SYSTEM 4 (Advantage BX Software 5.3.X)

INSTRUCTIONS FOR USE

850-000 840-000 852-000



BIODEX

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SYSTEM 4

This instructions for use document covers safe operation of the three System 4 dynamometer models. All three models have the same performance characteristics. The differences among the three models are based on the chair and dynamometer adjustments on the T-Base.

- 850-000 System 4 Pro Adjustable height chair, movable chair and dynamometer.
- **840-000 System 4 Quick-Set** Fixed height chair adjusts its position on the T-Base. Has a fixed dynamometer position relative to the T-Base.
- 852-000 System 4 MVP Fixed height chair similar to the Quick-Set.

Additional information and resources, including installation instructions, are available upon request or directly from the Biodex website, www.biodex.com.

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

Thank you, Biodex Medical Systems, Inc.

Contact Information



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Definition of Symbols

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

Symbol	Definition
(3)	Carefully read these instructions prior to use
(i	Operating Instructions
<u> </u>	Caution
•	General Mandatory Action
4	Dangerous Voltage
ı	"On" Power
0	"Off" Power
L	Pinch Point
<u>_</u>	Earth (ground)
\sim	Alternating Current
	Fuse
→•	USB Connector/Cable
((<u>`</u>))	Non-lonizing Electromagnetic Radiation
X	Waste in Electrical Equipment
62	Disposal Cassification and Identification of Equipment
M	Date of Manufacture
***	Manufactured By
MD	Medical Device
∱	Type B Applied Part
C€xxxx	CE Mark with Notified body reference

Product Certifications and Classifications

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

- IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)
- ANSI/AAMI ES60601-1:2005+A1:2012+C1:2009+A2:2010.
- CAN/CSA C22.2 No. 60601-1:14
- FDA Class II Equipment
- Type B Applied Part







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

NOTE: Component part lists, descriptions, calibration instructions, or other information used to assist service personnel to repair those parts of the equipment that are designated as repairable for this product are provided on the Biodex 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 System 4 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:





Cautions



NOTE: The 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 activity 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 activity. 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.



CAUTION:

- Allow only qualified, trained personnel to install, operate or service this system.
- No part of the system can be serviced while in use.
- Modification to Biodex equipment must be authorized and approved by Biodex. Replacement parts not provided by Biodex may adversely affect operation and must be approved by Biodex before installation/repair.
- 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.



CAUTION: 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.



CAUTION: Only use approved power supplies.



CAUTION: 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: 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.



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

Warranty

Refer to the warranty card included with the product or contact Biodex Support Services.

Important Safety Information



Considerations for Safe Operation of the System 4:

- 1. The clinician should always be present during testing or activity 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 activity 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 and reset at the completion of each test or activity 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 or activity 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 activity session, always inform the subject that the input attachment 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.)
- 10. Make sure the Dynamometer tilt and rotation are locked. Tilt and rotation should not be loose during an activity.
- 11. No liquids allowed during use.





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

1. Introduction

Intended Use

System 4 is intended to identify, treat, and document the physical impairments that cause functional limitations typical of sports injuries, orthopedics, pediatric medicine, and neurorehabilitation.

Indications for Use

The System 4 is used with patients that may have physical impairments that cause functional limitations. Athletic injuries may include hamstring injury, Anterior Cruciate Ligament (ACL) injury, knee osteoarthritis, lateral ankle sprains, and patellofemoral dysfunction. Other patients include orthopedic, pediatric, and patients with movement disorders, neurologic pathologies, or general deconditioning. System 4 testing can also identify muscle weaknesses to prevent workplace injury (occupational medicine).

Contraindications

Absolute Contraindications

- Acute strain (musculotendinous unit) or sprain (non-contractile tissue)
- Soft tissue healing constraints (such as 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

Operating Conditions

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

Transport and Storage Conditions

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

Water Resistance Rating: IPX0

Patient Group

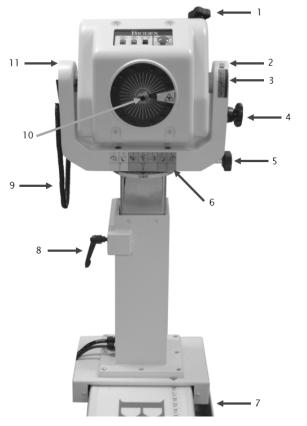
- Weight 30lbs. (13.60 kg) to 425lbs. (195 kg)
- Height: 39 inches (122 cm) 78 inches (198 cm)
- Age: 5 years 83 years



Figure 1.1. The System 4 Positioning Configuration.

2. Getting Started

Controls and Adjustments



- 1. Tilt Knob (locking)
- 2. Tilt Scale
- 3. Tilt Key
- 4. Locking Knob Storage
- 5. Rotation Knob (locking)
- 6. Position Color Code Label
- 7. Foot Pedals (travel) 850-000, 840-000 (not depicted)
- 8. Height Lever
- 9. Comfort Stop Pendant (patientheld)
- 10. Shaft Red Dot
- 11. Yoke



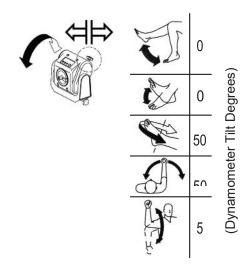
- 12. Rotate Counterclockwise Button
- 13. Rotate Clockwise Button
- 14. Hold/Resume Button
- 15. Comfort Stop

Figure 2.1. Dynamometer Positioning Controls and Adjustments.

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.

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 activity 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.

Comfort Stop: Prior to exercise, educating the user about the Comfort Stops can improve confidence and motivation when using the equipment.

When the Comfort Stop is used, a pop-up message gives two choices, Abort or Resume:



In the middle of a test, selecting the Abort icon will end the set. Selecting the Resume icon will allow the user to continue where the set left off. During a test where a patient is feeling uncomfortable, the user can select the Abort icon to finish the set rather than resuming it.

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



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



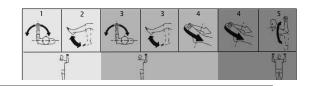
the dynamometer or the hand-held remote button causes immediate cessation of dynamometer shaft rotation.

The 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 fastener cuff.

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.

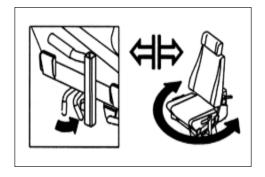
Positioning Chair



Figure 2.2. 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. Seat Back Tilt Handle
- 7. Seat Back Fore/Aft Handle
- 8. Stabilization Handles

Seat Rotation



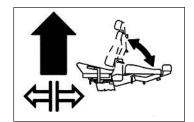
The positioning chair offers 360 degrees of rotation in the horizontal plane with détente settings at 15-degree intervals.

- 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.

Seat Back Tilt: This adjustment allows the user to select any of five seat back angle settings: 85, 70, 55, 40 and 25 degrees. To adjust the seat back tilt, pull up on one of the Seat Back Tilt Handles, located on either side of the lower seat back frame. Adjust the seat back to the desired angle. Release the handle and ensure that



it locks into the selected detente. Record the new seat back tilt angle from the Seat Back Tilt Indicator, located at the bottom on either side of the seat back frame.



CAUTION: Use caution when adjusting the chair position with the patient in the chair. 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.

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

Seat Back Fore/Aft: Crank the Seat Back Fore/Aft Handle, located at the back of the seat base, in a counterclockwise direction to move the seat back forward on the seat. Crank the handle in a clockwise direction to move the seat back toward the rear of the seat. Record the new fore/aft position from the Seat Back 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 Seat Back 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 test, exercise, and rehabilitation sessions. 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.

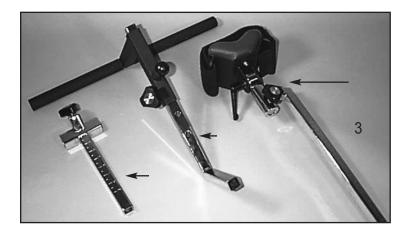


Figure 2.3. Positioning Chair Attachments:

- 1. T-Bar Adapter
- 2. Footrest
- 3. Limb-Support Pad

Seat Back Brace

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

- 1. Ensure the seat back 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 Seat Back Brace with the clevis on the seat back and insert the clevis pin.
- 3. Release the Seat Back Handle and lower the seat back to "10" on the seat back tilt scale.



Figure 2.4. Attaching the Seat Back Brace to the System 4 Seat Back Clevis.

- 4. Loosen the Seat Back 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 Seat Back 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.



Figure 2.5. Attaching the Seatback Brace to the System 4 Trolley Mount Clevis.

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

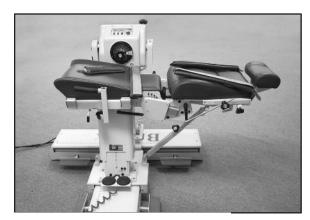


Figure 2.6. Seat Backbrace Installed and Ready for Use.

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 (I).

NOTE: At the end of each day, leave both the Green Dynamometer and Power switches ON. Then turn OFF the Main Power Switch. This will help prevent possible damage during storms, or electrical surges.

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.

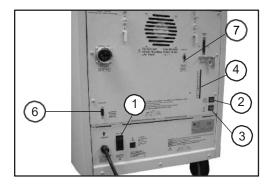
Computer Power Switch: Controls power to the computer and peripherals (including printer and monitor). In the ON position, power to computer, monitor and printer are ON. In the OFF position, power to the computer, monitor and printer are OFF.

NOTE: Be sure to properly exit and close 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.



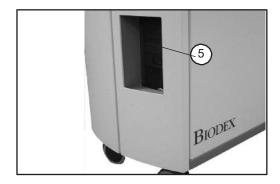


Figure 2.8. Rear Panel

Figure 2.9. Front Panel

Figures 2.8 and 2.9. The System 4 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 (LEDs)
- 5. CPU ON/OFF Switch
- 6. Remote Access for Analog Signals
- 7. Auxiliary RS 232 for RTK Interface

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 green dynamometer and computer power switches are set to the ON (I) position. They will be illuminated when ON.
- 3. Turn on the computer. Whenever the computer is shut down it must be turned on manually.
- 4. 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.
- 5. 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 System 4 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 at 1-631-924-9000 and Press 3 for Service.

Dynamometer Attachments



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.





CAUTION: Ensure finger guard is in place when using the knee and hip attachments. Placing hands or fingers between the dynamometer input shaft (or attachment) and the mechanical ROM stops may result in serious injury.

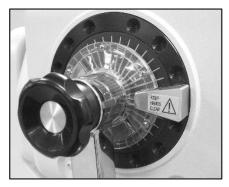


Figure 2.7. Finger Guard Positioned Correctly on Dynamometer for Knee and Hip Attachments.

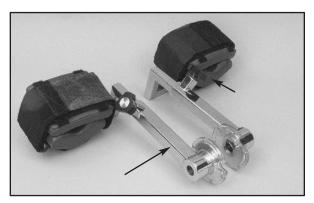


Figure 2.8. Knee Attachments (Left and Right)

Patterns: Knee: Extension/Flexion



Figure 2.9. Hip Attachments (Left and Right)

Patterns: Hip: Extension/Flexion, Abduction/Adduction

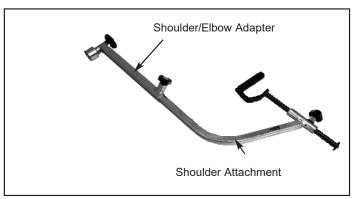


Figure 2.10. Shoulder Attachment (Insert in Shoulder/Elbow Adapter)

Patterns:

Shoulder: Extension/Flexion, Abduction/Adduction Diagonals

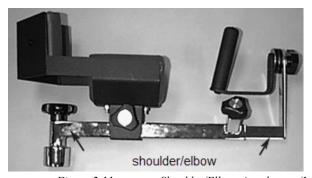


Figure 2.11. Shoulder/Elbow Attachment (Insert in Shoulder/Elbow Adapter)

Patterns:

Shoulder: Internal/External Rotation

Elbow: Extension/Flexion (remove cuff),

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

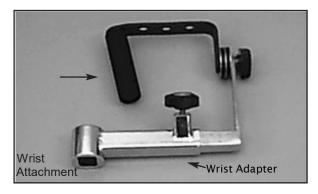


Figure 2.12. Wrist Attachment

Patterns:

Wrist: Extension/Flexion

Radial/Ulnar Deviation

Forearm: Pronation/Supination

Using the Combination Ankle Attachment

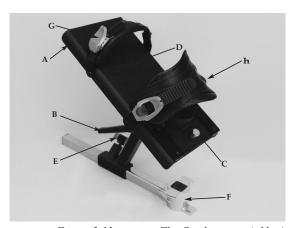
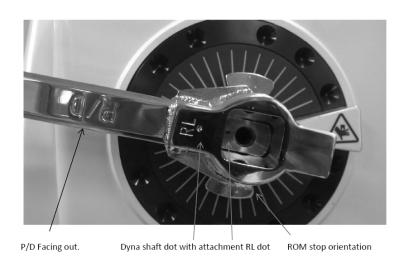
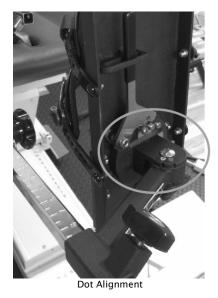


Figure 2.13. The Combination Ankle Attachment Adjustment Mechanisms.

- 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, 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 example below is for Plantar/Dorsiflexion.





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 activity 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.

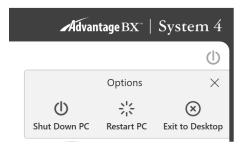
Heel Cup Position: To facilitate alignment of the subject's axis of rotation with the dynamometer shaft, it may be necessary to raise or lower the patient's foot on the footplate by adjusting the heel cup position. The Heel Cup Release Buttons are located on the top side of the footplate at the heel 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.

Shutting Down the System at the End of the Day

At the end of the day:

1. Close the Advantage BX Software application by selecting the Power icon at the top right corner of the screen. The following choices display: Shut Down PC, Restart, PC, and Exit to Desktop.



- 2. Choose the "Shut Down PC" option. It will close the application and shut down the PC. **NOTE:** Failure to shut down the system properly may result in lost or damaged files.
- 3. Leave both green Dynamometer and Power switches on.
- 4. Turn off the Main Power switch.

Regional Settings

Adjust the Regional Settings before using the software:

- 1. On the Home screen, select Utilities.
- 2. Select System Settings and enter the default code "159".
- 3. Select Regional Settings.
- 4. Choose your preferred Units (Metric or US units).
- 5. Change the other properties of the System (PC) according to your region (Language, Time Zone, Date and Time, Format). Once a language is chosen, the application will display text in that language.



The 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 System 4 offers several modes of operation.

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 (30° total carry-over) with a limited range of motion strengthening program performed isokinetically (Halbach, 1985.)
- 4. Select 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 <Set Limb Weight> 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 attachment. 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 mode, the Torques are set, 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 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.
- 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 activity modes on the System 4.
- 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 System 4 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 once 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 practice 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.

Set Up and Positioning Videos

Instructional videos on setting up and positioning for the System 4 can be viewed at any time on your phone, computer, or other devices. These videos will be updated continuously so you will not need to wait for a software upgrade to see the latest videos:



3. Software Operation

Advantage BX Software Update Instructions

To update to the latest version of the Advantage BX software:

1. Navigate to the Biodex Software Updates page:



https://www.biodex.com/physical-medicine/products/software-updates

2. Save the BiodexAdvantage_Rev5x.bioupdate file to a flash drive.

NOTE: If necessary, open the flash drive folder and drag and drop the file into the flash drive.

NOTE: Ensure the file is named exactly as shown here. If numbers in parentheses have been added, rename the file name to: BiodexAdvantage_Rev5x.bioupdate before starting the update.

- 3. Open your current version of the Advantage BX software to the Home screen.
- 4. Insert the flash drive into one of the USB ports on the Biodex System 4 computer.
- 5. The running Advantage BX software will automatically detect the update.
- 6. A Software Update pop-up appears. Click the OK icon. Then click the Update button to start the update process.
- 7. Once update is done, Remove the Flash drive.
- 8. Click the Finish button. The computer will restart.
- 9. The Advantage BX software will automatically start after a minute with the updated version.



IMPORTANT NOTE: Even though it is not part of the updater operation, you should still perform regular database backups (preferably on external media, if your facility allows it). In the event of any type of corruption, you will still be able to retrieve data up until a certain date.

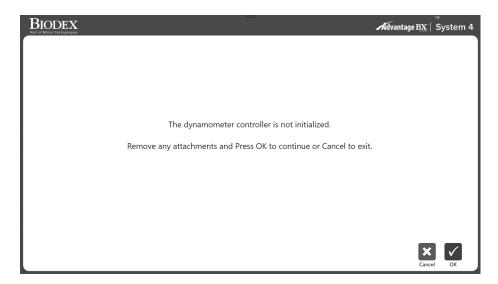
Getting Started

- 1. Turn on the dynamometer, computer, and touch-screen monitor.

 NOTE: Ensure the dynamometer is free of attachments, otherwise an error will display.
- 2. After the boot, it will launch the application software automatically (you can also double tap the Biodex System 4 shortcut). The screen below displays.



NOTE: The screen below will only display when the dynamometer is freshly powered on.



3. Select the OK icon to initialize or the Cancel icon to skip.

NOTE: Skipping initialization will cause the system to be disconnected from the hardware. Sessions cannot be performed. However, the application can browse offline to access patient records, if needed.

NOTE: The data in this Instructions for Use (IFU) manual may not represent real-world situations and the screens may not show the most current version of the software.

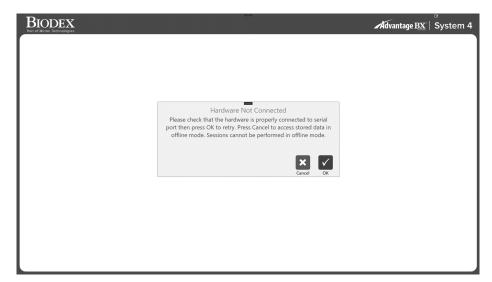
Home Screen



From the S4 Home screen, you can:

- Start a Protocol Based Activity
- Set up a Training session
- Access reporting capabilities
- · Access Utilities options
- Turn off the system using the power icon

NOTE: If the application software cannot connect to the hardware, then it will display the below message. This could be due to the serial cable not being properly connected or the COM port not being defined correctly. Check the connection and then click the OK icon to retry the connectivity.



Connection Status

On the bottom of the Home screen, the "COM" information on the left identifies the COM port that is talking to the hardware. The "Failed" or "Initialized" indicates the state the dynamometer is in.

Introduction: New Software

You may be familiar with using Advantage Software 4.X on the System 4. The following are some tips for how to use the new software, and the differences between the Biodex Advantage BX 5.X and Advantage 4.X Software.

Tips for Using Biodex Advantage BX™ Software

- 1. The screens progress based on the selection (not menu-driven). The program is designed so you can stay at a high level and enter basic information or enter more specific patient information for developing specific patient type goals.
- 2. Activity-based, not based on test or exercise.
 - a) Activity = Test or exercise using a protocol
 - b) **Training** = Biofeedback (not protocol-based)
- 3. Set-up videos are available via YouTube: https://www.biodex.com/videos/mjs-setup
- 4. Patient name is not required at the beginning; you will be asked again for the patient name before a test can be saved.
- 5. When you have started an Activity, and want to create a new protocol, press



- 6. New Activity Quick Start provides a list of Frequent Activities that builds as the system is used. Activities can be "pinned" so they appear at the top of the list for quick selection.
- 7. Look for the "Settings" button on screens, where relevant options that pertain to that screen can be selected. Example: On the ROM Set-up screen, settings provides the choice to always display the opportunity to weigh the limb for gravity correction. Note that even if weigh limb is presented, it does not have to be completed. The report screen settings allow you to select windowed or filtered data.
- 8. Practice reps: There is a setting to provide a choice of practice reps. When a button displays for practice reps, if selected (4) practice reps will be provided. If no practice rep button, then as many reps as the patient wants to complete are allowed, until no movement is detected, and the limb is in the start position.
- 9. Start position for all modes is always in towards position. When no movement is detected for (3 seconds) the activity can begin. If movement is detected, countdown starts again.
- 10. Curve Analysis: Allows curves to be overlayed for multiple activities at a time for comparison.

- 11. If a **Bilateral Activity (test)** is selected via repeating an activity, and only the involved side is desired, use the **skip button** to skip the uninvolved side.
- 12. Reports: Report by date or Report by patient

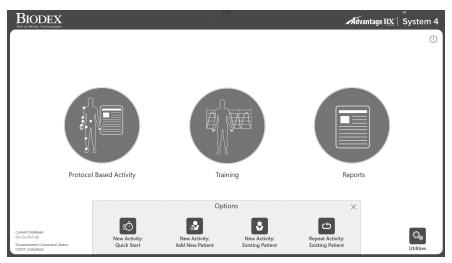
Note: Make a selection to Select a report type.

- a) Report by Date: Bottom Left Report by Patient: Top right
- 13. **Utilities** provide access to patient management and application settings.

Default Access code = 159

- a) Patient Management Add, delete, or edit patient information.
- b) **Protocol Management** This is where protocols can be created, edited or deleted. Specific patient activities can be viewed and managed.
- c) Application Settings
 - i. General preferences Sounds, weigh limb option, scoring window, torque in and torque out.
 - ii. Training settings Rest time, cushion setting, isometric contract/relax settings.
 - iii. Dynamometer settings Isokinetic, isometric, etc. threshold settings.
 - iv. **Analog Signal Settings** Where Torque, Position, and Velocity outputs are scaled. No longer requires a separate software program.
- d) System Settings Display, Regional, Security, Facility.
- e) Data Management
 - i. Database back-up and restore
 - ii. Exporting capabilities
- f) Goal Management
- g) Verify Calibration

Protocol Based Activity

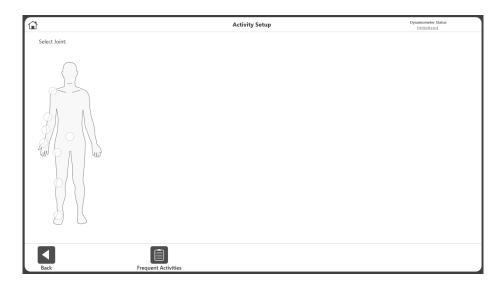


Click the Protocol Based Activity icon and four options will appear: New Activity: Quick Start, New Activity: Add New Patient, New Activity: Existing Patient, and Repeat Activity: Existing Patient.

New Activity: Quick Start

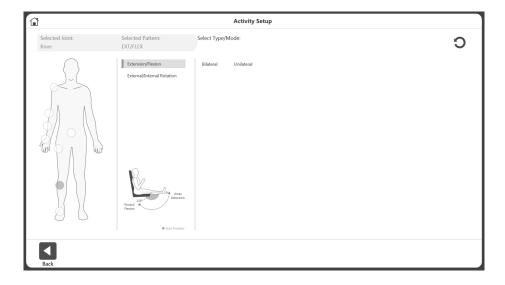
To start an activity without having to enter patient information at the beginning, select the New Activity: Quick Start option. At the end during the Save option, patient information will be required.

1. Select New Activity: Quick Start. The Activity Setup screen displays.

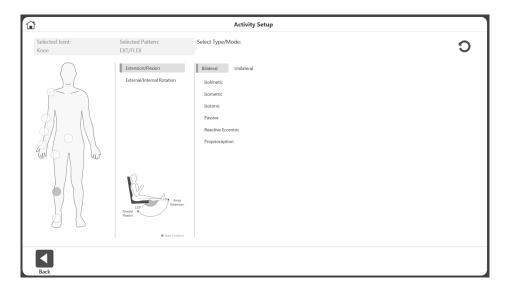


- 2. Select a joint: Shoulder, Elbow, Forearm, Wrist, Back, Hip, Knee, or Ankle.

 NOTE: To view your list of Frequent Activities, select the Frequent Activities icon. Within the Frequent Activities list you can remove an activity using the trash icon or pin it using the pin icon, which will move it to the top of the list.
- 3. Select Seated or Standing (if applicable/depending on Joint selection). Select a pattern.



- 4. Select a Type: Bilateral or Unilateral.
- 5. Select the Mode: Isokinetic, Isometric, Isotonic, Passive, Reactive Eccentric.



6. The list of available protocols will display (both built-in and custom) including built-in protocols for the ACLR-RTP tests and report. Select a protocol from the list.

NOTE: If no protocol is available, a protocol can be added by clicking the **the button** (see image below).

NOTE: The application supports closed chain and work simulation activities (see image below).

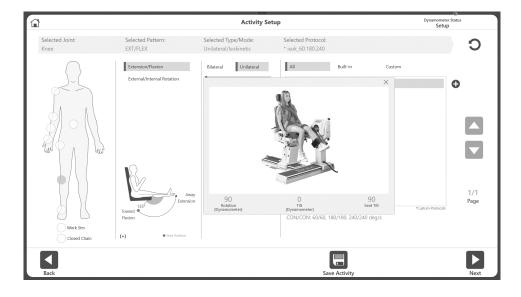


NOTE: At the top right, the Dynamometer Status will display as Setup, Idle (before an activity begins), or Acquiring Data.



NOTE: When a protocol is selected it displays information under "Details". Click the [+] to view more information about that protocol.

