ISOKINETIC MUSCLE FATIGUE

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ISOKINETIC MUSCLE FATIGUE

1. Background and Rationale

Muscle fatigue is clearly related to the ability to carry out routine daily living activities requiring sustained muscle contraction. It is also apparent that muscle strength and muscle fatigue can vary dramatically within individuals (1,2). Thus, muscle strength does not necessarily relate to muscle fatigue, implying that predicting functional capacity with only muscle strength may disguise the association between overall muscle function and the capacity for daily living. Moreover, in a recent study examining muscle functional properties in men and women age 60 to 80 years, it was shown that while men exhibited greater maximal voluntary strength, women exhibited significantly less fatigue than men (3). Again, this suggests that muscle fatigue may provide additional information regarding muscle function in the elderly and that measuring both muscle strength and muscle fatigue in men and women in Health ABC is justified.

A primary specific aim of Health ABC is to determine correlates of functional capacity in the elderly. Data on maximal isokinetic muscle strength of the leg extensors (concentric) at 60 degrees per second has been collected during the first and second examinations. Data on the role of muscle fatigue as an independent risk factor for disability and overall muscle function is sparse (4). Thus, using the KinCom isokinetic dynamometer we will measure muscle fatigue of the knee extensors and flexors (concentric) as an independent measure of muscle function and potential predictor of functional capacity, disability and morbidity at the year 3 examination. The same leg should be used at visit 3 as was measured at previous visits unless that leg can no longer be tested (see Exclusions, Section 3). We will test participants at 180 degrees per second, extension and flexion, in the concentric mode for one set of 30 repetitions.

2. Equipment and Supplies

- Kin-Com 125 AP Dynamometer
- Level with magnet
- Certified 5 kg (11 lb) weight with hook or handle and velcro strap for attaching weight to load cell
- Step stool, preferably with a handrail

2.1 Service and Maintenance

Health ABC has contracted with the Chattanooga group for an extended service contract to cover the length of the study. Planned Maintenance inspections must be scheduled every six months. Regular service schedules must be strictly observed.



2.2 Calibration

See Appendix 1 for step by step calibration instructions. These should be followed once a week if daily calibrations at the beginning of the study showed that the calibration is stable. Each clinic will have a certified 5 kg (11 lb) weight for calibration.

3. Safety Issues and Exclusions

The quadriceps test using the Kin-Com is generally safe and well tolerated by most older participants. However, injury may occur in patients with knee joint pathology or if the machine is operated incorrectly. To avoid injury during testing the mechanical hardware stops must always be in place when training or testing a participant. These pegs, attached to the Kin-Com dynamometer head, act as a backup to the manually determined software stop and start angles. The mechanical stops should be positioned 5° beyond the desired stop and start angles. Failure to place the stops properly may endanger the participant and damage the system. The patient interrupt switch should

always be in the participant's grasp during any activity on the Kin-Com. This switch enables participants to stop the lever from moving if they feel that speeds or forces are excessive.

Participants should not be tested on the dynamometer if they have any of the following conditions:

- History of cerebral aneurysm.
- Cerebral bleeding within the past six months.
- Blood pressure > 199/109 mm Hg
- Radial pulse > 110 or < 40 beats per minute
- Severe bilateral knee pain that would make the examination uncomfortable. Participants with severe unilateral knee pain can be tested on the opposite side.
- Previous total knee replacement; if unilateral, the other knee should be tested.
- Abnormal ECG reading at baseline (refer to Data from Prior Visits Report). The
 exclusions included Wolff-Parkinson-White (WPW) or ventricular pre-excitation,
 idioventricular rhythm, ventricular tachycardia, third degree or complete A-V
 block, any statement including reference to acute injury or acute ischemia, or
 marked T-wave abnormality.
- History of heart attack, angioplasty, or heart surgery within the past 3 months.
- New or worsening symptoms of chest pain, shortness of breath, fainting, or angina in the past 3 months.

Unless contraindicated, the participant should be measured on the same leg as they were measured at Visit 2 (see Health ABC Data from Prior Visits). However, some participants may have had a knee replacement since Visit 2, or may now have severe knee pain that precludes testing on the original leg. In that case, the other leg should be tested, unless it too has had knee replacement or another contraindication to testing. If a participant complains of pain during the test, the test should be discontinued.

4. Participant and Exam Room Preparation

The minimum space requirements for Kin-Com dynamometry is 9'x12', and a 12'x14' space is very comfortable.

