MULTI-JOINT SYSTEM

This instructions for use document covers safe operation of the Multi-Joint System 4 –850-000, 840-000, and 852-000.

Additional information and resources are available upon request or directly from the Biodex website, http://www.biodex.com.

If the desired information is not found, please feel to contact a local distributor or Biodex directly at supportservices@biodex.com

Thank you,
Biodex Medical Systems
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Definition of Symbols

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

<table>
<thead>
<tr>
<th>Symbol</th>
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<td>📚⚠️</td>
<td>Read instructions before using this product.</td>
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<td>⚠️⚠️</td>
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<td>⚪️ USB</td>
<td>USB Connector/Cable</td>
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Product Certifications and Classifications

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

- ETL Listed Electrical Equipment, Laboratory Use; Part 1, General Requirements for Safety conforms to UL 60601-1, CAN/CSA C22.2 No: 601-1-M90, IEC 60601-1, IEC 60601-1-4 and IEC 60601-1-2 and CE Marked.
- FDA Class II Equipment
- EC Certificate: EC #4132458

- Type B Applied Part

[CE Mark]

- Electromagnetic Compatibility: This equipment complies with the Medical Equipment ICC 60601-2 EMC Standard.

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

**Note:** Complete information on the Electromagnetic Compatibility for the Multi-Joint System can be located in the Compliance Supplement located on the Biodex website (www.biodex.com) or can be obtained by contacting Biodex Customer Service (see Contact information).

Authorized European Community Representative:

[EC REP]

Emergo Europe
Prinsessegracht 20
2514 AP, The Hague
The Netherlands
Warnings and Cautions

NOTE: The warnings, cautions, and instructions provided in this manual must be read, followed, and always kept available for consultation.

CAUTION: Do not modify this equipment without authorization from the manufacturer. Unauthorized modifications to this system are not permitted and void the manufacturer’s warranty. Unauthorized modification might result in a hazard to the user and/or patient.

CAUTION: Federal Law restricts this device to sale by or on the order of a medical practitioner. When prescribed for therapeutic purpose, a physician must define the use clearly (for example, total work, maximum heart rate, etc.) to reduce the risk of patient injury.

CAUTION: Before beginning any of the setups described in this manual:

- Ensure that all system wiring and cables are routed away from any area where they might be stepped on or rolled over by wheeled equipment.
- For testing and exercise patterns in which the positioning chair will be used, the chair should be set to its minimum height before allowing a subject to mount or dismount. It may also help to have a fixed location from which all subjects approach and leave the chair.
- Be aware that use of Biodex technology requires professional expertise for discerning appropriate treatment techniques. Each subject’s unique situation should be taken into account before beginning any type of testing or rehabilitation program. Ensure the operating instructions as well as the considerations, both physical and clinical, discussed throughout the manual before attempting to set up a subject for testing or exercise. Practice setups and positioning with a healthy subject before attempting to set up an injured patient.

Important Safety Information

Read the entire operation manual. Failure to read the manual might result in user error or inaccurate data. Save all documents for reference.

WARNING

- Allow only qualified, trained personnel to install, operate or service this system.
- No part of the system can be serviced while in use.
- If the equipment is modified, it must be thoroughly inspected and tested prior to usage with a patient to ensure safe operation.
- Do not use this system a manner other than specified in this guide. If the equipment is used in a non-specified manner, the protection provided by the equipment might be impaired and results could be compromised.

WARNING: Never leave patient unattended.
This medical electrical equipment requires special precautions for EMC and must be installed and used according to EMC information provided for this document.

**WARNING:** Only use approved power supplies.

**WARNING:** Connecting electrical equipment to a multiple socket outlet (MSO) effectively leads to creating an ME SYSTEM, and can result in a reduced level of safety.

**CAUTION:** Operation for: 115–230 VAC, 50/60 Hz.

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

**CAUTION:** The plug is considered the method of disconnecting the system from main power. Do not place the system in a position where the plug cannot be reached quickly.

**CAUTION:** The system is intended to remain in one location during operation. To relocate the system, the system is disconnected from power source. Use the wheels to move the system.

Contact information

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email: supportservices@biodex.com
www.biodex.com
1. Introduction

Indications for Use
The Multi-Joint System is used to identify, treat, and document the physical impairments that cause functional limitations typical of sports injuries, orthopedics, pediatric medicine, and neurorehabilitation.

Contraindications
What are the contraindications to isokinetic testing or exercising?

Absolute Contraindications:
- Acute strain (musculotendinous unit) or sprain (non contractile tissue)
- Soft-tissue healing constraints (i.e., immediately after surgery)
- Severe pain
- Extremely limited range of motion (ROM)
- Severe effusion
- Joint instability

Relative Contraindications:
- Subacute strain or chronic third-degree sprain
- Pain
- Partially limited ROM
- Joint laxity
- Effusion

Multi-Joint System

Figure 1.1. The Multi-Joint System Positioning Configuration.
Controls and Adjustments

Figure 1.2. Dynamometer positioning controls and adjustments.
1. Rotation Knob
2. Tilt Knob
3. Height Lever
4. Foot Pedals (travel) (850-000, 840-000)
5. Shaft Red Dot (on dynamometer shaft)
6. Rotate Counterclockwise Button
7. Rotate Clockwise Button
8. Hold/Resume Button
9. Comfort Stop
10. Locking Knob Storage
11. Position Color Code Label
12. Yoke
13. Tilt Scale
14. Tilt Key

Dynamometer

Dynamometer Rotation: To rotate the dynamometer in a horizontal plane, loosen the Rotation Knob by turning it counterclockwise. Rotate the dynamometer in either direction. To secure the dynamometer rotation position, tighten the knob in a clockwise direction and ensure that the dynamometer teeth are engaged. Use the Rotation Scale, located on the base of the dynamometer directly beneath the yoke, to note the new position.
**Dynamometer Tilt:** Permits rotation of the dynamometer on a vertical plane allowing the shaft axis to tilt upward or downward from the horizontal position. To tilt the dynamometer, support the dynamometer with one hand. With the other hand, loosen the Tilt Knob in a counterclockwise direction. Gently push or pull the dynamometer to the desired position. Tighten the knob firmly in a clockwise direction, and ensure that the dynamometer teeth are engaged, to secure the dynamometer in place. Use the Tilt Scale (located on the yoke) to note the new dynamometer tilt position. Use the Tilt Key (located directly beneath the Tilt Scale for a quick reference during patient set-up.)

**Dynamometer Height:** The dynamometer can be raised or lowered over a range of 14” (35.56cm). Loosen the Height Handle by turning it counterclockwise and simply apply hand pressure to the top or underside of the dynamometer to respectively raise or lower it. Retighten the handle to lock the dynamometer in position. Use the Height Scale, located on the mounting post, to note the new dynamometer height.

*Note:* The weight of the dynamometer is counterbalanced by a pneumatic assembly in the mounting post. When the locking handle is loosened, the dynamometer may tend to gently rise or fall, depending on the weight of attachments affixed to the shaft. After proper height is established, always secure the locking handle.

**Dynamometer Travel** (850-000, 840-000): The Foot Pedals allow the dynamometer to move along the travel in a horizontal plane left or right of the positioning chair. To move the dynamometer, press down on either foot pedal and slide the dynamometer to the desired location. Release the foot pedal to lock the dynamometer in place. To ensure stability, check that the dynamometer is fully locked in a detent (i.e., try to shake the dynamometer). Use the Position Scale on the travel to note position.

⚠️ **CAUTION: Shaft Red Dot (dynamometer shaft):** The small red dot on the end of the dynamometer shaft provides an index for proper alignment of attachments on the dynamometer setup. When affixing any attachment to the shaft, position the attachment ensuring that its dot for the side to be exercised aligns with the shaft red dot. Failure to properly align the dots may result in a reduced range of motion.

**Rotate Clockwise/Counterclockwise:** The Rotate buttons atop the dynamometer allow the shaft to be moved by pressing (and holding) the Rotate button corresponding to the direction the shaft must turn. This function of the Rotate buttons has no effect on the range of motion limits previously established in Setup Mode.