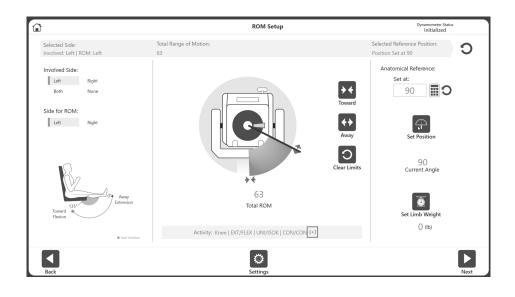
Also, for any selected Joint/pattern, if application has more info regarding the patient position/ Dyna/ Chair setup information, a [+] sign will appear right below the pattern picture. When clicked on that [+] sign, it will display the picture with additional setup information (see below).



NOTE: To add/pin the activity to the Frequent Activity list, select the Save Activity icon.

7. Select the Next icon. The ROM (Range of Motion) Setup screen displays.

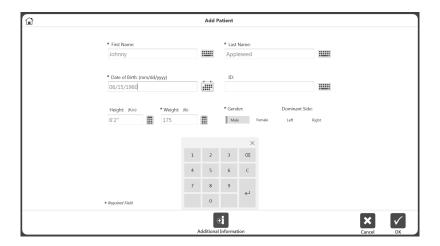
NOTE: Please see the Defining the ROM section for the next set of instructions.



New Activity: Add New Patient

If a patient does not exist in the system yet, the information can be added quickly using the New Activity: Add New Patient option.

1. Select the New Activity: Add New Patient icon. The Add Patient screen displays.



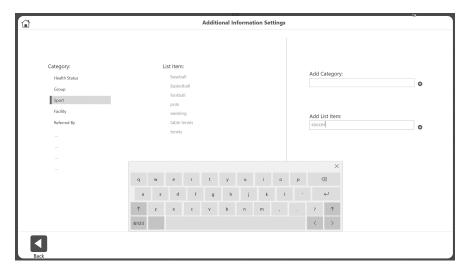
- 2. Enter information into the required fields: First Name, Last Name, Date of Birth, Weight, and Gender.
- 3. Select the OK icon to continue. Select the Cancel icon to cancel the action.

 NOTE: Click the Additional Information icon if you would like to add information the default categories: Health Status, Group, Facility, Alternate ID, Sport, or Referred By. The Additional Information screen will display.



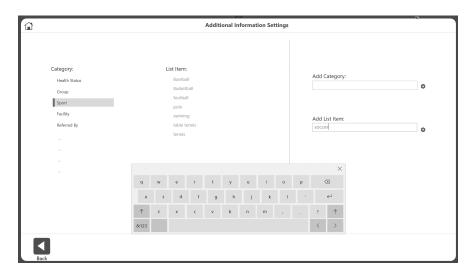
4. The Activity Setup screen displays. Follow the directions in the New Activity: Quick Start section above.

The Additional Information icon can be used to create goals based on activities (optional). For example, while adding a patient to the software, you can specify that the patient is a member of a certain sports team (you may be collecting information about a group of participants). When the data are exported, they can be grouped together to calculate normative data for that group or to generate goals.



To add new categories to Additional Information:

- 1. Click the Settings button on the Add Patient > Additional Information screen. Five built-in categories will display.
- 2. Enter the name of the new category in the Add Category field.
- 3. Click the 🔂 button. The new category will appear on the Category list.



To add an item to a category:

- 1. Select the category.
- 2. Enter the item into the Add List Item field.
- 3. Click the button.

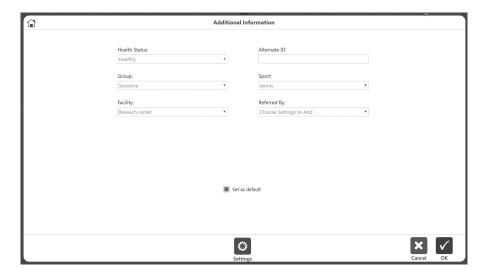
To add additional information for a patient:

- 1. Select values as needed for Health Status, Group, Facility, Alternate ID, Sport, and Referred By.
 - **NOTE:** Categories can be added as described in the previous section.
- 2. Click the OK icon. This information will be recorded and set as the default for that patient.



This information will be recorded as default for that patient. The next time that patient visits, any activity performed will be recorded under that category. It can also be overridden when saving the activity.

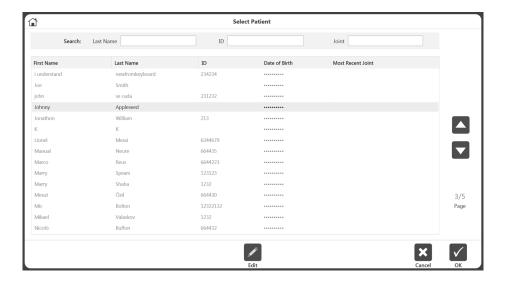
For example, if a patient's group was recorded as "Baseball" under Additional Information, that person becomes part of a research group and his data will be collected under "Baseball". If he returns for a rehab session while playing Tennis, we may want to keep that person in the Baseball group. To record the current session as "Tennis", use the Code/Comments screen at the end of the activity.



New Activity: Existing Patient

Once a patient already exists, select that patient from the list:

- 1. Select the New Activity: Existing Patient icon. The Select Patient screen displays.
- 2. Select an existing patient from the list. Use the up and down arrows to look through the list, if necessary.



3. Select the OK icon.

NOTE: The Edit icon may be used to change information for this patient. Edit information and select the OK icon when finished.

4. Follow the directions in the New Activity: Quick Start section.

Repeat Activity: Existing Patient

When you want to repeat a protocol with an existing patient, select the activity to repeat, rather than re-entering the same protocol information:

- 1. Select the Repeat Activity: Existing Patient icon.
- 2. Select an existing patient and select the OK icon. The ROM Setup screen displays for the last activity that user performed.
- 3. Follow the instructions in the Defining the ROM section.

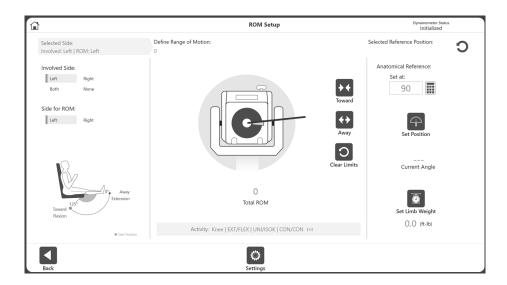
NOTE: On the Activity Setup screen, the hardware connection status will be displayed on the top right corner. The hardware needs to be connected in order to perform an activity.

NOTE: On Activity Setup screen, selecting the Save Activity icon will add the activity to the Frequent Activity list.

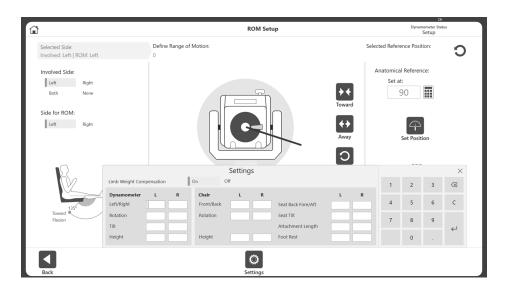
NOTE: After doing a Bilateral test for a baseline, the clinician may only be interested in studying the involved side of the subject for the next sessions. In this case, select and repeat the same Bilateral test that was performed for the baseline test. On the ROM setup screen, select the Involved side. Perform the activity on involved side. When prompted for the next side, use the Skip button and save the results. This ensures the same activity was repeated and can be displayed on the progress report.

Defining ROM

- 1. On the ROM (Range of Motion) Setup screen, select the Involved Side.
- 2. Select the Side for ROM.

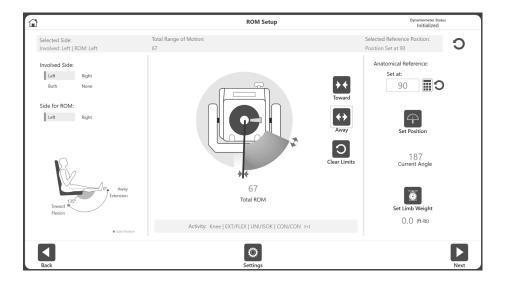


NOTE: The default Set Limb Weight option is ON.



NOTE: When enabled in the Application Settings, the user will be able to add chair settings information during ROM Setup. It will also display the limb weight option. Chair settings will display different options for recording the activity. This is helpful when a user wants to repeat an activity using the same settings as the previous activity. Enter whole or fractional numbers and click the x button when finished.

3. Position the dynamometer attachment to the Towards position and select the Toward icon to record the position. Arrows will display at the selected Toward limit.



4. Position the dynamometer attachment to the Away position and select the Away button to record the position. Arrows will display at the Away limit and the ROM will be shaded in. To start over, select the Clear Limits icon.

NOTE: It is recommended to set the Toward limit first, and then the Away limit. If the order is reversed, you will still be able to select the Set Position icon and progress to an activity.

NOTE: You can either set the ROM limits and then set the position, or you can set the position first (current angle) and then set the ROM limits according to the current angle.

NOTE: The Settings icon offers selections relevant to that particular screen.

5. Select the Set Position icon.

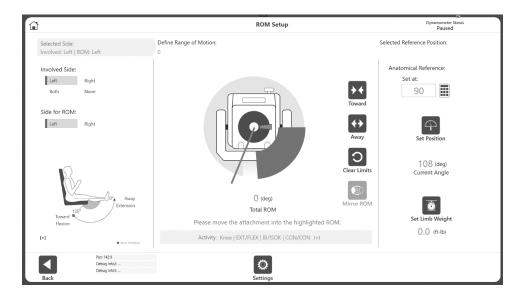
NOTE: The Anatomical Reference refers to the starting position of the joint and will change based on the joint selected. This value can also be edited if needed.

6. Select the Next icon to begin your activity.

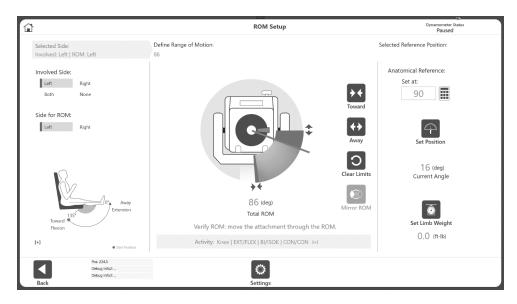
For Bilateral activities:

For Bilateral activities, during setting up the ROM for second side, application will display an additional button, Mirror ROM, which allow user to set a mirrored ROM for the second side. This is an optional feature. If user wants, they can use it or they can define their own ROM for the second side using Towards and Away button.

When Mirror ROM button is clicked, first it will clear any existing defined ROM and then it will paint a ROM which is mirrored to the previous side ROM. User then will have to verify the ROM by moving the attachment through the ROM.



If the attachment is outside the painted ROM, then another message will be displayed to tell user to bring it inside the painted ROM. Once ROM is verified then, application will inform the user and user can proceed to next step.



NOTE: Once Mirror ROM button is used, the button itself will be grayed out. If mirrored ROM does not work for desired usage, you can always create your own ROM.

Also, if the current position is not correct for the mirrored ROM, user can set the position using the Set Position button on that screen.

Protocol Based Activity Screen

Once the ROM has been defined and the Next icon is clicked, the Protocol Based Activity screen displays. Depending on the settings chosen for Practice (from Utilities on the Home Screen), either a Practice Trial button will appear, or a mandatory Practice Trial will be included at the beginning of the activity before each set.

1. Click the Start icon when ready to begin your activity. Complete the practice trial reps if they are included, then hold the attachment at the maximum Towards limit until the "3, 2, 1...GO!" pop-up message is displayed to begin the activity.



NOTE: Data collection does not start until after "GO!"

NOTE: The "3, 2, 1...GO!" pop-up message displays for all modes except Isometric.

- 2. The patient makes a series of Toward and Away motions as instructed by the clinician.
- 3. The Torque, Position, and Velocity will display in different colors on the graph. The Peak Torque, Total Work, and % CV will all be recorded on the left. Values will also display in Current Position and Total ROM. Protocol Progress will display on the right.



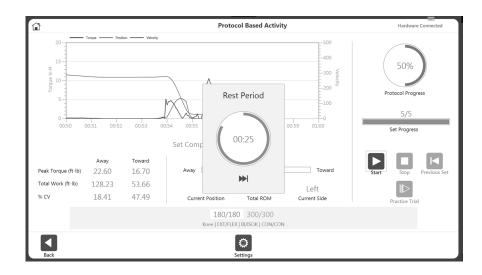
- 4. Once the activity has started:
 - a. The lines on graph will be displayed.
 - b. Metric of Peak Tq, Total Work and %CV will be displayed on the bottom of the graph.
 - c. Applied Torque displays the direction of the dyna shaft movement.
 - d. Set progress shows the progress in terms of number of reps, whereas the Protocol progress displays the overall progress of the protocol.
 - e. At the bottom, it highlights the current set and End By options (Reps, Time, Work) will be displayed on top of the progress bar for that selected set.



NOTE: Touch the graph where you want to display a target line/goal line/Scoring Window.

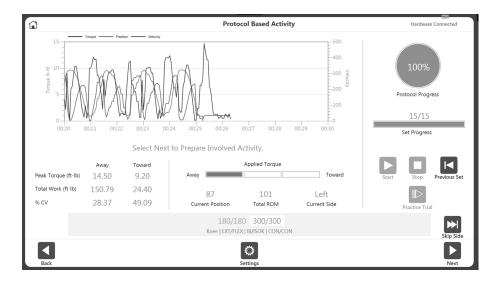
NOTE: If the patient becomes uncomfortable, click the Stop icon to stop the set.

5. Once a set is complete, it will display the Rest Period countdown (as defined in each protocol). After the count down, it will automatically start the next set (configurable from application settings option). The Rest Period can be stopped by clicking the Skip icon on the Rest Period pop-up.



NOTE: The current set will be highlighted in white with blue text. Once a set has been completed, it will turn to green text.

NOTE: When the Previous Set icon is clicked, a message will display asking whether you want to overwrite the previous set. You can either proceed or cancel the action.



6. Continue the activity on the opposite side or select the Skip Side icon to finish the activity. For a Unilateral activity, the Skip Side option will not be available.

NOTE: The Settings icon can be used to change the way the activity is being displayed on graph. For example, selecting Position under X Axis Options will change the graph from Torque vs. Time to Torque vs. Position. The application will remember and use the same settings for the next activities until the settings are changed again.



NOTE: Once you have begun an activity, the Start icon can be selected again and becomes a Pause icon. This allows you to pause at any time. Select the Pause icon and it will again become a Start icon, resuming your session.

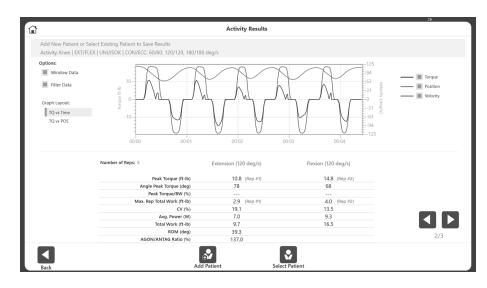
NOTE: Once a set is complete it will be displayed in green at the bottom and the next set will be highlighted. If the set needs to be repeated, click the Previous Set button. A warning will display letting you know what activity data will be overwritten.



NOTE: If the patient is unable to complete a set, select the Stop icon. This will cancel that particular set and will record as DNC (did not complete). The cancelled set will be displayed in red at the bottom. Click Start to begin the next set.

NOTE: The scaling for the X and Y axis is the same. Enough room has been left at the top of the graph to account for the fact that our Away motion (such as kicking out) is stronger than our Towards motion.

7. Once all necessary sets have been completed, the Results icon on the bottom right will become available. Select the Results icon; the Activity Results screen displays.



NOTE: The Activity Results screen offers a Single Activity export option. Further information can be found in the Exporting section.

Different graph options:

Application allow user to use different graph formats. User can choose either of the following graph format. This graph settings are appliable for both Protocol Based Activities and Training Activities. Graph options can be accessed via Settings button on those screens.

1) Torque vs Time – It represent Torque over time, shows the trend. Default, it will display the last 10 seconds and Y-axis will scale dynamically based on applied torque. X-and Y-axis are configurable through the Settings option. Graph lines will display Torque, Velocity and Position. These graph lines are also configurable and will remember user's last setting for next session. Target lines can be set by clicking on the graph area during an activity session.



2) Torque vs Position – displays the torque in split view graph, one for Towards and other one is for Away direction. It will display the Current rep, Previous rep, Peak Torque and Best work repetitions. Y-axis will dynamically adjust based on peak torque in either direction. These graph lines are also configurable and will remember user's last setting for next session. Target lines can be set by clicking on the graph area during an activity session.



3) Bar graph- displays a bar for each repetition. It will display up-to 40 bars at a time on screen. Advantage of bar graph, it shows the peaks of each rep and user can see the trend of peaks with each reps. Typically bar/reps will go from right to left for Continuous and/or End by Time modes. For End by Reps option only, it will have an additional option, under Settings, where user can choose to see Left to Right or Right to Left rep ordering (up to 40 reps). If user has more than 40 reps (even though they have chosen the option as End by Reps), application will auto switch to Right to left and show only the last 40 reps on screen.



NOTE: Bar graph option is not available for reports/ results screen. It is only available during activity.

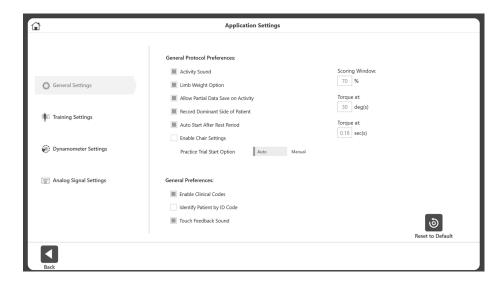
Practice Reps with Activity

There are two ways to perform practice reps with Activity: Including practice reps before each set or performing practice reps as needed.

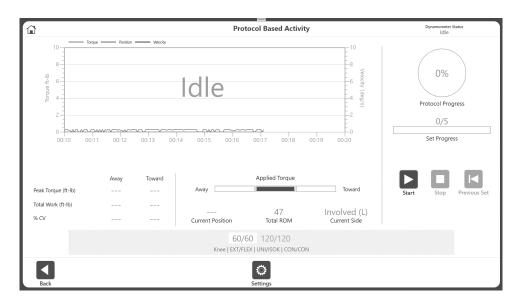
Option A: Include Practice Reps before Each Set (Default Setting)

- 1. Navigate to Utilities>Application Settings>General Settings.

 NOTE: You may be asked for your Access Code after selecting Application Settings.
- 2. The Practice Trial Start "Auto" option should be selected, making a practice trial *mandatory* before each activity.

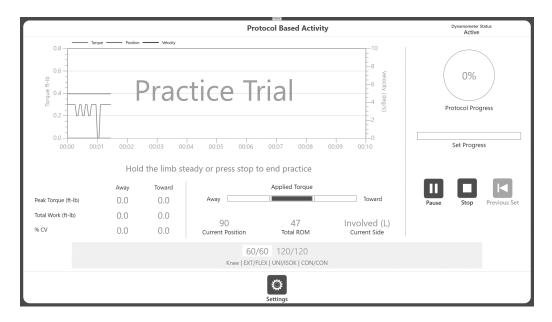


- 3. Navigate to the Home screen and select Protocol Based Activity.
- 4. Select a protocol and set your ROM. **NOTE:** The Practice Trial icon will not be available because practice reps are now mandatory.

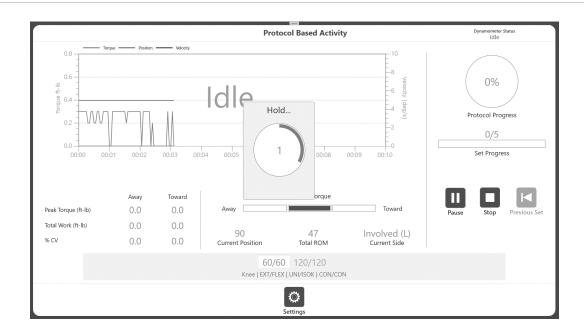


5. Select the Start icon to begin the Practice Trial. The "Practice Trial" text will appear on screen indicating that it is a practice session.

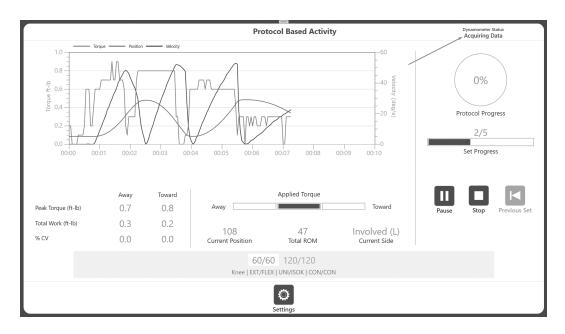
NOTE: There are an unlimited amount of practice reps. Practice Trials will have the same properties (speed, torque, etc.) as the activity. Practice Trial results are not recorded.



- 6. To start the actual Activity Session, click the Stop icon. Alternatively, you can let go of the attachment, letting it fall back to the Start position. When no movement is detected from the shaft, the Activity Session will begin. If the attachment is not at the Towards position, a "Hold limb at Toward position to start activity" message appears otherwise it will begin activity session.
- 7. If the attachment is in Towards position, then immediately a "Hold" pop-up message counts down, "3, 2, 1...GO!" will appear.



8. Start the activity only after "GO" word appears on that pop-up. If the movement started before the "GO" message, the dynamometer will be in idle mode which will not start the activity. It will display "Idle" instead of "Acquiring data" which indicates the session was not started.



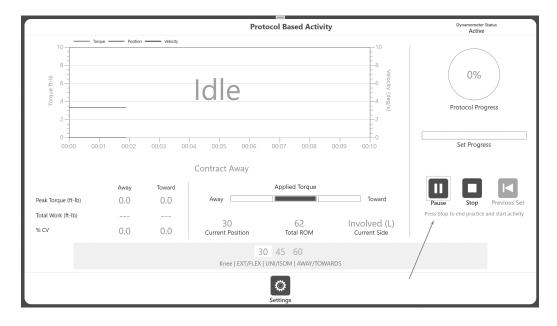
- 9. Complete the Activity Session (as shown in the Protocol Based Activity section) and an "Activity Complete" message appears.
- 10. Select the Results icon and then the Save icon from the Activity Results screen if you want to save the results of your Activity Session. Or return to the Home screen.

Practice Reps in Isometric Mode

- 1. Click the Start icon for a Practice session. The message "Arm will move to position, press Start again" displays.
- 2. Click the Start icon. It will display "Arm in position, press Start to begin test".



- 3. Click the Start icon and the Practice Trial begins. The Stop icon will be available.
- 4. Clicking the Stop icon will allow you to exit the Practice Trial. And it will immediately start the session for activity.



5. Based on the protocol it will display a message "Start Contract Away" or Towards. Apply torque to start the activity in isometric mode.



- 6. Complete the Activity Session (as shown in the Protocol Based Activity section) and an "Activity Complete" message will display.
- 7. Select the Results icon and then the Save icon from the Activity Result screen if you want to save the results of your Activity Session. Or return to the Home screen.

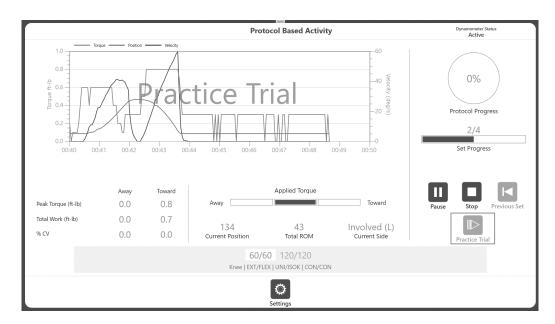
NOTE: There are no Practice Trials available in Passive Mode.

Option B: Perform Practice Reps as Needed

- 1. Navigate to Utilities > Application Settings > General Settings.

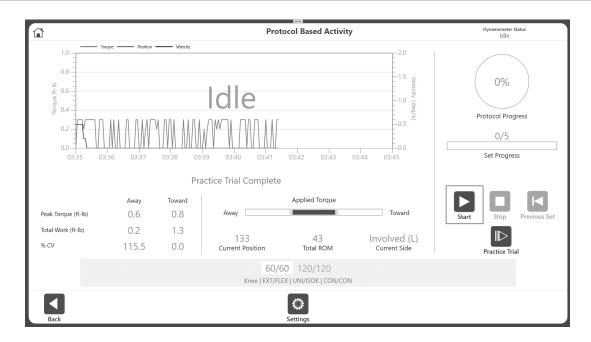
 NOTE: You may be asked for your Access Code after selecting Application Settings.
- 2. Ensure that "Manual" is selected for Practice Trial Start Option.
- 3. Navigate to the Home screen and select Protocol Based Activity.
- 4. Select a protocol and set your ROM.
- 5. Click the Start or Practice Trial icon.

 NOTE: Clicking Start forfeits your Practice Trial.

