

ISOMETRIC STRENGTH (ISOMETRIC CHAIR)**TABLE OF CONTENTS**

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ISOMETRIC STRENGTH (ISOMETRIC CHAIR)

1. Background and rationale

Lower extremity strength is of critical importance to maintaining independence and mobility in old age. Isometric strength assesses force against a fixed object and is highly correlated with our other measure of strength, isokinetic strength, measured by the Kin-Com Dynamometer. The isometric chair is a portable device designed to measure strength with knee extension, and was designed specifically for the Health ABC study. We will be comparing how well the isometric chair and the Kin-com measure change in strength over time.

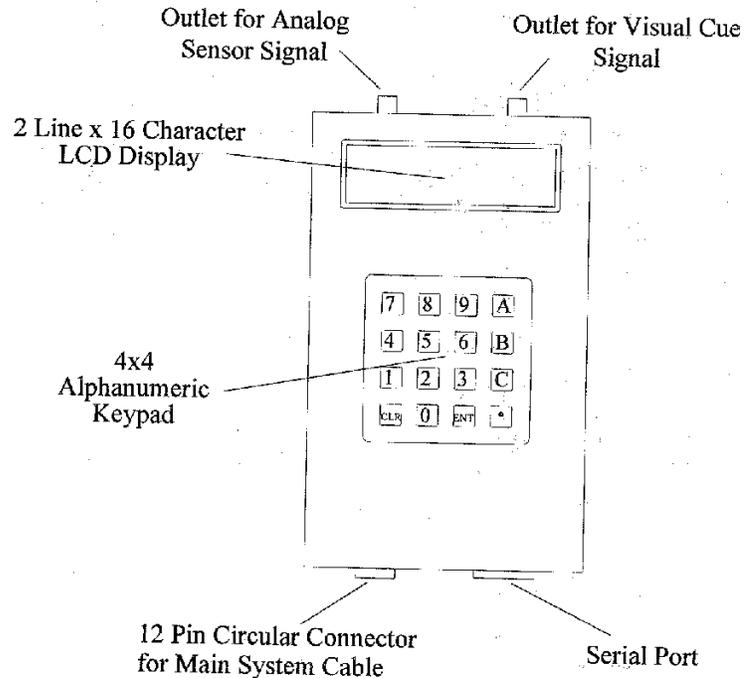
2. Equipment and supplies

- Adjustable-height chair
- Torque sensing assembly
- Visual cue and bar graph unit
- Central control and processing unit with alphanumeric liquid crystal display and 4x4 keypad.
- Replacement trolley Velcro straps
- Tape measure
- Kim-wipes™

2.1 LITEK

Vertical Range: (Measured from floor to top surface of seat)	0.40 - 0.67 meters (in ~12 cm increments)	(16 - 26.5 inches) (in ~ 0.5 inch increments)
Seat Depth:	0.41 meters	(16 inches)
Adjustable Backrest Range: (Measure from front of seat)	0.25 - 0.51 meters	(10 - 20 inches)
Seat Width:	0.485 meters	(19 inches)
Span Between Arms:	0.55 meters	(21.5 inches)
Nominal Weight Capacity: (136 kg)	1335 Newtons	(300 pounds)
Weight: (12.5 kg)	122 Newtons	(27.5 pounds)

2.2 Central electronic control and processing system



The central control unit is a microprocessor-based controller that serves as the user interface and real-time computational engine for the system. It performs a number of critical tasks, including:

- * Delivery of visual cue and feedback, and capture and processing of sensor data
- * Calculation of maximum torque
- * Calculation and display of false-real time torque measurements in sub-second intervals
- * Execution of user commands received via a menu-driven interface
- * Display of processed results on an alphanumeric Liquid Crystal Display (LCD)
- * Coordination of interactive sensor calibration procedures
- * Providing direct access to analog sensor signals and the green light cue.