**Hold/Resume:** Stops shaft rotation. Press this button a second time to resume the test or exercise session. One Hold/Resume button is located atop the dynamometer next to the
Comfort Stop. A second Hold/Resume button is activated by a hand-held remote located to the right of the control panel on the Clinical Data Station (CDS) cart.

**CAUTION: Comfort Stops (Dynamometer, Remote):**
These buttons provide the subject with the ability to instantaneously terminate exercise in any mode. Depressing either the large red button atop the dynamometer or the hand-held remote button causes immediate cessation of dynamometer shaft rotation.

The principal purpose of this control is to guard against moving the subject into a portion of the range of motion that, for any reason, is contraindicated. It should be noted that activating a comfort stop after the onset of discomfort will result in a stoppage of movement while the subject is still in the undesirable portion of the range. Should this occur in Isokinetic or Isotonic mode, with concentric contractions selected, the operator should immediately press the Stop button on the control panel, press Start to free the shaft and allow rotation toward a more comfortable point in the subject’s ROM. (With the shaft free, the operator should manually place the subject in a position such that the limb will not move in the direction of gravity.)

**CAUTION:** Extra consideration is required for resuming dynamometer shaft rotation in the Passive or Reactive Eccentric mode as the patient may be assisted further into a painful portion of the ROM. In this case, remove the patient immediately from the attachment by releasing the hook and loop fastner cuff.

Educating the subject about the use of the Comfort Stops (prior to exercise) also serves to improve confidence and motivation by reducing apprehension regarding the equipment.

*Note: As a safety precaution, the system will not function in any mode if the Remote Comfort Stop is not connected to the dynamometer.*

**Dynamometer Position Color Code Label:** Located on the Dynamometer Yoke Pivot Plate, the Dynamometer Position Color Code Label helps the user to quickly position the dynamometer according to the pattern selected. Rotate the dynamometer to the yellow color code positions when setting up to test or exercise the patient’s left side. Rotate the dynamometer to the blue color code positions for right side testing or exercise. Patterns that use the same positioning for both sides utilize the green color code areas.
**Positioning Chair**

**Seat Rotation:** The positioning chair offers 360 degrees of rotation in the horizontal plane with detente settings at 15-degree intervals. To rotate the seat in either direction, turn the Seat Rotation Handle toward the rear of the seat. The Seat Rotation Handle is located beneath the seat between the forward receiving tube and forward buckle. While holding the Seat Rotation Handle, swivel the seat to the desired position. Release the handle to lock the seat in place, making sure the seat sets in the appropriate detente. Note the seat rotation position on the Seat Rotation Scale, located beneath the seat on the seat post.

**Chair Foot Pedals:** The Chair Foot Pedals allow fore/aft adjustment of the positioning chair in relation to the dynamometer. To move the chair along the travel, press down on either foot pedal and slide the chair to the desired location. Release the foot pedal to lock the chair in place. To ensure stability, check that the chair is fully locked in a detente. Use the Chair Position Scale, located on the travel, to note the new position.

**Seatback Tilt:** This adjustment allows the user to select any of five seatback angle settings: 85, 70, 55, 40 and 25 degrees. To adjust the seatback tilt, pull up on one of the Seatback Tilt Handles, located on either side of the lower seatback frame. Adjust the seatback to the desired angle. Release the handle and ensure that it locks into the selected detente. Record the new seatback tilt angle from the Seatback Tilt Indicator, located at the bottom on either side of the seatback frame.

**Seat Height (850-000):** The motorized seat may be automatically raised or lowered over a range of 14 inches. To adjust the seat height, step down on the <▲> or <▼> Seat Height Foot Switches, located at the rear base of the chair.

*Note: The seat may be raised or lowered with the subject seated. Ensure that all wires are clear and the patient is not strapped to any attachment before beginning to raise or lower it.*

**Seatback Fore/Aft:** Crank the Seatback Fore/Aft Handle, located at the back of the seat base, in a counterclockwise direction to move the seatback forward on the seat. Crank the handle in a clockwise direction to move the seatback toward the rear of the seat. Record the new fore/aft position from the Seatback Fore/Aft Scale, located along each side of the seat frame near the back belt buckle.

**Cervical Support:** To reposition the Cervical Support, use one hand to hold the support ensuring it will not slip down. With the free hand, turn the Cervical Support Locking Knob in a counterclockwise direction until loose. Lift up or push down on the support until the desired position is achieved. Turn the locking knob in a clockwise direction until tight to secure the support in place.
**NOTE:** Be sure to support the Cervical Support with one hand before loosening the locking knob. If the Cervical Support is not supported, it may slide down and pinch a hand as the knob is loosened.

**Stabilization Straps:** The Positioning Chair is fitted with a Thigh Strap and Buckle (secured toward the front on each side of the seat frame), a Pelvic Strap and buckle (secured directly beneath the Seatback Tilt handle on the seat back frame,) and a pair of Shoulder Straps and buckles (secured toward the back on each side of the seat base). To secure any strap, lift the buckle handle, insert the strap into the buckle and pull until tight but not uncomfortable for the patient. Press the buckle handle all the way down to secure.

**Receiving Tubes:** There are four receiving tubes located on the seat. Two are positioned at the front of the seat, left and right of center. The remaining two tubes are located one on each side of the seat. These tubes receive the T-Bar, Limb Support Pad and Footrest. Each receiving tube has a locking knob. To loosen the knobs, turn them counterclockwise. To tighten the knobs, turn them clockwise.

**Stabilization Handles:** Located on the side receiving tubes, these handles can be used by the patient for added support, stabilization, and consistent hand positioning during exercise and rehabilitation sessions. They should not be used during test session. These stabilization handles are also convenient for the clinician as a means to pull or push the chair fore or aft on the T-base.
Figure 1.3. Positioning Chair Adjustments (850-000).
1. Seat Rotation Handle
2. Receiving Tubes
3. Chair Foot Pedals
4. Seat Height Foot Switches
5. Cervical Support Adjustment Knob
6. Seatback Tilt Handle
7. Seatback Fore/Aft Handle
8. Stabilization Handles
Figure 1.4. Positioning Chair Attachments:
1. T-Bar Adapter
2. Footrest
3. Limb-Support Pad

Seatback Brace

The Seatback Brace is designed to provide added stability when the seatback is used in a lowered position at zero degrees seat rotation for side lying, supine and prone patterns (particularly of the hip). The Seatback Brace is adjustable and simple to use. Once installed, set-up takes only seconds.

1. Ensure the seatback is in the up position. Rotate the seat to 0 degrees on either side of the seat rotation scale.

2. Line up one rod-end swivel of the Seatback Brace with the clevis on the seatback and insert the clevis pin.

3. Release the Seatback Handle and lower the seatback to “10” on the seatback tilt scale.

Figure 1.5. Attaching the Seatback Brace to the Multi-Joint System Seatback Clevis.
4. Loosen the Seatback Brace locking knob. Extend the lower part of the brace and insert the rod-end swivel into the trolley mount clevis. Insert the clevis pin.

5. Position the patient per protocol; lock the Seatback Brace locking knob to secure. Be sure to loosen the seat locking knob when adjusting the height of the seat or the position of the seat back.

6. To rotate the seat to the opposite 0-degree position, disconnect the lower end of the back only. Repeat steps four and five.

The Controller

(Located at the bottom, rear, of Computer Data Station)

Main Power Switch: Controls main power supply to controller, computer and dynamometer. Contains a circuit breaker to protect against extreme power surges. Breaker is reset by turning the Power Switch OFF (0) and ON (l).

Note: It is not necessary to turn the system OFF each day. Use the Dynamometer and Computer Power Switches described below for daily shutdown. Use the Main Power Switch only if the system is shutdown for an extended period of time.

Dynamometer Power Switch: This switch controls power to the dynamometer. In the ON position, power to the dynamometer is enabled. In the OFF position, the dynamometer is on Standby.

Computer Power Switch: Controls power to the computer and peripherals (including printer and monitor). In the ON position, power to computer, monitor and printer are ON. In the OFF position, power to the computer, monitor and printer are OFF.

Note: Be sure to properly exit and close down the Software application and Windows Programs before turning off the computer.