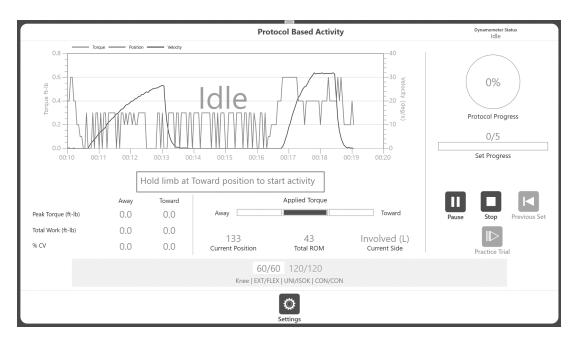


NOTE: The practice reps can be ended by clicking the Stop icon. There will be a maximum of four practice reps. Practice Trials will have the same properties (speed, torque, etc.) as the activity. Practice Trial results are not recorded.

6. Once practice trial is completed (or stopped), click on the Start button to start the activity. At this moment, the state of the dynamometer will be "Idle", and it will be displayed on screen as "Idle".

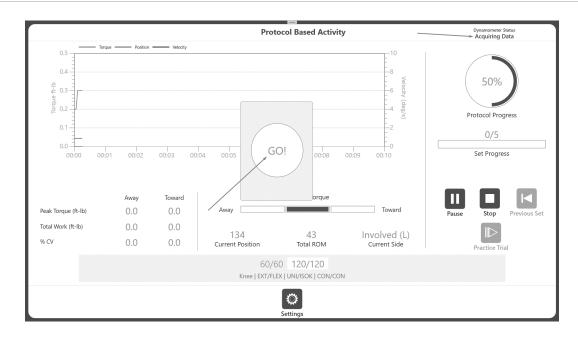


7. If the attachment is not at the Towards position, a "Hold limb at Toward position to start activity" message appears (see image below).



8. If the attachment is in Towards position, then immediately a "Hold" pop-up message counts down, "3, 2, 1...GO!" will appear.

NOTE: Start the activity only <u>after</u> "GO" word appears on that pop-up. If the movement started before the "GO" message, the dynamometer will be in idle mode which is will not start the activity and it will display "Idle" instead of "Acquiring data" which indicates session was not started.



9. Complete your Activity Session (as shown in the Protocol Based Activity section). If you wish to save the results, click on Results button to go to the next Screen (Activity Results) and then click the Save icon.

NOTE: Using the Practice Trial button as needed, all modes (except Passive which does not have practice trial), will operate as described above.

Activity Results

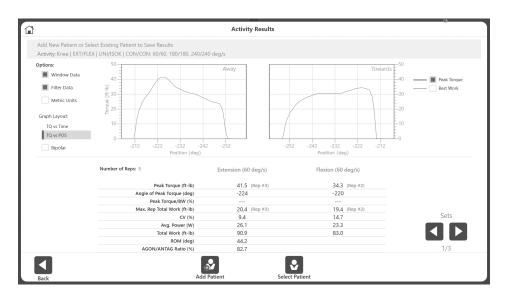


IMPORTANT NOTE: If the "Test Completion Screen Time Out" setting is chosen (Utilities>System Configuration> Display Settings), after the set amount of time expires on the Activity Results screen, you will be returned to the Main Menu in 30 seconds whether or not the results have been saved. The Save icon must be clicked in order for your work to be saved.

NOTE: The sample data shown in this section is for reference only and does not represent real-life data.

(Continuing from previous section - performing activity).

1. View your Activity Results



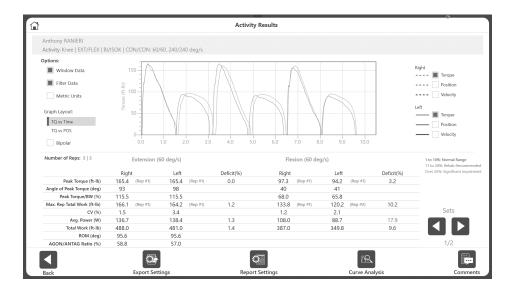
- 2. Add a new patient or select an existing patient from the bottom section of the screen. Once the Patient information is available, the Save icon will become visible. Also, Peak TQ/BW values will be dashed until there is a patient associated with the activity.
- 3. Select the Save icon if you wish to save the results. Once the result is saved, additional options will be available.

NOTE: Data are not saved until the Save icon is clicked.

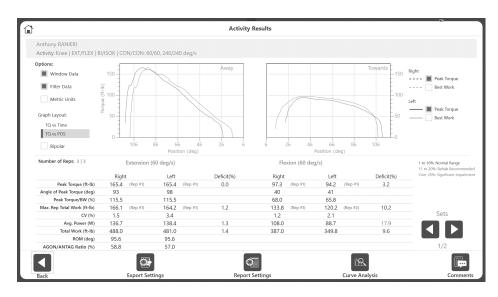
Activity results can also be viewed on previously saved activity results as well. To access Activity Results screen go to Utilities > Patient Management > Select a patient > Select a Stored Activity then click on Results button. In this case, above three steps are not needed.

4. The Activity Results screen allows you to change the settings of the results. Options like Window Data (for ISOK only), apply Filter, change the view of the graph to Position based or Time based graph, selection of Best Work, Peak Torque (for Position based graph), selection of Torque, Velocity and Position (for Time based graph) can be used. The

graph(s) and metrics on the results screen will reflect the changes made. Use the left and right arrow buttons to view information between different sets.

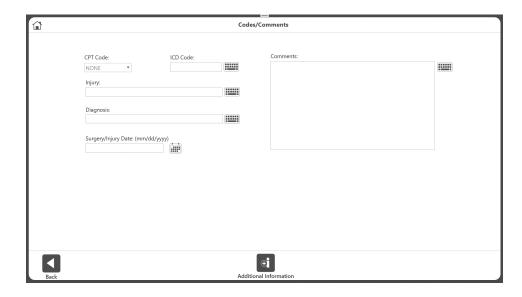


5. Data is saved in raw format. Post-processing on the data with these settings is applied on an ad-hoc basis for viewing purposes, and does not alter originally saved data.



NOTE: If graph area does not display any lines, make sure the line options on the right side of the screen has at least one option selected. Graph lines are remembered for each type of graphs for next sessions.

6. Use the Comments icon to add comments to the results, if needed. Comments will be saved with the result and report will display those comments.



NOTE: Reports will include a surgery/injury date if available.

To add a surgery/injury date:

- a) Click Utilities on the Home screen.
- b) Go to Patient Management and enter the access code (default code is 159).
- c) The Activity Results screen displays.
- d) Select a patient and an activity.
- e) Click the Results icon.
- f) Click the Comments icon.

Export Settings and Report Settings:

Export settings allow to export the viewed results in .txt format. User will be able to control whether to export all metrics of the result including data points or just export the Data points by turning ON the "Only Data Points" option. It also allows to change the default file name of the exporting file. File format is described later in "Data Exported Format" segment.



Report settings allow to select different type of reports applicable to the currently viewing result. User can apply post processing filters from the Activity Results screen for printed report. Additional options specific to reports will also be available under report settings. Actual report can be printed by clicking on the Report button on the Report Settings option.





IMPORTANT NOTE: Just a reminder to perform regular database backups (preferably on external media, if your facility allows it). In the event of any type of corruption, you will still be able to retrieve data up until a certain date.

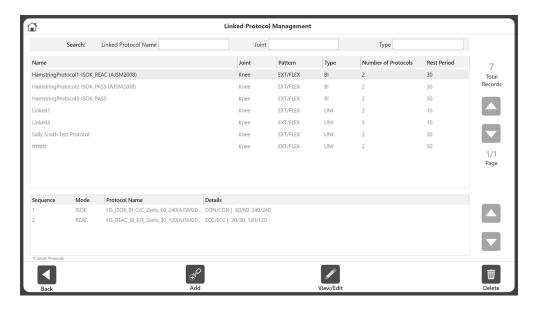
Linked Protocols

Linking protocols saves the clinician several steps when rehab sessions are to be conducted using different protocols. It also provides more time for the patient to spend exercising since less time is spent on software setup. A patient could, for example, be set up for ten minutes of passive motion, followed in succession by bouts of isometric and isokinetic exercise. Once linked protocols are established and the patient is appropriately set up, the rehabilitation session can proceed from beginning to end seamlessly.

There are three factory-set linked protocols in the software, all for hamstrings (see image below). Use the following instructions to create your own linked protocols.

Creating Linked Protocols

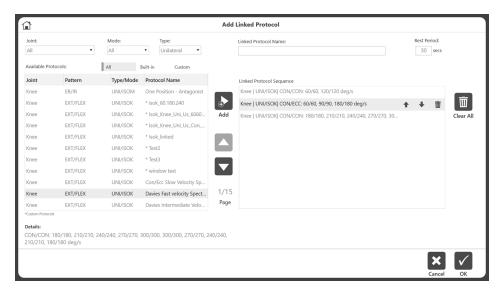
- 1. Click the Utilities icon on the Home screen.
- 2. Click the Protocol Management button.
- 3. Click the Linked Protocol Management button.
- 4. Click the Add button.



NOTE: Up to 10 protocols can be linked for each linked protocol.

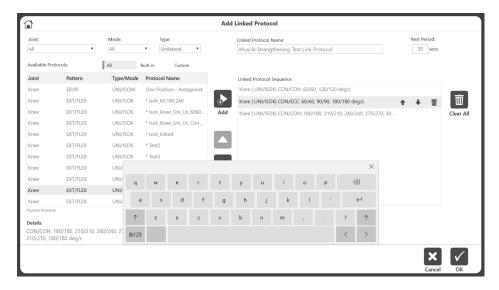
- 5. Filter results by using the Joint, Mode and Type fields, if needed.
- 6. Select a protocol from the left side and click the Add button.

7. Repeat selecting a protocol and clicking the Add button until all the protocols you want linked are shown in the Linked Protocol Sequence pane on the right side.



NOTE: A pop-up message will display if you try to link protocols that have different joints or patterns. Similarly, linked protocols must match as either unilateral or bilateral.

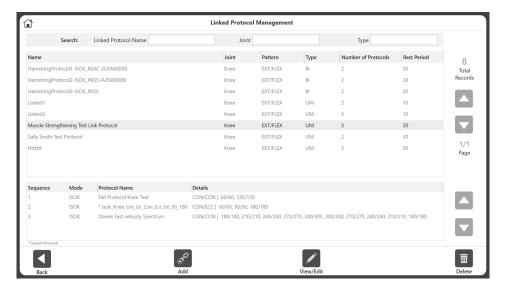
8. Name the Linked Protocol by typing into the Name field at the top of the screen.



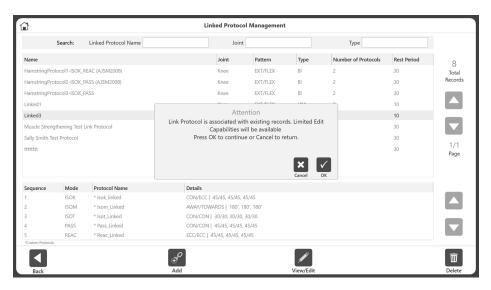
NOTE: Change the order of the protocols by using the up and down arrows.

NOTE: The Clear All button will remove all selections.

9. Click the Okay button. The new linked protocol will display on the Linked Protocol Management screen.



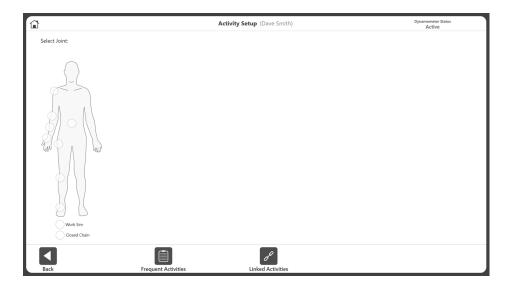
NOTE: Certain linked protocols may have limited editing capabilities when they are already associated with existing records.



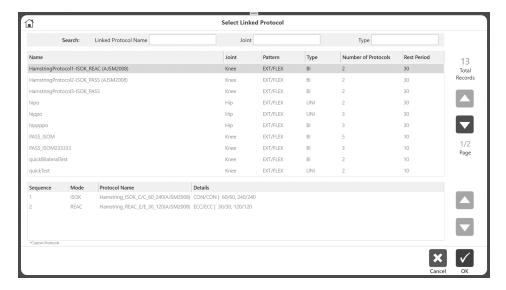
Running a Linked Protocol

- 1. Click the Protocol Based Activity icon on the Home screen.
- 2. Select any of the following to:
 - New Activity: Add New Patient
 - New Activity: Existing Patient
 - Repeat Activity: Existing Patient
- 3. For example, if you chose New Activity: Existing Patient, select a Patient.

 NOTE: Linked Activity Icon will not appear if New Activity: Quick Start option is selected.



4. Click the Linked Activities button. Select the Linked Protocol from the available linked protocol list.



5. Set up the ROM (see the Defining ROM section for further instructions).

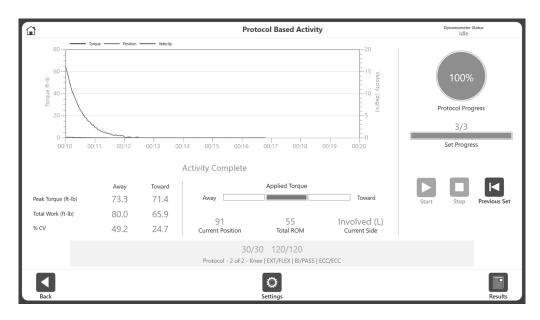
- 6. On Protocol Based Activity screen, click the Start button to start the linked activity session. All the linked protocols will be displayed in gray at the bottom of the screen in the order they will be performed.
- 7. Once a protocol finishes, the application will display the rest countdown between protocols that is defined during linked protocol creation. Once the rest period is over, the application will start the next protocol. You will have the option to cancel by selecting the Skip icon on the pop-up.

At this stage, you will also have option to change the ROM for the next protocol.

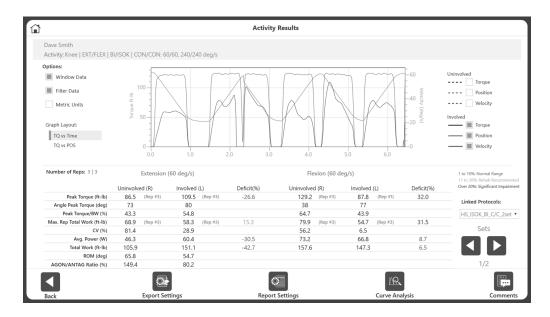
NOTE: After each protocol, the application will automatically save the activity results. A message will also display confirming that the results were saved.

For a Bilateral linked activity, all the protocols on one side should be finished first, then change sides, and perform the same protocols on the other side. This requires only one physical side change to perform a Bilateral activity.

8. Complete the activity and click the Results button.



 The Activity Results Screen displays. On the screen, user can use Left and Right arrow button to navigate between the sets of that protocol. To see the sets of other linked protocols, use the Linked Protocols drop-down menu to select other linked protocol results.



Export Settings and Report Settings:

For linked activities only, an additional option exists under Export and Report Settings: All Linked Activities. If this is ON, then for Export, it will export all linked the activities in .txt format on the given location. Similarly, for report, if this is selected, then it will combine all the linked activities and display it as a single report.

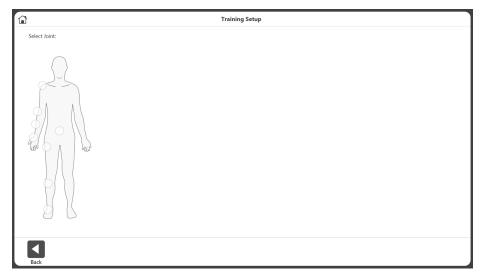


IMPORTANT NOTE: Just a reminder to perform regular database backups on external media (if your facility allows it). In the event of any type of corruption, you will still be able to retrieve data up until a certain date.

Training Setup

To start a new Training session:

1. Click the Training icon. The Training Setup screen displays.



NOTE: Use the Home icon at the top of the screen at any time to return to the Home screen.

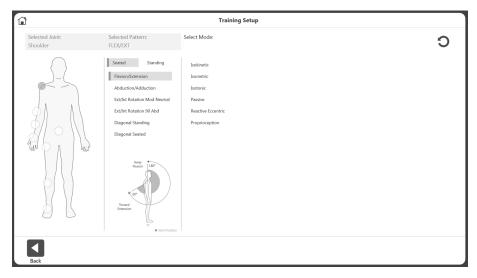
NOTE: Select the Back button to return to the previous screen.

2. Select a joint: Shoulder, Elbow, Forearm, Wrist, Back, Hip, Knee, or Ankle.

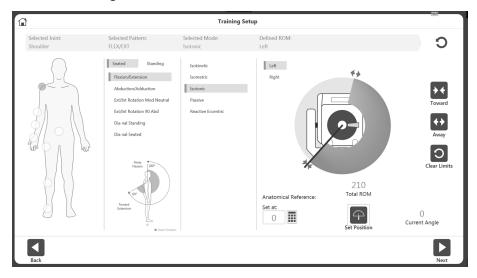


3. Select Seated or Standing (if applicable). Select a pattern.

4. Select a mode.



5. Select a side: Left, Right, or None.



- 6. Position the dynamometer attachment to the Toward position and select the Toward button to record the position. Arrows will display at the selected Toward limit.
- 7. Position the dynamometer attachment to the Away position and select the Away button to record the position. Arrows will display at the Away limit and the ROM will be shaded in.

NOTE: To start over, select the Clear Limits icon.

NOTE: It is recommended to set the Toward limit first, and then the Away limit. If the order is reversed, you will still be able to select the Set Position icon and progress to an activity.

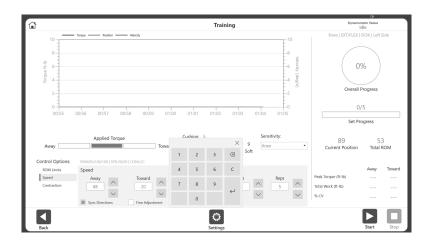
8. Select the Set Position icon.

NOTE: The Anatomical Reference refers to the starting position of the joint and will change based on the joint selected.

9. Select the Next icon to begin your activity.

Training

- 1. The Training screen will display:
 - a. A Graph option in the middle.
 - b. The top right portion will display the overall progress and Set progress.
 - c. The Peak Torque, Total Work, %CV are displayed on the bottom right.
 - d. Start, Stop and Settings button.



e. The current speed, torque, and ROM will be displayed throughout the activity (see image below).

NOTE: Speed, Torque, and %ROM Limits can be adjusted after a session has started.

NOTE: It is recommended to start with a smaller %ROM and increase it during a session. The %ROM can be made smaller or larger during a session, but no larger than the maximum ROM in the initial ROM setup.



NOTE: Under the Set Progress bar, the set number for multiple sets can be displayed.

NOTE: Use the up and down arrow buttons or type directly into the Away and Toward fields to change the values for speed and torque in the Speed and Torque option boxes. When Fine Adjustment is checked, clicking on the up/down button will increase/decrease the speed/torque value by 1. You can also enter information directly into the End by Options section in addition using to the up and down buttons.

NOTE: The settings icon gives additional options during a Training session, including Graph Display, Grid, X-Axis Options, and Y-Axis Options.



2. Choose Control Options from the Training screen before starting a session.



3. Control options can be changed during the session (after starting the session) but the End by Option is not allowed.

NOTE: Enabling the End by Option allows the clinician to specify how the session terminates, such as the number of sets and the number of repetitions for each set. End by Options can be directly entered using the keypad.

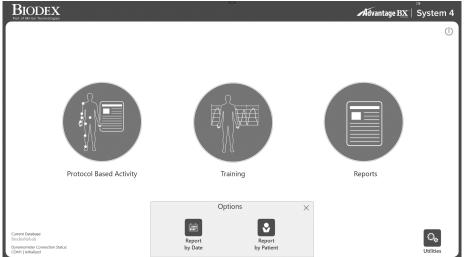
NOTE: The number of Control Options depends on the Mode you have selected. For example, Passive mode has four Control Options, and Isometric mode has two Control Options.

- 4. Once you have begun an activity, the Start icon can be selected again and becomes a Pause icon. This allows you to pause at any time. Select the Pause icon and it will again become a Start icon, resuming your session.
- 5. The Settings icon can be used to change the way the activity is being displayed on graph.

Reports

To access reports:

1. Select the Reports icon. Two options are displayed.

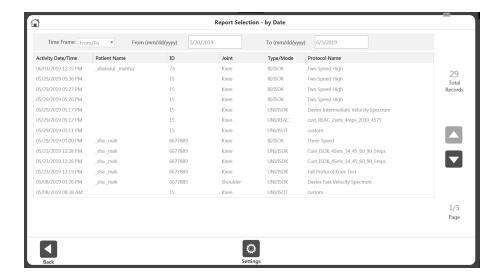


2. Select the Report by Date or the Report by Patient icon.

Report by Date

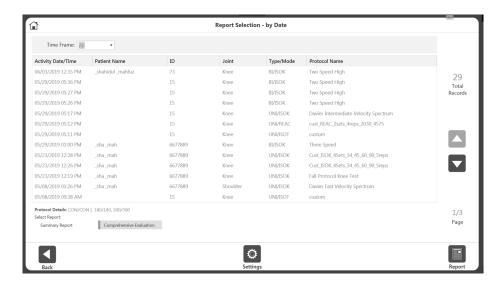
The Report by Date screen displays the list of activities within the date range defined. This option allows access to individual reports, not progress reports.

1. Select the Report by Date icon. The Report Selection - by Date screen displays.

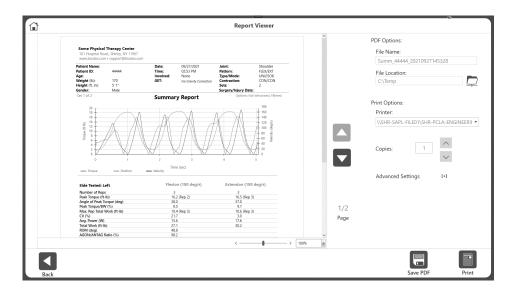


- 2. Select an activity, or, if you need to narrow the results further, first choose from the options in the Time Frame drop-down menu:
 - All See all recorded activities.
 - From All activities after a date.
 - Prior to All activities prior to a date.
 - From/To Enter a date range.

- 3. Select an activity.
- 4. Select a report type on the bottom left: Summary Report or Comprehensive Report. The Report icon on the bottom right will become visible.



5. Select the Report icon. The Report Viewer screen displays.



6. Select the Print icon to print the report, the Save PDF icon to save the report as a PDF, or the Back icon to go to the previous screen.

NOTE: Save PDF button will be grayed out until output file name & location are not given. Advanced Settings option can be used for further printer specific settings.

NOTE: If graph area does not display any lines, make sure at least one line options is selected under the Settings button. Graph lines are remembered for each type of graphs for next sessions.

Report Settings:

Once a Report Type is selected, the Settings icon will display. Select the Settings icon to change Report Settings as needed. Any settings applied to the report will not change original data. The settings are applied to display post-processed data. This settings option can be used for both "Report By Patient" and "Report By Date". These settings will remain in the application's memory for the next session.

Depending on the activity selected, the following options will display:

Windows Data - Default is ON. When ON, it will window the data. Only available for Isokinetic activities. Any data point below the Isokinetic Window Threshold will be truncated.

Filter Data - Default is ON. When ON, it will apply a filter to the data.

Torque vs Position - Default is OFF. If ON it will display the Torque vs Position graph. When OFF, the Torque vs Time graph displays.

Print as Unilateral - Default is OFF. This is available only for the Bilateral activities. When ON, it will display the Bilateral report as Unilateral report.

Metric Units - Default is OFF. This option will be displayed for a US-configured system. This allows you to change the System unit on the fly from US to Metric units.

When ON, it will display reports in metric units. When the report is closed, the system will return to its original system units.

US Units - Default is OFF. This option will be displayed for a Metric-configured system. It will give the option for displaying "US units" and can be used to change the report to US units on the fly. When the report is closed, the system will return to its original system units.

All Linked Activities - Only available for activities that were performed as Linked Activities. All Linked Activities allow you to create a combined report with all Linked activities.

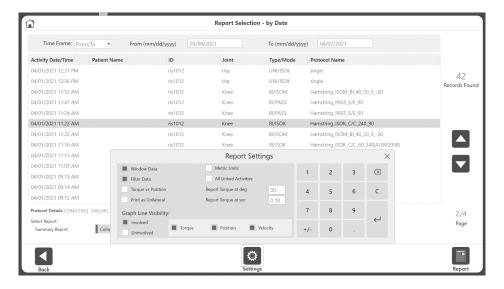
Graph Line Visibility - By default, you have the option to select a graph line for the Torque vs Time graph. You can turn the Torque, Position, and Velocity graph lines ON or OFF for the report. When the Torque vs Position option is ON, the graph line option changes to Peak Torque and Best Work.

NOTE: If the selected activity is a Bilateral, then you can choose the Involved and Uninvolved side, if involved/uninvolved was selected during activity. Or it will display Left/Right side option.

Report Torque at deg - Only available for the Comprehensive Report type. The report will display the Torque at the angle you entered (default is 30).

Report Torque at sec - Only available for the Comprehensive Report type. The report will display the Torque at the second you entered (default is 0.18). However, you will be allowed to enter one digit after the decimal.

Bipolar- Allows to display the graph in Bipolar or non-Bipolar.