2.3 Sensor

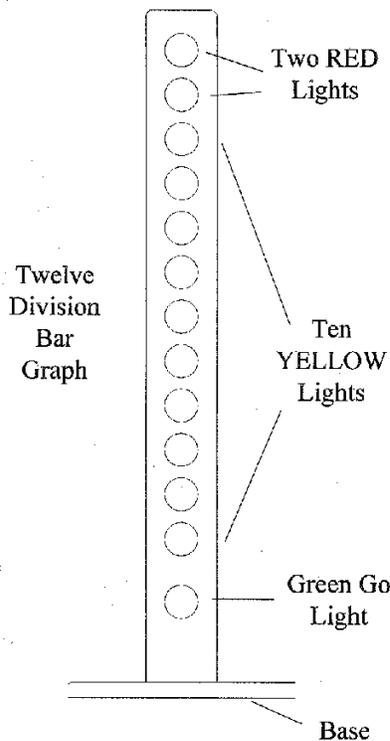
The sensor measures force. Torque is calculated as the product of force and torque arm length. The torque arm length is equal to the length measured between the lateral joint

line of the knee and the bottom surface of the heel plus 0.0251 m, which is the distance from the top surface of the trolley platform and the transducer axis.

2.4 Quick-connect trolley

Distance from floor to top of platform on which the heel rests:	4.6 inches
Distance from top of platform to transducer axis:	0.99 inches
Trolley weight:	3.4 pounds

2.5 Visual cue and bar graph unit



13 light emitting diodes ~1.9 cm (3/4 inch) in diameter (all but green light covered for this test)

1 green visual cue go light

12 bar graph lights (10 yellow, 2 red)

Main Body Size: 15.3 x 1.6 x 1.57 (inches)

Base Size: 5.1 x 3.8 (inches)

Note: for the Health ABC study, the red and yellow lights will be covered. The participant will only see the green light.

2.6 Power supply

A hospital-grade power supply unit provides safe isolated power to the system. The unit is plugged into a standard 3-prong AC outlet. The unit has a built-in circuit-breaker protection with no overshoot on turn-on or turn-off and delivers only low voltage/low current DC power to the chair electronics. No AC power is delivered beyond the wall-mount power supply.

2.7 Calibration tube and quick-connect hook

A 6 5/8-long stainless steel tube and a stainless steel hook/quick connect hook are provided for easy system calibration.

3. Service and maintenance

3.1 Warranty

Bio Logic Engineering Inc. warrants all parts and labor for 30 days after delivery against faulty workmanship or defective materials. The warranty does not include damage resulting from improper handling and accidents. In addition, the warranty does not cover unauthorized repairs or alterations to any part of the system. All returns must be preceded by contacting Bio Logic to obtain return authorization.

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Dexter, MI 48130-9771
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3.2 Service

If the system should become defective within the warranty period due to faulty workmanship or defective materials, Bio Logic will repair or service any defective parts free of charge. In the event of damage due to improper handling or accident within the warranty period, Bio Logic will provide service, charging parts, travel expenses, shipping and labor at a rate of \$100 per hour. After the warranty expires, Bio Logic will

- Results, including maximum torque (Nm), maximum rate torque (Nm/sec), reaction time (msec), and time to 50% MVTD (msec)
- If test not performed, why?
- Which connecting rod was used?
- What is the seat height?
- What is the seat depth?

Note: To obtain values for maximum torque, maximum rate torque, reaction time, and time to 50% MVTD, go to the main menu and press “B=Display;” this will display all the values you need to record. Keep pressing “B” to toggle between values.

NOTE: IT IS VERY IMPORTANT TO RECORD PARTICIPANT RESULTS AS THE CENTRAL CONTROL UNIT DOES NOT STORE THEM INTERNALLY. THE UNIT WILL ALLOW YOU TO RETRIEVE ONLY THE RESULTS OF THE PREVIOUS TRIAL.

8. Administration

8.1 Determine which knee can be tested

Determine which knee can be tested:

