If a clinician is logged in, selecting “Done” will revert to the Client Add/Search screen.

Progress Report Screen

To switch from the Session Report to the Progress Report, select the Progress button. The Progress Report provides customizable comparisons of Client performance throughout their treatment. Select the dates of sessions that you would like to view on the left. To select, tap next to the desired dates. To deselect, tap the box again. As you choose dates a check box will appear, and they will be added to the line graph displayed.

To customize the data shown on the graph open the drop down box located at the upper right corner of the graph. Data options are Force, Work, Power, and Percent on Target. When you have only one Session selected, the Session Report icon becomes active. Pressing it will load the Session Report for that session.

Figure 2 - Progress Report Screen

Export Reports

The Export function on the Report screens allows for saving and printing reports.

The exported Session Report contains charts for force and work performed over the duration of the exercise. The force chart does not include data from the warm-up and cool down periods, however, the work chart does. In addition, the Session Report contains a table that provides comparison metrics of each leg, where applicable.

The exported Progress Report contains a chart for all selected metrics, and shows the change in each metric between sessions. If the Dosing metric is selected, the Dosing Chart shows the change over all dosing sessions that the user has performed. In addition, the Progress Report contains a table at the bottom that provides comparison metrics between the first selected session and the last selected session.

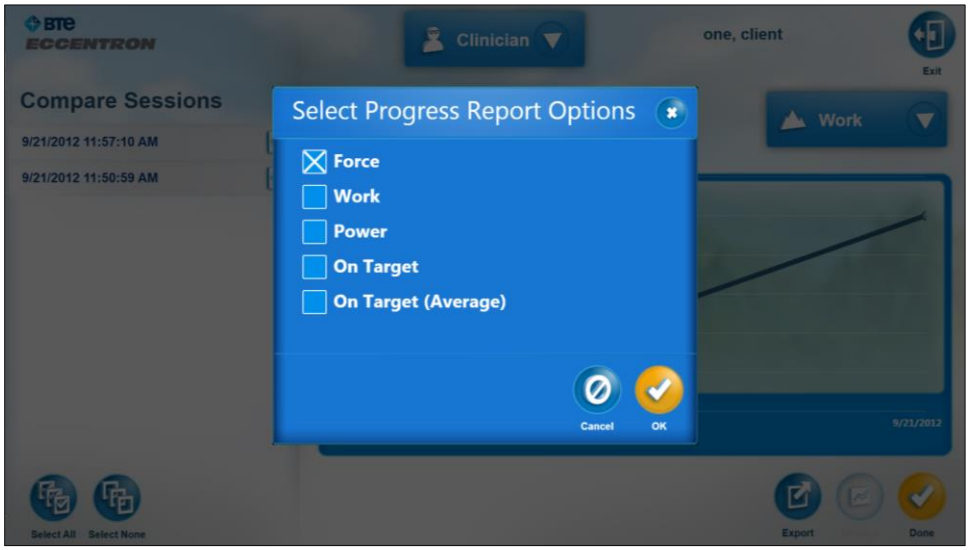


Figure 3 - Export Report Options

When you select Export, the software provides a filename, which CANNOT be modified. Use the following steps to export either a Session or Progress Report.

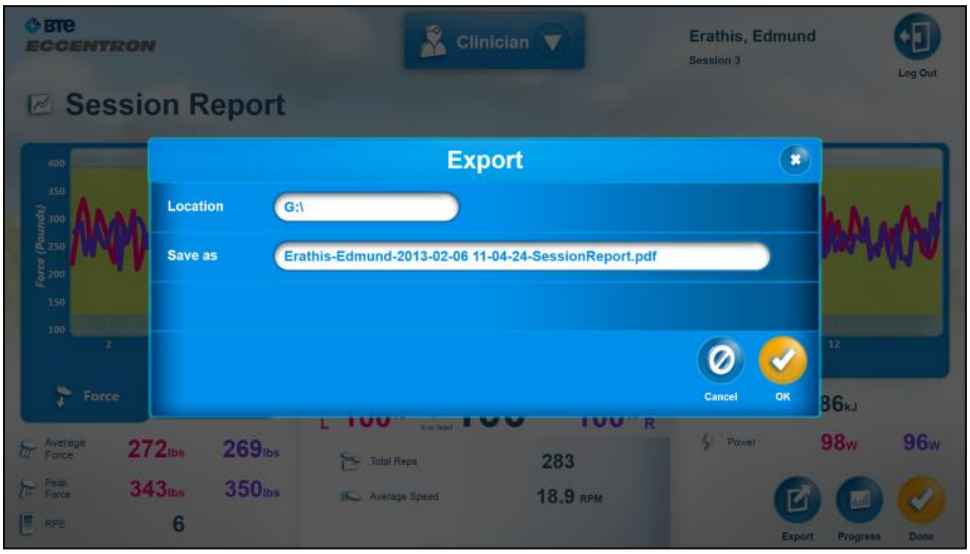


Figure 4 - Export File Naming

1. Insert a flash drive into the USB port.
2. Select the Export icon.
3. If the report is a Progress Report, an options dialog will be displayed. Select all metrics that you want to have displayed on the Progress Report.
4. The folder location and file name will display. These fields CANNOT be edited.
5. Select OK to launch the Report Preview Screen, or Cancel to stop export.
6. Press OK to complete the export, or Cancel to stop the export.
7. Remove the external device and print the files from your system.