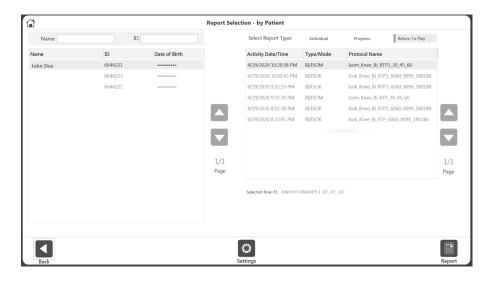


Report by Patient

Use the Report by Patient option to access a report for an individual patient.

- 1. Select the Report by Patient icon. The Report Selection by Patient screen displays.
- 2. Select a patient.

NOTE: You may also search by typing the patient's name into the Name field or the patient's ID into the ID field.



3. Select a Report Type: Individual, Progress, or Return to Play (see the Return to Play section), or Hamstring Mixed Ratio.

Individual Report

- 4. Select an activity from the list.
- 5. Select Summary Report or Comprehensive Report or Multi Angle Report (for Bilateral Isometric only). The Report icon will display.
- 6. Select the Report icon. The report will load and the Report Viewer screen will display.
- 7. Select the Print icon to print the report or the Save PDF icon to save the report. **NOTE:** The Back and Home icons can be utilized at any time.

Progress Report

4. Select two activities from the list.

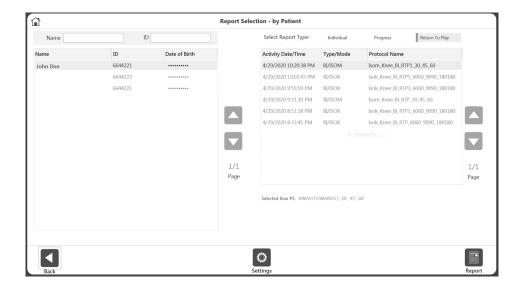
NOTE: After one activity has been selected, the rest of the results will automatically filter to show activities that can be grouped with the selected activity.

NOTE: To deselect a row, click it again.

NOTE: The activities must each have a different date. The Type/Mode, Speed, and details of the two selected activities must be matching. If any of these conditions are not met, an error message will display explaining that the report is not available.



- 5. Choose Left or Right side for a Bilateral progress report. For Unilateral, this option is not required.
- 6. Select the Report icon. The report will load and the Report Viewer screen will display.
- 7. Select the Print icon to print the report or the Save PDF icon to save the report.



8. Continue to follow the prompts. If Left or Right was chosen as the involved side during the ROM setup, you will select either Involved or Uninvolved. If None/both was chosen during ROM setup, select Left or Right.

NOTE: You may select the Settings icon to change the Report Settings. Any settings applied to the report will not change the original data. The settings change the way the post-processed data is displayed.

Report Formulas

The Bilateral Report shows a deficit on one side of the body, where U = the uninvolved side and I = the involved side.

Deficit = $\{(U-I/U) \times 100$

The Progress Report compares two dates, where T = test.

% Change = {(T2-T1)/T1} x 100

et 1 of 2	Pr	ogress Re	port	Options: Not Windowed, Not Filtered		
	Extension (60 deg/s)			Flexion (6	Flexion (60 deg/s)	
	5/23/2019		Difference (%)	5/23/2019	5/23/2019	Differenc
Number of Reps	5	5		5	5	
Peak Torque (ft-lb)	1.1 (Rep 4)	.9 (Rep 5)	18.2	1.2 (Rep 1)	1.0 (Rep 1)	16.7
Avg. Peak Torque (ft-lb)	1.0	.5		1.0	.6	
Angle of Peak Torque	102.0	68.0		104.0	67.0	
Peak Torque/BW (%)	.8	.7		.9	.8	
Time to Peak Torque (msec)	1300.0	20.0		110.0	420.0	
Torque at 30 (deg)	.0	.0	0.0	.0	.0	0.0
Torque at 0.18 (sec)	.0	.0	0.0	.0	.0	0.0
CV (%)	.0	.0		14.6	.0	
Max. Rep Total Work (ft-lb)	(Rep 1)	(Rep 4)	0.6	(Rep 1)	(Rep 4)	42.9
Work/BW (%)	.1	.1		.2	.1	
Total Work (ft-lb)	.7	.4	36.7	.9	.3	62.2
Work First Third (ft-lb)	.3	.1		.4	.1	
Work Last Third (ft-lb)	.2	.3		.2	.2	
Work Fatigue (%)	43.8	-188.6		60.6	-160.3	
Avg. Power(W)	.1	.0	60.2	.2	.1	25.1

Return to Play

The Anterior Cruciate Ligament Reconstruction Return to Play (ACLR-RTP) report is intended to provide an easy-to-understand status of muscle strength with respect to the reconstructed knee and its un-injured counterpart knee, as well as a comparison to age and gender-based goals. Biodex Isokinetic strength test scores are considered essential objective criteria along with functional, agility, and psychological readiness testing in the return to play decision. The Biodex Isometric test report and Isometric testing is typically used in the early phases of ACL rehabilitation. It obtains muscle strength status while protecting the graft. The selected report criteria, goals and protocols are based on current literature and have been reviewed by a consensus of experienced orthopedic sports medicine clinicians. 1:2:3:4:5

Protocols

There is one isometric default protocol with a test angle of 60 degrees. Several Isokinetic test protocols are based on Isokinetic test speed preference. You can also create a protocol of your choice with up to three (3) Isokinetic speeds or three (3) Isometric test angles. A protocol can be marked as Return to Play (RTP) and can be used for Knee, Isokinetic/Isometric, and Bilateral, can have up to 3 sets and will have a corresponding RTP report.

¹ Kyritsis P, Bahr R, et al. Likelihood of ACL graft rupture: not meeting six discharge criteria before return to sport is associated with four times greater risk of rupture. Br J Sports Med: 50:946-951 Published 2016 May 23. doi:10.1136/bjsports-2015-095908

² Grindem H, Snyder-Mackler L, et al. Simple decision rules can reduce reinjury by 84% after ACL reconstruction: The Delaware-Oslo ACL Cohort Study. Br. J Sports Med. Published 2016 May 9:50 804-808. doi 10.1136/bjsports-2106-096031

³ Webster K.E., Feller J.A, Development and Validation of a Short Version of the Anterior Cruciate Ligament Return to Sport after Injury (ACL-RSI) Scale. The Orthopedic Journal of Sports Medicine, 6(4), 2325967118763763 doi: 10.1177/2325967118763763

⁴ Anderson M.A., et al, The Relationship among Isometric, isotonic and isokinetic Concentric and Eccentric Quadriceps and Hamstring Force and Three Components of Athletic Performance. JOSPT 14:3, 114-120. Published 1991

⁵ Struzik A. et al, Ratios of torques of antagonist muscle groups in female soccer players. Acta of Bioengineering and Biomechanics 20:1. Published 2018 doi: 0.5277/ABB-0094-2017-02

Goal Management

Goals are provided for the each of the built-in test protocols. Goals are speed, age and gender based. For symmetry, the goal is independent of speed, gender or age. It is simply comparing one leg to the other.

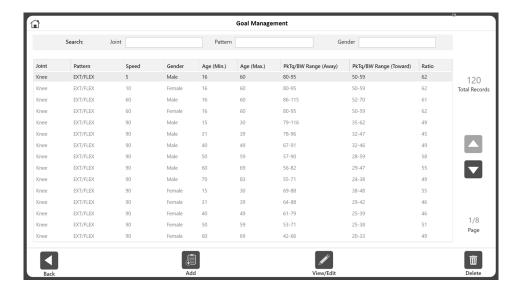
Symmetry formula = Involved/Uninvolved \times 100

NOTE: The goals for the RTP report are specific to the protocols as described on the following page.

Test Results

Symmetry: If the goal of each leg's Average Peak Torque or Total Work is achieved $\geq 90\%$ a Green will be noted by the result. If symmetry is below the goal, a red \times will be noted. The other Isokinetic strength measurements are compared to protocol, gender and age specific goals. If the goal is met, the value will be in green. If the goal is not met, the value will be in red.

NOTE: Average Peak Torque was chosen because it removes the "got lucky on one rep". Since symmetry is a comparison of one side to another with a goal of $\geq 90\%$ symmetry, Avg. PT provides a more homogenous result that is more representative to present within or outside of the $\geq 90\%$ goal range.



To access Goal Management:

- 1. On the Home screen, click Utilities.
- 2. Click Goal Management. A list of goals will display in two categories: General and RTP. **NOTE:** It will default to displaying the General goals. To view the RTP Goals, click the RTP option.

From the Goal Management screen you can:

- Add a custom goal.
- Edit custom goals or view built-in goal data.
- Narrow down the goals using the Search function or up and down arrows. Clicking on the column heading will also sort the list.

NOTE: These goals will be used on the Summary report and/or RTP report.

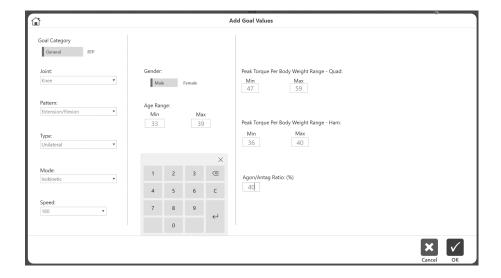
Add/Edit Goals

Custom goals can be added for both the General and RTP categories. Only custom goals can be edited.

General Goals

To enter goals for Isokinetic protocols:

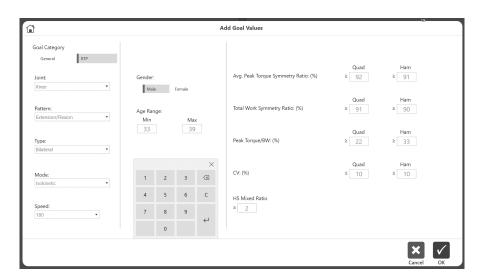
- 1. Select all applicable values for joint, pattern, speed, gender, age range, etc.
- 2. Click the OK icon to save the goals.



RTP Goals

To enter goals for RTP protocols:

- 1. Select Knee for the Joint value.
- 2. Select either Isokinetic or Isometric for the Mode value.
- 3. Select values for pattern, speed, gender, and age range.
- 4. Click the OK icon to save the goals.



NOTE: For further information, visit the System 4 Clinical Resources page:

https://www.biodex.com/physicalmedicine/products/dynamometers/system-4-pro/clinical-resource-manual



ACLR-RTP Isometric and Isokinetic Report Protocols and Goals

Isometric

Built-in Protocols

Angle: 60 degrees

Direction: Away and Towards Contraction time: 10 seconds

Relaxation Time: 10 seconds

Reps: (3)

Goals

Quadriceps:

Avg PT ftlb: Symmetry ratio \geq 90%

PT/BW % Quads:

Age 15-25 Male 100% Female 90% decrease

10% per decade* **Hamstrings:**

Avg PT ftlb: Symmetry ratio > 90%

PT BW % Hamstrings

Age 15-25 Male 70% Female 60% decrease

10% per decade.*

H/Q Ratio: Male and Female $\geq 60\%$

Isokinetic

Built-in Protocols

#1	speed: 6	0	180
	reps	5	20
	rest (sec)	60

#2 speed 60 300 reps 5 15 rest (sec) 60

#3 speed: 60 180 240 reps: 5 5 15 rest (sec) 30 30

#4 speed: 60 180 300 reps: 5 5 20 rest (sec) 30 30

#5 speed: 180 240 reps 5 15 rest (sec) 30

#6 speed 180 300 reps 5 15 rest (sec) 30

Goals

Symmetry Ratio: All speeds Male and

Female, all ages

Quadriceps: Avg PT & TW (ftlb) \geq 90% Hamstrings: Avg PT & TW (ftlb) \geq 90%

COV: All speeds Male and Female, all ages

Quadriceps: $\leq 12-15\%$ Hamstrings: $\leq 12-15\%$

Quadriceps

PT/BW % (15-25 years) decrease 10% per

decade beyond 25 yrs*

60 deg/sec: male 100% female: 90% 180 deg/sec: male 60-75% female 50-65% 240 deg/sec: male 50-65% female 40-55% 300 deg/sec: make 40-55% female 30-45%

Hamstrings

PT/BW % (15-25 years) decrease 10% per

decade beyond 25 yrs*

60 deg/sec: male 70% female 60%

180 deg/sec: male 40-55% female 35-50% 240 deg/sec: male 35-50% female 30-45% 300 deg/sec: male 30-45% female 25-35%

H/Q ratio

60 deg/sec: ≥ 60% 180 deg/sec: ≥ 70-75% 240 deg/sec: ≥ 70-75% 300 deg/sec: ≥ 75-80%

^{*} Bottom end goal is > 10% minimum.

RTP Goal Management

The application has a predefined set of RTP goals. Custom goals can be created as necessary.

To access Goal Management:

- 1. Click Utilities on the Home screen.
- 2. Click Goal Management.



NOTE: The goals, previously known as "normative data", can be found under the General Goal category.

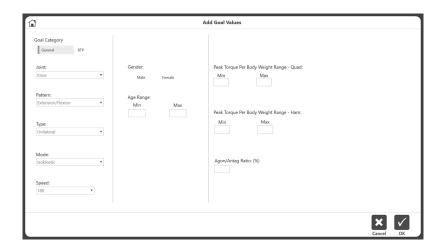


- 3. Click the Add icon to add General or RTP Goals.
- 4. Click the View/Edit icon to edit General or RTP Goals.

Add/Edit Goals

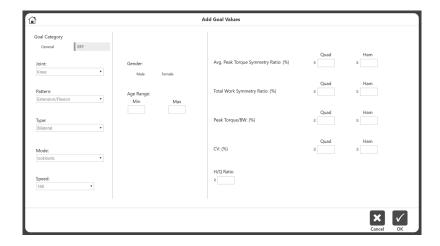
To enter information for the General Goal category (Isokinetic goals):

- 1. Enter information into the applicable fields.
- 2. Click the OK icon to save.



To enter information for RTP Goals:

- 1. Enter information into the applicable fields.
- 2. Click the OK icon to save.



NOTE: RTP goals are only for the Knee joint and can be Isokinetic or Isometric.

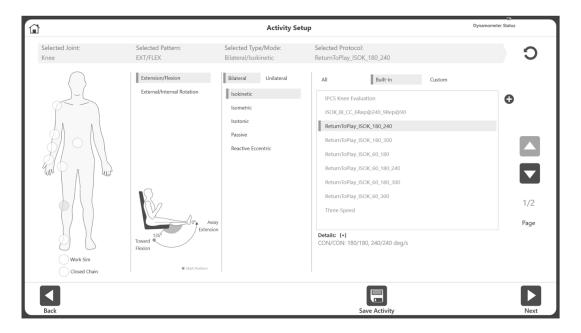
Return to Play Test

This section discusses the three ways to complete a Return to Play Test.

NOTE: The first method is recommended because it utilizes the built-in RTP Protocols, which come with goals.

To complete a Return to Play Test using one of the built-in RTP Protocols:

- 1. Click Protocol Based Activity on the Home screen.
- 2. Select from the Activity Options one of the four (4) choices:
 New Activity: Quick Start, New Activity: Add New Patient,
 New Activity: Existing Patient, or Repeat Activity: Existing Patient.
- 3. Select Knee for the Joint.
- 4. Select Extension/Flexion, Bilateral, and Isokinetic or Isometric.
- 5. All of the built-in RTP protocols will display (select one).



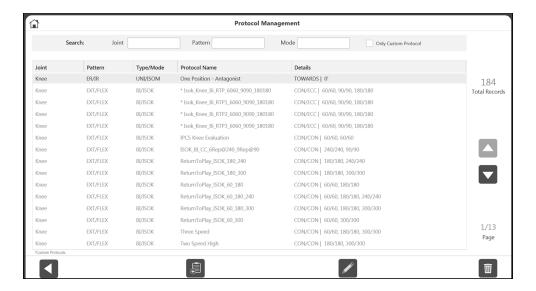
- 6. Click the Next icon.
- 7. Set the ROM.

NOTE: Always start with the Uninvolved side.

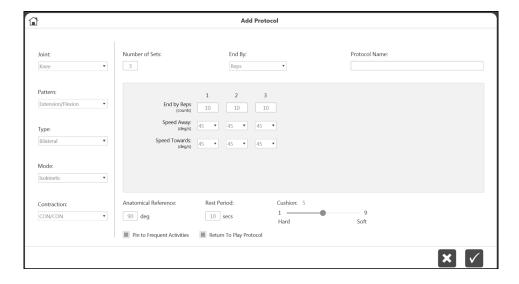
- 8. Perform the test.
- 9. Select the Next icon and prepare the activity by switching to the knee attachment for the opposite knee.
- 10. Set the ROM.
- 11. Perform the test.
- 12. Select the Results icon to view the test results.
- 13. Select Return to Play under Select Report.
- 14. Click the Report icon. The RTP Report will display.

If you prefer to create your own RTP Protocol rather than using one of the built-in RTP Protocols:

- 1. On the Home screen, select Utilities.
- 2. Select Protocol Management.



- 3. Select the Add icon (must be Knee, Bilateral, and either Isokinetic or Isometric).
- 4. Enter a name in the Protocol Name field.



- 5. Adjust the speed if necessary, using the Speed Away and Speed Towards drop-down menus.
- 6. Make sure the Return to Play Protocol box is selected (green).
- 7. Select the OK icon to continue performing the test.

NOTE: Selecting a RTP Protocol already in the system will ensure that you are provided with goals/normative data.

NOTE: A RTP Protocol can also be created by using the (+) icon on the Activity Setup screen.

NOTE: The application looks for available custom protocols when displaying goals on the report. When custom protocols are not available, built-in goals will be used. If the application has both custom and built-in protocols for the same joint/pattern/gender, it will pick the one with the tighter age range.

To create your own RTP Protocol with a new patient:

- 1. Click Protocol Based Activity on the Home screen.
- 2. Select New Activity: New Patient.
- 3. Enter all necessary New Patient information and click the Next icon.
- 4. Select Knee for the Joint.
- 5. Select Extension/Flexion, Bilateral, and Isokinetic or Isometric.
- 6. All built-in RTP protocols will display (select one).



- 7. Click the Next icon.
- 8. Set the ROM.

NOTE: Always start with the Uninvolved side.

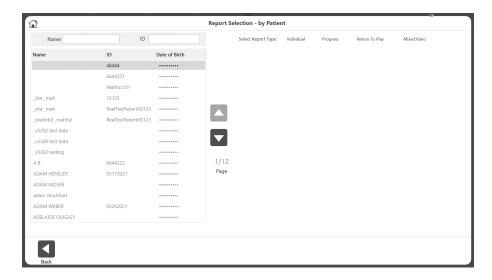
- 9. Perform the test.
- 10. Select the Next icon and prepare the activity for the next knee by switching to the knee attachment for the opposite knee.
- 11. Set the ROM.
- 12. Perform the test.
- 13. Select the Results icon to view the test results.
- 14. Select Return to Play under Select Report.
- 15. Click the Report icon. The RTP Report will display.

Return to Play Report

The Return to Play report can be accessed through the Reports option or the Activity Results screen.

Reports

- 1. Select Reports on the Home screen.
- 2. Select Report by Patient (preferred method) or Report by Date.
- 3. Select the Patient.

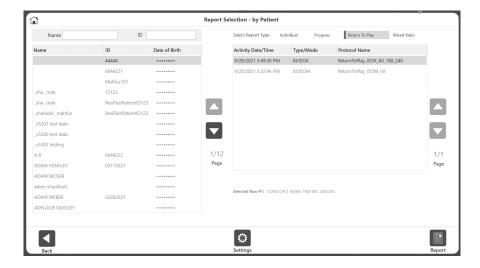


4. For the Report Type, choose Return to Play. Only the activities performed with a RTP Protocol will be displayed.

NOTE: If you forgot to mark an activity as RTP, navigate to Protocol Management, Select the protocol, then click on the three dots (...) on the selected protocol and mark it as RTP Protocol.

5. Choose a Bilateral activity (Isokinetic or Isometric).

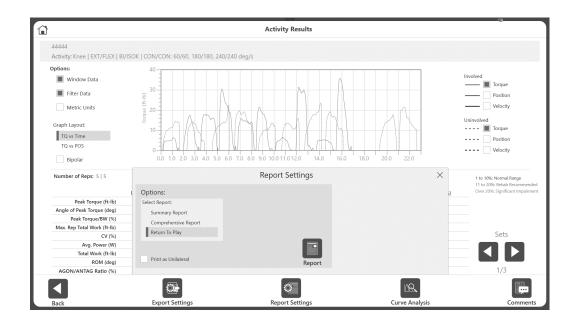
NOTE: Up to two activities can be chosen under Report by Patient, as long as they are different types (one Isokinetic and one Isometric). The Report by Date and Activity Results screens only allow one Isokinetic or one Isometric activity to be chosen.



6. Click the Report icon. The report will display on the Report Viewer screen.

Activity Results

- 1. On the Home screen, click Utilities.
- 2. Select Patient Management.
- 3. Select a patient.
- 4. Select an Activity.
- 5. On the Activity Results screen, select Return to Play as the report type under Options for Report Settings.
- 6. Click the Report icon. The report will display on the Report Viewer screen.



Isokinetic ACLR Return to Play Report

NOTE: The data shown is for demonstration purposes only and does not reflect the actual age of the patient.

Patient Name:	A. Wright	Gender:	Male	Test Date:	5/5/2020
Patient ID:	2155	Involved:	Right	Surgery Date:	09/12/2019
Age:	21				
Weight (lb):	180	GET:	Left: 22 ft-lb at 20°		
Height (ft, in):	6' 0"		Right: 19 ft-lb at 21°		

ACLR Return to Play Report - Isokinetic

Options: Windowed, Filtered

		Unv (L)	Inv (R)	Symmetry Ratio(%)
Quadriceps				
Avg. Peak Torqu	ue (ft-lb)	77.5	77.5	100.0
Total Work (ft-It	o)	414.5	463.1	111.7
Peak Torque/BV	V (%)	44.2	45.7	Goal: ≥ 60-75
CV (%)		2.5	3.4	Goal: ≤ 12-15
Hamstring				
Avg. Peak Torqu	ue (ft-lb)	39.7	35.6	89.7
Total Work (ft-II	o)	199.6	198.5	99.4
Peak Torque/BV	V (%)	22.9	20.7	Goal: ≥ 40-55
CV (%)		3.6	4.4	Goal: ≤ 12-15
H/Q Ratio (%)		51.2	45.9	Goal: ≥ 70-75

1		100.0%▼	
		≥ 90%	~
	-	≥ 90%	V
		111.7%	
50		100	
1		▼ 89.7%	
		≥ 90%	×
		≥ 90%	*
		99.4%	•
50		100	

		Unv (L)	Inv (R)	Symmetry Ratio(%)
	Quadriceps			
	Avg. Peak Torque (ft-lb)	58.8	56.4	95.9
	Total Work (ft-lb)	766.2	781.7	102.0
S	Peak Torque/BW (%)	38.4	35.4	Goal: ≥ 40-55
leg/	CV (%)	11.8	10.1	Goal: ≤ 12-15
00	Hamstring			
30	Avg. Peak Torque (ft-lb)	36.8	26.2	71.2
	Total Work (ft-lb)	408.3	305.3	74.8
	Peak Torque/BW (%)	23.9	16.3	Goal: ≥ 30-45
	CV (%)	10.5	8.2	Goal: ≤ 12-15
	H/Q Ratio (%)	62.5	46.4	Goal: ≥ 75-80



Comments: Diagnosis: Comments:	
Clinician:	

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Software Version: 5.2.00

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BIODEX

Isometric ACLR Return to Play Report

39.9

54.0

Peak Torque/BW (%)

H/Q Ratio (%)

38.5

54.1

NOTE: The data shown is for demonstration purposes only and does not reflect the actual age of the patient.

atient Name:	A. Wrig	ht		Gender:	Male	Test Date:	5/5/2020
atient ID:	2155			Involved:	Right	Surgery Date:	09/12/2019
ige:	21				-		
Veight (lb):	180			GET:	Left: 21 ft-lb at 19°		
leight (ft, in):	6' 0"				Right: 20 ft-lb at 19°		
		AC	LR Re	turn to Plav Re	eport - Isometi	ric	Options: Filtere
				_			
		Unv (L)	Inv (R)	Symmetry Ratio(%)			98.0% 🗸
Quadriceps							
Avg. Peak Torqu	e (ft-lb)	127.2	124.7	98.0			≥ 90%
					50		100
Peak Torque/BV	/ (%)	74.2	70.2	Goal: ≥ 100			
0							98.2% 🗸
Hamstring							≥ 90%
Avg. Peak Torqu	e (ft-lb)	68.7	67.4	98.2			2 90 %

Goal: ≥ 70

Goal: ≥ 60



Comments: Diagnosis: Comments: Clinician: BIODEX © Biodex Medical Systems, Inc. Software Version: 5.2.00 Page 1 of 1

Hamstring Injury Reports

Regardless of whether you have an existing process for protecting and strengthening hamstrings, the objective test protocols offered with the System 4 will provide valuable, isolated muscle-performance data. Test results, combined with established, targeted outcomes, can be used for pre-emptive injury screening, managing rehabilitation, and determining readiness for return-to-play.