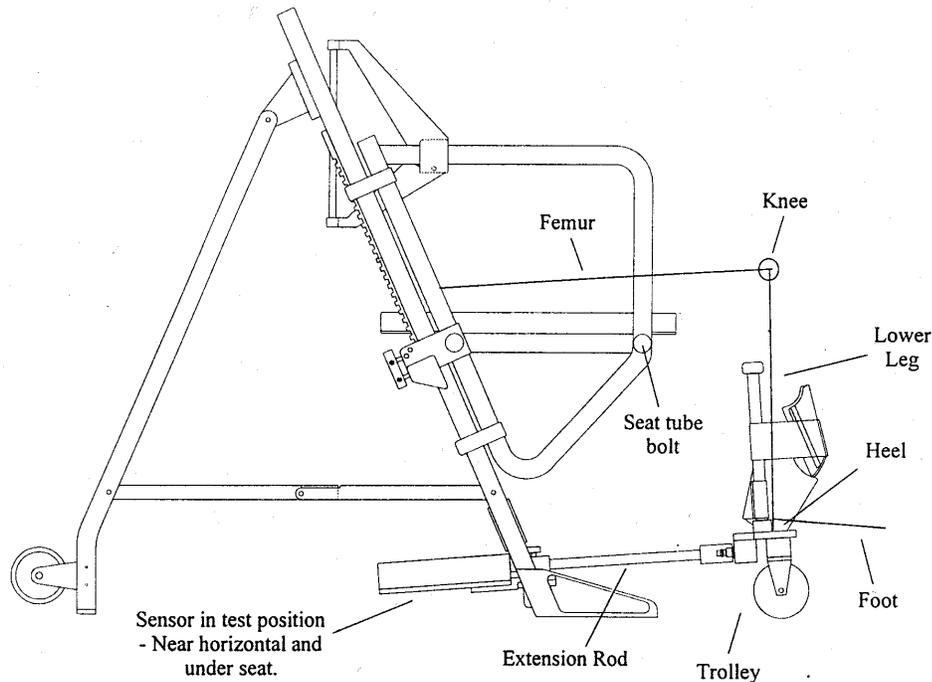
Script: “Have you ever had knee surgery on either leg where all or part of the joint was replaced?”

Unless contraindicated, the participant should be measured on the same leg as they were measured at Year 3. If the participant did not have the Isometric Chair test during Year 3, measure on the same leg of their last Kin-Com exam. For most participants, the last Kin-Com exam will have been done on the same day that they are being administered the Isometric Chair test. Look on page 20 of the Year 6 Clinic Visit Workbook to see which leg was tested during the Kin-Com exam. If the participant did not have the Isometric Chair measurement at Year 3, and if they were excluded from the Kin-Com exam during Year 6, refer to the Data from Prior Visits Report to see which leg was tested during the most recent Kin-Com exam. If the participant never had a Kin-Com exam, test the right leg unless contraindicated. If the participant has had a knee replacement since Year 3, that precludes testing the original leg.

If the participant has had bilateral knee replacements, do not test.

8.2 Positioning the participant on the isometric chair

Use the same positioning parameters from the Year 3 visit to position the participant in the chair. The rod length, vertical seat height, and seat depth will be on the Data from Prior Visits Report.



Instruct participant:

Script: “Now I would like you to sit in the chair with your hands holding onto the arm rests of the chair. Please hold onto the arm rests during all testing.”

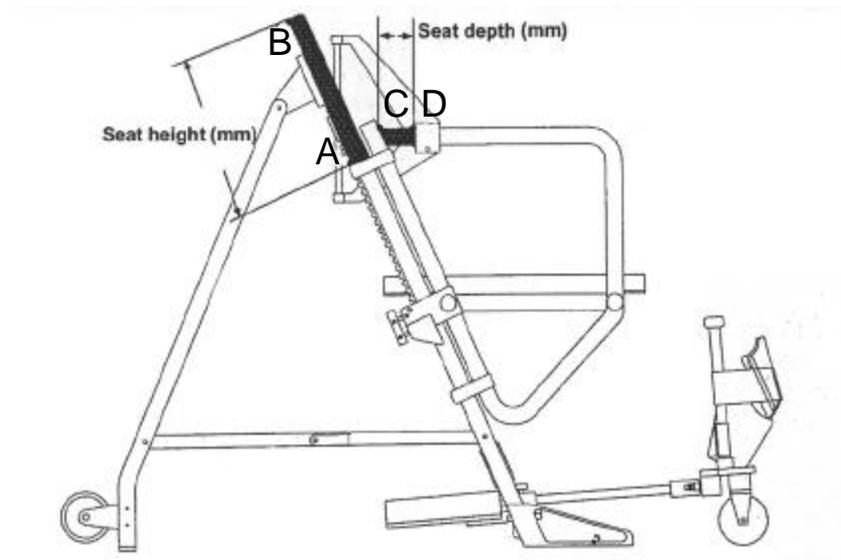
Instructions for participant who had no previous isometric chair test:

- 1) If the participant did not have a previous isometric chair test, determine which connecting rod should be used during the test. The middle connecting rod will be used a majority of the time. To determine which extension rod should be used:

Position the participant on the chair: The middle of the participant’s thigh should be at the end of the chair with their knee joint at a 90-degree angle. This will determine what size connecting rod to use. If the knee joint is not at a 90-degree angle, change the connecting rods until the 90-degree angle is achieved.