Note: Keep the USB drive in its port for at least 30 seconds after the export has begun. If the USB drive is removed too soon, then the file will be on the drive in the XPS format instead of in the PDF format.

Session Report Sample

Edmund Erathis

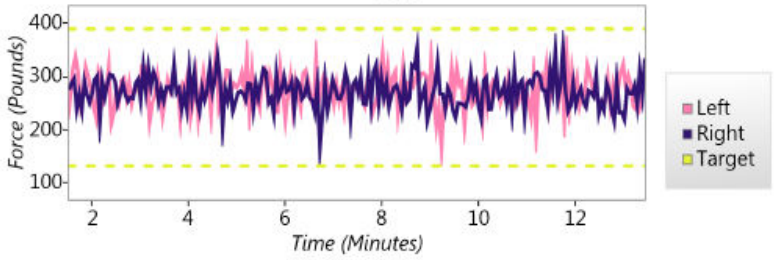
2/6/2013
Session: 3

BTE Eccentron

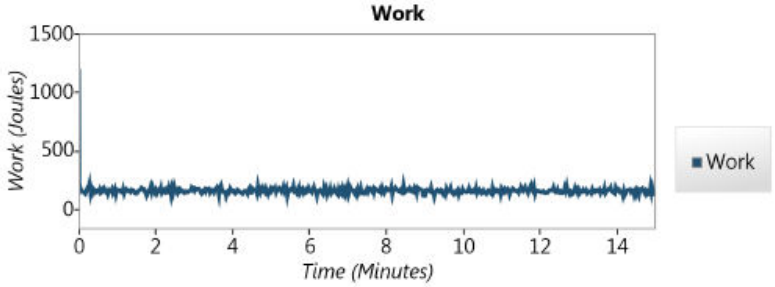
Session Report

The Eccentron is a system used for lower extremity eccentric resistance strength training. This report provides the performance measures for the designated treatment session.

Force



Work



	L	R	Difference	Combined
Avg Force	**272.4** Pounds	**269.3** Pounds	**-1.14** %	**541.7** Pounds
Peak Force	**343.1** Pounds	**350.1** Pounds	**-2.00** %	**693.2** Pounds
Work	**86** kJ		N/A	
Power	**98.23** W	**96.17** W	**-2.10** %	**194.4** W
% on Target	**100** %	**100** %		**100** %

Total Reps	**283**	Target Force	**259** Pounds
Duration	**15:00** mm:ss	Target Range Min	**129** Pounds
Average Speed	**18.87** rpm	Target Range Max	**388** Pounds
RPE	**6**		

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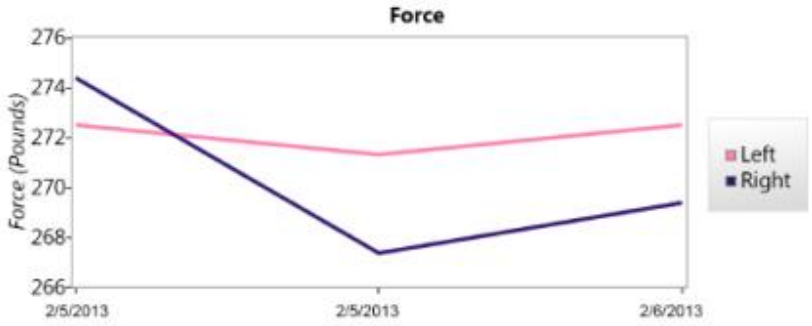
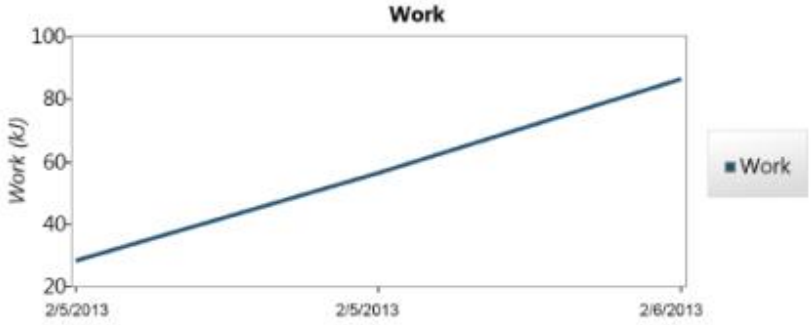
Progress Report Sample