The hamstring injury tests and corresponding reports include:

- 1. Mixed Ratio
- 2. Lengthened State

Mixed Ratio Test

The Mixed Hamstring/Quadriceps (H/Q) Ratio Test uses a ratio of eccentric and concentric flexion peak torque. In athletes where this ratio was greater than 1.4, hamstring injuries were significantly reduced. ⁶

The test protocol consists of two separate bilateral knee extension/flexion tests. One test is an isokinetic concentric/concentric test at 60 degrees and 240 degrees per second. The other test is an eccentric test performed either using the reactive eccentric or passive mode at 30 degrees and 120 degrees per second. The completed report takes results from each test to present a mixed ratio based on the eccentric peak torque at 30 degrees per second and concentric peak torque at 240 degrees per second.

Use the Standard Knee Attachment



Mixed Ratio Test Positioning



⁶ Croiser JL, Ganteaume S, Binet J, Genty M, Ferret JM. Strength Imbalances and Prevention of Hamstring Injury in Professional Soccer Players. The American Journal of Sports Medicine. April 30, 2008.

Mixed Ratio Goal and Setup

- Goal: Mixed HEcc/QConc ratio greater than 1.4.
- Dynamometer Orientation: System 4 Pro: 90° System 4 Quick Set: 45°
- Dynamometer Tilt: 0°
- Seat Orientation: System 4 Pro: 90° System 4 Quick Set: 45°
- Axis of Rotation: Axis is through the lateral femoral condyle on the sagittal plane
- Ready Position: Full Flexion
- Parts Needed: Standard Knee Attachment (Right or Left)

Mixed Ratio Test Protocol Settings: Isokinetic Concentric

- Type: Test
- Protocol: Isokinetic, Bilateral
- Joint: Knee
- Pattern: Extension/Flexion
- Contraction: CON/CON
- Number of Speeds: 2
- End by Reps: First set: 3; Second set: 5
- Speed Away: First Set: 60°/sec; Second Set: 240°/sec
- Speed Toward: First Set: 60°/sec; Second Set: 240°/sec
- Anatomical Reference: 90
- Rest Time (between sets) 60 seconds

NOTE: We recommend using Gravity Correction. During ROM setup, once limb weight is measured, it serves as the Gravity Correction for the application.

The Eccentric portion of the protocol can be performed using either the Reactive Eccentric protocol or Passive Eccentric protocol.

Mixed Ratio Test Protocol Settings: Reactive Eccentric

Type: Test

Protocol: Reactive Eccentric

Joint: Knee

Pattern: Extension/Flexion
 Contraction: ECC/ECC
 Number of Speeds: 2

End by Reps: First set: 3; Second set: 4

Speed Away: First Set: 30°/sec; Second Set: 120°/sec
 Speed Toward: First Set: 30°/sec; Second Set: 120°/sec

• Anatomical Reference: 90

• Rest Time (between sets) 60 seconds

NOTE: Torque limits will vary. When torque limits are set, the subject must exert at least one tenth (10%) of the torque limit to keep the dynamometer shaft moving. If the subject exceeds the limits, the unit will stop.

Mixed Ratio Test Protocol Settings: Passive Mode for Eccentric

Type: Test

Protocol: Passive

Joint: Knee

• Pattern: Extension/Flexion

• Contraction: ECC/ECC

• Number of Speeds: 2

End by Reps: First set: 3; Second set: 4

Speed Away: First Set: 30°/sec; Second Set: 120°/sec
 Speed Toward: First Set: 30°/sec; Second Set: 120°/sec

Pause: 0 seconds

• Anatomical Reference: 90

 Set torque limits high so patient does not exceed the torque limit, which will stop the arm motion.

For convenience, we have built-in protocols with the above parameters:

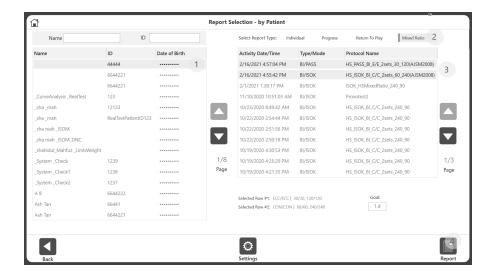
- 1. Isokinetic Concentric is "Hamstring_ISOK_C/C_60_240(AJSM2008)"
- 2. Reactive Eccentric is "Hamstring_REAC_E/E_30_120(AJSM2008)"
- 3. Passive Eccentric is "Hamstring_PASS_E/E_30_120(AJSM2008)"

Mixed Ratio Report

When a Hamstring activity is performed using the built-in protocols, based on the Crosier protocol⁷ from the American Journal of Sports Medicine (AJSM), the "Hamstring Return to Play" report can be accessed from the Report by Patient option and requires two activities to be selected.

To view a Mixed Ratio Report using built-in protocols:

- 1. Select Reports on the Home screen.
- 2. Select Report by Patient.
- 3. Select the Patient.
- 4. Select Mixed Ratio from the Select Report Type row at the top.



- 5. Select two any two Bilateral activities Either a combination of:
 - ISOK with a Passive Eccentric or
 - ISOK with a Reactive Eccentric
- 6. The default Goal is 1.4 when using the Crosier protocol8.

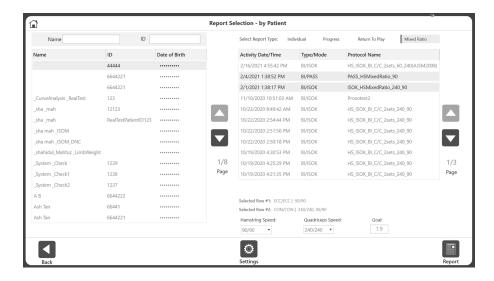
NOTE: Goals are protocol specific. If a different protocol is used, a new goal can be entered for that protocol under Report by Patient when selecting Mixed Ratio Report. The goal used on the report can be changed to a value between 0.1 and 5.0.

7. Click the Report icon. The Mixed H/Q Ratio Report displays.

Croiser JL, Ganteaume S, Binet J, Genty M, Ferret JM. Strength Imbalances and Prevention of Hamstring Injury in Professional Soccer Players. The American Journal of Sports Medicine. April 30, 2008.
 Ibid.

To view a Mixed Ratio Report using activities that were not built-in protocols:

- 1. Select Reports on the Home screen.
- 2. Select Report by Patient.
- 3. Select the Patient.
- 4. Select Mixed Ratio from the Select Report Type row at the top.



- 5. Select any two Bilateral activities either a combination of:
 - ISOK with a Passive Eccentric or
 - ISOK with a Reactive Eccentric
- 6. Select a Hamstring speed, Quadriceps speed, and enter a Goal.

 NOTE: The first speeds for Hamstring and Quadriceps are displayed by default.

 NOTE: The default Goal is 1.4 based on information from the American Journal of Sports Medicine. The goal used on the report can be changed to a value between 0.1 and 5.0.
- 7. Click the Report icon. The Mixed H/Q Ratio Report displays.

Sample Mixed H/Q Ratio Report

Some Physical Therapy Center

101 Hospital Road, Shirley, NY 11967 www.biodex.com • support@biodex.com

Patient Name: 44444 Patient ID: Age: 60 Weight (lb): 170 Height (ft, in): 5' 1" Gender: Male

Date: Time: Involved:

10/6/2020 01:38 PM Left No Gravity Correction

Joint: Pattern: Type/Mode: Contraction: Sets: Surgery Date: Knee EXT/FLEX BI/ISOK CON/CON

Options: Windowed, Filtered

Hamstring Return To Play Mixed H/Q Ratio Report

Eccentric - 30 deg/s

10/6/2020 1:38:52 PM

Flexion - Hamstring

Inv (L)

Peak Torque (ft-lb)

12.6

Concentric - 240 deg/s

10/6/2020 1:38:17 PM

Extension - Quadriceps

Unv (R)

Unv (R)

17.6

Inv (L)

Peak Torque (ft-lb)

7.3 14.9

Mixed Ratio

Flexion - Hamstring /Extension - Quadriceps Unv (R) Inv (L) Goal / CON 240 deg/s 1.2 >1.4 ECC 30 deg/s 1.7







Peak Torque: Mixed Ratio:

Highest muscular force output at any moment during a repetition. Indicative of a muscle's strength capabilities.

Strength imbalances and low H/Q ratio represent a modifiable factor to reduce Hamstring injuries.

Mixed H/Q ratio goal > 1.4

Reference:

Croisier JL, Ganteaume S, Binet J, Genty M, Ferret JM.

Strength Indialances and Prevention of Hamstring Injury in Professional Soccer Players.

A Prospective Study. The American Journal of Sports Medicine 2008. DOI: 10.1177/0363546508316764

Comments:

Diagnosis:

Comments:

Clinician:

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Software Version: 5.2.03

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BIODEX

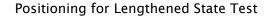
Lengthened State Multiple Angle Comparison Test

This test examines peak torque symmetry where limb position puts the hamstring in a lengthened (stretched) state.

Quick Reference list for the Lengthened State Multiple Angle Comparison Test:

- Isometric contraction in the towards direction at 40°, 20°, 0° and -20°
- Dynamometer Orientation: System 4 Pro 90° System 4 Quick Set: 45°
- Dynamometer Tilt: 0°
- Seat Orientation: System 4 Pro 90° System 4 Quick Set: 45°
- Seatback Tilt: 70°-85°
- Hip flexed at 130°
- Knee Flexion from 90° to 0°
- Axis of Rotation: Axis is through the lateral femoral condyle on the sagittal plane
- Ready Position: Flexion at 80°
- Parts needed:
 - Dynamometer: Lengthened State Hamstring upper attachments with knee pads (Right and Left)
 - Positioning chair: Limb Support Pad, T-Bar

Use the Hamstring Attachment







NOTE: Additional information on hamstring injury rehabilitation is available in this paper.⁹

⁹ Brandon Schmitt, DPT ATC, Tim Tyler PT ATC, Malachy McHugh PhD. Hamstring Injury Rehabilitation and Prevention of Reinjury using Lengthen State Eccentric Training: A New Concept. IJSPT Vol 7, No. 3 June 2012, 333.

Use the following settings for the Lengthened State Multiple Angle Comparison Test:

Protocol: Isometric, Bilateral

• Joint: Knee

Pattern: Extension/FlexionContraction Direction: Toward

• Number of Positions: 4

• End by Reps: 2 at each position

• Angle: 40° 20° 0° -20°

Contraction Time: 5 seconds
 Relaxation Time 5 seconds
 Anatomical Reference: 0

Rest Time: (between sets) 30 seconds

For convenience, we have built-in protocols with the above parameters named "Hamstring_ISOM_BI_40_20_0_-20". You can create your own custom protocol by changing any of the parameters except for the angles. Pass/fail criteria will remain the same for built-in and custom protocols.

Hamstring "tightness" can be captured independently for the right and left hamstring. It is noted as Passive Torque, or "Passive Tq" on the Multiple Angle Comparison report. A passive stretch is applied at 20° above the horizontal. The measurement is made in the Biodex Advantage BX Software through gravity correction and is deducted from the flexion torque.



The pass/fail goals for the Lengthened State Protocol are:

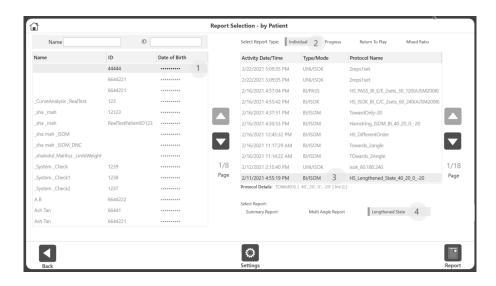
PASS: Deficit <20% in lengthened state (-20 degree angle) and average of all angles deficit <20%. FAIL: Deficit >20% in lengthened state (-20 degree angle) or average of all angles deficit >20%.

Lengthened State Report

The Lengthened State Report can be accessed through the Report by Date or Report by Patient options when the selected activity is Isometric, Bilateral, and using the Toward direction up to 4 angles.

To view a Lengthened State Report:

- 1. Select Reports on the Home screen.
- 2. Select Report by Patient.
- 3. Select the Patient.
- 4. Select Individual for Report Type.
- 5. Select an activity that is Bilateral and Isometric (BI/ISOM), and only used the Towards direction.



6. Click the Report icon. The Lengthened State Report displays.

NOTE: This report option is not available for Unilateral Isometric or Bilateral Isometric with both the Towards and Away directions.

Sample Lengthened State Report

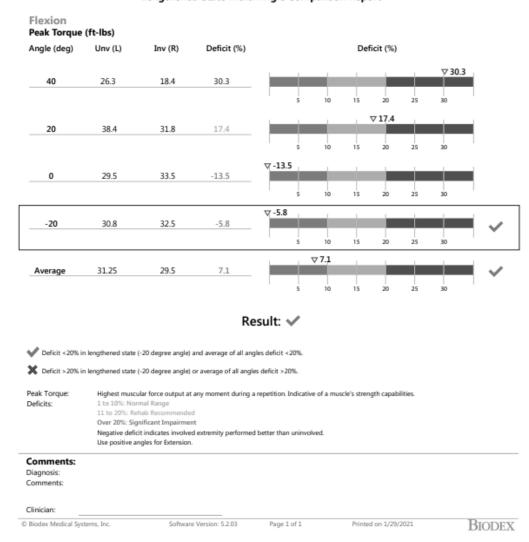
Some Physical Therapy Center

101 Hospital Road,, Shirley, NY 11967 www.biodex.com • support@biodex.com

Patient Name:		Date:	1/30/2021	Joint:	Knee
Patient ID:	44444	Time:	03:02 PM	Pattern:	EXT/FLEX
Age:	59	Involved:	Right	Type/Mode:	BI/ISOM
Weight (lb):	180	Passive Tq:	Unv 17 ft-lbs at -35 deg	Contraction:	TOWARDS
Height (ft, in):	6' 0"		Inv 24 ft-lbs at -35 deg	Sets:	
Gender:	Male			Injury Date:	09/12/20

Options: Filtered

Hamstring Return To Play Lengthened State Multi Angle Comparison Report



Curve Analysis

Curve Analysis allows for in-depth annotation and comparison of results from different tests. Test data can be turned into reports and used to communicate test results to doctors, third-party payers, and employers.

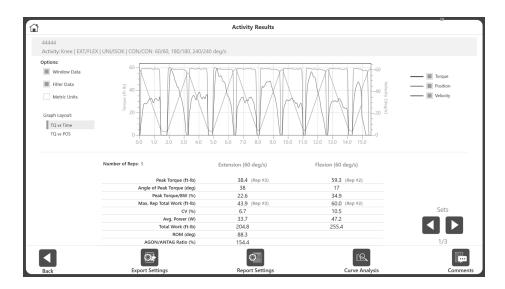
Two important terms we will be discussing in this section are "Base Activity" and "Overlay Other Activity". The Base Activity is the activity we will be selecting that we want to compare to another activity. The Overlay Other Activity is what we will be using to compare to that Base Activity.

In the Legacy System 4 software, you could select a test, save the curve and add a separate activity to compare it to. Once a curve was saved, it could be changed, but only by starting over. A benefit of the Advantage BX Software is the ability to switch back and forth between the Base Activity and Overlay Activities. The activities can be added, removed, and switched around as needed in order to overlay and compare certain curves on the same graph.

Accessing Curve Analysis

There are two ways to access Curve Analysis:

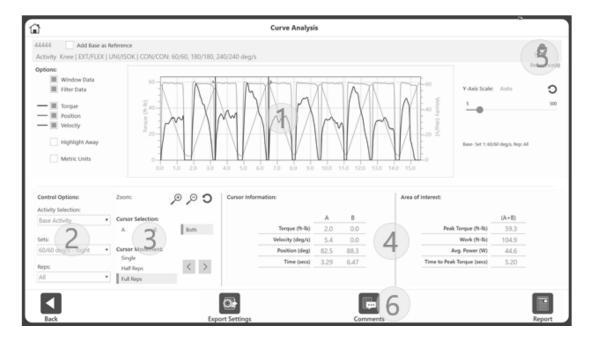
- 1. After completing an activity, click the Curve Analysis icon on the Activity Results screen. **NOTE:** Curve Analysis will only be available on the Activity Results screen after saving an activity.
- 2. a) Select Utilities on the Home screen, then select Patient Management.
 - b) Select a patient.
 - c) Click the Next button.
 - d) Select an activity.
 - e) Click the Results icon.
 - f) Click the Curve Analysis icon.



The Curve Analysis screen displays.

Curve Analysis Operation

This sample activity demonstrates how Curve Analysis works. This activity is performed using the Knee, Extension/Flexion, Unilateral Isokinetic, Concentric/Concentric protocol with three speeds - 60, 180, and 240 deg/s.

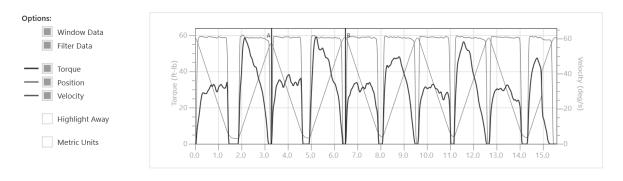


Segment 1 of the screen shows Data related controls and Graph related controls. The graph is located in the middle of the screen. The right side of the screen has a Y-Axis control. It also features activity information.

Data related controls:

- Window Data (Isokinetic only)
- Filter Data
- Units

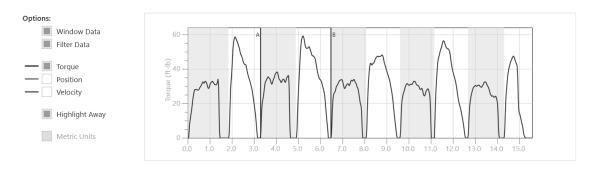
NOTE: Window Data and Filter Data default to ON. You can toggle between ON and OFF, which will also apply to the graph and data displayed on-screen.



Graph related controls:

- Torque
- Position
- Velocity
- Highlight Away
- Initial state: Initially it displays "All" reps on graph.
- Cursor A and B will be pointing to the Peak Torque and/or Peak Velocity (for ISOT) rep
- Y-Axis Control will default to Auto scale but can be adjusted using slider option
- Highlight Away -When this option is enabled, this will highlight the away direction rep on the graph. Usually "Away" is followed by a "Toward"

NOTE: Torque, Position, and Velocity are also ON by default, and those lines will be displayed on the graph. These controls can be turned OFF and ON as needed.



Activity based information is located in the upper right part of the screen.

- The example in the image "Base: Set 1: 60/60 deg/sec, Rep: All" means that the base activity is selected, you are on Set 1, and all reps are shown. The current rep will always be shown, such as "Rep: 3 of 5".
- As you add Reference activities, selection options for those activities will display. For example, if a Base activity is on Rep 4, the Reference activity will be on Rep 3:

Base- Set 1: 60/60 deg/s, Rep: 4 of 5 Ref#1- Set 1: 60/60 deg/s, Rep: 3 of 5 Ref#2- Set 1: 60/60 deg/s, Rep: 5 of 5

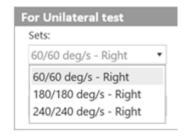
Segment 2 of the screen contains:

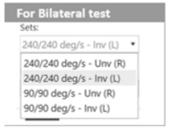
 Activity Selection - The Base Activity displays by default. Overlay Activities will in the drop-down menu after being added.



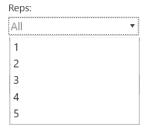
• Sets - Drop-down menu displays the speeds/angles/velocities. The default is the first speed/angle/velocity. The side used to perform the activity is also displayed. One drop-

down item for each set displays for Unilateral. Two items for each set display for Bilateral.



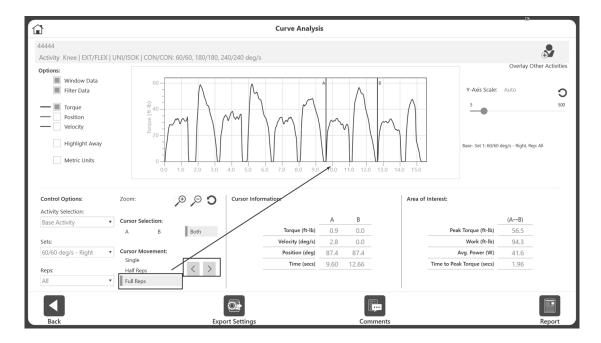


• Reps - Drop-down lists all reps. Choose a particular rep or All reps.



Segment 3 of the screen shows:

- Cursors The A and B cursors, or vertical lines on the graph, can be dragged with the mouse. Their movement can also be controlled using:
 - Cursor Selection A, B, or Both
 - Cursor Movement:
 - Single Cursor will move with discreet values.
 - Half Rep Cursors will move to next Half rep forward or backward.
 - Full Rep Cursors will move to next Full rep forward or backward.



Segment 4 of the screen shows:

- Cursor Information Displayed for Cursors A and B. Wherever the cursor is, it will display the value under A & B column.
- Area of Interest Displays certain information like Peak Torque, Work, Average Power and Time to Peak Torque within the range of A & B.

NOTE: Time to Peak Torque is relative to Cursor A. Between Cursor A and B, application will figure out time to reach to the peak torque from cursor A.

Area of Interest:

A Base Activity will look like the following:

Cursor Info	rmation:		
		Α	В
	Torque (ft-lb)	2.0	0.0
	Velocity (deg/s)	5.4	0.0
	Position (deg)	82.5	88.3
	Time (secs)	3.29	6.47

	(A+B)
Peak Torque (ft-lb)	59.3
Work (ft-lb)	104.9
Avg. Power (W)	44.6
Time to Peak Torque (secs)	5.20

It will look like the following with Overlayed activities:

Cursor Information:				
	<u>Base</u>		Ov	y #1
	Α	В	Α	В
Torque (ft-lb)	33.4	32.9	1.4	0.0
Velocity (deg/s)			2.8	0.0
Position (deg)			88.5	87.3
Time (secs)	6.99	10.21	6.99	10.21

Area of Interest:		
	<u>Base</u>	Ovly #1
	(A↔B)	(A↔B)
Peak Torque (ft-lb)	48.3	48.4
Work (ft-lb)	97.5	97.3
Avg. Power (W)	40.9	40.8
Time to Peak Torque (secs)	1.79	0.31

NOTE: In the snapshot above, the A & B cursor information is blank because the Overlay activity is selected. If the Base activity was selected, then the Overlay activity would have blanks; information for velocity and position can only be shown for one activity at a time.

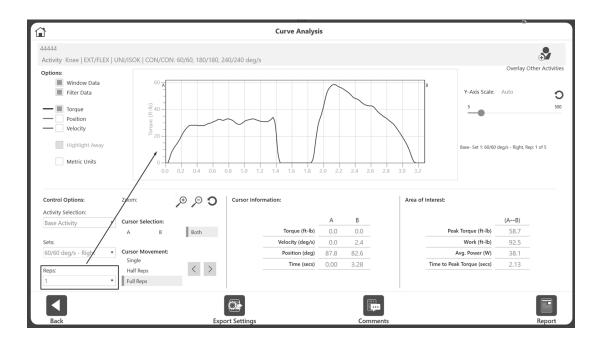
Segment 5 of the screen is described in the Overlaying Other Activities section.

Segment 6 of the screen is described in the Comments/Report and Export sections.

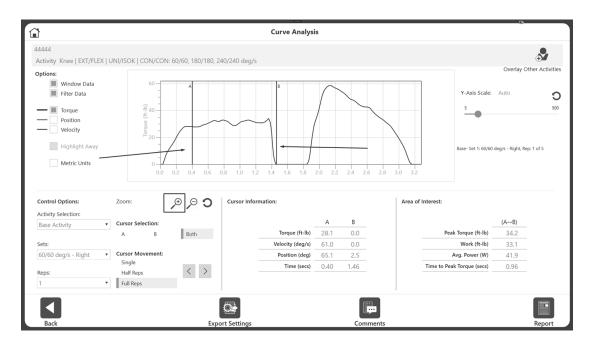
Selecting a Rep

The Rep drop-down menu will show "All" by default.

- Select a Rep from the Reps drop-down menu and the graph will display that Rep.
- The A and B cursors will be at each end of the graph.
- The Cursor Information and Area of Interest data will reflect the selected region.



• For a closer look, move the cursors to either side of the area of interest. Then click the Zoom button to view the area between the cursors.



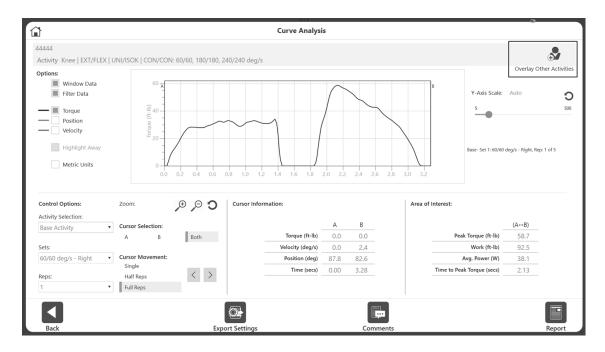
• Clicking the Zoom reset button will display All Reps again, rather than the Rep that was selected. You can also select "All" from the Rep drop-down menu at any time.