Ideally, this test should be performed after a short period of warm-up exercise. If possible, it is recommended that the 20-meter walk be performed prior to the fatigue test.

5. Detailed Measurement Procedures

Health ABC will use the Kin-Com 125 AP dynamometer. This dynamometer has an automatic positioning feature that stores and recalls a participant's exact positioning and testing protocol from one examination to the next. It is important for this longitudinal study that the methods of strength testing and the participant positioning be consistent throughout the study. Therefore, the settings from Year 2 should only be changed if: 1) the shin pad could slide up and down on the participant's leg, or

2) the lever arm length is too long and touches the top of the foot or prevents the participant from flexing their foot to a 90 degree angle. Short lever arm lengths should be left as is.

Step-by-step instructions for use of the Kin-Com for a participant who has been tested before can be found in Appendix 2. If a participant did not have a baseline or Year 2 exam but can be measured now, follow the procedures in Appendix 3 (new participant). Participants who can no longer be tested on the same leg as at Visit 2, but can be measured on the other leg can be set up by following the instructions in Appendix 2, but doing a <u>new</u> test. The step-by-step instructions for positioning the participant for the new leg are listed in Appendix 2 following the .

5.1 Record Keeping

A form is provided as a backup to the computer storage of patient positioning and for a summary record of isokinetic dynamometry testing performed on each participant. In addition, certain data are entered into the Kin-Com database via the keyboard. This includes participant name, Health ABC Enrollment ID # (in the "physician" space in patient information), and the Staff ID of the examiner (in the "clinician" space). It is important to complete all four of these fields to allow the participant to be positively identified in the data sent to the Coordinating Center for analysis.

Record which leg is being tested (see Data From Prior Visits Report for the leg that was tested at Visit 2). Record participant positioning parameters, whether participant completed the practice and fatigue tests, and if not, the reason(s) for not completing them. For both complete and incomplete tests, also record peak torque, fatigue index, mean peak force, CV peak force, total work, power, total number of repetitions completed, time to peak torque, and repetition number that peak torque occurred for both extension and flexion.

Important: A printout of the report forms should also be made immediately after each testing session and kept in the participant's record in case of computer failure.

5.2 Administration

5.2.1 Determine Contraindications or Disabilities of Right Knee

- 1) Look at radial pulse measurement on the Weight and Radial Pulse form (in the Year 3 Clinic Visit Workbook, page 7). If the radial pulse is > 110 or < 40 beats per minute, do not administer the fatigue test.
- 2) Look at the blood pressure measurement on the Blood Pressure form (in the Year 3 Clinic Visit Workbook, page 8). If the systolic blood pressure is > 199 mmHg and/or diastolic blood pressure is > 109 mmHg, do not administer the fatigue test.
- 3) Before administering the fatigue test, check the participant's Data from Prior Visits Report to see if the Marquette ECG reading from baseline was categorized with one of the abnormalities listed below:
- Wolff-Parkinson-White (WPW) or ventricular pre-excitation
- Idioventricular rhythm
- Ventricular tachycardia
- Third degree or complete A-V block
- Any statement including reference to acute injury or acute ischemia, or marked T-wave abnormality
- 4) If the participant indicates that they have ever suffered a cerebral aneurysm, record this on the Kin-Com form and <u>do not continue</u>. <u>Testing is contraindicated in these</u> participants.

Script: "Has a doctor ever told you that you had an aneurysm in the brain?"

5) If the participant indicates that they have suffered a cerebral hemorrhage in the past six months, record this on the Kin-Com form and <u>do not continue</u>. <u>Testing is contraindicated in these participants</u>.

<u>Script</u>: "Has a doctor told you that you had a cerebral hemorrhage (bleeding in the brain) in the last six months?"

6) If a participant reports heart attack, angioplasty, or heart surgery in the past 3 months, or new or worsening symptoms of chest pain, shortness of breath, fainting, or angina in the previous 3 months, do not administer the fatigue test.