CPU ON/OFF Switch: Use this switch to turn the CPU ON/OFF.
**Status/Diagnostics Panel (LEDs):** This panel provides information to assist in troubleshooting of dynamometer/control panel problems. In the event of a system malfunction, always be sure to record that LEDs light before attempting to correct a problem or restart the system. Contact a Service Representative whenever the status panel indicates a malfunction.

![Figure 1.8. Rear Panel](image1)

![Figure 1.9. Front Panel](image2)

**Figures 1.8 and 1.9. The Multi-Joint System Controller front panel (right) and rear of unit (left):**
1. Main Power Switch
2. Dynamometer Power Switch
3. Controller Power Switch
4. Status/Diagnostics Panel (LED’s)
5. CPU ON/OFF Switch

**Dynamometer Attachments**

![Figure 1.8. Shoulder Attachment (Insert in Shoulder/Elbow Adapter)](image3)
Patterns:
Shoulder: Ex/Flex Ab/Ad Diagonals

Figure 1.9. Shoulder/Elbow Attachment (Insert in Shoulder/Elbow Adapter)

Patterns:
Shoulder: In/Ex Rotation
Elbow: Ex/Flex (remove cuff)

Note: Only one Shoulder/Elbow Adapter is supplied. The same adapter is used with the Shoulder Attachment and Shoulder/Elbow Attachment.

Figure 1.10. Knee Attachments (Left and Right)

CAUTION: Ensure finger guard is in place when using this attachment. See Figure 1.16.
Figure 1.11. Wrist Attachment

Patterns:
Wrist: Ex/Flex
Radial/Ulnar Deviation
Forearm: Pro/Supination

Figure 1.12. Hip Attachments (Left and Right)

Patterns:
Hip: Ab/Ad Ex/Flex

⚠️ CAUTION: Ensure finger guard is in place when using this attachment. See Figure 1.16.
Patterns:
Ankle: Plantar/Dorsi Flexion Inversion/Eversion

Note: See Using the Combination Ankle Attachment (next section).

Patterns:
Knee: Ex/Flex

**CAUTION:** Placing hands or fingers between the dynamometer input shaft (or attachment) and the mechanical ROM stops may result in serious injury.
Using the Combination Ankle Attachment

![Image of the Combination Ankle Attachment](image)

Figure 1.15. The Combination Ankle Attachment Adjustment Mechanisms.

A. Footplate Rotation Lever
B. Footplate Tilt Lever
C. Heel Cup Release Buttons
D. Footplate
E. Adapter Locking Knob
F. Ankle Attachment Adapter
G. Toe Strap
H. Ankle Strap

The Combination Ankle Attachment (#830-331) is color-coded to facilitate set ups for all ankle patterns. To prepare the attachment for use, simply line up the appropriate color coded position tags for footplate tilt and rotation with the red dots on the attachment shaft and Footplate Rotation Lever.

The footplate color codes are as follows:

White “P” to Red Dot: Plantar/Dorsiflexion
Green “I” to Red Dot: Inversion/Eversion

Adjusting the Footplate

**Footplate Rotation:** The Footplate Rotation Lever is located on the underside of the footplate at the toe end. Pull the lever and hold it back while rotating the footplate until the desired color-coded position tag aligns with the lever. Release the lever and ensure that the appropriate foot-plate peg is secured in the lever’s notch.

**Footplate Tilt:** The Footplate Tilt Lever is located on the underside of the footplate just above the color-coded position tags. Loosen the lever and tilt the footplate to align the color-coded
tags per test or exercise protocol by aligning the white “P” with the red dot for plantar/dorsiflexion or the green “I” to the red dot for Inversion/Eversion. Tighten the lever to secure the footplate in place.

Heel Cup Position: To facilitate alignment of the subject’s axis of rotation with the dynamometer shaft, it may be necessary to raise or lower the patient’s foot on the footplate by adjusting the heel cup position. The Heel Cup Release Buttons are located on the top side of the footplate at the heel end. Squeeze the Heel Cup Release Buttons together and slide the support cup to the desired position. Release the buttons to lock the heel cup in place.

Toe and Ankle Straps: Once all adjustments to the footplate have been completed, secure the patient’s foot using both the foot and ankle straps. To secure the toe and ankle straps, thread each strap through its respective buckle. Pull up on the narrow end of each buckle to ratchet the strap tight. Pull up on the wide end of each buckle to loosen the strap.
2. Operation

Considerations for Safe Operation of the Multi-Joint Systems:

1. The clinician should always be present during testing or exercise sessions. Do not allow subjects to test or exercise by themselves.

2. Range limits should always be set after the subject is positioned according to protocol and before switching to a test or exercise mode. Limits should never be set at points that are beyond the safe maximum allowable range of motion for the individual subject.

Always assume that previously set limits are inappropriate for successive subjects, or for successive joints on the same subject. Limits should be canceled by pressing Set-up, Start and Set-up again at the completion of each test or exercise session.

3. Range of motion limits should be set ensuring that the mechanical stop on the attachment or fixture will not contact the mechanical stop on the dynamometer. Metal-to-metal contact of these parts during operation will override the system’s normal deceleration function (cushion), causing harsh impacts at ends of ROM.

4. Always educate subject as to function and use of the Comfort Stop buttons. Always place the hand-held remote Comfort Stop (on black coiled cord) in the subject’s free hand before the start of any test, exercise or biofeedback session.

5. During set-up, check subject positioning and ability to complete range of motion (slowly) prior to securing stabilization straps. Ensure that both the positioning chair and dynamometer are securely locked in detentes before allowing subject to move through ROM.

6. Before beginning any test or exercise session, always inform the subject that the input arm will now be able to move.

7. Always keep the surrounding area free of equipment and other personnel, especially when the passive mode is to be used. Check for clear, unobstructed path of movement pattern (through complete ROM).

8. Do not operate equipment that has malfunctioned until it has been serviced by a qualified technician or use has been approved by a Service Representative.

9. Use equipment only with recommended power supplies, grounding, and surge suppression. (Refer to site survey or contact Service Department for specifications).

CAUTION: Placing hands or fingers between the dynamometer input shaft (or attachment) and the mechanical ROM stops may result in serious injury.
Readying the System for Use

1. Turn the main power switch on the back of the controller to the ON (1) position (see Figure 1.8).

2. Ensure that the dynamometer and computer power switches are set to the ON (I) position.

3. Upon power up, a message will be displayed on the monitor that the system needs to be initialized. Initialization consists of a self-test during that the firmware checks to ensure that the dynamometer and associated hardware are working properly. Initialization must be performed any time the system is turned ON following system shut-down or an interruption in power supply.

4. Remove any attachments from the dynamometer input shaft and select <OK> to proceed with initialization. The dynamometer input shaft will turn fully clockwise and counterclockwise. If any problems are encountered, the system will display an error message. If all circuits and phases of the Multi-Joint System dynamometer and hardware are working properly, no error message will be presented and the display advances to the Dynamometer Operation screen. The message “Set ROM Limits” should now be displayed in the System Status window at the top of the screen. The system is now ready for use.

*Note:* Should a coded initialization error message be displayed, contact Biodex Customer Service.

Shutting Down the System at the End of the Day:

At the end of the day, switch the computer and dynamometer power switches, located on the back of the controller, to the OFF position. If the Multi-Joint System will not be used for an extended period of time, switch the controller OFF via the Main Power switch on its rear panel.

*Note:* Exit both the Advantage Software and the Windows program prior to shutting down the system. Failure to do so may result in lost or damaged files. To quit Windows and shut down the computer:

1. Close the Advantage Software application by selecting the <X> in the top right corner of the screen.
2. Select the <Start> button at the lower left side of the screen to access the Start menu.
3. Select the <Shut Down> to bring up the Shutdown window.
4. Select <Yes> to shutdown the computer. A screen message will be displayed when it is safe to turn the computer OFF.

Following is a general guideline for use of the system in each of its operating modes. These guidelines are of a mechanical nature and do not reflect use of the computer software. They are presented only as an example to help familiarize the user with the mechanical aspects of equipment set-up and each of the various modes of operation.

