

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

1.	Background and rationale	2
2.	Equipment and supplies.....	2
2.1	LITEK.....	2
2.2	Central electronic control and processing system.....	3
2.3	Sensor	3
2.4	Quick-connect trolley.....	4
2.5	Visual cue and bar graph unit	4
2.6	Power supply	5
2.7	Calibration tube and quick-connect hook	5
3.	Service and maintenance.....	5
3.1	Warranty.....	5
3.2	Service	5
4.	Calibration	6
5.	Safety issues and exclusions.....	6
6.	Participant and exam room preparation	6
7.	Record keeping.....	6
8.	Administration.....	7
8.1	Determine which knee can be tested	7
8.2	Positioning the participant on the isometric chair.....	8
8.3	Demonstration and practice.....	11
8.4	Test.....	11
9.	Procedures for performing the measurement at home.....	12
10.	Quality Assurance.....	12
10.1	Training and Certification.....	12
10.2	Certification Requirements.....	13
10.3	Quality Assurance Checklist	13
	Appendix 1 Calibration of Isometric Chair.....	15
	Appendix 2 Step by step instructions for testing participant.....	17

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. Isometric strength will be measured in Year 3 of Health ABC using a portable device (Lightweight Isometric Torque Evaluator for the Knee [LITEK, Biologic, Inc.]) so that we can compare it to a home measure if the participant cannot come to the clinic. The isometric chair is a portable device designed to measure strength with knee extension, and was designed specifically for the Health ABC study.

2. Equipment and supplies

- LITEK
- Central electronic control and processing system
- Sensor
- Quick-connect trolley
- Visual cue and bar graph unit
- Power supply
- Calibration tube and quick-connect hook
- Tape measure
- Kim-wipes™

2.1 LITEK

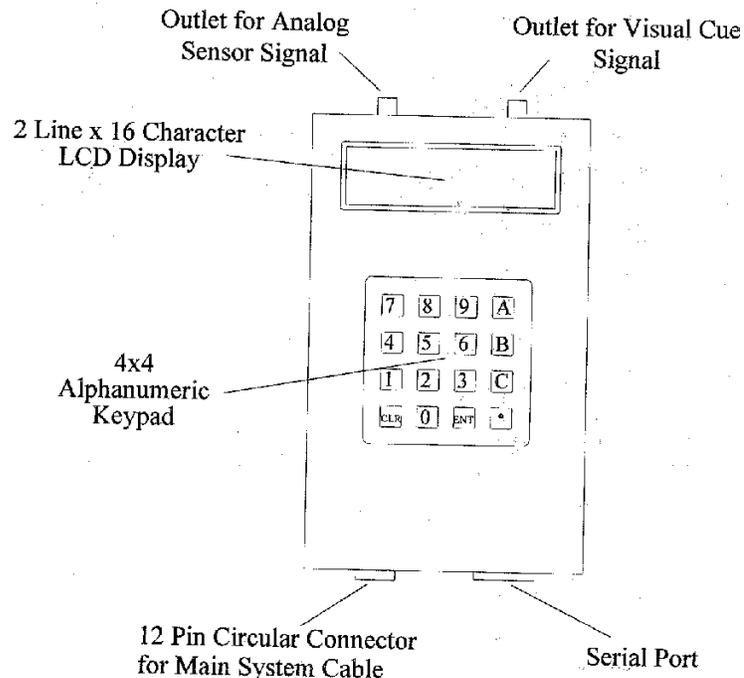
Vertical Range: (Measured from floor to top surface of seat)	0.40 - 0.67 meters (in ~12 cm increments)	(16 - 26.5 inches) (in ~ 0.5 inch increments)
Seat Depth:	0.41 meters	(16 inches)
Adjustable Backrest Range: (Measure from front of seat)	0.25 - 0.51 meters	(10 - 20 inches)
Seat Width:	0.485 meters	(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

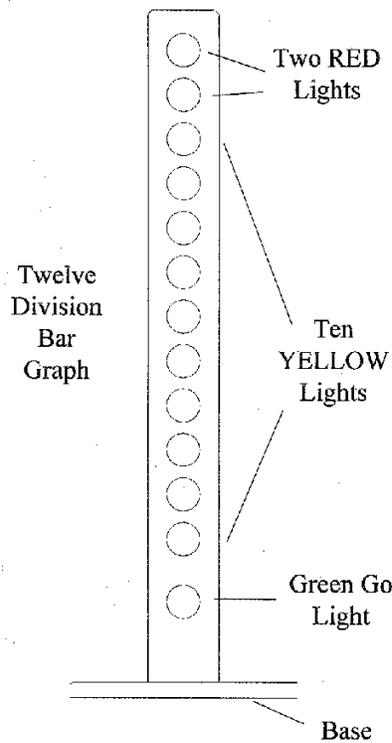
The sensor measures force. Torque is calculated as the product of force and torque arm length. The torque arm length is equal to the length measured between the lateral joint

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.