<u>Script</u>: "First we need to ask you a few questions to see if you should try the test. Within the past 3 months,

```
"... have you had a heart attack?"
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- "... have you had angioplasty?"
- "... have you had heart surgery?"

"Within the past 3 months, have you seen a health professional or thought about seeing a health professional for new or worsening symptoms of

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"... chest pain?"
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"... shortness of breath?"

"...fainting?"

" . . . angina?"

If the answer is "Yes" to any of the above questions, do not administer the fatigue test.

7) Determine which knee can be tested.

<u>Script</u>: "Have you ever had knee surgery on either leg where all or part of the joint was replaced?"

Refer to the Health ABC Data from Prior Visits Report for the leg that was tested at Visit 2. If not contraindicated by a new knee replacement, test the same leg as at Visit 2. (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 <u>never</u> 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.

8) We are interested in knowing whether or not one leg is weaker than the other. However, this information will not determine which leg to test.

"Have you ever had an injury that has made one leg weaker than the other?"

9) If both knees have been replaced, do not test. Otherwise, with reference to the leg of interest, determine whether pain will prevent them from doing the test.

"Is it difficult for you to either bend or straighten either of your knees fully due to pain, arthritis, injury or other condition?"

10) If the participant indicates that these conditions exist, determine whether the leg can be tested by using a simple manual test. Have the participant extend their knee until the knee is flexed 60 degrees down from the fully extended position. The tester asks the participant to extend the knee and tests manually that the task is correctly understood.

Put hands above the participant's ankle and ask the participant to press against your hands. Keep your elbows extended and use the weight of your upper body to resist the push.

After having tried the movement, the participant should be asked:

Script: "Did you have pain in your knee that stopped you from pushing hard?"

Record results of manual test on Kin-Com form. Do not test if neither leg can be tested without excessive pain.

5.2.2 Stopping rule for the fatigue test

If the participant reports a significant degree of any of the following symptoms stop the test:

- Chest pain, tightness, or pressure
- Trouble breathing or shortness of breath
- Feeling faint, lightheaded, or dizzy

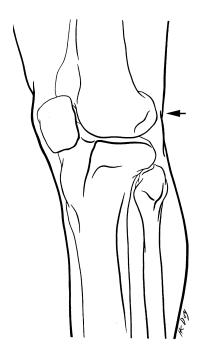
5.2.3 Positioning the Participant on the Kin-Com

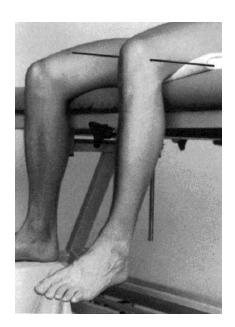
1) Participants are positioned sitting and with the back supported according to instructions. Stabilizing straps are placed across the pelvis and the distal thigh of the leg to be tested. Be sure the participant sits all the way back against the back of the chair and the stability straps are snug enough to prevent the participant from using other muscle groups to help the thigh muscle. The participant's untested leg should hang free without support.

<u>Script</u>: "Now I would like you to sit in the chair with your hands comfortably in your lap. Please keep your hands in your lap during all testing."

2) Position the participant using the dynamometer positioning parameters stored at Visit 2 (see Appendix 2). Be sure to set all positioning parameters, including those that must be set manually, to match the parameters used at Visit 2.

IMPORTANT: After positioning the participant, be sure to proceed to Manual Mode, then touch Index Location and check whether all positioning parameters <u>including lever arm length</u> are correctly entered, then touch Accept. Touch Enter to save this participant position and touch Yes when asked "Positional data for this patient/side/joint/movement exists. Do you want to overwrite?" **It is very important to follow these steps to ensure that all positioning parameters including lever arm length are correctly stored to allow later deletion of data files without loss of positioning information.** As a backup, lever arm length as well as all positioning parameters will be recorded on the exam form. Detailed step-by-step instructions for carrying out these important tasks are included in Appendix 2.





3) If the opposite leg must be tested, or if the participant has not been tested before, the participant must be positioned correctly in the dynamometer. The knee joint (lateral femoral epicondyle [see figures above]) is aligned with the rotational axis of the dynamometer. This can usually be accomplished by adjusting the dynamometer up/down and in/out. Occasionally seat angle up/down and seat in/out adjustments must be made. The resistance pad at the end of the lever arm is placed approximately two finger widths above the ankle bones (malleoli). (See figure below.) In very tall participants place the resistance pad as near to the ankle as possible.