Overlaying Other Activity

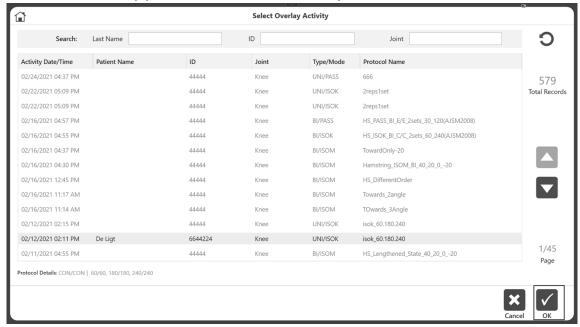
In this section we will be using Unilateral Isokinetic activities. Overlaying Bilateral activities will be discussed in a later section.

To Overlay an activity:

- 1. Decide which set of the Base Activity will be compared by choosing from the Set drop-down menu. "All" Reps will be displayed for Base Activity.
- 2. Click the + Overlay Other Activities icon in the top right corner.

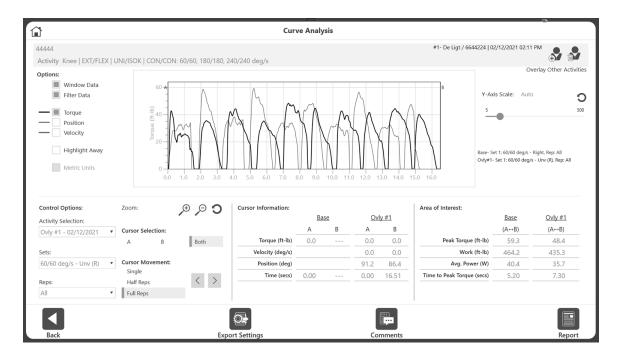


3. Select the activity you would like to use for comparison.



NOTE: The list of activities you can choose from will automatically be filtered by:

- Other activities included in the Base activity (i.e. same patient name/id). If needed, use the reset filter button to get the full list of activities.
- Based on Activity mode, closed chain, and non-linear vs angular to ensure that the selected Rep and overlay activity are comparable.



After adding the overlay activity, all reps will display.



If needed, choose the Rep number to take a closer look for Overlay Activity.

4. Choose Base Activity from the Activity Selection drop-down menu.



5. Choose the Rep number to take a closer look for Base Activity. The two reps overlapping each other will display.

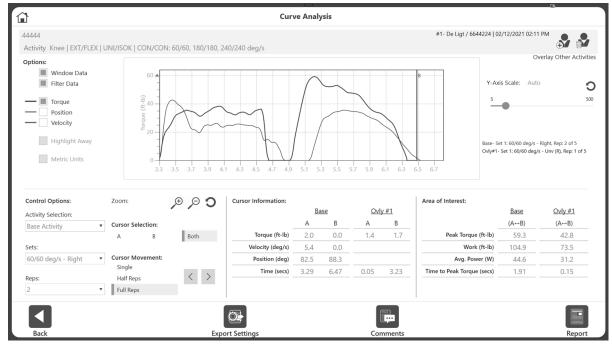


TIP: First, choose a Base Activity by selecting a particular Set and a Rep. Then select an overlay activity, Set, and Rep.

Switching Between Activities

In the previous example, Rep 1 was the Base Activity and Rep 2 was the Overlay Activity. To change the Base Activity Rep of the same Set:

- 1. Select Base Activity from the Activity Selection drop-down menu.
- 2. Select 2 from the Reps drop-down menu.



NOTE: The following information will display for the currently selected activity, both in the graph and the information panes on the screen:

- Position and Velocity
- A and B Cursors
- Zoom and Cursor Movement

If the overlay activities Rep needs to be changed, too:

- 3. Switch to Overlay activity on the "Activity Selection" drop-down menu.
- 4. Then, select 2 from the Reps drop-down menu.
- 5. Switch back and forth as many times as needed until it displays the desired area of interest for comparison.

NOTE TO LEGACY SYSTEM USERS: Once a curve was selected with a particular Set and Rep, a "Save" button had to be used on the Legacy system. Once the Save button was used, that curve remained on-screen without the option to reselect the set/rep. It was locked (unless you cleared and repeated your work). Later, the Legacy system allowed you to select another patient test, set, and rep, which created two overlayed graphs.

On the Advantage BX software, there is no need to save an activity. Saving the activity will limit the capability to choose different sets/reps.

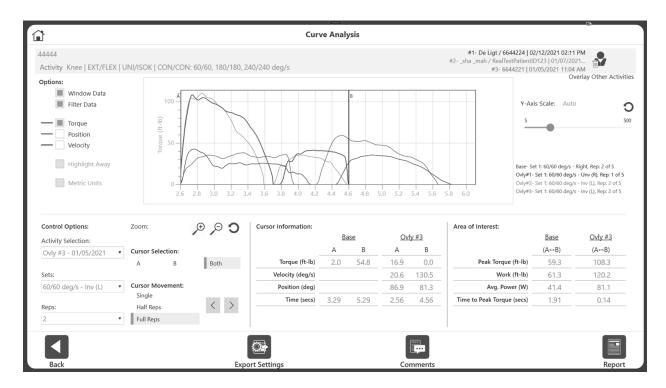
Adding and Removing Overlay Activities

Up to three activities can be overlayed. You can also select the same activity as an overlay activity. Sometimes you may need to compare Rep 1 and Rep 2 of the same activity. In that case, select the same activity as the Base Activity as your Overlay Activity.



Once all activities are overlayed, the option to add more activities will disappear. To remove and then add a new overlay activity:

- 1. Click the Remove icon of the "Overlay Other Activities" option in the top right corner.
- 2. This will remove the most recently added overlay activity.
- 3. Add more overlay activities as needed.



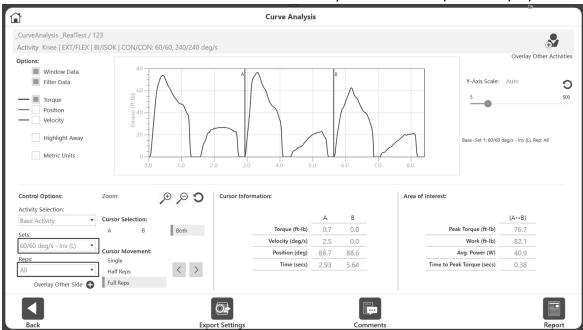
NOTE: Once all overlay activities are removed, the Remove icon will disappear.

Comparing Each Side of a Bilateral Test

In the previous section, we added overlay activities using a unilateral activity. The same steps can be applied to a bilateral activity. To compare one side to another, we add the same activity as the Overlay activity, selecting the other side of the same set. The application will have a button to do just that for bilateral activities only.

To compare one side of a Bilateral test to another side:

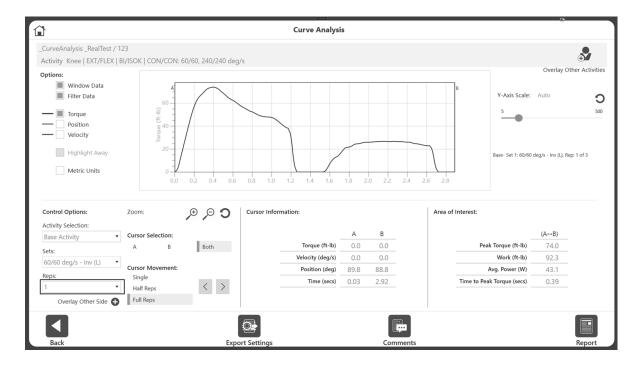
- 1. Select Utilities from the Home screen and click the Patient Management button.
- 2. Select a patient.
- 3. Select a Bilateral test.
- 4. Click the Results icon and then click the Curve Analysis icon. "All" reps will display.



5. Select a set/side from the Sets drop-down menu. The drop-down will display Speeds (or velocity or angles) and indicate the side. For example, you can select Involve(L) side.

Control Options:

6. Then select a Rep from the Rep drop-down menu. It will display the rep on the graph for that set.



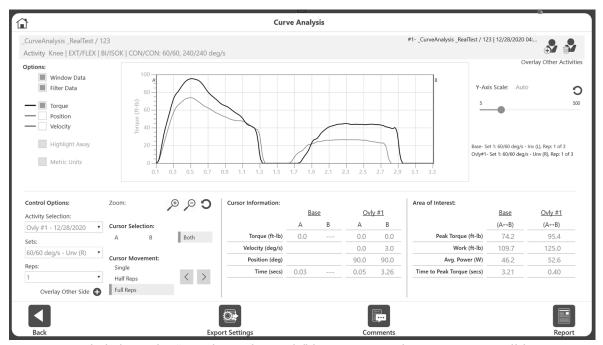
7. To compare the other side (same Set, same Rep), click the "Overlay Other Side" button.

Control Options:

Activity Selection: Base Activity Sets: 60/60 deg/s - Inv (L) Reps: 1 Overlay Other Side

- 8. It will add the same activity, same set, same rep of the Other side.

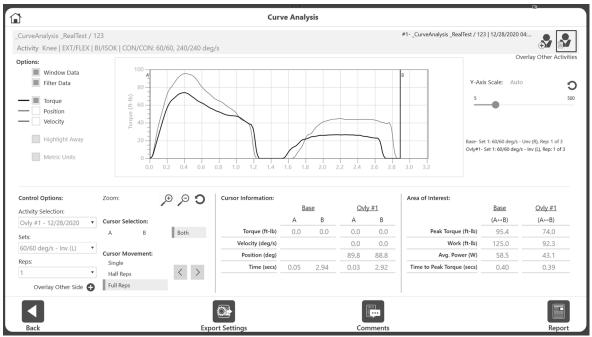
 NOTE: In our example, we selected 60/60-Involve (L) as the Base activity. Clicking the Overlay Other Side button automatically added the 60/60-uninvolve (R) side as the Overlay Activity (Ovly #1) for reference.
- 9. The graph will display two graph lines overlaying each other.



NOTE: Avoid clicking the "Overlay Other Side" button more than once as it will keep adding the same side, same rep activity as the overlay activity.

To select a different set and compare both sides:

1. Remove any previously added sides by clicking the Remove button in the top right corner.



- 2. Select the appropriate Set and Side.
- 3. Select the Rep.
- 4. Click the "Overlay Other Side" button, located under the Reps drop-down menu.

Curve Analysis Reporting

To add comments to the report:

- 1. Click the Comments icon.
- 2. Add comments by typing into the Comments field. **NOTE**: This comment will appear only on curve analysis report and will not be saved against the activity.

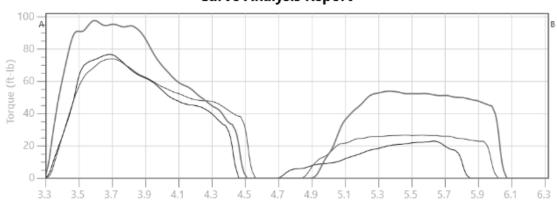


3. Click the x button at the top right of the keyboard when finished. Comments will display at the bottom of the report.

Patient Name:	RealTest	Date:	12/28/2020	Joint:	Knee
Patient ID:	123	Time:	04:44 PM	Pattern:	EXT/FLEX
Age:	60	Involved:	Left	Type/Mode:	BI/ISOK
Weight (lb):	175	GET:	Left: 17 ft-lb at 35°	Contraction:	CON/CON
Height (ft, in):	5' 8"		Right: 16 ft-lb at 32°	Sets:	2
Gender:	Male			Surgery/Injury Dat	te:

Curve Analysis Report

Options: Windowed, Filtered



	Ba		Ovly	#1	Ovly	. #2
	Da.	3C	Oviy		Oviy	#2
ursor Information	A	В	А	В	Α	В
rque (ft-lb)	0.0		0.7		2.9	0.0
elocity (deg/s)	0.0		2.5		6.3	2.7
osition (deg)	89.8		88.7		89.9	89.6
ime (secs)	0.03		2.93		3.27	6.29
rea of Interest	(A-	→B)	(A+	→B)	(A-	→B)
ak Torque (ft-lb)		74.0	7	76.7	9	97.7
rk (ft-lb)		93.7	9	90.1	13	35.6
J. Power (W)		42.0	4	10.3	(50.7
me to Peak Torque (secs)		0.39		0.38		0.29
t	60	/60	60,	/60	60,	/60
p	1 0	of 3	2 0	of 3	2 0	of 3
le	Uninvo	lved (R)	Uninvo	lved (R)	Uninvo	lved (R)
te/Time	12/28/202	0 04:44 PM	12/28/2020	0 04:44 PM	12/28/202	0 04:44 PM

Curve Analysis Exporting

To export data:

- 1. Click the Export Settings icon on the Curve Analysis screen.
- 2. Choose to export data for Current View or All Reps.
- 3. Click the Export icon. The output file is a .txt file that is space separated, not tab or comma separated.



Sample Current View Format

The application will export the selected Rep 1.

_shamah 202012281644									
	Knee EXT	/FLEX	BI IS	SOK CON/CON	60/60 240/24	0 deg/s	Filtered: Yes	Windowed:	Yes
	SIDE	Set	Rep	mSec	TORQUE	POSITION	POS_(ANAT)	VELOCITY	
	Right	1	-	0	0.0	166.2	90.2	0.0	
	Right	1	-	10	0.0	166.2	90.2	0.0	
	Right	1	-	20	0.0	166.1	90.1	0.0	
	Right	1	-	30	0.0	166.1	90.1	0.0	
	Right	1	-	40	0.0	166.1	90.1	0.0	
	Right	1	1	50	0.0	166.0	90.0	0.0	
	Right	1	1	60	0.8	165.8	89.8	2.8	
	Right	1	1	70	1.8	165.6	89.6	6.0	
	Right	1	1	80	4.0	165.3	89.3	12.1	
	Right	1	1	90	7.5	164.9	88.9	21.5	
	Right	1	1	100	12.6	164.4	88.4	34.1	
	Right	1	1	110	18.0	163.8	87.8	44.5	
	Right	1	1	120	23.4	163.3	87.3	51.7	
	Right	1	1	130	28.3	162.7	86.7	55.7	
	Right	1	1	140	33.4	162.1	86.1	59.3	
	Right	1	1	150	37.5	161.5	85.5	60.0	
	Right	1	1	160	41.4	160.9	84.9	60.2	
	Right	1	1	170	45.0	160.3	84.3	60.3	
	Right	1	1	180	48.5	159.7	83.7	60.4	
	Right	1	1	190	52.0	159.1	83.1	60.6	
	Right	1	1	200	55.6	158.4	82.4	60.7	

Sample All Reps Format

_shamah	202	20122816	544					
Knee EXT/F	LEX I	BI ISOK	CON/CON	60/60 240/24	0 deg/s	Filtered: Yes	Windowed:	Yes
SIDE S	et 1	Rep	mSec	TORQUE	POSITION	POS_(ANAT)	VELOCITY	
Right	1	-	0	0.0	166.2	90.2	0.0	
	Data	a Trunca	ated					
Right	1	1	50	0.0	166.0	90.0	0.0	
Right	1	1	60	0.8	165.8	89.8	2.8	
Right	1	1	70	1.8	165.6	89.6	6.0	
	Data	a Trunca	ated					
Right	1	1	3230	0.0	166.0	90.0	0.0	
Right	1	1	3240	0.0	166.0	90.0	0.0	
Right	1	1	3250	0.0	166.0	90.0	0.0	
Right	1	1	3260	0.0	166.0	90.0	3.0	
Right	1	2	3270	2.9	165.9	89.9	6.3	
Right	1	2	3280	6.1	165.7	89.7	12.6	
Right	1	2	3290	11.3	165.3	89.3	22.3	
	Data	a Trunca	ated					
Right	1	2	6260	0.0	165.5	89.5	0.0	
Right	1	2	6270	0.0	165.6	89.6	0.0	
Right	1	2	6280	0.0	165.6	89.6	0.0	
Right	1	2	6290	0.0	165.6	89.6	2.7	
Right	1	3	6300	2.7	165.5	89.5	5.9	
Right	1	3	6310	5.8	165.3	89.3	11.9	
Right	1	3	6320	10.7	165.0	89.0	21.2	
Right	1	3	6330	17.7	164.6	88.6	33.8	
Right	1	3	6340	24.7	164.0	88.0	44.4	
Right	1	3	6350	31.6	163.4	87.4	51.8	
Right	1	3	6360	37.6	162.8	86.8	56.0	
Right	1	3	6370	44.0	162.2	86.2	59.6	
Right	1	3	6380	49.4	161.6	85.6	60.5	
Right	1	3	6390	54.8	161.0	85.0	60.8	
Right	1	3	6400	60.0	160.4	84.4	61.0	

Data Exported Format

- a. File Name Exported as Patient Name/ID and Test Date/Time separated by underscores.
- b. First line Contains the Patient Name/ID and Test Date/Time.
- c. Second line Joint, Pattern, Type, Mode, Contraction, speeds or angles or velocities. Also displays whether the Windowed or Filter option was used to export this file:

```
_sha__mah 202012281644
Knee EXT/FLEX BI ISOK CON/CON 60/60 240/240 deg/s Filtered: Yes Windowed: Yes
```

- d. Third Line Shows the column name of the data points.
 - a. For Unilateral:

```
Set Rep mSec TORQUE POSITION POS (ANAT) VELOCITY
```

b. For Bilateral:

SIDE	Set	Rep	mSec	TORQUE	POSITION	POS	(ANAT)	VELOCITY

e. Fourth line and beyond shows the following data points (sampling rate @100Hz):

Right	1	-	0	0.0	166.2	90.2	0.0
Right	1	_	10	0.0	166.2	90.2	0.0
Right	1	-	20	0.0	166.1	90.1	0.0
Right	1	-	30	0.0	166.1	90.1	0.0
Right	1	-	40	0.0	166.1	90.1	0.0
Right	1	1	50	0.0	166.0	90.0	0.0
Right	1	1	60	0.8	165.8	89.8	2.8
Right	1	1	70	1.8	165.6	89.6	6.0
Right	1	1	80	4.0	165.3	89.3	12.1
Right	1	1	90	7.5	164.9	88.9	21.5
Right	1	1	100	12.6	164.4	88.4	34.1

Note: The output .txt format data will display the value according to reginal settings.

Bilateral Columns

SIDE Set Rep mSec TORQUE POSITION POS (ANAT) VELOCITY

Unilateral Columns

Set Rep mSec TORQUE POSITION POS_(ANAT) VELOCITY

- Data in the Set column shows the set number and "Rep" shows the Rep number. The Set number shows 1 which represents the 60/60 set and Set 2 will represent 120/120 for our example data/activity.
- Rep number "1" will denote where the Data points of Rep 1 started and ended. In the example below, Rep 1 went from 130 milliseconds (ms) to 2080. Rep 2 went from 2110 to 3930 ms.
- The Torque column has positive and negative values to show the direction of the torque applied. For an ISOK CON/CON activity, extension shows positive torque and flexion shows negative torque.

			11161415					
				CON/CON 60/6				No
Set	Rep		mSec	TORQUE 1.0	POSITION	POS_(ANAT)	VELOCITY	
1	-		0	1.0	147.1	136.9	0.5	
		Data	Truncat	ed 1.4				
1	1		130	1.4	147.7	136.3	10.1	
1	1		600	7.9	174.7	109.3	59.8	
1	1		610	7.8	175.3	108.7	59.8	
		Data	Truncat	8.0				
1	1		860	8.0	189.6	94.4	32.0	
		Data	Truncat	ed 3.9				
1	1		2070	3.9	147.6	136.4	0.4	
1	1		2080	4.1	147.6	136.4	3.0	
		Data	Truncat	-64				
				4.8				
1	2		2120	5.0	148.0	136.0	16.0	
		Data	Truncat	ed				
1	2		2300	10.0	156.6	127.4	59.7	
		Data	Truncat	10.0 sed 3.2 3.4 sed				
1	2		3920	3.2	147.5	136.5	-0.3	
1	2		3930	3.4	147.5	136.5	1.7	
		Data	Truncat	ed				
_								
1	3		3980	4.4	147.9	136.1	15.0	
		Data	Truncat	ed				
1	3		4320	9.7	165.8	118.2	59.8	
1	3		4470	10.1	174.8	109.2	59.8	
1	3		4480	10.2	175.4	108.6	59.8	
				10.2		108.0	59.8	
				10.2		107.4	59.8	
				10.2		106.8		
1	3		4520	10.2	177.8	106.2	59.8	
1	3		4530	10.2 10.1 10.1	178.4	105.6	59.8	
1			4540	10.1	179.0	105.0	59.8	
1			4550	10.1	179.6	104.4	59.7	
1	3		4560	10.0	180.2	103.8	59.7	
1	3		4570	9.9	180.8	103.2	59.7	

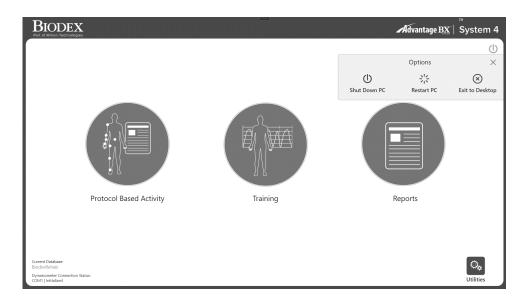
Dynamometer Status

A Communication Error message will display if the dynamometer has been disconnected from the software. Reconnect the computer cable from the dynamometer to the PC and select the Resume icon to recover.

NOTE: You may need to restart the PC after the cable has been reconnected.

If the Resume icon does not recover the system, perform a full power cycle:

1. Shut down the PC by selecting the Power icon on the top right of the screen and selecting "Shut Down PC".



- 2. On the back of the cart, turn the Main Power switch off and then back on.
- 3. Turn the PC power back on (left side of the cart).

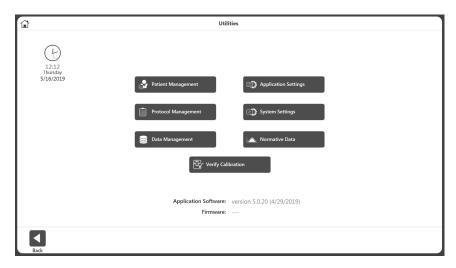
Under the Dynamometer status current state of the machine will be displayed. Throughout the application we have the following dyna status:

- 1. **Setup** Used on Activity Setup/ ROM Setup/ Training Setup screen. The movement of the attachment will be less than or equal to 45 deg/s.
- 2. **Idle** Before any activity starts, or the rest period in between sets application sets the machine state in idle mode which will be less than or equal to 45 deg/s.
- 3. **Active** During the practice trial or during Training session, dyna status will be Active. It will move the attachment according to the set speed. This state will not record any data.
- 4. **Acquiring Data** (also considered as Active state). This is only applicable to the Protocol Based Activity screen. When an activity is being performed, machine will be in data collection mode. This does not mean data is being saved. Activity will have to saved later.
- 5. **Paused** when the Hold Resume button is pressed (on dyna or from the application screen) it will display Paused state. User can resume from this state.
- 6. **Comfort Stop** When the comfort stop is pressed, it will display the state as comfort stop. User can resume from this state.
- 7. Any other Error condition- It can be COMM timeout, Fault codes displayed

Utilities

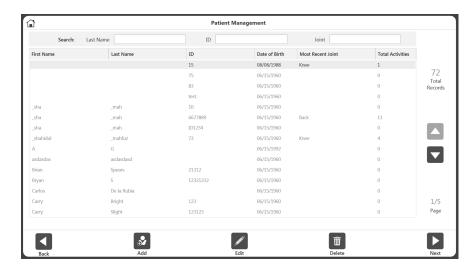
Accessing the Utilities options may require an access code to be entered. The default access code is 159. We recommend changing it.

NOTE: The access code is always enabled for the Utilities, Protocol Management, Patient Management, Application Settings, and Data Management. This cannot be disabled. You can change the access code in the System Settings, and enable an access code for entering the application.



Patient Management

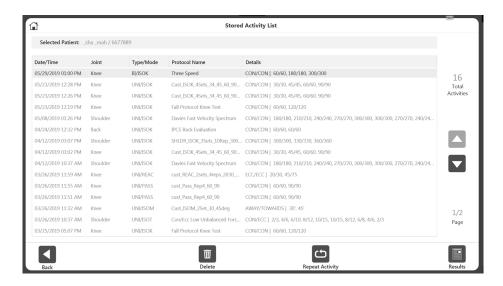
- 1. Enter Access Code 159 and select the OK icon.
- 2. Select the Patient Management button.



3. On the Patient Management screen, select a patient using the touch screen and the up and down arrows or use the Add icon to add a new patient. You can also use the Back icon to return to the previous screen, the Edit icon to edit the highlighted patient, and the Delete icon to delete the highlighted patient.

NOTE: A patient can be searched for using the search criteria given on the top section. Alternatively, the list can be sorted by clicking on the column headers. When searched, it will display the activities in joint group of that patient.

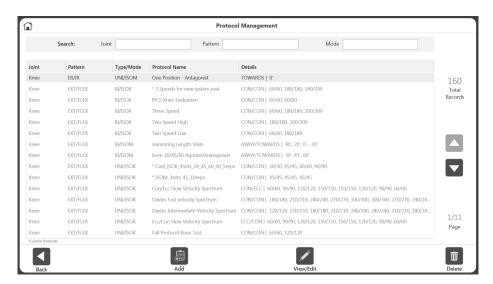
- 4. Select the Next icon.
 - **NOTE:** The patient must have one or more activities for the Next icon to appear.
- 5. Select an activity from the Stored Activity List screen. If the Next button is clicked from the search result of Patient Management screen, it will display only the activities of that Joint type. To see all of the activities regardless of joint, use the Reset button on the right top corner on the Stored Activity List screen.