Modes of Operation

The Multi-Joint System offers several modes of operation. These are selected via the Advantage Software package. A brief review of each mode follows.
**Biofeedback Operation** – Biofeedback Operation incorporates all the functions that, in earlier versions of Multi-Joint Systems, were controlled by the front panel. In this mode, clinicians can set up and begin patient exercise without entering patient-specific data such as name, address, weight, etc. When BioFeedback mode is selected, all settings default to match the last biofeedback session. Patient exercise data is displayed on the graph in real-time, but cannot be printed or saved.

**Isokinetic Mode** – In this mode, the dynamometer acts to control velocity, allowing the subject to accelerate up to, but no higher than, the maximum speed value selected for each direction of shaft rotation (accommodating resistance). The subject may freely decelerate or change direction of movement at any point within the range of motion.

The following general procedure is provided to help clarify use of Isokinetic mode.

**Isokinetic Mode Clinical Applications:**

1. The Isokinetic mode may be used at higher speeds in order to simulate functional or sports activities. It can also be used early on in the rehabilitation process to prevent compression and translation in the knee joint.

2. The Isokinetic mode may be used with differing bi-directional velocities to simulate functional activities or place the focus of the activity on one specific muscle group.

3. There is a 15-degree physiologic overflow in strength on each side of the end ROM (30º total carry-over) with a limited range of motion strengthening program performed isokinetically (Halbach, 1985).

4. Choose con/ecc or ecc/con to isolate one muscle group.

5. Exercising at a specific speed has shown strength gains that overflow to both faster and slower speeds. However, there is enough research to demonstrate that by exercising at every 30 degrees/second, physiological overflow will occur with regards to specific strengthening at each speed exercised (Davies, G.J., 1987.)

6. In the Isokinetic mode, the Force-Velocity relationship of muscle dictates that as speed of contraction increases concentrically, the muscular tension (and, therefore, torque) decreases. (Davies, G.J., 1987.)

7. A velocity spectrum is recommended that will start the subject at either a high or low speed, depending on the pathology and status of the subject, and progress to other speeds. Varying the number of repetitions (i.e., less reps at slow speeds, more reps at high speeds), will help keep the work performed consistent over the range of the velocity spectrum.

8. Exercising at higher speeds has shown excellent benefits for endurance gains. This will limit compression on joints, tension developed in the muscles and tendons, and generally allows the subject to do larger numbers of sets or repetitions; which transfers to daily activities.

9. Keep in mind the stretch shortening cycle. It has been found that an eccentric contraction performed before a concentric contraction results in a more forceful concentric contraction than a concentric contraction performed alone (Duncan, P., et. al., 1989). High speed contractions followed by slow speed contractions will simulate an isolated plyometric activity.

**The Passive Mode** – The Passive mode allows the dynamometer to provide continuous motion at constant velocity, with direction changes occurring only when range of motion limits are
reached. In Passive mode, the dynamometer initiates motion when the <Start> button is pressed, requiring no active participation by the subject.

**Passive Mode Clinical Applications:**

1. The Passive mode is frequently used post-operatively for the benefits of continuous passive motion, which assist with nourishment of the joint.
2. The Passive mode may be used isokinetically in the agonistic direction and passively in the antagonistic direction or vice versa.
3. The Passive mode may be used to exercise or test isokinetically. Subjects that cannot meet the speed will be passively moved through this portion of the range.
4. The Passive mode may be used for passive stretching. When this is performed, the torque limits in each direction should be set low. If the subject feels uncomfortable, they may resist the motion and the unit will stop (e.g., if the clinician is trying to increase knee flexion, the subject will be passively flexed). If at any time the subject is uncomfortable, the flexion movement may be resisted and isometrically exceed the toward torque limit. This will stop the unit. The <Pause> buttons can also be used to hold the patient at the end ROM corresponding to the direction the pause is set.
5. For knee, shoulder flex/ex, ab/ad, and lumbar movements, ensure torque limits are set to overcome limb weight.
6. Passive motion may be used to warm-up and cool-down a subject, stretching ROM, and to perform contract/relax protocols. Used during rest periods, passive motion can help prevent muscles from “tightening up” before the next set of repetitions.
7. By instructing the subject to move the limb at a speed that will keep the Away and Toward Applied Torque Indicator ON and the middle Applied Torque Indicator OFF, the Passive mode can be used to provide biofeedback and stimulate joint and muscle mechanoreceptors to improve proprioception.
8. In the case of poor muscle strength, passive mode allows for active assistive motion that will initiate or continue motion of the subject.
9. Contract/Relax may be performed in the Passive mode. Range of motion limits are selected to include the entire range the subject should be able to achieve that day. It is recommended that the <Limit Set> buttons are set no more than five degrees outside of the beginning range. Percent Range dials are decreased to an appropriate level ensuring the entire range is comfortable. The subject is placed on the unit with the comfort stop in hand. As the subject is passively moved in one direction, force is exerted in the opposite direction. The torque limit in the opposing direction must be set low enough ensuring that the subject exceeds the limit and performs an isometric contraction. At this time, the clinician slightly increases the range of motion using the Percent Range dial in the appropriate direction. The procedure is repeated for as many cycles as desired.
10. Immediately after exercise, some subjects exhibit joint effusion. Application of ice while moving passively at 20 degrees per second has been reported to reduce post exercise swelling and discomfort. This may also be performed in conjunction with electric stimulation to further assist edema control.
**Isometric Mode** – In this mode, the dynamometer maintains zero velocity at any selected point in the range of motion. Significant change in joint angle and overall muscle length does not occur.

**Isometric Mode Clinical Applications:**
1. The Isometric mode may be used pre- or post-surgery with discretion.
2. The Isometric mode may be used near a painful range for strength carryover into the painful range. Overflow has been found to be plus or minus as much as 10 degrees.
3. Isometric holds can be checked for quality of contraction. Monitoring these can help set goals and monitor progress.
4. The Isometric mode can be used very effectively to initiate contractions sub maximally. Make sure to stabilize other body parts to prevent compensation. Relaxation can be assisted by the application of heat, cold, or biofeedback.

**Isotonic Mode** – In this mode, the dynamometer requires the patient to meet a minimum selected torque limit in order to move the input arm. Thus, speed is variable but torque is constant.

**Isotonic Mode Clinical Considerations:**
1. The Isotonic Mode may be used concentrically or eccentrically to train a selected muscle group.
2. Torque limits may be set independently (in each direction) for agonist/antagonist muscle groups in order to focus the activity on one specific muscle group or compensate for dominance in strength of either the agonist or antagonist muscle group.
3. In this mode it is possible to set a “pre-load” for the patient to overcome prior to movement. This ensures that the patient is performing the contraction with a minimal amount of force.
4. Concentric/concentric isotonics can be completed before concentric/eccentric movements. This improves safety for the patient as the limb will not be forcibly moved into any portion of the range of motion should the patient not have ample neuromuscular control.

**The Reactive Eccentric Mode** – In this mode the dynamometer responds to torque exerted by the patient by moving in the opposite direction of the applied torque.

In Reactive Eccentric or mode, the <Torque> buttons on the Control Panel are used to specify a window of desired human force output. To initiate shaft motion, the subject is required to meet a minimum torque threshold corresponding to 10% of the <Torque> button setting. If the subject exceeds the torque limit value selected for either direction of motion, the shaft stops rotating until the subject’s force output is reduced to within the desired range. The subject is therefore required to exceed a specified torque value to achieve motion, and to keep torque output at the specified level to continue movement.

Low torque limits require greater neuromuscular control. Setting a torque limit of 20 ft-lb (27Nm) will require 2 ft-lb (2.72Nm) of force to initiate motion and 20 ft-lb (27Nm) to stop, resulting in a window of 18 ft-lb (24.41Nm). Setting the window at 100 ft-lb (136Nm) results in
a window of 90 ft-lb (122.4Nm). Reactive Eccentric mode allows for direction changes at any point in the range of motion.

**Reactive Eccentric Mode Clinical Applications:**

1. The Reactive Eccentric mode may be used to perform submaximal or maximal eccentrics.

2. The Reactive Eccentric mode may be used to work on proprioception. When torque limits are set, the subject must exert at least one-tenth of the torque limit to keep the shaft moving. If the subject exceeds the limits, the unit will stop.