The Kin-Com automatically records any changes to the dynamometer positioning and seat that might have been changed while fine tuning the participant's positioning. The software will also prompt the operator to make any necessary changes to the dynamometer tilt (parameter A) and rotation (B); lever arm stops (C&D); and seat rotation (E), back angle (F), bottom depth (G), or bottom angle (H). These changes in the manual parameters must be read from the dynamometer and entered manually into the program so that future measurements can be standardized.

5.2.4 Test Parameters

- 1) The computer joint angle is adjusted to anatomical joint angle by referencing the machine at 90° when the participant's knee is at 90°. The machine reference angle must then be entered as 90° (see Appendix 2).
- 2) To correct for gravity, the participant's limb is weighed at approximately 45°. Weighing and gravity correction are covered in detail in Appendix 2.
- 3) Start and stop angles are set at 90° and 30°. Follow the instructions in Appendix 2. <u>It is important that the start and stop angles be set correctly</u>. Testing from 89° to 31° is not the same as testing from 90° to 30°.
- 4) A practice trial will consist of one set of three repetitions at 50 % effort to familiarize the participant with the procedure and provide a warm-up period.
- 5) Test concentric extension and flexion, one set of 30 repetitions, to assess muscle fatigue parameters.
- 6) Don't save data from practice session on computer.

5.2.5 Test

1) Administer practice trial.

<u>Script</u>: "We are going to have you practice this test at about half your maximal effort for 3 kicks of the leg back and forth. This is so you can get the feel of the speed of the movement. Don't stop between the back and forth movement."

2) Once the participant has practiced the testing procedure, tell them that you will now begin the actual testing.

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¹ Note to investigators analyzing Kin-Com data: By setting anatomical joint angle based on machine joint angle, there may some error in the actual range of motion measured. This error may be the result of anatomical differences between participants so that the actual range of motion measured may not be 30° to 90°, although the range of motion will cover a 60° arc. In addition the seat angle (usually 15° above horizontal) will generally affect the true joint angle, and in turn affect the actual range of motion measured. The range tested within participant will be constant from visit to visit, but may vary across participants. This should be taken into account when describing the Kin-Com protocol.

<u>Script</u>: "Now we need you to do 30 repetitions. This will take about 30 seconds. This time pump your leg back and forth as hard as you can right from the beginning of the test. We want to see how well you can maintain your strength as your leg becomes tired. Please do not pace yourself to try to save your strength for the end. If you experience any leg or knee pain, or pain, tightness, or pressure in your chest, if you become short of breath or if you feel faint, lightheaded or dizzy, let me know and we'll stop the test. When I say begin, go as hard and as fast as you can. Ready, begin."

Look at the participant while they are doing the test to see if they are doing their maximal effort.

(Encouragement during the maneuver): After the first rep, "As hard as you can!" at 5 reps - "Great job!" at 10 reps - "Looks Good!" at 15 reps - "Great job! You're halfway there!" at 20 reps - Keep working. Only 10 more to go" at 25 reps - "You're doing great. Only 5 to go."

- 3) If the participant is able to complete the test, record the information as required on the exam form.
- 4) If the participant is <u>not able</u> to complete the test, record the information as required on the exam form for an incomplete test, including reasons for stopping the test.

5.2.6 Diskette Backup of Data

Once a week, the data manager should make a copy of all data collected since the last backup in the study. The backup will be sent to UCSF every other week for downloading into the data system, and another copy should be maintained by the sites. The whole set of diskettes constitutes a complete backup of your Year 3 data. Detailed instructions for making a diskette back up are given in Appendix 4. In addition, a Kin-Com Data Transfer Form should be filled out and sent in with the data.

To determine which files to back up, the sites should keep a log of all Kin-Com fatigue exams done. Each time a backup diskette is made, the log entries corresponding to the exams copied to diskette should be marked to denote that they have been copied and sent to the Coordinating Center. All Year 3 exams should continue to be stored on the Kin-Com computer until the Coordinating Center directs you to delete them.