6. Select the Results icon, the Repeat activity icon, the Delete icon, or the Back icon. **NOTE:** For instructions on how to add Additional Information for a patient, see the "New Activity: Add New Patient" section.

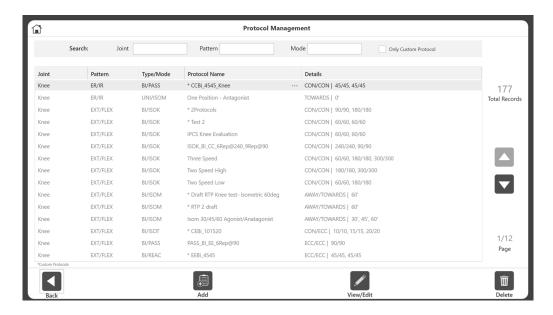
Protocol Management

- 1. Enter Access Code 159 and select the OK icon.
- 2. On the Protocol Management screen, select a protocol.
- 3. You can Search for a protocol at the top of the screen, Add a protocol using the Add icon, View or Edit a protocol using the View/Edit icon, Delete a protocol using the Delete icon, or use the Back button to see the previous screen.

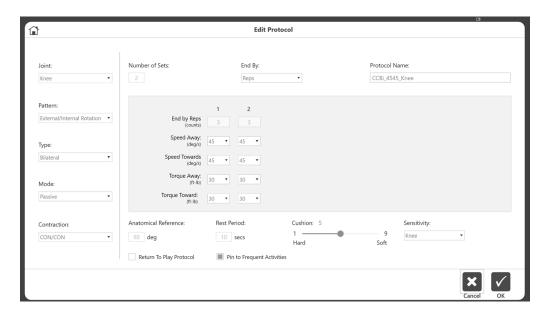


NOTE: Custom protocols are marked with an asterisk (*). Built-in protocols cannot be edited/deleted.

NOTE: The properties of a protocol cannot be changed because it would affect the results. If a protocol is already being used, save it under a new name to change it. Protocols that have been used are marked with three dots. To change the name, click on the three dots, and change the name on the Rename Protocol screen.



NOTE: A protocol cannot be renamed after it has been used to save an Activity.



4. Select the Home icon to return to the Home screen when finished.

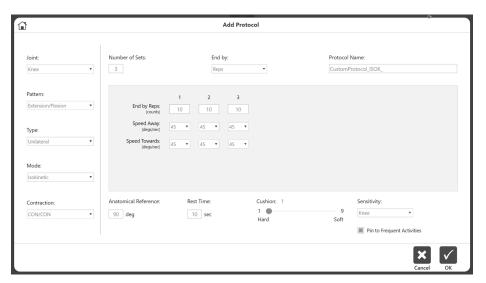
Add Protocol

- 1. On the Protocol Management screen, click the Add icon.
- 2. Select the Joint, corresponding Pattern, Type, Mode, and Contractions.
- 3. Enter a value for Number of Sets. This will create columns for Sets.
- 4. Choose the End By option Reps, Work, Time.
- 5. Enter the values for each set in the middle section of the screen. Different information will be required depending on the type of Mode and Contractions.
- 6. Enter other information such as Anatomical Reference, Rest Time, Cushion, Sensitivity and Pin to Frequent Activity.

NOTE: The default, joint-based attachment sensitivity settings can be made higher or lower. When the attachment and sensitivity do not match, the attachment will vibrate. For example, when wrist sensitivity (which has higher sensitivity) is used with a shoulder attachment, then the attachment will vibrate.

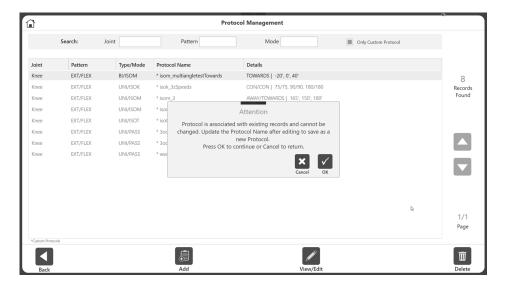
NOTE: Adding to the Frequent Activity list allows quick access the protocol during the setup.

7. Enter a Protocol Name. It must be a unique name, otherwise error messages will appear.



View/Edit Protocol

- 1. On the Protocol Management screen, Select a protocol from the list and click on View/Edit button.
- 2. On the next screen it will display the details of the Protocol. **NOTE:** If a protocol is built-in or has already been used for a saved activity result, you will not be allowed to edit that protocol.
- 3. If the protocol is not used yet, and not a factory protocol, any properties of the protocol can be changed. Otherwise, a message will display explaining that the protocol cannot be changed.



4. If a protocol is already used, you may want to change certain details. For example, to change the Rest Time you can open the protocol and change the rest time. Then Save As and you will be prompted to change the Protocol Name.



Data Management

Exporting

The Exporting functionality and various export formats available will be explained in this section. Multiple Data Export can be accessed through Data Management, while Single File Export can only be accessed from the Activity Results screen. Sampling rate for the point points in any export format is 100Hz.

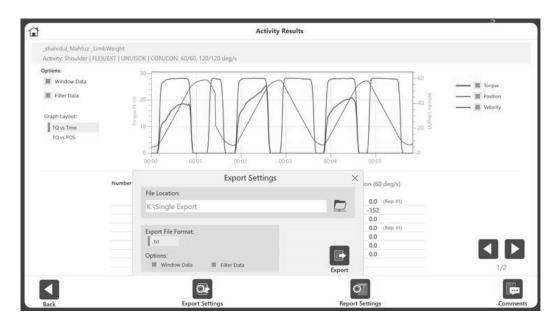
Single File Export

To export a single file:

- 1. On the Home screen, click Utilities.
- 2. Select Patient Management.
- 3. Select a patient.
- 4. Select an Activity.
- 5. On the Activity Results screen, select the File Location.

 NOTE: The Export File Format for single file export is .txt.
- 6. Select Options, such as Windows Data and Filter Data.

 NOTE: For Linked Protocols, click the Export Settings icon. Then, click the box for All Linked Activities to ensure all the data is exported together.
- 7. Select the Export icon.

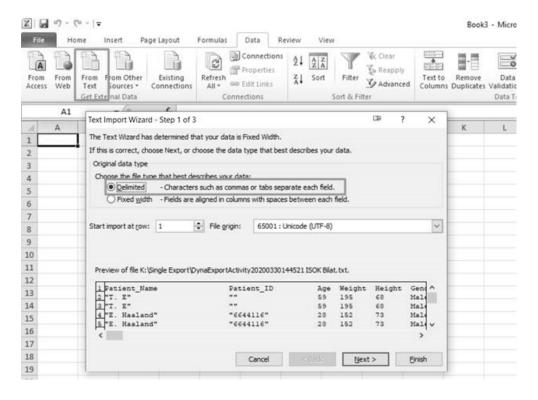


Sample exported .txt file with Data Points only:

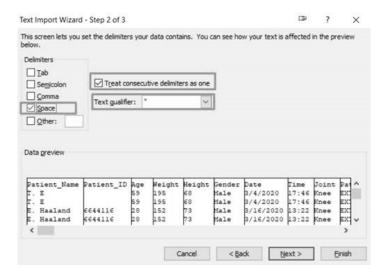
John	Doe	20203	11161415					
				CON/CON 60/6				No
Set	Rep		mSec	TORQUE	POSITION	POS_(ANAT)	VELOCITY	
1			0	1.0 ed	147.1	136.9	0.5	
		Data	Truncat	ed 1.4				
1	. 1		130	1.4	147.7	136.3	10.1	
		Data	Truncat	ed				
1	. 1		600	ed 7.9	174.7	109.3	59.8	
1	. 1		610	7.8	175.3	108.7	59.8	
		Data	Truncat	ed 8.0				
1	. 1		860	8.0	189.6	94.4	32.0	
1	. 1		2070	3.9	147.6	136.4	0.4	
1	. 1		2080	4.1	147.6	136.4	3.0	
		Data	Truncat	ed				
1	. 2		2110	4.8	147.8	136.2	12.3	
1	. 2		2120	5.0	148.0	136.0	16.0	
		Data	Truncat	ed				
1	. 2		2300	10.0	156.6	127.4	59.7	
		Data	Truncat	ed 3.2				
1	. 2		3920	3.2	147.5	136.5	-0.3	
1	. 2		3930	3.4	147.5	136.5	1.7	
		Data	Truncat	ed				
				4.2				
1	. 3		3980	4.4	147.9	136.1	15.0	
		Data	Truncat	ed				
1	. 3		4320	9.7	165.8	118.2	59.8	
1	. 3		4470	10.1 10.2 10.2	174.8	109.2	59.8	
1	. 3		4480	10.2	175.4	108.6	59.8	
1	. 3		4490	10.2	176.0	108.0	59.8	
				10.2		107.4		
				10.2		106.8	59.8	
				10.2		106.2	59.8	
				10.2		105.6		
	. 3		4540	10.1	179.0	105.0		
	. 3		4550	10.1	179.6	104.4	59.7	
	. 3		4560	10.0 9.9	180.2	103.8	59.7	
1	. 3		4570	9.9	180.8	103.2	59.7	

- 8. Open the application of your choice to import the .txt file (example: Microsoft Excel). **NOTE:** It is best to import the .txt file in Excel prior to opening. Might want to omit the first two lines before importing since those are not data points.
- 9. Click the Data tab.
- 10. Select the From Text icon.
- 11. Run through the Text Import Wizard, clicking the "Delimited" radio button and clicking the Next button.

NOTE: The images below are based on Microsoft Office 2010. Other versions may have the settings under a different menu.



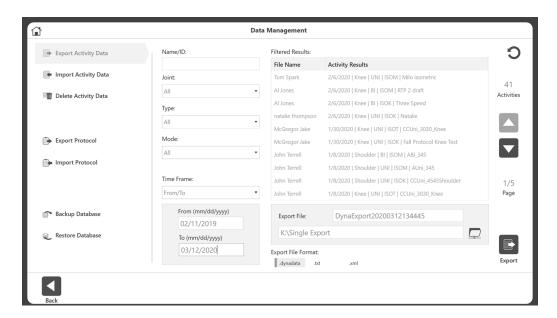
- 12. Ensure only the box for "Space" is checked under Delimeters.
- 13. Check the box for "Treat consecutive delimiters as one" and select the asterisk (*) in the Text qualifier field.
- 14. Select the Next button.
- 15. All metrics from the Comprehensive Report will be shown.



Multiple Data Export

To export data:

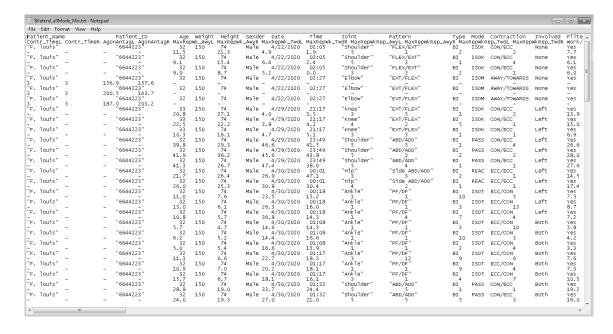
- 1. Select Utilities on the Home screen.
- 2. Select Data Management.
- 3. Click Export Activity Data.



- 4. Your search can be filtered by using the Name/ID, Joint, Type, Mode, and Time Frame fields.
- 5. Ensure the file location is correct.
- 6. For Export File Format, select from the following file types:
- .dynadata Export from one Advantage BX PC to import to another Advantage BX PC.
 This file is in compressed format and is not human readable.
- .txt Includes all metrics from the Comprehensive Report. Can be imported to Excel or other applications for normative data or any other usage. Data can be exported as either Bilateral or Unilateral (it cannot be combined).

NOTE: Does not include individual activity Data Points.

NOTE: In the column headings, "Awy" stands for Away, "Twd" stands for Towards, "L" stands for left, and "R" stands for Right.



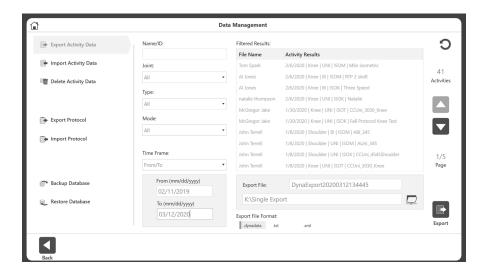
- .xml The most detailed format, it shows all of the information from a Comprehensive Report, and additional metrics including:
 - · Patient Information
 - Test Parameters
 - · Set Information
 - · Rep Information
 - · Data Points

```
<?xml version="1.0" encoding="UTF-8" standalone="true"?>
<AdvantageBXTestResults fileVersion="1.0">
     <TestResultCount>2</TestResultCount
    <SWVersion>5.2.00 (5/4/2020)</SWVersion>
    <TestResult>
        <PatientInfo>
             <FirstName>Jadon
             <LastName>Sancho</LastName>
            <PatientID>6644116</PatientID>
<Age>20</Age>
            <Weight>168</Weight>
<Height>71</Height>
             <Gender>Male</Gender>
         </PatientInfo>
        <TestParam>
<TestDate>4/5/2020</TestDate>
             <TestTime>21:35</TestTime>
             <Joint>Knee</Joint>
             <Pattern>Extension/Flexion</Pattern>
<Type>Unilateral
             <Mode>Isotonic</Mode>
             <Contraction>CON/CON</Contraction>
             <Sets>1</Sets2
             <Involved>Left</Involved>
            <Involved>Letr/Involved>
<GOM_Limit_Away>
<ROM_Limit_Toward>20/ROM_Limit_Toward>
<GET>*Left: 15 ft-lb at 71°*/GET>
<Window_Threshold>70

<Velocity_Threshold>15
/Velocity_Threshold>
             <Filtered>Yes</Filtered>
             <Windowed>No</Windowed>
             <Cushion_Filtered>Yes</Cushion_Filtered>
             <Cushion_Decel>6</Cushion_Decel>
             <Units>US</Units>
         </TestParam>
            <SetInfo>
                 <SetNumber>1</SetNumber>
                 <Reps>5</Reps>
                <Away>
<Torque>12</Torque>
                     <Peak_Velocity>23.4</Peak_Velocity>
```

NOTE: Exported data will always use a decimal point to separate the decimal digits point (with dot, not comma format) as per XML W3 standards.

7. Select the Export icon.

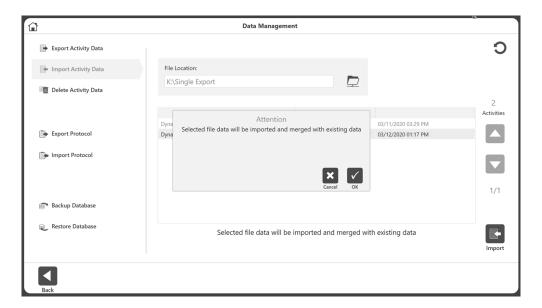


NOTE: Export Activity Data operation may take time depending on how much data is selected to export.

Importing Activity Data

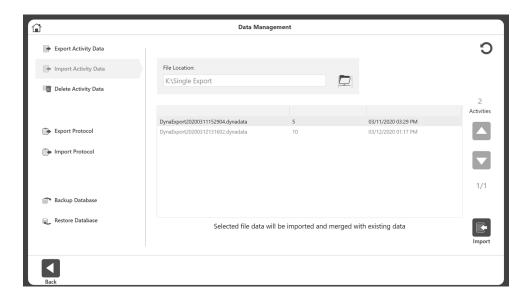
To import a file:

- 1. Click Utilities on the Home screen.
- 2. Select Data Management.
- 3. Select Import Activity Data.
- 4. Specify the File Location.
- 5. Select the file. A pop-up message will appear that says, "Selected file data will be imported and merged with existing data"
- 6. Click the OK icon.



7. Select the Import icon.

NOTE: The application can import a dynatata file, but not .xml or .txt files.



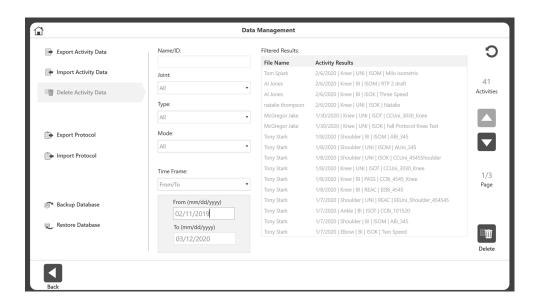
Deleting Activity Data

To delete multiple files:

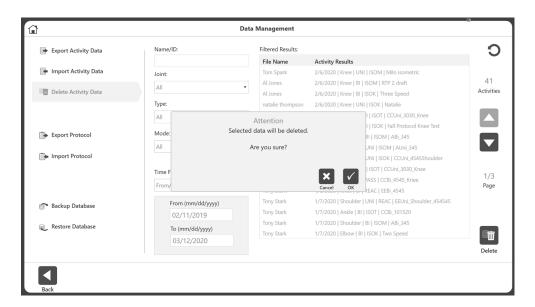
- 1. Navigate to the Home screen and select the Utilities option.
- 2. Select Data Management.
- 3. Select Delete Activity Data.
- 4. The Name/ID, Joint, Type, Mode, and Time Frame fields can be used to filter the search.
- 5. Select the files you want to delete and select the Delete icon.



IMPORTANT NOTE: Data will be deleted permanently. Perform this operation with caution.



- 6. A Delete confirmation message will pop up. Select:
 - a) the OK icon to delete
 - b) the Cancel icon.



Backup Database

The backup database will back up the unit's database and the changes made to the settings of that unit. It is not a data export option.



IMPORTANT NOTE: We recommend regular database backups (preferably on external media, if your facility allows it). In the event of any type of corruption, you will still be able to retrieve data up until a certain date.

- 1. Click Utilities on the Home screen.
- 2. Click Data Management.



- 3. Select Backup Database.
- 4. Select the folder icon. A pop-up for location selection displays. The pop-up will display all the local drives, removable drives, and mapped network drives.
- 5. Select a location and select the OK icon.
 - **NOTE:** Once a folder is selected, it will be remembered the next time.
- 6. The application will display an auto-generated File Name. You can change the filename if desired.
- 7. Click the Backup icon.
- 8. It will display message notifying the process's progress or outcome.

NOTE: Different databases created with the application can be backed up and restored, not just single databases, as of version 5.3.00.

NOTE: We recommend periodic backups.

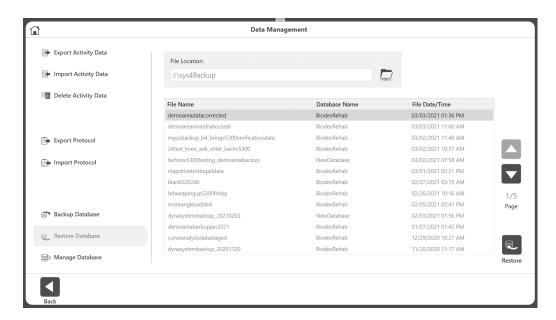
Restore Database

The Restore Database option will restore the unit to the previously backed up data and the changes made on settings.



IMPORTANT NOTE: Perform this operation with caution to avoid a mix up of older database backups. This operation will restore data to the backup date.

1. Enter the Access Code 159 and select the OK icon.



- 2. Select Restore Database.
- 3. Select the folder icon. A pop-up for location selection displays.
- 4. Select a location and select the OK icon. The pop-up will display all the local drives, removable drives, and mapped network drives.

NOTE: Once a folder is selected, it will be remembered for the next time.

- 5. A list of available backup files will be displayed as a list.
- 6. Select a row from the list and then click the Restore button.
- 7. A progress or outcome message will display. A restart of the application may be required and prompted.

Manage Databases

The Manage Data operation allows you to Create Database (blank/ with existing data), Delete Database and Switch Database. You can create as many databases as necessary.

NOTE: "Biodex Rehab" is the default database. It cannot be renamed or deleted.

- 1. Click Utilities on the Home screen.
- 2. Click Data Management.
- 3. Click Manage Database.

Switch Database

To switch between existing databases:

- 1. On the Home screen, click Utilities.
- 2. Click Data Management.
- 3. Click Manage Database.
- 4. Under Active Database, click the arrow to view the drop-down menu.
- 5. Select the database you want.
- 6. Click the OK icon.

NOTE: Changing the database will not affect the application or system settings.

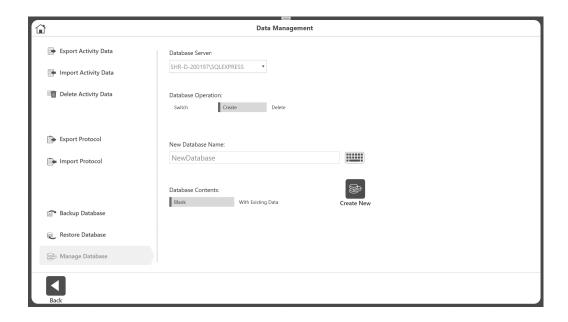
Create a Database

To create a blank database:

- 1. On the Home screen, click Utilities.
- 2. Click Data Management.
- 3. Click Manage Database.
- 4. For Database Operation, select Create.
- 5. Under Database Contents, select Blank.
- 6. Name the database by typing into the New Database Name field.
- 7. Click the Create icon.
- 8. A pop-up will display saying that the database has changed, and the application will restart. Click the OK icon if you want to switch immediately to the newly created database. Click Cancel if you do not want to change the current database.
- 9. If OK icon was clicked, on the restart of the application, the new database name will appear on the bottom of the Home screen, which will be the current database.

To create a database with existing data:

- 1. On the Home screen, click Utilities.
- 2. Click Data Management.
- 3. Click Manage Database.
- 4. Select Create under Database Operation.
- 5. Name the database by typing into the New Database Name field.
- 6. Under Database Contents click Existing Data.
- 7. Click the Create New icon.
- 8. A pop-up will display saying that the database has changed, and the application will restart. Click the OK icon if you want to switch immediately to the newly created database. Click Cancel if you do not want to change the current database.
- 9. If OK icon was clicked, on the restart of the application, the new database name will appear on the bottom of the Home screen, which will be the current database.



Delete Database



IMPORTANT NOTE: Databases along with their data will be deleted permanently. Perform this operation with caution.

To delete any custom created databases:

- 1. On the Home screen, click Utilities.
- 2. Click Data Management.
- 3. Click Manage Database.
- 4. Under Database Operation, select Delete.
- 5. Choose the database you want to delete.
- 6. Click the Delete icon.

NOTE: "Biodex Rehab" is the default database. It cannot be renamed or deleted.

Application Settings

The Application Settings option allows settings to be changed. Any changes made on this screen will be saved.

NOTE: When the Reset to Default icon is selected, it will only reset your current selection.

- 1. Enter Access Code 159 and select the OK icon.
- 2. On the Application Settings screen, select General Settings, Training Settings, Dynamometer Settings, or Analog Signal Settings. Once selected, the appropriate options for that setting will display on the right side of the screen.



General Settings

General Protocol Preferences:

- Limb Weight Option enable/disable option to set Limb Weight on ROM setup.
- Enable Chair Settings Toggle between displaying/hiding the Chair Settings option on ROM Setup screen.
- Activity Sound controls the sound of the Activity Start, complete, rep sound.
- Allow Partial Data Save on Activity If enabled, allows you to save partial data.
 You will not be able to skip side if disabled.
- Auto Start After Rest Period Automatically starts the next set after a rest period is over.
- Practice Trial Start Option Toggle between Auto or Manual for the Practice Trial Start Option. When Auto is selected, the practice trial will begin before the user is able to start the activity. When Manual is selected, you will be able to start the activity without practicing. However, a Practice Trial button will appear as needed.
- Scoring Window Allows you to change the value of the scoring window used on the activity screen. The default setting is 70%.

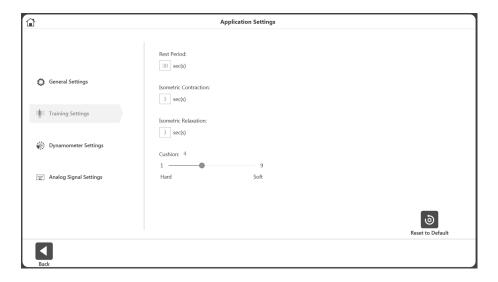
- Torque at Used on report settings for Comprehensive report type for a specific position. The default setting is 30 deg(s).
- Torque in Used on report settings for Comprehensive report type for a specific amount of time. The default setting is 0.18 sec(s).

NOTE: Refer to the torque descriptions on page 27 of the manual for further information.

General Preferences:

- Enable Clinical Codes Enter/select a different code on Code/Comments screen.
- Identify Patient by ID Code Enabling this will make the First and Last name not required. If unchecked, First and Last name will be required.
- Touch Feedback Sound Control the touch sound.