Bio Logic Engineering Inc.
1675 North Lima Center Road
Dexter, MI 48130-9771
Phone: (734) 433-9256
e-mail: 104232.2652@Compuserve.com

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

charge parts, travel expenses, shipping and labor for service at our standard rate, presently \$100 per hour which is subject to change at any time. Replacement of parts is at the discretion of Bio Logic. Any part(s) replaced become property of Bio Logic.

4. Calibration

See Appendix 1 for step-by-step calibration instructions. These should be followed once a week. Each clinic needs two weights for calibration with a difference of at least 15 to 20 pounds between weights.

5. Safety issues and exclusions

Participants should not be tested for the isometric knee strength if they have bilateral total knee replacements. If they have had one knee replaced, the other knee should be tested.

Unless contraindicated, the participant should be measured on the same leg as they were measured at Year 2 when they were administered the Kin-Com test. (Note: if the participant did not have the Kin-Com test during Year 2 but did have the test during Year 1, measure the leg that was tested during Year 1, unless contraindicated.) To determine which leg was tested, see the Data from Prior Visits Report. If the participant has had a knee replacement since Year 2, that precludes testing the original leg. If the Kin-Com test has never been administered refer to the Data from Prior Visits Report to see which hip was scanned at Visit 1 and test the same side, unless contraindicated.

The isometric knee strength should be terminated if knee pain prevents the participant from pushing hard after either Trial 1 or after Trial 2.

If knee pain prevents the participant from pushing hard after Trial 1 or Trial 2, then the other leg, if it has no knee replacement, should be tested.

6. Participant and exam room preparation

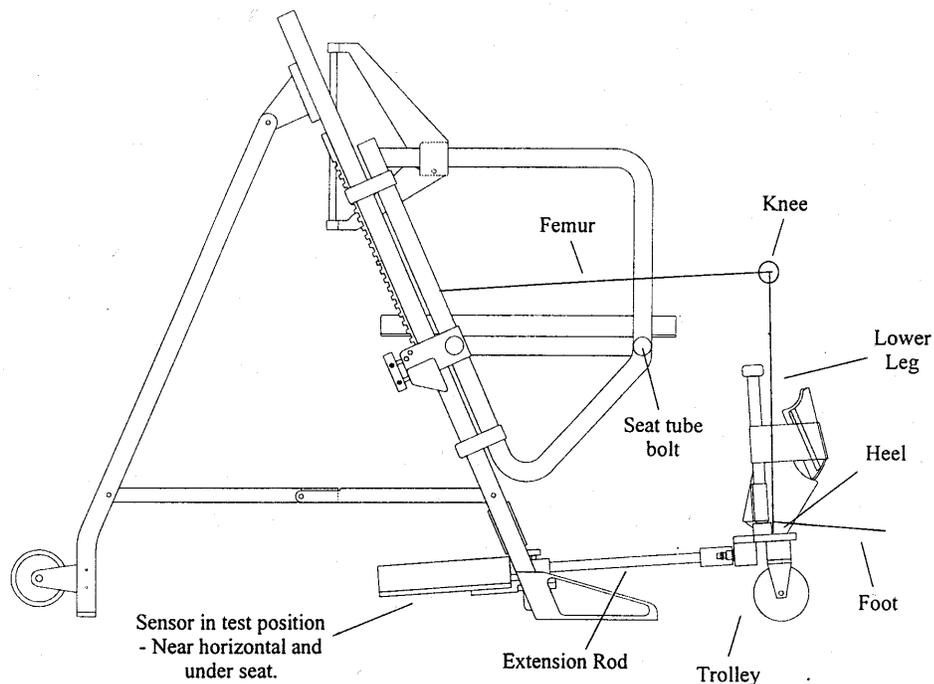
The chair should be placed in a quiet office or exam room that can accommodate the participant and the examiner.

7. Record keeping

which leg was tested during the Kin-Com test at Visit 1. If not contraindicated by a new knee replacement, test the same leg as Visit 1.) If the participant has never had the Kin-Com test, test the same side, unless contraindicated, as the side where the hip was scanned during the DXA exam at Visit 1 (see Data from Prior Visits Report to see which side hip was scanned).