2) Vertical seat adjustment

- a. Proper seat height will allow for a ~1-finger cushion between the participant's thigh and the cushion of the seat.
- b. The leg should run parallel with the connecting rod. The connecting rod is at a slight angle so you want the participant's leg to run at the same slight angle.
- c. Record the position of the seat height by measuring the distance between the top end of the seat back and the first stop as noted below.



3) Horizontal adjustment of mesh bracket

The knee joint should first be at a right angle as discussed above in determining which connecting rod to use. Once the knee is in position, the back support should be moved forward or back to provide substantial lower back support.

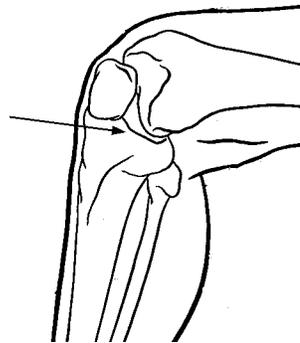
Record the position of the mesh bracket by measuring the distance in mm as noted above. Be sure to measure the mesh bracket on both sides of the chair. The seat depth should be exactly the same on both sides.

Instructions for all participants (whether they had the isometric chair test previously or not) adjust the following:

1) Lateral adjustment of the sensor

The sensor should run parallel with the shaft of the thigh when observed from above.

- 2) Place padding under the non-tested leg until the foot is no longer touching the floor.
- 3) Strap the participant into the chair using the belt. The belt should be placed across the lap of the participant.
- 4) Place a Kim-wipe™ on the trolley heel and then place the participant's heel onto the trolley.
- 5) Check the Data from Prior Visits Report for the participant's lower leg length. If the participant has not done the isometric chair test previously, measure from the mid-knee joint (top of the lateral tibial condyle - see figure below) to the base of the trolley. Record this measurement in the LCD.



To change lower leg length on the display go to the main menu and press "C=Cal." Press "C" until "change lower leg length" appears on the screen. Press "enter." Enter leg length in meters. Press "enter." Also record the leg-length measurement on the Isometric Strength data collection form (in the Year 6 Clinic Visit Workbook).

- 6) Strap the participant's heel into place using the shin pad connected to the trolley. **The shin pad should not be strapped too tightly to the participant's leg. There should be at least 2 finger breadths of play so that the participant's heel comes off the heel rest during the strength test. Allow the pad to give a little.**
- 7) Perform one final check on participant positioning, particularly knee joint angle and parallel position of shaft of the thigh. You may need to have the participant move forward or back a little in the chair to get a 90 degree angle (check with a T-square) at the knee.

8.3 Demonstration and practice

Give the participant one practice trial at a 50% effort. This allows the participant to get the feel for how this test is going to go. Make sure that the participant relaxes and exhales slowly while pushing.

Script: “OK, this first test is going to be a practice test. When I say ‘push,’ all I want for you to do is to push forward against the pad. Please don’t hold your breath as you push. Just relax and exhale slowly. The pad will not move. Since it’s a practice test, I just want you to give me a 50% effort. I want you to push for 4 seconds or as long as you can. Ready, push, push, push, OK relax.”

Then give the participant one practice trial at a 100% effort.

Script: “Now I need you to try a practice test at full effort. When I say ‘go,’ push as hard as you can. Ready, push push, push, OK relax.”

The examiner should watch the participant closely to make sure that they are not pushing down on the heel rest during the test. **It is very important that the heel come off the rest during the test. Pushing down on the heel rest will falsely elevate the results.** If they are pushing down on the heel rest during the test, the test should be started again and the participant instructed to kick out. Loosen the strap, if needed to give enough room for the heel to come off the heel rest.

If the participant has knee pain during the practice push, do not test that leg. Do not record anything under Trial 1 Maximum Torque, Max Rate Torque, Reaction Time, and Time to 50%, and mark the “Yes” response option to the question: “Did participant have knee pain?” (Trial 1) (page 22, Year 6 Clinic Visit Workbook). Measure the lower length of the other leg and record this measurement at the top of page 23, and test the other leg.

8.4 Test

Once the participant has practiced the testing procedure, tell them that you will do the real test. Again, make sure that the participant relaxes and exhales slowly while pushing. Turn the green light toward the participant.