Note: Any practice sessions should be deleted before making the diskette to be sent to UCSF. In addition, any remaining Year 1 or 2 exams should be deleted for each participant who has a Year 3 exam file. This will prevent the dataset from becoming overly large. Detailed instructions for deleting files are also included in Appendix 4.

6. Procedures for Performing the Measurement at Home

This examination is not feasible for home visits.

7. Alert Values/Reporting to Participants

When the testing is completed, tell the participant that it looks like they have "done well."

8. Quality Assurance

8.1 Training and Certification

Training will be provided at the Year 3 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. It is especially useful to practice on volunteers who are not knowledgeable about what to expect. 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 "naive" volunteers

8.2 Certification Requirements

Complete training requirements

- Recite exclusion criteria
- Demonstrate calibration and adjustment of Kin-Com
- Perform test on two volunteers under the observation of clinic QC officer or designated Kin-Com expert.

8.3 Quality Assurance Checklist

Log indicates calibration according to schodule
 Log indicates calibration according to schedule
Checked Data from Prior Visits report for baseline ECG exclusion
Consults radial pulse and blood pressure form to determine blood
 pressure exclusion
Asks eligibility questions
Consults Data from Prior Visits Report to choose side to test
Performs manual test to determine pain exclusion
Participant positioning correctly determined (from stored values if repeat test, by fine tuning in the manual mode if first test occasion)
Index Location checked and patient positions re-saved for each participant
Manual hardware stops in place
Patient interrupt switch in participant's hand during demonstration and testing and its operation properly explained
Gravity correction correctly applied (leg weight is stable)
Correct instructions given while demonstrating procedure
Practice trial completed successfully
Standard level of encouragement (motivation and feedback) offered to participant
Key points from script stated and clearly delivered
Data saved to Kin-Com file
Data completely and accurately recorded: peak torque, fatigue index, mean peak force, CV peak force, total work, power, total number of repetitions completed, time to peak tor que, and repetition number that peak torque occurred for both extension and flexion.
Reports printed and placed in participant's file
Form correctly filled out

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9. References

- 1. Lewis SF, Fulco CS. A new approach to studying muscle fatigue and factors affecting preformance during dynamic exercise in humans. In: Exer Sport Sci Rev, vol. 26, Holloszy JO, ed. Baltimore: Williams and Wilkins, 1998, pp 91-116.
- 2. Maughan RJ, Nimmo MA, Harmon M. The relationship between muscle myosin ATP-ase activity and isometric endurance in untrained male subjects. Eur J Appl Physiol 1985;54:291-96.
- 3. Hicks AL, McCartney N. Gender differences in isometric contractile properties and fatigability in elderly human muscle. Can J Appl Physiol 1996;21:441-54.
- 4. Mundale MO. The relationship of intermittant isometric exercise to fatigue of handgrip. Arch Phys Med Rehab 1950;51:32-53.
- 5. Trappe SW, Costill DL, Goodpaster BH, Pearson DR. Calf muscle strength in former elite distance runners. Scan J Med Sci Sports 1996;6:205-210.

APPENDIX 1 Kin-Com Calibration Procedure Part I Diagnostics

From the Kin-Com Main screen: Touch screen anywhere

- 1. Select Kin-Com
- 2. Select System Utilities
- 3. Type: test
- 4. Type: yes
- 5. Select option 1
- 6. Select option 1
- 7. Position mechanical stop C at 2; mechanical stop D at 34
- 8. Make sure the load cell is firmly attached to the lever arm.
- 9. Position lever arm in approximately the horizontal position and pick up the patient abort switch.
- 10. MAKE SURE THE LEVER ARM IS UNOBSTRUCTED AND WILL NOT CONTACT ANY OBJECT! The lever arm will be moved passively throughout the full range of motion of the machine. This will be done at various speeds including full speed (250+ degrees per second). DO NOT STAND CLOSE ENOUGH TO BE STRUCK BY THE LEVER ARM DURING THIS PROCEDURE. During the Diagnostic check the software will actuate the lever arm several times and at several speeds. Do not get in the path of the lever arm until you have completed the Diagnostic check and have safely returned to the Kin-Com software.
- 11. Press Enter and the Diagnostics program will run.
- 12. Press the Patient abort switch when requested.
- 13. When the message Diagnostics program complete appears, press escape.
- 14. Press escape repeatedly until you return to the main menu.
- 15. This concludes the Diagnostic portion of the calibration procedure. If any problems were encountered during diagnostics, they would be reported on the screen. If problems are encountered, call service at 800-494-3398.

Part II Load Cell