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

8.2 Positioning the participant on the isometric chair



1) 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.”

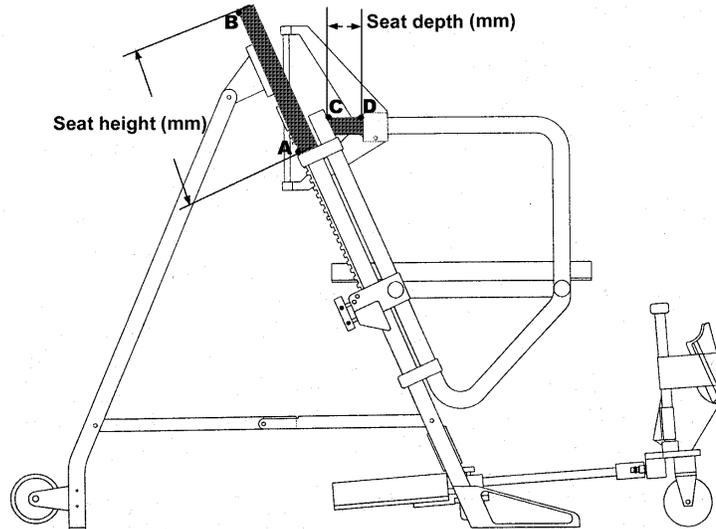
2) Determine which connecting rod should be used during the test. The middle connecting rod will be used a majority of the time. To determine which extension rod should be used:

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.

3) 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.



4) Horizontal adjustment of mesh bracket

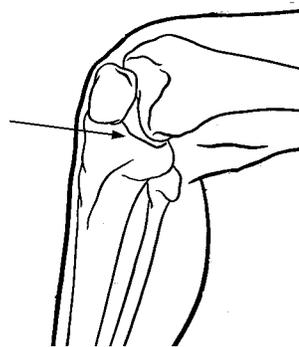
The knee joint should first be at a right angle as discussed above in determining which connecting rod to use. Once the knee is in position, the back support should be moved forward or back to provide substantial lower back support.

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.

5) Lateral adjustment of the sensor

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

- 6) Place padding under the non-tested leg until the foot is no longer touching the floor.
- 7) Strap the participant into the chair using the belt. The belt should be placed across the lap of the participant.
- 8) Place a Kim-wipe™ on the trolley heel and then place the participant's heel onto the trolley.
- 9) Measure the participant's lower leg length. 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 3 Clinic Visit Workbook).

- 10) 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.**
- 11) 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.”

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 17, Year 3 Clinic Visit Workbook). Measure the lower length of the other leg and record this measurement at the top of page 18, 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.”

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
- Seat height recorded on Isometric Chair Supplemental Form
- Back support moved to provide maximum lower back support
- Seat depth recorded on Isometric Chair Supplemental Form
- Sensor was parallel with the shaft of the participant's thigh
- Padding placed under the non-tested knee
- Participant strapped into chair properly
- Lower leg length 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%.

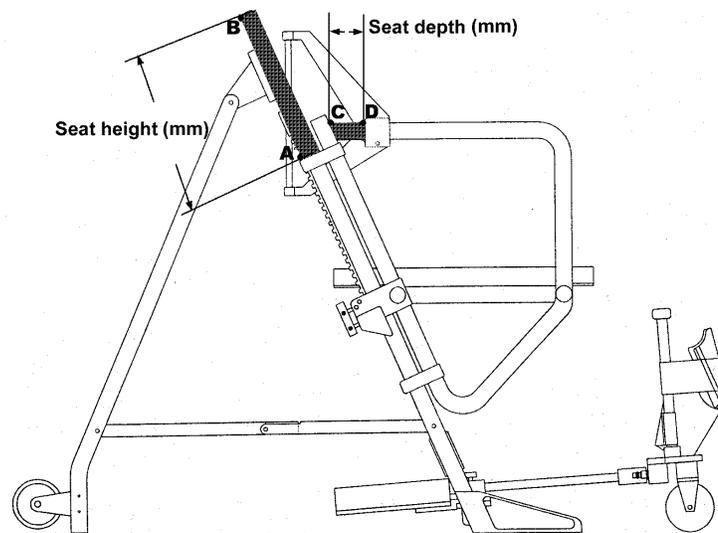
Both field centers should mark the expected calibration torque units and actual #kg on the weight being used.

Pittsburgh units are: 22.67 kg / 228 Nm.

Memphis units are: 20 kg / 198 Nm.

Appendix 2 Step by step instructions for testing 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 record all results.
22. Press "A" to run another isometric capture test.
23. 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.