   Low torque limits require greater neuromuscular control. Setting a torque limit of 20 ft-lb (27Nm) will require 2 ft-lb (2.72Nm) of force to initiate motion and 20 ft-lb (27Nm) to stop, resulting in a window of 18 ft-lb (24.41Nm). Setting the window at 100 ft-lb (136Nm) results in a window of 90 ft-lb (122.4Nm).

3. At higher velocities the stretch reflex is more active than at lower velocities.

4. It is possible to generate 30-40% more force eccentrically than concentrically. (Set the torque limits appropriately.) In that the stimulus for strength gain is contraction intensity, it is suggested by some research that eccentric contractions will result in significant strength gains. (Knuttgen, H.G., et. al., 1971; Komi, P.V., 1972).

5. There is patient specific eccentric speed above which muscular force will not increase. (Knuttgen, H.G., et. al., 1972).

6. Eccentric contraction involves a “training” of the non-contractual elements of muscle ensuring the muscle "learns" to function in a higher force environment. (Komi, P.V., 1972).

7. In eccentric exercise, the force increases as the velocity of contraction increases (up to a certain point) that is in contrast to concentric exercise in which the force decreases as the speed of contraction increases. (Davies, G.J., 1987.)

8. It has been suggested that eccentric exercise produces the greatest force in the least amount of time (Komi & Cavanaugh, 1977).

9. Eccentric contractions enhance muscle force production and are less costly metabolically than concentric contractions (Bosco & Komi, 1979, Asmussen, 1953).

10. Eccentric rehabilitation is usually performed no more than two times a week secondary to delayed onset muscle soreness.

**Additional Considerations**

1. Very often clinicians use the following progression during the rehabilitation process: Passive mode, isometrics, multi-angle isometrics, sub-maximal eccentrics, and concentric isokinetics.

2. Electrical stimulation may be used in conjunction with any of the tests or exercise modes on the Multi-Joint System.

3. Consider ending a rehabilitation set by work or time, especially if the goal is to improve endurance.

4. Giving subjects copies of their rehabilitation reports can help with motivation.
5. Submaximal exercise prevents neural dissociation, promotes articular cartilage nourishment and proprioception, and retards muscular atrophy.

6. Delayed Onset Muscle Soreness (DOMS) is not usually apparent until one to two days after treatment. Work sub maximally to minimize and develop protocols accordingly.

7. The Multi-Joint System is a versatile piece of equipment, making it difficult to document every possible setup position. If a non-documented position is used, document it. If it becomes a position that is used often, send the information to Biodex.

**Proper Testing Technique**

1. Verify calibration at least twice a month. If data will be used in court or for research, calibrate and verify before a test is performed.

2. Be consistent in warm-up procedures, commands, setups and instructions, (i.e., Four total repetitions, first one at 25% effort, second at 50% effort, third at 75% effort and, finally, 100% max effort.)

3. Each patient should perform trial repetitions before each speed to become familiar with what to expect.

4. Be sure to familiarize the subject with the equipment before testing to eliminate a learning curve. It is recommended that the patient perform two or three exercise sessions on the system prior to testing.

5. Use proper stabilization techniques, making every attempt to restrict motion only to the area of interest. Body parts on either side of the joint(s) being rehabilitated or tested should be firmly secured. Studies have reported significant differences in data generated with and without stabilization. Uncontrolled movement leads to testing errors. If stabilization devices are added or removed, document it.

6. Axis alignment of the dynamometer shaft with the subject’s anatomical axis of rotation is crucial to ensure that during testing and rehabilitation the pattern performed is consistent with the proper biomechanics of the joint. Correct alignment also helps eliminate stressful loading of the joint and recruitment of other muscle groups.

7. Use standardized setups. If an unconventional setup is used, document it.

8. Make sure to set the correct anatomical reference angle. The internal goniometer of the software is based on this reference angle, and is important for later data interpretation.

9. Verbal and visual encouragement should be consistent.

*Note: Allowing a patient to view the monitor during a test may cause the patient to change force output based on perception. For testing consistency, it is recommended that the patient not be allowed to view the monitor.*
3. Software Operation

Patient Selection Window

This window is used to keep track of the patient's general information and test history. The Patient Selection Window displays information such as general patient information, admission dates, release dates, as well as diagnosis. From this window view patient test/exercise information can be viewed and notes can be added. Patient records can be organized by adding or deleting patients and/or tests.

<table>
<thead>
<tr>
<th>Icon</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open</td>
<td>Opens a study record previously saved on disk. The operator selects from an alphabetized list of study names. Typing the first letter of the last name will jump ahead into the list. Studies can be reviewed or additional tests may be administered.</td>
</tr>
<tr>
<td>Add Patient</td>
<td>Creates a new study record and prompts the operator for the subject's description, diagnosis, and medical history. Fields highlighted in red are required fields and once saved, are no longer editable. Click on &lt;Save&gt; or &lt;Cancel&gt; to close the window.</td>
</tr>
<tr>
<td>Edit</td>
<td>Activates the patient information form and allows existing information to be edited. Note that the fields highlighted in red are no longer editable. The operator must complete this operation by clicking &lt;Save&gt; or &lt;Cancel&gt;.</td>
</tr>
<tr>
<td>Save</td>
<td>Saves changes to the patient’s form following an Add or Edit operation.</td>
</tr>
<tr>
<td>Cancel</td>
<td>Cancels an Add or Edit operation.</td>
</tr>
<tr>
<td>Del Test</td>
<td>Deletes an individual test (or study) from the patient's History file.</td>
</tr>
<tr>
<td>Del Patient</td>
<td>Deletes a patient record (and all associated tests) from the History file.</td>
</tr>
<tr>
<td>Pain Scale</td>
<td>The Pain Scale documents the patient's subjective pain by selecting a value of 1-10. <strong>Note:</strong> The Pain Scale can be updated during each visit.</td>
</tr>
<tr>
<td>Close</td>
<td>Closes the window.</td>
</tr>
</tbody>
</table>
Protocol Definition Window

This window is used to select a test/exercise protocol for the current patient. In the protocol database, there exists a factory-installed list of standard protocols from which to select. Follow steps (1 to 3) to select a protocol.

1. Click on the Protocol icon located on the toolbar to open the "select a protocol" window.
2. Click the "+" to expand items and the "-" to hide defined protocols in the list.
3. Highlight the desired protocol and click <Select> to advance to the ROM screen or click <Edit Protocol> to edit the selected protocol.

The user may link a series of protocols by clicking <Link Protocol> on the toolbar. The following table provides descriptions for the Protocol Definition toolbar options.

<table>
<thead>
<tr>
<th>Icon</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Protocol]</td>
<td>Enables a user to select a factory standard or previously saved custom protocol. The user may select mode, joint, pattern, and contraction from drop-down lists for any given protocol.</td>
</tr>
<tr>
<td>![Favorites]</td>
<td>Enables a user to retrieve previously saved custom protocols. Click &quot;+&quot; to expand items and &quot;-&quot; to hide custom protocols in the list.</td>
</tr>
<tr>
<td>![Add]</td>
<td>Enables a user to create a custom protocol and add to the current list. The operator must complete this operation by clicking &quot;Save&quot; or &quot;Cancel&quot;.</td>
</tr>
<tr>
<td>![Edit]</td>
<td>Activates the patient information form and allows existing information to be edited. Note that the fields highlighted in red are no longer editable. The operator must complete this operation by clicking &lt;Save&gt; or &lt;Cancel&gt;.</td>
</tr>
<tr>
<td>![Save]</td>
<td>Saves changes to the patient's form following an Add or Edit operation.</td>
</tr>
<tr>
<td>![Cancel]</td>
<td>Cancels an Add or Edit operation.</td>
</tr>
</tbody>
</table>
| ![Delete] | Deletes the current protocol record.  
**Note:** The user will not be able to repeat any previous tests performed using the current protocol once the delete function successfully completes. |
| ![Link] | Enables a user to link a series of protocols to create a customized sequence. The user may save protocol combinations for future testing. |
| ![Close] | Closes the window. |
Linked Protocol Window

This window is used to customize a series of protocols that can be used again. Follow steps (1 to 6) to create a sequence of protocols.