Script: “OK, now we will do the real test. As soon as you see the green light go on I want you to push as hard as you can against the pad. You’re going to give a 100% effort. I want you to push for 4 seconds or as long as you can. We will do three trials. Please don’t hold your breath as you push. Just relax and exhale slowly. Ready, (green light) Push, push, push, OK relax.”

NOTE: IT IS VERY IMPORTANT THAT YOU GIVE STANDARD ENCOURAGEMENT DURING THE TEST.

Wait 25 seconds between each trial just to let the participant relax their leg. Do not wait too long between trials as it will increase their leg strength.

If the Maximum Torque measurement exceeds 300 Nm for any trial, record this trial in the nonscannable margin of the data collection form and have a second examiner come in to assess if the participant is performing the test correctly. Repeat the participant trial and record the values for this trial.

Perform no more than three trials on each leg. If after Trial 1 or Trial 2 the participant is feeling KNEE pain that prevents them from pushing hard, perform the test on the other leg. If they feel KNEE pain on the other side, discontinue the tests.

NOTE: MAKE SURE THAT THE PAIN THAT THE PARTICIPANT FEELS IS KNEE PAIN AND NOT LEG PAIN. THE PARTICIPANT MAY FEEL SOME PAIN ON THE SHIN DUE TO THE SHIN PAD.

9. Procedures for performing the measurement at home

This examination is performed the same way at home as it is in the clinic.

10. Quality Assurance

10.1 Training and Certification

Training will be provided at the Year 6 training session in Pittsburgh. The training will consist of machine operations and the fundamentals of testing, as well as study-specific procedures. After the initial training session, operators should practice on other staff members and themselves until reliable measurements are achieved. Training should include:

- observe measurement by experienced examiner
- read manufacturer's user's guide and Health ABC OM with goal of understanding
 - the proper use of equipment
 - the proper calibration and adjustment of equipment
 - exclusions and safety considerations
 - detailed testing procedures
- practice on colleagues and volunteers who have no previous knowledge of the protocol

10.2 Certification Requirements

- Complete training requirements
- Recite exclusion criteria
- Demonstrate calibration and adjustment of isometric chair
- Perform test on three volunteers under the observation of clinic QC officer or designated isometric chair expert.

10.3 Quality Assurance Checklist

- Participant questioned regarding knee replacement
- Checked Data from Prior Visits report to determine side to test
- Participant correctly positioned in chair with knee joint at a 90-degree angle
- Appropriate connecting rod chosen and recorded on form
- Vertical seat adjustment correctly made (either from Data from Prior Visits Report or new adjustment).
- Seat height recorded
- Back support moved to provide maximum lower back support (depth determined either from Data from Prior Visits Report or new adjustment).
- Seat depth recorded
- Sensor was parallel with the shaft of the participant's thigh
- Padding placed under the non-tested knee
- Participant strapped into chair properly
- Correct lower leg length (from Data from Prior Visits Report) entered into LCD or measured from mid-knee joint to base of the trolley

- Kim-wipe placed on the trolley heel
- Participant's heel correctly placed into the trolley and strapped into place using shin pad (not too tight)
- Performs final check for participant positioning (90 degree angle, thigh parallel to connecting rod)
- Practice trial completed successfully
- Standard level of encouragement (motivation and feedback) offered to participant
- Key points from script stated and clearly delivered
- Test is correctly performed by participant: the heel must come off the rest, with the leg kicking out.
- 25 seconds passed between each trial
- Data completely and accurately recorded:
 - leg being tested
 - leg length
 - maximum torque
 - maximum rate torque
 - reaction time
 - time to 50% MVTD
 - if test not performed, why?
- Form correctly filled out
- Reviewed form for completeness

Appendix 1 Calibration of Isometric Chair**Part I**

1. Place isometric chair on its back
2. Flip sensor so that the back of the sensor is pointing up.
3. Slide calibration tube through the hole in sensor and into the foot of the chair. The sensor should be pointing straight up; NOT at an angle.
4. Insert the extension arm in sensor.
5. Insert the quick connect hook into the extension rod.
6. At the menu screen, press "C=CAL."
7. Press "C" until "Calibrate Torque Sensor?" appears on the screen.
8. Press "enter."
9. Enter the 1st weight in kilograms (preferably 0-the two weights used during calibration MUST have a 15 to 20 kg difference.)
10. Press "enter."
11. If using a weight greater than "0" hang the 1st weight from the quick connect hook. If using "0" kilograms, then there is no weight to hang.
12. Press "enter."
13. If any weight is applied, remove weight.
14. Enter the 2nd weight in kilograms (again the 2nd weight MUST be 15 to 20 kg more than the 1st weight).
15. Press "enter."
16. Hang the 2nd weight from the quick connect hook. Make sure that the protective metal cover is not touching the sensor.
17. Press "enter."
18. Remove 2nd weight from quick connect hook.
19. Press "enter."