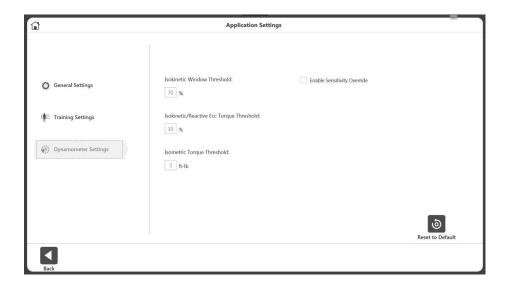
Training Settings



Set the default values of the training session for:

- Rest Period Default 30 second for rest period between sets for Training.
- Isometric Contraction Contraction time 3 seconds for Training.
- Isometric Relaxation Relaxation time 3 seconds for Training.
- Cushion Default Cushion settings for Training.

Dynamometer Settings



We recommend keeping the default settings on the device. Properties can be changed if needed.

- Set the Isokinetic Window Threshold The subject can accelerate up to, but no higher than, a maximum speed value (default is 70%).
- Isokinetic/Reactive Ecc Torque Threshold The subject is required to meet a minimum torque threshold corresponding to 10% of the Torque setting (defaults to 10%). The subject may not exceed the torque limit set, ensuring the force output is kept within the desired range.
- Isometric Torque Threshold The force limit defaults to 3 ft-lb. (4.1 Nm) as the dynamometer is to maintain zero velocity in Isometric Mode.
- Enable Sensitivity Override Controls the visibility of the Sensitivity option on Training and creating custom protocol.

Analog Signal Settings

The Analog Signal Settings configure the scale factors and operating modes of the analog signal outputs for velocity, torque, and position. With this configuration capability, the analog signals can be custom tailored to provide the best and most appropriate analog data for a wide variety of uses.

The Remote Access port is an output of analog signals of velocity, torque, and position data in real-time directly from the monitor control Digital Signal Processor (DSP). In addition, a synchronization pulse is issued whenever the real-time data is updated. This alerts the monitoring equipment that the real-time data output has changed.



Once the settings are made, the Analog Signal Settings will be permanently set in the System 4 even if the unit is completely shut down and restarted. The current settings can always be verified by coming to ASA Settings screen on the software - it will show the current active settings for that connected hardware.

Analog Signal Resolution Affected by Scale Factor

The analog signals range from -5 volts to +5 volts, resulting in a total range of 10 volts. With the standard Remote Access option available, all analog output signals are at full scale (full scale being the default). Full scale for torque as an example is -512 ft-lb to +512 ft-lb (-696 to +696 Nm), for a total range of 1024 ft-lb (1392 Nm). This results in an output resolution scale factor as follows:

```
1024 ft-lb (1352 Nm) = 10 volts, where
1 ft-lb (1.36 Nm) = 9.8 milli-volts
```

9.8 milli-volts is well below the signal noise rated for this port, therefore it is not possible to see 1 ft-lb increments on this analog signal. The utility provides scaling options separately for all three analog signals; therefore, if typical usage is well below the maximum levels, 1 ft-lb (1.36 Nm) increments can be seen on typical analog monitoring equipment. For example, applying a range of +/- 0 to 64 ft-lb (87 Nm), the output resolution scale factor would look as follows:

```
128 ft-lb (174 Nm) = 10 volts, where
1 ft-lb (1.36 Nm) = 9.8 \text{ milli-volts}
```

78.1 milli-volts is well above the worst case of signal noise (15 - 35 mV); therefore, increments as low as $\frac{1}{2}$ to $\frac{1}{2}$ ft-lb (0.34 to 0.68 Nm) can be seen reliably.

Operating Modes

The Output Frequency, or update rate, controls how frequent the system will change the analog outputs. The highest update rate is 2,000 times per second, which is the default. If this high frequency is not needed or causing problems with the monitoring equipment, the update rate can be lowered. Every time the analog signals are output, the synchronization signal is pulsed also. Therefore, the update rate controls how frequent the synchronization signal is pulsed.

The Output Mode selects the state in which the analog signal outputs are updated. The options are as follows:

On Always - Always output regardless of current operational state.

Off (disabled) - Totally shuts down the analog signal outputs.

Auto- when active – Is automatically ON when the system is in an ACTIVE state; meaning not stopped and not in hold. It won't trigger analog output when the system is in the SETUP/IDLE state. Dynamometer status can be found on the top right corner of the BX software. When that shows Active, machine is in Active state.

Note here that, during Protocol Based Activity we have two states of active state - ACTIVE and ACQUIRING DATA state. On Training, we have only one active state (ACTIVE).

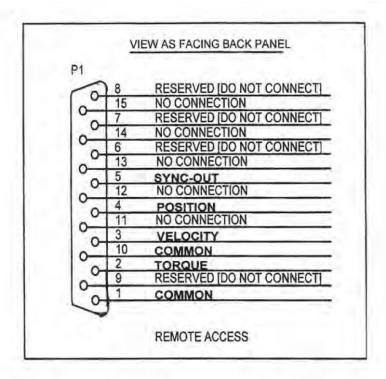
Table of Scale Range and Factors

Scaling Option	Range	Scale Factor
Velocity:		
0 - 512 deg/sec	-521 to +512 deg/sec	9.8 mV per deg/sec
0 - 256 deg/sec	-256 to +256 deg/sec	19.5 mV per deg/sec
0 - 128 deg/sec	-128 to +128 deg/sec	39.1 mV per deg/sec
1 - 64 deg/sec	-64 to +64 deg/sec	78.1 mV per deg/sec
0 - 32 deg/sec	-32 to +32 deg/sec	156.3 mV per deg/sec
Toque:		
0 - 512 ft-lb (696 Nm)	-521 to +512 ft-lb (-708 to +696 Nm)	9.8 mV per ft-lb
0 - 256 ft-lb (348 Nm)	-256 to +256 ft-lb (-348 to +348 Nm)	19.5 mV per ft-lb
0 - 128 ft-lb (174 Nm)	-128 to +128 ft-lb (-174 to +174 Nm)	39.1 mV per ft-lb
1 - 64 ft-lb (87 Nm)	-64 to +64 ft-lb (-87 to +87 Nm)	78.1 mV per ft-lb
0 - 32 ft-lb (43.5 Nm)	-32 to +32 ft-lb (-43.5 to 43.5 Nm)	156.3 mV per ft-lb
Position:		
Full scale (~ 306 degrees)	0 to 306 degrees	29.2 mV per degree
ROM only (varies	Ex: 45 degrees	Ex: 198.7 mV per degree

There are many types of devices to which you can connect. Biodex provides the "pin outs" and leaves it up to the end user to make the interface cable. Because of the popularity of this application, many companies have cables available for their devices. Check with a particular interface device manufacturer. If not, make a cable to communicate if the other device's connections are known.

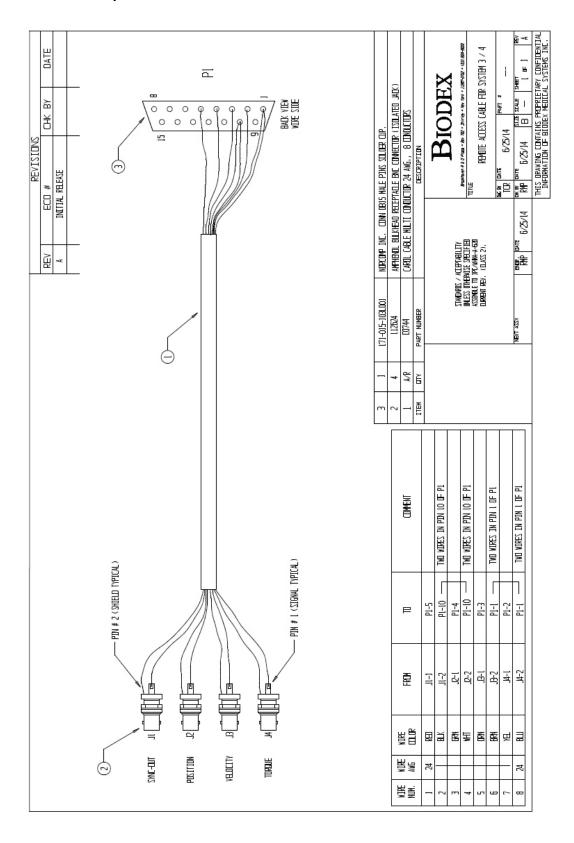
The connection is labeled REMOTE ACCESS on the back of the Biodex CDS cart. It is a DB-15 female connector.

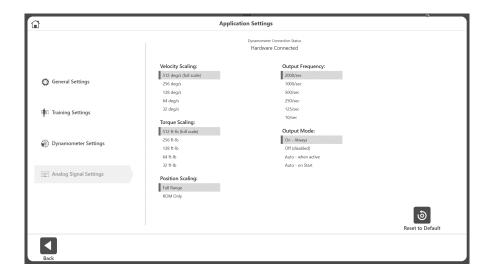
Remote Access Connection - DB-15 Female Connector



PIN#	DESIGNATION	DESCRIPTION
1	Common	Signal ground
2	Torque	Analog torque signal
3	Velocity	Analog velocity signal
4	Position	Analog position signal
5	Syncout	TTL pulse
6-9	reserved	Do not connect!
10	Common	Signal ground [same as pin 1]
11-15	not connected	

BNC Cable Example





To adjust the Analog Signal Settings:

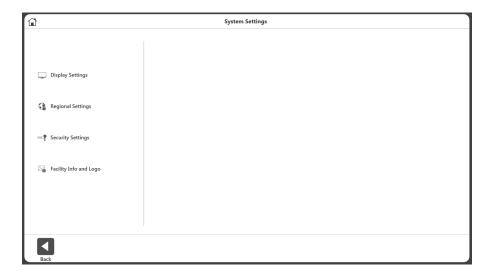
- 1. Select Utilities on the Home screen.
- 2. Select System Settings and then Analog Signal Settings.
- 3. Set the Velocity Scaling, Torque Scaling, Position Scaling, Output Frequency, and/or Output Mode.
- 4. Select the Back or Home icon to return to a previous screen.



IMPORTANT NOTE: It is necessary to have connection between pc and the dynamometer to save the changes of these settings, since these Analog Signal Settings are stored in flash memory in the System 4 unit, NOT in the Advantage BX software.

System Settings

Any changes made to the System Settings on this screen will be saved. When the Reset to Default icon is selected, it will only reset the section the user is currently on. Each of the System Settings will be explained in this section.



Display Settings



To adjust the Display Settings:

- 1. Select Utilities on the Home screen.
- 2. Select System Settings.
- 3. Select Display Settings. The following display settings can be changed:
 - Test Completion Screen Time Out Set the time between off to 30 minutes. If enabled, when set time expires on the Activity Result screen, the user will be returned to Main Menu in 30 seconds whether or not the results are saved.
 - Screen Saver Displays during inactivity. Can be off to 30 minutes.
 - Monitor Displays on Internal monitor by default. If External, it will duplicate the view on both monitors.
 - Screen Brightness Depending on the PC/Tablet, if available, controls the brightness.
 - Volume Settings Controls the volume of the PC.
 - Touchscreen Keyboard/Keypad Enable/Disable the on-screen keyboard.

Regional Settings



To adjust the Regional Settings:

- 1. Select Utilities on the Home screen.
- 2. Select System Settings.
- 3. Select Regional Settings. The following properties of the System (PC) can be changed:
 - Regional Format Regional settings can be selected from the dropdown.
 - Language Select from a pre-defined list of languages. The application will then display the text in those languages.
 - Time Zone Set the time zone.
 - Units Set Metric or US units.
 - Time, Date, and/or Time Format Set the date/time of the PC and format.

Security Settings



To adjust the Security Settings:

- 1. Select Utilities on the Home screen.
- 2. Select System Settings.
- 3. Select Security Settings. The following settings can be adjusted:
 - The Access Code can be required or not required at Startup.
 - The Default Access Code can be changed. The user will need to enter the default access code and then type and re-type the new code.

Facility Info and Logo



To change the Facility Info and Logo:

- 1. Select Utilities on the Home screen.
- 2. Select System Settings.
- 3. Select Facility Info and Logo. The following settings can be adjusted:
 - Add the Facility name, address, phone/web/email information into the text hoxes
 - Facility information can be displayed on reports and the home screen.

To add a logo:

- 1. Click on the button to bring up the location browser.
- 2. Select the logo file from the location browser.
- 3. Click the OK button to apply the logo. A preview of the logo will display.
- 4. If needed, the current logo can be removed (using the trash icon) and then use the button to add another logo.

4. Clinical Education

Biodex supplements on-site training with many training resources. The Instructions for Use (IFU) manual can be found on the Biodex website on the Manuals tab at: www.biodex.com/s4.



Clinical Guidelines, webinars, and research documents are available at www.biodex.com and the Biodex YouTube channel offers instructional videos. Support staff is also available to assist with clinical and mechanical questions and problems.

It is important to spend time practicing on the Dynamometer. Practice helps to improve the clinician's skill level and effectiveness with patients' care. Initial on-site training typically lasts 3-4 hours depending on the number of clinicians present.

5. Software Updates

Software updates are available on the Biodex website: https://www.biodex.com/physical-medicine/products/software-updates



6. Maintenance

Cleaning Instructions

Cleaning should be performed after every patient's use. 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 activity 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.

Verify Calibration

- 1. From the Home screen, click the Utilities icon.
- 2. Click the Verify Calibration button.
- 3. Enter the name of the person performing the verification on the Verify Calibration screen.
- 4. Select the Continue icon.



- 5. Watch the video. Remove any attachments from the shaft and elevate the pedestal.
- 6. Select the Continue icon.
- 7. Watch the video. Attach the shoulder attachment and then attach the calibration weight. Allow it to settle.
- 8. Select the Continue icon.

- 9. Watch the video. Remove the calibration weight.
- 10. Select the Continue icon. The attachment will move automatically to the Horizontal position.
- 11. Watch the video. Attach the calibration weight horizontally and allow it to settle.
- 12. Select the Continue icon.
- 13. Verification will occur if torque is within the acceptable tolerance range.
- 14. Click the Report button to get the Verification History report. The report for previous verification can be accessed anytime by clicking the Report button.

NOTE: A Verification Failure message will display if torque is not within the acceptable tolerance range. If the system will not verify within an acceptable range, please contact Biodex Service (see contact information).

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.

NOTE: The attachment will not be released and will not proceed to the next step when weight is detected.

NOTE: Additional information can be found at: www.biodex.com/s4



Disposal

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

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

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

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

7. Definition of Terms

PEAK TORQUE (TQ) (ft-lb): Highest force output during a repetition. Indicative of a muscle's strength capabilities.

AVG. PEAK TQ (ft-lb): The averages peak torque at each repetition. Represents the average force output of a given set.

PEAK TQ/BW (%): Highest force output normalized to bodyweight. Compared to goal.

TIME TO PEAK TORQUE (ft-lb): A measure of time from the start of the muscular contraction to the point of highest torque development. An indicator of the functional ability to produce torque quickly.

ANGLE OF PEAK TORQUE (deg): A test of the functional ability of a joint showing the point in the ROM where peak torque is achieved.

TORQUE AT 30° (ft-lb): Displays the torque produced for each direction at the pre-selected position. The position of 30° is a critical point in knee stabilization, since the knee flexes to about 30° during normal ambulation.

TORQUE AT 0.2 seconds (ft-lb): Displays the time rate of tension development. The time of 0.2 is preselected because it has been documented that, upon heel strike, it takes the leg extensors 0.2 seconds to develop enough force to support the body in normal ambulation. Possibly one of the best indicators of a rehabilitated joint.

COEFFICIENT OF VARIANCE (%): Indicative of reproducibility of performance. Lower values demonstrate higher reproducibility.

MAX REP TO TOTAL WORK (ft-lb): Total force output for the repetition with greatest amount of work. Indicative of a muscle's capability throughout range of motion.

WORK/BW (%): Ratio displayed as a percentage of the maximum work repetition to the subject's bodyweight.

TOTAL WORK (ft-lb): The sum of work for every repetition performed.

WORK FIRST THIRD, LAST THIRD (ft-lb): The entire activity is divided into thirds. This is the total work of the first 1/3 of the reps and the last 1/3 of the reps.

WORK FATIGUE (ft-lb): The ratio of the difference, expressed as a percentage, between the work in the first 1/3 to the work in the last 1/3 of the test bout. W(first 1/3) / W(last 1/3) = %

PEAK POWER (W): Peak power output (PPO), also known as peak work rate, is a common measure of exercise intensity. The highest rate of doing work.

AVG. POWER (W): The average rate of doing work.

ACCELERATION TIME (msec): Total time used to reach isokinetic speed. Indicates muscle's neuromuscular capabilities to move the limb at the beginning of the ROM.

DECELERATION TIME (msec): Total time used to go from isokinetic speed to zero speed. Indicates a muscle's neuromuscular capabilities to eccentrically control the limb at the end ROM.

ROM (deg): Greatest range the joint achieved. Allows analysis of test curves in relationship to joint Range of Motion.

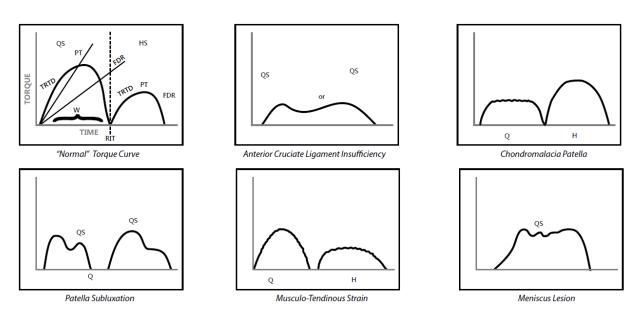
AGON/ANTAG RATIO (%): Reciprocal muscle group ratio. Excessive imbalances may predispose a joint to injury.

TORQUE (ft-lb): A function of force and distance from the axis of rotation as measured by the Biodex dynamometer.

GOAL: Unilateral comparison of peak torque to body weight ratio to literature published on specific joints and pathologies.

WINDOWED DATA VS. ALL DATA: Windowed Data eliminates all data that was not generated at isokinetic speed (ie: acceleration, deceleration, artifact spiking). All Data is valuable when reviewing data from PTs who may not be capable of catching isokinetic speed during every repetition.

CHARACTERISTICS OF PATHOLOGIES (DAVIES, 1992): A data interpretation guide. Illustrated below.



FORCE (F): Any action that displaces an object - linear displacement.

DEFICIT (%): Deficit percentages of 1-10% indicate that there are no significant differences between muscle groups. Percentages of 11-20% indicate that rehabilitation is recommended to improve muscular balance. Over 20% represents a significant impairment. Negative deficits indicate that the involved performed better than the uninvolved.

GRAVITY EFFECT TORQUE (GET) LIMB WEIGHT: Weight of the body's limb in the attachment. Used to eliminate the additional torque applied to the muscle being tested. Limb weight is added to torque values when working against gravity and subtracted when working with gravity.

WORK: Force multiplied by distance produced throughout the entire ROM. The area under the curve.

POWER (P): Rate of doing work. Work/time it takes to perform the work.

SYMMETRY: A simple comparison of involved limb to uninvolved expressed as a ratio: Involved/Uninvolved \times 100. It is recommended that limb symmetry goals are \geq 90% for Return to Play.

8. Specifications and Certifications

Clinical Data Station:

PC with Windows 10 Enterprise LTSC

Biodex Advantage BX™ Software

22" flat panel touchscreen with integrated speakers

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

Calibration Kit

Operating space: 64 square feet (6 square meters) (850-000, 852-000)

Certification:

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

1: 2012 reprint)

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

CAN/CSA C22.2 No. 60601-1:14

IEC 60601-1-2:2014

Electrical Requirements:

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: 25" wide, 19" deep, 41" high (64 × 48 × 104cm)

T-Base & Chair: 52" wide, 65" deep, 60" high (132 \times 165 \times 152cm) **Attachment Cart:** 33" wide, 20" deep, 40" high (85 \times 51 \times 102cm)

Dynamometer Performance Specifications:

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)

Torque accuracy is +/-1% of full scale (500 ft-lbs [680Nm])

Torque is factory calibrated

Position range is 306°

Position accuracy is + / -1° of rotation

Torque verification fixture is 50 ft-lbs +/- 0.5 ft-lbs (68Nm +/- .68Nm)

Velocity Accuracy is +/-2% of full scale (500 deg/sec)

Environmental Condition:

Operating Temperature: 10°C to 37°C (50°F to 100°F).

Transport & Storage Temperature: -20° C to 70° C (-4° F to 158° F).

Relative Humidity: 20% to 90% non-condensing.

Atmospheric Pressure: Sea Level 101kpa (14.7psi) to 10,000 feet, 69 kpa (10.1 psi)

NOTE: Specifications and Certifications continued on the next page.

Analog Signal Settings

Accuracy: ± 2%. Resolution: 16 Bits.

Minimum Vout Increment: 152.5uv

Signal Noise:

15 mVrms [20KHz Bandwidth].

35 mVpp [20 μ S minimum, 150 μ S maximum width].

Response Time: 500μS.

Connector: DB-15 male "D" Connector. Output Short Circuit Duration: Infinite.

Output Impedance: 100S

Individual Signals

Torque* Analog torque signal 5 volts is cw torque (512 ft-lb)

0.0 volts is 0 ft-lb

-5.0 volts is ccw torque (512 ft-lb)

Scale Factor= 9.76 mV/ft-lb

Velocity Analog velocity signal

5 volts is full scale cw speed (512 deg/sec)

0.0 volts is 0 deg/sec

-5.0 volts is full scale ccw speed (512 deg/sec)

Scale Factor= 9.76 mV/[deg/sec]

Position Analog position signal

4.60 volts is when dyna shaft is fully cw

-4.28 volts is when dyna shaft is fully ccw

Scale Factor= 28.7 mV/[deg]

Total ROM is 306 degrees; Total Vout =8.88V

Synchronization Digital TTL pulse

Active High

29µs Pulse width Continuous

Indicates voltage output update, [~2KHz], mode dependent

Accessories

Accessory	Model Number
Dual Position Ex/Flex Back Attachment	830-450
Closed Chain Attachment	830-520
Work Simulation Tools Attachment	830-269
UE Hemiparetic Attachments	830-540
Left Pivot Anti-Shear Attachment	830-260
Right Pivot Anti-Shear Attachment	830-261
Pediatric Left Knee Attachment	830-474
Pediatric Right Knee Attachment	830-475
Pediatric Shoulder Attachment	821-321
Hamstring (set) Attachment	830-550
Pediatric Hip Attachment	830-316
Chair Wedge	830-113

9. Electromagnetic Compatibility/Immunity

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Use of accessories and cables other than those specified or provided by Biodex of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. Do not use unapproved components. Only use system components provided with the system or obtained from the company as supplies or replacements.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the SYSTEM 4 system including cables specified by Biodex. Otherwise. degradation of the performance of this equipment could result.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS (Per IEC 60601-1-2:2014)

SYSTEM 4 is intended for use in the electromagnetic environment specified below. The customer or user of the SYSTEM 4 should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guide	
RF emissions CISPR	Group 1	The SYSTEM 4 uses RF energy for internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class A		
Harmonic emissions IEC 61000-3-2	Complies	The SYSTEM 4 is suitable for use in all establishments other than domestic and those connected to a low voltage power supply	
Voltage fluctuations/ emission oscillations IEC 61000-3-3	Complies	network which supplies buildings used for domestic purpose	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY (Per IEC 60601-1-2:2014)

SYSTEM 4 is intended for use in the electromagnetic environment specified below. The customer or user of the SYSTEM 4 system should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 Test level	Compliance Level	Electromagnetic environment - recommendations
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 2 kV, +4 kV, +8 kV contact +/- 2 kV, +4 kV, +8 kV, +15 kV air	IEC 60601-1-2 Test Level	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30% applicable.
Electrical fast	+/-2kV	IEC 60601-1-2	Mains power quality should be that of a typical

transient/burst, Power Ports IEC 61000-4-4		Test Level	domestic or hospital environment.
Electrical fast transient/burst, I/O Ports IEC 61000-4-4	+/-1kV	IEC 60601-1-2 Test Level	Mains power quality should be that of a typical domestic or hospital environment.
Surge, Power Ports IEC 61000-4-5	+/- 1 kV line to line		Mains power quality should be that of a typical domestic or hospital environment.
Voltage Dips and Interrupts IEC 61000-4-11	>95% dip in Ut for 0.5 cycle 60% dip in Ut for 5 cycles 30% dip in Ut for 25 cycles >95% dip in Ut for 5 cycles	IEC 60601-1-2 Test Level	Mains power quality should be that of a typical domestic or hospital environment.
Power frequency, Magnetic Immunity IEC 61000-4-8	30 A/m RMS		Power frequency magnetic fields should be at levels characteristic of a typical public low- voltage power supply network that supplies buildings used for domestic purposes, commercial or hospital, clinic environment.
Conducted Immunity, Power Ports IEC 61000-4-6 Conducted Immunity, I/O Ports IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	IEC 60601-1-2	Portable and mobile RF communications equipment should be used no closer to any part of the SYSTEM 4, including cables, then the recommended separation distance calculated from the equation applicable to the frequency of the transmitter recommended separation distance.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz		Recommended separation distances: d = 1.2√P 80 M Hz to 800 MHz d= 2.3√P 800 MHz to 2.7 GHz 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 R F transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment market with the following ((**)) symbol:

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.

- a. 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 the SYSTEM 4 is used exceeds the applicable RF compliance level above, the SYSTEM 4 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SYSTEM 4.
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

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