1. Click on the Create Linked icon located on the toolbar to open the setup window.
2. Fill out the Linked Protocol Name field highlighted in red.
3. In the Protocol Selection sub-window, click the "+" to expand items and the "-" to hide defined protocols in the list.
4. Highlight the desired protocol and click the <Insert> button located on the toolbar.
5. Repeat steps 3 and 4 as many times as desired.
6. Click the Save icon located on the toolbar to save the recorded information.

All saved Linked Protocol sequences will be displayed in the Protocol selection window for future use. The following table provides descriptions for the toolbar operations.

<table>
<thead>
<tr>
<th>Icon</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="create_icon" alt="Create" /></td>
<td>Enables a user to link a series of protocols to create a customized sequence. The user may save protocol combinations for future testing.</td>
</tr>
<tr>
<td><img src="edit_icon" alt="Edit" /></td>
<td>Activates the patient information form and allows existing information to be edited. Note that the fields highlighted in red are no longer editable. The operator must complete this operation by clicking &lt;Save&gt; or &lt;Cancel&gt;.</td>
</tr>
<tr>
<td><img src="insert_icon" alt="Insert" /></td>
<td>Enables a user to create a custom protocol and add to the current list. The operator must complete this operation by clicking &lt;Save&gt; or &lt;Cancel&gt;.</td>
</tr>
<tr>
<td><img src="remove_icon" alt="Remove" /></td>
<td>Enables a user to remove a protocol from the sequence.</td>
</tr>
<tr>
<td><img src="save_icon" alt="Save" /></td>
<td>Saves changes to the patient’s form following a Create or Edit operation.</td>
</tr>
<tr>
<td><img src="cancel_icon" alt="Cancel" /></td>
<td>Cancels a Create or Edit operation.</td>
</tr>
<tr>
<td><img src="delete_icon" alt="Delete" /></td>
<td>Deletes the current protocol record. Note: The user will not be able to repeat any previous tests performed using the current protocol once the delete function successfully completes.</td>
</tr>
<tr>
<td><img src="single_icon" alt="Single" /></td>
<td>Returns to the protocol definition window.</td>
</tr>
<tr>
<td><img src="close_icon" alt="Close" /></td>
<td>Closes the window.</td>
</tr>
</tbody>
</table>
Dynamometer Operation Window

This window provides the user the ability to jump between test, exercise, and BioFeedback mode. Operations can be started and stopped from this window. In the middle of this window is a graph that monitors real-time torque applied versus time during dynamometer operations. The patient’s name, joint, patterns, and other information about the current mode are also displayed in this window.

The following table provides descriptions for the Dynamometer Operation Window toolbar options.

<table>
<thead>
<tr>
<th>Icon</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Switch]</td>
<td>Enables a user to switch into test mode.</td>
</tr>
<tr>
<td>![Expand]</td>
<td>Enables a user to retrieve previously saved custom protocols. Click “+” to expand items and “-” to hide custom protocols in the list.</td>
</tr>
<tr>
<td>![BioFeedback]</td>
<td>Enables user to switch into BioFeedback mode.</td>
</tr>
<tr>
<td>![Anatomical Setup]</td>
<td>View Anatomical Setup Window. This window will assist in displaying a “help” AVI movie or still image on how to set up an individualized ROM pattern.</td>
</tr>
<tr>
<td>![Graph Settings]</td>
<td>Enables a user to change how the dynamometer operation window displays data. The user can also enable/disable graph settings.</td>
</tr>
<tr>
<td>![Help]</td>
<td>Opens the Help wizard.</td>
</tr>
<tr>
<td>![Stop]</td>
<td>Enables a user to stop an operation.</td>
</tr>
<tr>
<td>![Start]</td>
<td>Enables a user to start an operation.</td>
</tr>
<tr>
<td>![Not Ready]</td>
<td>Indicates the dynamometer “not ready” state.</td>
</tr>
<tr>
<td>![Idle]</td>
<td>Indicates the dynamometer is in the “idle” state.</td>
</tr>
<tr>
<td>![Repeat/Skip]</td>
<td>Enables a user to repeat or skip a set in a protocol on the current side. The change is consistent with the disallowance of toggling back beyond one side.</td>
</tr>
</tbody>
</table>
Set Range of Motion (ROM)

Figure 3.1. Set Range of Motion (ROM) Screen.
<table>
<thead>
<tr>
<th>Icon</th>
<th>Step #</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setting the ROM (steps 1 to 5):</td>
<td></td>
<td></td>
</tr>
<tr>
<td><img src="image1" alt="icon" /></td>
<td>1</td>
<td>Click the icon to display the ROM window (if it is not already displayed).</td>
</tr>
<tr>
<td><img src="image2" alt="icon" /></td>
<td>2</td>
<td>Select the side to be tested from the Side Selected section.</td>
</tr>
<tr>
<td><img src="image3" alt="icon" /></td>
<td>3</td>
<td>Click &lt;Clear Limits&gt; to clear the previous ROM limits.</td>
</tr>
<tr>
<td><img src="image4" alt="icon" /></td>
<td>4</td>
<td>Position the dynamometer arm to the Away position according to the side selected and click &lt;Set&gt; in the Away Limit section to record the position.</td>
</tr>
<tr>
<td><img src="image5" alt="icon" /></td>
<td>5</td>
<td>Position the dynamometer arm to the Towards position according to the side selected and click on &lt;Set&gt; in the Toward Limit section to record the position.</td>
</tr>
<tr>
<td>Anatomical Calibration (steps 6 to 8):</td>
<td></td>
<td></td>
</tr>
<tr>
<td><img src="image6" alt="icon" /></td>
<td>6</td>
<td>Verify that the correct side is selected.</td>
</tr>
<tr>
<td><img src="image7" alt="icon" /></td>
<td>7</td>
<td>Position the subject's joint at Reference angle.</td>
</tr>
<tr>
<td><img src="image8" alt="icon" /></td>
<td>8</td>
<td>Click on the Goniometer (Calibrate Position) icon to record position. If gravity correction is not needed, click on &lt;Continue&gt; to Finish ROM Setup.</td>
</tr>
<tr>
<td>Gravity Correction (steps 9 to 12 optional):</td>
<td></td>
<td></td>
</tr>
<tr>
<td><img src="image9" alt="icon" /></td>
<td>9</td>
<td>Position joint at the angle of maximum gravity effect.</td>
</tr>
<tr>
<td><img src="image10" alt="icon" /></td>
<td>10</td>
<td>Press &lt;HOLD&gt;.</td>
</tr>
<tr>
<td><img src="image11" alt="icon" /></td>
<td>11</td>
<td>Click on the Scale icon to record the limb weight.</td>
</tr>
<tr>
<td><img src="image12" alt="icon" /></td>
<td>12</td>
<td>Press &lt;RESUME&gt;.</td>
</tr>
<tr>
<td><img src="image13" alt="icon" /></td>
<td>13</td>
<td>Click on &lt;Continue&gt; to finish ROM Setup.</td>
</tr>
</tbody>
</table>
View Anatomical Setup

This window lets the user select a ROM pattern to view for reference. ROM patterns include away and toward directions as well as degrees by which to set the dynamometer. There are two methods for viewing:

1. Picture View
2. AVI View

Picture View

Picture view displays a drawing of the ROM pattern selected.

Figure 3.2. Example of a Picture View.
AVI View

AVI view opens Windows® media player with a movie on "how to" setup the dynamometer for the selected ROM pattern. Note that the AVI movie files are very large in size. The user has the option at installation to place them on the hard drive or read off of the CD-ROM.

Note: Slight delays in movie frames may be experienced depending on the speed of the CD-ROM drive.

![Example of an AVI View](image)

Report Wizard

The Report screen is used to select options and reports for preview and/or printing. As report options are checked, the available reports are presented in a list box. Reports can be viewed by clicking on an entry in the list box and clicking on the <Print> or <Print Preview> buttons. The Summary of test information window displays information about the current patient and the associated tests. It is a good idea to check this window to assure that all of the tests associated with the selected protocol are available for reporting. In general, the steps for creating reports are:

1. If a Progress report is desired, click on the Progress Reports option. The program will determine what sides are available for progress reporting (left or right). If both sides are
available, select the desired side. Using the drop-down menu, select a test date for comparison. The program will automatically order the test dates comparing the most recent test date to the previous test date.