If the Kin-Com is not already set up for measuring the <u>right</u> leg, do so before beginning the load cell calibration.

From the Kin-Com Main screen: Touch screen anywhere.

- 1. Select Kin-Com
- 2. Select Exercise
- 3. Select Protocol
- 4. Select Calibration
- 5. Select Continuous
- 6. Select Turn On Anatomical Reference
- 7. Move lever arm to horizontal and check with a level.
- 8. Select Enter
- 9. Actual joint angle is: 0; Select Enter
- 10. Grasp the load cell, **not the lever arm**, and move lever arm down a few degrees towards vertical.
- 11. Select Enter
- 12. Select Enter
- 13. Grasp the load cell, not the lever arm, and move the lever arm up towards horizontal until Stop Angle = 0.
- 14. Select Enter
- 15. Select Set Start Angle
- 16. Grasp the load cell, not the lever arm, and move the lever arm down towards vertical until Start Angle = 90
- 17. Select Enter
- 18. Select Enter
- 19. Force should read zero.*
- 20. Select Start Exercise.
- 21. Pull up on load cell for about one second.
- 22. Place a known weight (11 lb or 5 kg) on the load cell. This is most easily done by attaching the weight to the load cell with a velcro strap.
- 23. Force should read 50 Newtons**
- 24. Remove weight.
- 25. Select Escape

*If the reading flickers back and forth between +1 or -1 and 0, this may be as close as you can get. If force does not flicker between 0 and +/-1 or read zero with lever arm vertical, remove cover from Kin-Com, find the decal on the computer that shows the location of pot #7 force gain and #8 force zero adjustment (offset). With the lever arm vertical, adjust the zero adjustment screws until force reads zero.

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 ** If force reading does not read 50 Newtons in the horizontal position with the 11 lb (5 kg) weight attached, adjust #7 (gain) until it reads 50 Newtons. Calibration is complete.

APPENDIX 2 Health ABC Kin-Com Fatigue Protocol (Continuous) Repeat Participant

- Power-up the Kin-Com.
- Touch the screen anywhere to enter the Kin-Com Main menu.
- Touch Kin-Com to access the main menu.
- Touch Patient Positions.
- Touch Patient Position.
- Select Patient from scroll box.
- Touch Enter
- Select side.
- The leg measured at the Year 2 visit is shown. If you are about to measure the same leg, continue. If you must change legs (see instructions on the data form), see instructions at below
- Touch Enter.
- Follow on-screen instructions to position the unit in the Patient's position for knee extension.

A box comes up that says: "Automatic positioning has been completed. Press anywhere to advance to the Manual Mode."

- At Manual Mode, touch Index Location, check to see that lever arm length is correct (Note: You will have to position the pad on the participant's shin to verify this measurement) Do not change from Year 2 values unless lever arm is too long and participant is uncomfortable or cannot flex foot to 90 degrees.
- Use the arrow buttons on the keyboard to move the highlight bar to the appropriate positions(s). If any adjustments have been made, type in the correct number(s), including lever arm length, and touch Accept.
- Touch Enter to save this Participant position.
- A scroll box will appear that says "Positional data for this patient/side/joint/movement exists. Do you want to overwrite?" Touch Yes.
- Touch escape once.
- Touch Evaluation to access the evaluation program.
- The patient scroll box will be displayed, select the appropriate participant's name.
- Touch Enter to accept this participant.
- Review Patient Information. NOTE: if any information was omitted at the first visit, it may be entered now (e.g., Health ABC Enrollment ID #, etc). If a different

examiner is conducting the exam at Visit 3 than at Visit 2, the staff ID ("Clinician") should be corrected. If no changes need to be made, touch Enter.

- A blue message box will display: You will need the following attachments: Double Shin pad" (you already have it)
- Touch Turn ON Gravity Compensation.
- Move Lever Arm to horizontal position (Check with a level).
- Touch Enter (you will get the joint specification screen again)
- Touch Enter
- Touch New Test
- Touch Protocol
- Select the fatigue protocol (i.e., touch Enter).
- Touch Continuous
- Set Lever arm length:

The correct lever arm length should be displayed.

Move the load cell to the displayed length.

- Touch Enter.
- Place participant on machine and fasten the stabilization straps securely.
- Set anatomical reference.
 - Select joint position; move lever arm to vertical position (pointing down, check with a level)
 - Touch Enter to record mechanical position of the lever arm at 90°.
 - Enter Actual joint angle; 90.
 - Touch Enter.
- Move joint angle positive.
 - Move the knee towards flexion.
- Press Enter to record the direction as positive.
- Press Enter to advance to the next screen.
- Move Lever Arm to Current angle: =42° for Right knee; 44° for Left knee.
- Move mechanical stop C to 13 for Right knee; D to 25 for Left knee, touch Enter.