Part II
Checking Calibration

1. After calibration procedure is completed, keep chair on its back in calibration position.
2. Press "C" until menu for "reset torque baseline level" is reached.
3. Press "enter." (This resets torque baseline level for the calibration position.)
4. Press "C" again to reach "change of length of lower leg" in menu.
5. Press "enter."
6. Press "1" for leg length (arbitrary value).
7. Press "enter."
8. Press "A" to get to "Real Time Torque Display" on menu (will read zero).
9. Hang the calibration weight.
10. Record calibration torque reading in calibration log. (Note that this is not a real torque as the leg length is arbitrarily set to 1.)
11. If calibration is not within ± 3 calibration torque units of expected value, contact QA officer immediately.
12. Report any other concern about calibration to QA officer. Note that the system has an internal check that causes an "error" reading if calibration drifts by more than 3%.

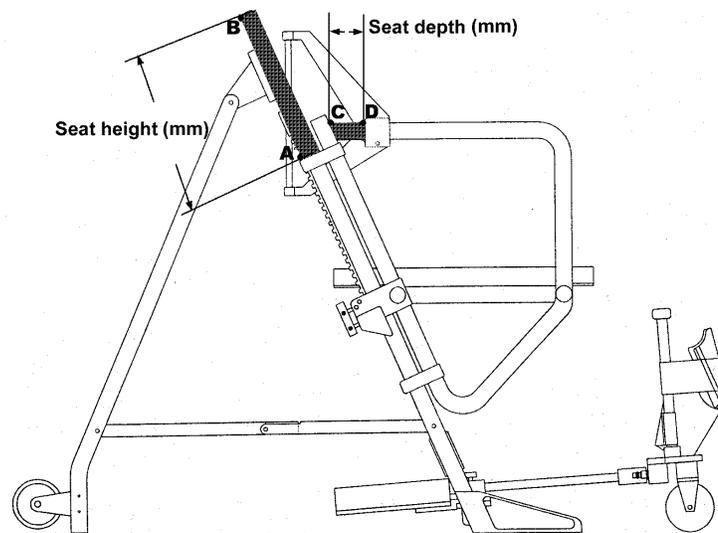
Both field centers should mark the expected calibration torque units and actual #kg on the weight being used.

Pittsburgh units are: 22.67 kg / 228 Nm.

Memphis units are: 20 kg / 198 Nm.

Appendix 2 Step by step instructions for testing new participant

1. Have participant sit in isometric chair.
2. Determine which connecting rod should be used (see operations manual).
3. Place connecting rods into central control unit.
4. Connect trolley into connecting rod.
5. Place participants heel onto the trolley.
6. Adjust seat height. Shaft of thigh should be parallel with connecting rod and at a slight angle. There should be approximately a finger width between the seat and the participant's thigh. Make sure that leg NOT being tested is NOT resting on the ground.
- 6.5 Record seat height position. Measure in mm as noted on picture below.



7. Adjust mesh back. Should provide substantial low back support.
- 7.5 Record seat depth position. Measure in mm as noted on picture above. Check that both sides are equal.
8. Place participant's heel into the heel rest.
9. Measure lower leg length from mid-knee joint to the base of the trolley.
10. Strap participant into the chair.
11. Place ankle strap above ankle. Allow some give when strapping ankle into trolley.
12. Perform one final check of participant positioning (knee at 90 degree angle, thigh parallel to connecting rod).
13. At menu screen on LCD, press "C=CAL" until lower leg length appears.
14. Press "enter."
15. Put lower leg length value in meters into LCD.