2. Choose one or more Report options. As options are selected, the list of available reports will change to reflect only those reports that are available for the given set of options.

![Choose Report]

3. Select a report by clicking on the report description. The selected report is highlighted.

4. Click on Print Preview to view the report.

5. Click on Print to make a hard copy.

6. Click on Print All to display options for printing all the reports.

**Report Options:**

<table>
<thead>
<tr>
<th>Report Option</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Window Isokinetic Data</td>
<td>Applies to isokinetic protocols only - filters out points in the isokinetic data curve that are below the specified dynamometer speed.</td>
</tr>
<tr>
<td>Torque vs. Position Graph</td>
<td>All graphs in reports are normally plotted as Torque vs. Time. This option causes Position (in degrees) to appear on the x-axis of graphs in reports.</td>
</tr>
<tr>
<td>Use Metric Units</td>
<td>Causes the y-axes of all graphs to display information in metric units.</td>
</tr>
<tr>
<td>Print all Reports</td>
<td>All reports that apply for the current test are printed.</td>
</tr>
<tr>
<td>Print as Unilateral</td>
<td>Applies to bilateral tests only - allows the operator to print unilateral style reports for a bilateral test. This option is useful for printing results on partially completed tests.</td>
</tr>
<tr>
<td>Monochrome</td>
<td>Applies to Isomap tests only - causes Isomap images to be printed using a black and white (monochromatic) scale instead of color.</td>
</tr>
</tbody>
</table>

**Notes:**

*Progress reports can only be printed for tests that are similar. Both tests must be of the same protocol type (bilateral or unilateral), mode (isokinetic or isometric) and speed (or position). When Progress is checked, the program automatically filters out the tests that do not qualify for progress reporting.*

*Incomplete bilateral tests can be used for progress reporting. If a subject undergoes a complete bilateral evaluation and at a later date is tested for follow-up on the involved side only, the program will generate a progress report for the involved side. Please note that the two tests must be identical in protocol. In other words, the follow-up test on the involved side must be a bilateral protocol even though it is considered "incomplete" as a bilateral procedure. The Print as Unilateral report option will print reports for an incomplete bilateral test.*
Rehab Summary Report Generation


![Choose Report:]

   Graphical Evaluation
   General Evaluation
   Comprehensive Evaluation
   Narrative Cover Letter
   Rehab Session Summary

2. Choose the report by clicking on the report description. The item will become highlighted, click on Print Preview to advance to the Rehab Session Summary Report Selection screen.

3. Select the protocols from the Available Exercise Protocols list, which will be used in the rehab summary. Select the protocol by clicking on it and click on ADD - -> to add it to the list or by clicking on ADD ALL- -> to add all the available exercise protocols to the Selected Protocol list.

![Available Exercise Protocols]

   12/17/2004 TEST BI: KNEE EXT/AFX ISOK. CON/CON 60/60, 180/180
   12/17/2004: EXR UNI KNEE EXT/AFX ISOK. CON/CON 60/60, 180/180
   12/17/2004: EXR UNI KNEE EXT/AFX ISOK. CON/CON 60/60, 180/180
   12/17/2004: EXR UNI KNEE EXT/AFX ISOK. CON/CON 60/60, 180/180
   12/17/2004: EXR UNI KNEE EXT/AFX ISOK. CON/CON 60/60, 180/180

   Note: At least two protocols must be added into the Selected Protocol list in order to generate a Rehab Summary Report. If existing rehab data is saved for recall, a warning message box like the one below is displayed.

![System Warning]

   Warning: Values saved for recall will be lost. Continue?

   Yes   No

4. When the protocols to be used in the report are selected, select the type of data to graph from the Select Data to Graph section.

![Select Data to Graph]

   Strength
   ROM
   Pain
   Other 1
   Other 2
   Other 3
   Other 4

   Note: Up to five data types to graph may be selected from the Select Data to Graph section.
5. Choose the side(s) to graph from the Sides section. Involved is always checked as default. To compare both sides, select the uninvolved side. There is an Option section allowing the user to specify if a graph legend is to be generated. If graph legend is unchecked, labels will be plotted above the generated line(s).

6. Save the current graph settings by clicking on <Save Settings> buttons. Otherwise, click on <Continue> to proceed with the Rehab Graph Data screen.

7. The Rehab Graph Data screen puts all of the selected rehab graph protocol's data into a data grid. The user can modify data values from this screen.

   **Note:** If data for recall is not saved, modified data values from this screen will only be reflected for this graph session. Saving rehab data for recall does not modify the graph data within the database.

8. Click OK to generate the Rehab Graph Report.

**Curve Analysis**

The Curve Analysis Window allows the user to customize the way the curve analysis is viewed. The user can print or log to file the curve analysis graph for future reference.

**Select Patient** - Prompts the operator to select a patient's study record that has been previously saved on disk. Click and highlight the patient name and test or exercise record to view. Click the <Select> button to open the selected study record in the Curve Analysis window. Patient name and protocol used is displayed at the top of the screen.

**Data Set** - This drop down list allows the user to choose any tested speed of the selected patient's study record to display in the Curve Analysis window.

**Y Scale** - This setting is the units of torque in ft-lb viewed on the left side of the curve analysis window. The factory setting for Y Scale is set to Auto and will adjust units displayed.
accordingly. The Y Scale may be set to a user specified maximum or minimum by unchecking the Auto box, type in a new setting and press the <Re-scale> button to update the Curve Analysis window.

**Cursors** - When Cursors are enabled the user is able to place an "A" and "B" cursor line for easy identification of specific areas between reps directly on the Curve Analysis window.

![Cursors](image)

To place cursor lines, click in the check box next to Enable Cursors to turn cursors on. A smaller Cursors window will pop up with exact cursor location coordinates.

![Cursors Table](image)

To move the cursor line(s), first select the line to move in the Move drop down box. By clicking the arrows next to the Single selection, the selected cursor will move one single step at a time. The arrows next to the Half Rep will move the cursor half of a rep at a time and the full rep will move the selected cursor one full rep.

The Select Rep drop-down menu zooms In to view only the selected rep. Zoom out to full view again simply by pressing the <Zoom Out> button.

**Overlay** - This selection allows user to add a curve legend to each rep displayed in the Curve Analysis window. User is able to Save and/or Clear curve legends.

**Display** - The display box allows the user to customize the view of the Curve Analysis data window.

![Display Options](image)

**Menu** - The <Print> button is located here and will print the Curve Analysis window to the selected printer. The <Log to file> button allows user to view and print the Curve Analysis data in Windows Notepad (file name curve.dat). The <Close> button will close the window.
BioFeedback Mode

The BioFeedback mode allows the clinician to setup an exercise session without entering any patient data. There are two ways to use BioFeedback. The first way is to enable the End By option. This option allows the clinician to specify how the session terminates, the number of sets and the number of repetitions for each set. Step 7 explains End By in more detail. The second method is to uncheck the End By option. In this mode, the clinician manually controls the beginning and end of the session by clicking on the <Start> and <Stop> buttons.

![BioFeedback Display Options Screen](image)

*Figure 3.4. BioFeedback Display Options Screen.*

**Note:** When switching into BioFeedback mode, ROM setup is required to prompt for new ROM limits.
Setting New ROM Limits

1. Touch the <Mode> button to make a dynamometer mode selection.

![Mode Options](image)

**Figure 3.5. <Mode> Options.**

2. Click <Select Joint/Pattern> to make a joint and pattern selection.

![Select Joint/Pattern Options](image)

**Figure 3.6. <Select Joint/Pattern Options>**.

3. Click <End Stop: Cushion (1)> to select the desired cushion level.

![End Stop: Cushion (1) Options](image)

**Figure 3.7. <End Stop: Cushion (1)> Options.**

4. Click <ROM SET> to set the ROM (see Figure 3.8). The ROM Setup Dialog will appear. This dialog is used to set the Range of Motion limits (see Set Range of Motion).