- Screen will show current angle close to 42 degrees, touch Enter

*

- With the participant's limb attached to the pad, ask them to relax.
- When the weight reading stabilizes, touch Enter.
- Limb weight will be displayed.
- Ask the participant to contract and then relax their leg and repeat from *
- If your weight reading agree, press enter, otherwise repeat again until you have a reading you think is accurate
- Touch Enter

- Set Stop angle:
 - A blue box will display last angle of 30 degrees.
 - Grasp the load cell and move the lever arm to 30 degrees.
 - Press Enter to record stop angle.
- Move mechanical stop C back to 8, and D to 19 for Right Knee; C to 20 and D to 30 for Left Knee.
- Set start angle:
 - A blue box will display last angle of 90 degrees.
 - Grasp the load cell and move the lever arm to 90 degrees; make sure it is on 90 before you press Enter)
 - Press Enter to record the start angle and advance to the next screen.

Testing

- Ask participant to push up and down on the pad with 50% effort for 3 repetitions. Touch Start Test. After 3 trials, touch Stop Test.
- Touch No. Do not save data to a patient file.
 - Ask participant to push up and down on the pad with maximum effort
 - Touch Start Test
 - Touch Stop Test
 - Touch Yes. Save data to patient file.
 - Touch Escape.
 - Touch Escape again.
 - Touch Escape again.

Touch Reports

- Touch Continuous
- Select Patient
- Touch Enter
- Select Date
- Touch Enter
- Touch Enter again
- Touch Enter again
- Touch Power/Work
- Touch Time Graph
- Touch Print
- Touch Enter 3 times
- Touch Escape
- Touch Numeric: Off
- Touch Print

• Touch Enter 3 times

TO CHANGE LEGS

- Touch the screen anywhere.
- Follow on-screen instructions to position the unit in the standard preset position for knee extension/flexion
- Place participant on machine and fasten the stabilization straps securely.
- Touch the screen anywhere to proceed to Manual Mode for fine tuning adjustment for this participant.
 - Make the necessary adjustments so the participant can be taken passively through the range of motion without the shin pad moving up or down the shin.
 - If adjustments to the manual positions A-H are necessary, make the adjustments
 - Touch Index Locations and check to see that lever arm length is correctly entered. Use the arrow buttons on the keyboard to move the highlight bar to the appropriate manual position(s) and type in any changes. Touch Accept.
- Touch Enter to save this as a Participant position.
 - A patient scroll box will be displayed. Select Patient and enter all appropriate data.
- Touch Enter to accept, or Re-do to make changes.
- A blue message box will display: "Adding positional data to the Patient Position Database."
- Touch screen anywhere to continue.
- Return to

APPENDIX 3 Health ABC Kin-Com Fatigue Protocol (Continuous) New Participant

- Power-up the Kin-Com.
- Touch the screen anywhere to Enter the Kin-Com Main menu.
- Touch Kin-Com to access the main menu.
- Touch Patient Positions.
- Touch Preset Position.
- Touch joint: Knee.
- Touch Ext./Flex
- Touch side: Right or Left as appropriate.
- Touch the screen anywhere.
- Follow on-screen instructions to position the unit in the standard preset position for knee extension.
- Place participant on machine and secure stabilization straps
- Touch the screen anywhere to proceed to Manual Mode for fine tuning adjustment for this participant.
 - Make the necessary adjustments so the participant can be taken passively through the range of motion without the shin pad moving up or down the shin.
 - If adjustments to the manual positions A-H are necessary, make the adjustments, then touch Index Locations. Make sure the lever arm length is correctly entered. Use the arrow buttons on the keyboard to move the highlight bar to the appropriate position(s). Type in the new number(s) and touch Accept.
- Touch Enter to save this as a Participant position.
 - A patient scroll box will be displayed. Select New Patient and enter all appropriate data. This includes entering the Health ABC Enrollment ID # in the space for physician and the examiner's Health ABC staff ID in the space for clinician.
- Touch Enter to accept, or Re-do to make changes.
- A blue message box will display: "Adding positional data to the Patient Position Database."
- Touch screen anywhere to continue.
- Touch Evaluation to access the evaluation program.
- The patient scroll box will be displayed with the appropriate participant's name highlighted.
- Touch Enter to accept this participant.

- After reviewing patient information, touch Enter.
- A blue message box will display: "You will need the following attachments: Double shin pad" (you already have it)
- Touch Turn ON Gravity Compensation
- Move Lever Arm to horizontal position (check with a level)
- Touch Enter (you will get joint specification screen)
- Touch Enter.
- Touch Protocol
- Select Fatigue, then touch Enter
- Touch Continuous
- Set Lever arm length:
 - The lever arm length is the distance from the axis of rotation to the end of the load cell.