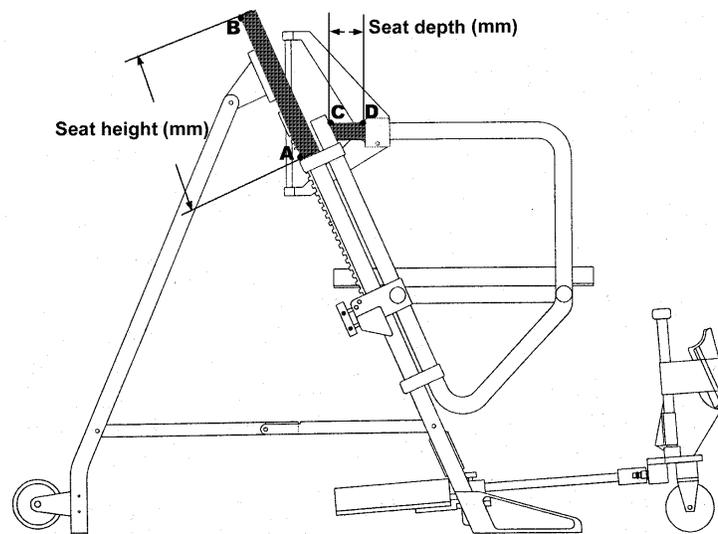
16. Press “enter.”
17. Have participant hold onto arm rests.
18. Select “A=Test” until “Run Isometric Test?” appears.
19. Press “enter.”
20. As soon as the green light comes on, have participant push as hard as they can for 4 seconds or as long as they can.
21. Press "B" to view the Maximum Torque value. If the value is less than 300 Nm record all results. If the Maximum Torque value is 300 Nm or greater, record this trial in the nonscannable margin of the data collection form and have a second examiner assess if the participant is performing the test correctly.
22. Retest and record all results.
23. Press “A” to run another isometric capture test.
24. Repeat steps 17 to 22 for three trials only.

NOTE: IF ANY KNEE PAIN OCCURS THAT PREVENTS PARTICIPANT FROM PUSHING HARD AFTER TRIALS 1 OR 2, PERFORM TEST ON OTHER LEG. IF PAIN ON OTHER LEG AFTER TRIALS 1 OR 2 TERMINATE TEST.

Appendix 3 Step by step instructions for testing repeat participant

Note: If the participant is not optimally seated for this test based on the seat height and depth measurements listed on the Data from Prior Visits Report, set up the test as though the participant is a new participant. It is more important that the test be administered with the participant in the proper position than reproducing a mistake in positioning from Year 3.

1. Have participant sit in isometric chair.
2. Determine which connecting rod should be used (see Data from Prior Visits Report).
3. Place connecting rods into central control unit.
4. Connect trolley into connecting rod.
5. Place participants heel onto the trolley.
6. Adjust seat height. Set at measurement listed on Data from Prior Visits Report.
- 6.5 Record seat height position (from Data from Prior Visits Report).



7. Adjust mesh back. This is determined by moving the mesh to reproduce the seat depth that is listed on the Data from Prior Visits Report. Should provide substantial low back support.
- 7.5 Record seat depth position. This should be the same as the position listed in the Data from Prior Visits Report. Check that both sides are equal.
8. Place participant's heel into the heel rest.
9. Record lower leg length from mid-knee joint to the base of the trolley (See Data from Prior Visits Report). Measure if different leg is being tested than was tested previously.

10. Strap participant into the chair.
11. Place ankle strap above ankle. Allow some give when strapping ankle into trolley.
12. Perform one final check of participant positioning (knee at 90 degree angle, thigh parallel to connecting rod).
13. At menu screen on LCD, press "C=CAL" until lower leg length appears.
14. Press "enter."
15. Put lower leg length value in meters into LCD.
16. Press "enter."
17. Have participant hold onto arm rests.
18. Select "A=Test" until "Run Isometric Test?" appears.
19. Press "enter."
20. As soon as the green light comes on, have participant push as hard as they can for 4 seconds or as long as they can.
21. Press "B" to view the Maximum Torque value. If the value is less than 300 Nm record all results. If the Maximum Torque value is 300 Nm or greater, record this trial in the nonscannable margin of the data collection form and have a second examiner assess if the participant is performing the test correctly.
22. Retest and record all results.
23. Press "A" to run another isometric capture test.
24. Repeat steps 17 to 22 for three trials only.

NOTE: IF ANY KNEE PAIN OCCURS THAT PREVENTS PARTICIPANT FROM PUSHING HARD AFTER TRIALS 1 OR 2, PERFORM TEST ON OTHER LEG. IF PAIN ON OTHER LEG AFTER TRIALS 1 OR 2 TERMINATE TEST.