After the Range of Motion limits have been set, ROM limits can be adjusted using the <SET> button under "% ROM" and using "-" to decrease or "+" to increase the current setting. Refer to Figure 3.9 and Figure 3.10 below. To make both sides (away/toward) hold the same settings, make sure there is a green check mark on the option labeled "Synchronize both directions". Apply the changes by clicking <DONE>. 


5. To set/adjust speed and torque settings if applicable, click on the <SET> button in the sections labeled Speed and Torque. Refer to Figure 3.11 below. Change the settings by clicking "-" to decrease current setting or "+" to increase the current setting. Refer to Figure 3.12 and 3.13 below. To make both sides (away/toward) hold the same settings and make sure there is a green check mark on the option labeled "Synchronize both directions". Apply the changes by clicking on the <DONE> button.

6. To adjust the contraction and pause settings (if applicable), click on the <SET> button in the sections labeled Contraction and Pause. Refer to Figure 3.14 below. Change the contraction settings by clicking on the button labeled with the current setting. Refer to Figure 3.15 below. To change the pause settings click on "-" to decrease current setting or "+" to increase the current setting. Refer to Figure 3.16 below. To make both sides (away/toward) hold the same settings for Pause, make sure that there is a green check mark on the option labeled "Synchronize both directions". Apply the changes by clicking on the <DONE> button.
7. Click the button located next to "End by:" to select how sets are terminated. Change the settings by clicking "-" to decrease current setting or "+" to increase the current setting of the End By type. The End By Selection option is disabled:
   - When using Panel control on carts that have a hardware front panel.
   - In Test and Exercise.

![End By](image)

![End By Options](image)

**Note:** In Isometric mode, "End by" is always set to end by repetition. Select the contraction type by clicking on the <Contraction Type> button and select the following choices: AWAY/TOWARD, AWAY, or TOWARD.

![Contraction Type](image)

![Contraction Type Options](image)

8. Click the following icon to start a BioFeedback session:
4. Maintenance

Cleaning Instructions

With the system turned OFF, wipe down all surfaces with a damp cloth. Mild soap and water can be used to remove stains and scuff marks. Pay particular attention to the upholstery that can be damaged by exposure to perspiration and other body fluids.

**Note:** DO NOT use cleaning solutions containing ammonia or alcohol to clean upholstery. Mild soap and water should be sufficient. Allow the system to dry thoroughly before resuming testing, rehab or exercise sessions.

A leather cleaner/conditioner can be used monthly on all upholstery.

Hardware

As needed, inspect all locking and adjustment mechanisms for signs of wear or damage.

If there are any questions or if further assistance is required, contact the Customer Service Department.

Calibration Verification

The System is shipped factory calibrated. The only maintenance required to ensure that it remains calibrated is to perform a Calibration verification procedure once a month as described below:

1. Select <File> from the System Menu tool bar and select <Verify Calibration> from the drop-down menu. The Calibration Verification screen is displayed.
2. Enter a name in the red field. This is required to perform the verification.
3. Attach the long shoulder attachment to the dynamometer (remove any handgrip).
4. Select <ROM Set> to advance to the Set Dynamometer Range of Motion screen.
5. Set <Clear Limits>.
6. Allow the long shoulder attachment to hang vertically ensuring that Total ROM equals zero degrees. Select <SET> for the TOWARD Limit.
7. Move the long shoulder attachment away until Total ROM is 90 degrees. Select <SET> for the AWAY Limit.
8. Move the long shoulder attachment to Vertical and calibrate the position. Select <Continue> to return to the Verify Calibration screen.
10. Move the long shoulder attachment to full horizontal (90 degrees). Select <Start>.
11. Insert the calibration weight until the detent pin engages (toque = 50.0 ft-lbs, 67.8 NM).
12. Select <Verify Calibration> when ready.
13. When finished, remove the calibration weight and select <Exit> to return to the Dynamometer Operation screen.

**Note:** If a message is displayed indicating an Invalid Calibration, repeat the calibration procedure. If the message is displayed three times, contact Biodex Customer Service.

14. Select <Report> to generate a printed report that can be filed for later reference.
15. If desired, select <History> to generate a listing of all Calibration Verifications performed on the machine.
16. Select <Exit> to advance to the Dynamometer Operation screen.
Note: For research applications, the user may want to perform the Calibration Verification after a specific number of patients in case questions regarding the validity of the data arise at a later date.

Additional information can be found at:


Disposal

An appropriate waste disposal company is to be contacted (i.e., the local collection point for waste separation). Properly dispose of the device at the end of its service life:

• The device packaging is disposed of through resource recycling.
• The metal parts of the machine go to scrap metal disposal.
• Plastic parts are disposed of as hazardous waste.

The disposal of equipment must be in accordance with the respective national regulations.

Wear parts are considered hazardous waste! After being replaced, wear parts must be disposed of according to country-specific waste laws.
5. Specifications and Certifications

Features:
- Flat Panel LCD Touchscreen Monitor
- Multi-Mode operation: Isokinetic, Isometric, Isotonic, Reactive Eccentric and Passive
  - Concentric speed up to 500 deg/sec
  - Eccentric speed up to 300 deg/sec
  - Concentric torque up to 500 ft-lb (680 Nm)
  - Eccentric torque up to 400 ft-lb (542 Nm)
  - Passive speed as low as .25 deg/sec
  - Passive torque as low as .5 ft-lb (.68Nm)
  - Isotonic torque as low as .5 ft-lb (.68Nm)

Clinical Data Station:
- Windows™ based PC (current model)
- Windows™ Operating System
- Biodex Advantage Software
- LCD Flat Panel Touch-Screen Color Monitor with integrated Speakers
- Color Printer

Attachments for Ankle, Knee, Shoulder, Elbow, Wrist and Hip (850-000)

Attachment Cart
- Calibration Kit

Operating space: 64 square feet (6 square meters)

Certification: ETL and cETL listed to UL 60601-1, CAN/CSA C22.2 No.: 601-1-M90 and EN60601-1. CE conformity to M.D.D. 93/42/EEC

Electrical Requirements:
- 208/230VAC, 50-60Hz, 8 amps
- Requires 20A isolated dedicated service
- Hospital Grade Plug must be rated for 230VAC; 15 amps minimum
- North American Units supplied with NEMA 6-20P
- Equipment should have means to isolate its circuits electrically from the supply mains on all poles, simultaneously.

Mechanical Specifications: Total Weight: 1350 pounds (612kg)

Physical Dimensions:
- CDS Cart: 27 inches wide, 24 inches deep, 66 inches (69cm × 61cm × 168cm) high
- T-Base & Chair: 52 inches wide, 65 inches deep, 60 inches (132cm × 165cm × 152cm) high
- Attachment Cart: 50 inches wide, 26 inches deep, 50 inches (127 cm × 66cm × 127) high

Dynamometer Performance Specifications:
- Torque accuracy is +/-1% of full scale (500 ft-lbs [680Nm])
- Torque is factory calibrated
- Position range is 330 degrees
- Position accuracy is + / -1 degree of rotation
- Torque verification fixture is 50 ft-lbs +/- 0.5 ft-lbs (68Nm +/- .68Nm)
TRANSLATION CERTIFICATION


Date: July 31, 2018

To whom it may concern:

This is to certify that the attached translation from English into German (Germany) is an accurate representation of the documents received by this office.

The documents are designated as:

- XS4 IFU 18-142.docx

Note, the reviewer introduced text that deviates from the source:

Original translation “Konzentrische-konzentrisch” was updated to “Konzentrisch-konzentrische”

Original translation “Belastung” was updated to “Beschwerden”

Original translation “bei der Weichgewebeheilung” was updated to “durch Heilungsprozesse des Bindegewebes”

Original translation “konzentrischen” was updated to “konzentrisch”

Original translation “Bildschirm” was updated to “Menüpunkt”

Siobhan Copage, Project Manager in this company, attests to the following:

“To the best of my knowledge, the aforementioned documents are a true, full and accurate translation of the specified documents.”

Signature of Siobhan Copage