 - Enter the correct number on the numeric pad on the screen.
- Touch Enter.
- Set anatomical reference.
 - Select Joint Position
 - Move lever arm to vertical position (pointing down, check with level)
 - Touch Enter to record mechanical position of the lever arm at 90°.
 - Enter Actual joint angle: 90 using screen keypad.
 - Touch Enter
- Move joint angle positive.
 - Move the knee towards flexion.
- Press Enter to record the direction as positive.
- You will see a blue message box saying "Anatomical reference is now set for knee extension"
- Press Enter to advance to the next screen.
- Blue text will tell you to "Move the lever arm as close to the horizontal position...." Ignore this message. Current angle will be displayed
- Move Lever Arm to Current angle: = 42° for Right knee; 44° for Left knee
- Move mechanical stop C to 13 for Right knee; D to 25 for Left knee
- Screen will show current angle close to 42 degrees, touch Enter

*

- With the participant's limb attached to the pad, ask them to relax.
- When the weight reading stabilizes, touch Enter
- Limb weight will be displayed
- Ask the participant to contract and then relax their leg and repeat from *

- If your weight readings agree, press enter, otherwise repeat again until you have a reading that you think is accurate
- Touch Enter
- Set Stop angle:
 - Grasp the load cell (not the lever arm) and move the lever arm to 30 degrees.
 - Press Enter to record stop angle.
- Move mechanical stop C back to 8 and D to 19 for Right Knee; C to 20 and D to 30 for Left Knee
- Set start angle:
 - Grasp the load cell (not the lever arm) and move the lever arm to 90 degrees.
 - Press Enter to record the start angle and advance to the next screen.

Testing

- Ask participant to push up and down on the pad with 50% effort for 3 repetitions. Touch Start Test. After 3 trials, touch Stop Test.
- Touch No. Do not save data to a patient file.
 - Touch Start Test
 - Touch Stop Test
 - Touch Yes. Save data to patient file.
 - Touch Escape.
 - Touch Escape again.
 - Touch Escape again.

Touch Reports

- Touch Continuous
- Select Patient
- Touch Enter
- Select Date
- Touch Enter
- Touch Enter again
- Touch Enter again
- Touch Power/Work
- Touch Time Graph
- Touch Print
- Touch Enter 3 times
- Touch Escape
- Touch Numeric: Off
- Touch Print
- Touch Enter 3 times

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APPENDIX 4 Protocol for Diskette Backup

First make a backup tape in case problems occur when erasing old data files.

- Make sure your backup tape is in the drive.
- From the Main screen Touch Utilities in the lower right hand corner of screen.
- Touch System Utilities
- Touch Files Manager
- Touch Backup Data Files
- · Touch Backup to tape
- Type Yes
- Program will automatically back up all data files.

Next erase any practice sessions as well as <u>Year 1 or 2</u> files <u>for participants who have</u> had Year 3 exams only

- Touch Kin Com
- Touch Utilities
- Touch System Utilities
- Touch Erase Data Files
- Scroll down the list of participants* to the first file you wish to delete. With file highlighted, touch Enter Tag. A check mark will appear next to the file. If you check the wrong file, touch Enter Untag. The check mark will disappear. When erasing Year 1 or 2 files, check the exam dates carefully and delete only the old data.
- Scroll down to next file you wish to delete and repeat the process until all practice sessions and extra files are check marked.
- Touch Erase Selected Files.
- Touch Escape to exit System Utilities.
- Touch Database Utilities
- Touch Delete Patient Positions
- Go to each <u>practice patient</u> and touch Enter. The screen will show which tests (e.g. right knee) have been done on that participant and ask you to indicate which test position you want to delete. If there are more than one, scroll to the position(s) you want to delete, then touch Enter. The system will ask if you really want to delete this patient's positions. Touch Yes. <u>Do not erase patient positions for real Health ABC participants</u>.
- Touch Escape several times until you return to the main menu

Finally, using your Kin-Com log as a guide, make an archive copy of all new data to be sent to the Coordinating Center (see instructions above). Make a second diskette copy

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for your own archives. Keep the backup tape to reuse the next time you archive your data.

- Touch Kin Com
- Touch Utilities
- Touch System Utilities
- Touch Copy Data Files
- Touch Copy Files from C: to A:
- Scroll down screen, tagging each file to be copied (use your log to determine which have not yet been archived). With file highlighted, touch Enter Tag. A check mark will appear next to the file. If you check the wrong file, touch Enter Untag. The check mark will disappear.
- When all files to be archived have been tagged, touch Copy Selected Files
- Wait until copying process is complete (this may take some time)
- Touch Escape three times