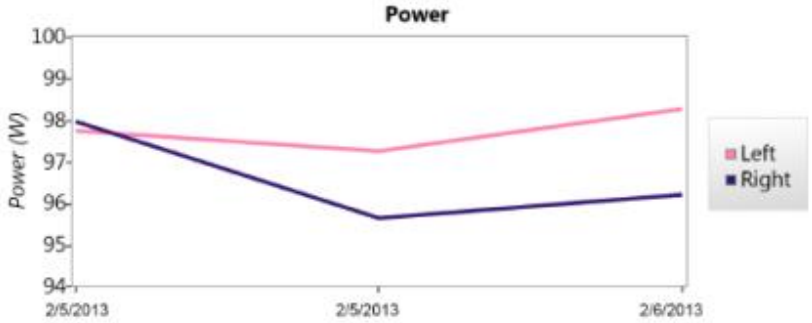
Edmund Erathis 2/6/2013 **BTE Eccentron**

Progress Report

The Eccentron is a system used for lower extremity eccentric resistance strength training. This comparison report provides performance measures across multiple dates in order to assess effectiveness of the Eccentron strength training program (or a progressive eccentric training program).







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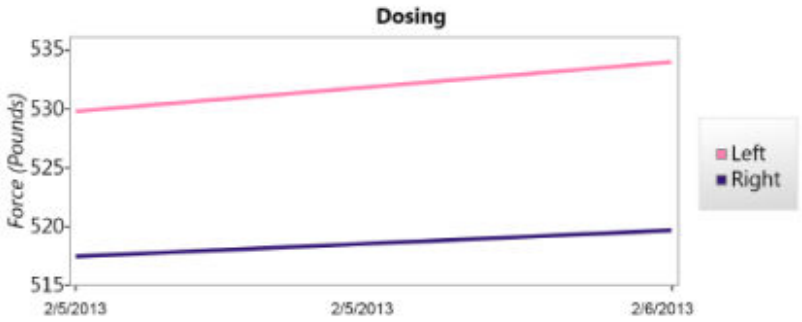

First / Last Date Comparisons	L	Change	R	Change
Avg Force	**272.4 / 272.4** Pounds	**0** %	**274.3 / 269.3** Pounds	**-1.82** %
Peak Force	**343.1 / 343.1** Pounds	**0** %	**335.7 / 350.1** Pounds	**4.29** %
Work	**28.00 / 86.00** kJ		**207** %	
Power	**97.70 / 98.23** W	**0.54** %	**97.93 / 96.17** W	**-1.80** %
% on Target	**100.0 / 100.0**	**0** %	**100.0 / 100.0**	**0** %
Dosing	**529.6 / 533.8** Pounds	**0.79** %	**517.3 / 519.5** Pounds	**0.43** %

Average Speed	**18.80 / 18.87** rpm	**0.35** %
Session Duration	**300.0 / 900.0** Seconds	**200** %

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Appendix

EMC Guide

Guidance and manufacturer's declaration – electromagnetic emissions		
Eccentron is intended for use in the electromagnetic environment specified below. The customer or the user of Eccentron should assure that it is used in such an environment		
Emissions test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 1	Eccentron uses RF energy only for its internal function. The RF emissions from the Eccentron are very low and not likely to cause interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	Eccentron is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/flicker emissions 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
Eccentron is intended for use in the electromagnetic environment specified below. The customer or the user of Eccentron should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV to ±1 kV differential mode ±0.5 kV to ±2 kV common mode	±0.5 kV to ±1 kV differential mode ±0.5 kV to ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Power Frequency, Magnetic Fields IEC 61000-4-8	3A/m	3A/m	Magnetic field levels should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment.

<table>
<tr><th colspan="4">Guidance and manufacturer’s declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">Eccentron is intended for use in the electromagnetic environment specified below. The customer or the user of Eccentron should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity test</td><td>IEC 60601 test level</td><td>Compliance Level</td><td>Electromagnetic environment guidance</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6

Radiated RF
IEC 61000-4-3</td><td>3 Vrms
150 kHz to 80 MHz

3 V/m
80 MHz to 2.5 GHz</td><td>3 Vrms

3 V/m</td><td>Portable and mobile RF communications equipment should be used no closer to any part of Eccentron, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance
$d = 1.2\sqrt{P}$
$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz
$d = 2.3\sqrt{P}$ 800 MHz to 2.5GHz
where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [1]
should be less than the compliance level in each frequency range.[2]

Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td colspan="4">NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">[1] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Eccentron is used exceeds the applicable RF compliance level above, Eccentron should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating Eccentron.

[2] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

Recommended distance between portable/mobile RF communication equipment and Eccentron

Eccentron does not need to be used in a radiated RF controlled environment. Customers or users of Eccentron shall maintain the minimum safe distance between portable/mobile RF communication equipment (transmitter) and Eccentron to prevent electromagnetic interference. The minimum distance shall be accordance with the maximum output of the communication equipment as recommended below.

Rated Maximum output power of transmitter W	Separation distance according to the frequency of the transmitter		
	150Khz to 80Mhz $d = 1.2\ e^{P}$	80Mhz to 800Mhz $d = 1.2\ e^{P}$	800Mhz to 2.5 GHz $d = 1.2\ e^{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.